

**Colorectal Cancer:
A Comparative Study of Models of Health Care
Delivery in Two Adjacent Trusts in South Wales**

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**A Submission presented in fulfilment of the
requirements of the University of Glamorgan / Prifysgol
Morgannwg for the degree of Master of Philosophy**

January 2009

Declaration

Statement 1

This thesis is the result of my own investigation, except where otherwise stated. Other sources are acknowledged by giving explicit references.

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Statement 2

This work has not previously been accepted in substance for any degree and is not being submitted in candidature for any degree at any other University, other than the degree of M Phil of the University of Glamorgan.

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Acknowledgements

I would like to thank the colorectal units of both hospitals for giving me access to their databases to conduct this study. This research project was possible due to the wholehearted support of Prof. P. N. Haray, consultant colorectal surgeon, North Glamorgan NHS Trust, who initiated the project and provided guidance and motivation to see it through. I am also grateful to him for the time and effort spent out of hours for editing and correcting this dissertation. I would like to thank Prof. M. E. Foster, consultant colorectal surgeon, Pontypridd and Rhondda NHS Trust, for his advice and constant moral support throughout the project.

I am also thankful to Prof. D. Cohen, Professor of Health Economics, University of Glamorgan who, as the Director of Studies, gave me guidance, support and was especially patient while I was writing up my thesis.

My special thanks to Fasih Alam, Research Fellow at the University of Glamorgan not only for providing me with statistical support for this project but also improving my knowledge of SPSS®.

I would like to record my gratitude for the support from various audit staff in locating and collecting case notes. My special thanks to Ms. Lisa Wells and Mrs. Pam Green, colorectal department secretaries at Prince Charles Hospital who have provided me with help and support.

I am thankful to my wife, Priti for her time and patience whilst I spent time to do this project. I am also grateful to my sons Avaneesh (Athrv) and Adhit for keeping my stress levels low!

Abstract

Introduction

Survival in colorectal cancer patients is dependant on the stage of the cancer at diagnosis. Referral via an appropriate pathway to a specialist service is vital to the early detection of colorectal cancer but there is neither a standard referral system nor a nationally agreed referral pathway in the UK. Though studies have compared individual components of different models of health care in colorectal cancer, this is the first study comparing two models in their entirety.

Hypothesis

The distinct model of service delivery in Trust A picks up a higher percentage of early colorectal cancers than the model of service delivery in Trust B.

Method

The study compares colorectal cancers diagnosed from two adjacent Trusts in Wales during a three year period. The samples obtained after rigid exclusions correlate the two models of health care with the stage of cancer at diagnosis.

Results

Trust A has a higher emergency and urgent workload. The overall pick up of early cancers is similar in both Trusts. However, there is a higher pick up rate of early colorectal cancer in Trust A, when GPs accessed the specialist service using an urgent referral through the elective route. Trust A had lower overall waiting times for the first clinic appointment but there was no difference for urgent cases between the two Trusts. Specialists in Trust B had a higher rate of re-prioritisation of urgent GP referrals to the non urgent category.

Conclusion

There appears to be no significant difference in the overall pick-up rate of modified Dukes' A colorectal cancers between the two models of health care delivery. The higher pick up rate of early colorectal cancer in Trust A was achieved only where GPs sent patients into the specialist service using an urgent referral through the elective route.

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List of Abbreviations

MDM	Multidisciplinary meeting
MDT	Multidisciplinary Team
RACRC	Rapid access colorectal clinics
ACPGBI	Association of Coloproctology of Great Britain and Ireland
NHS	National Health Service
GP	General Practitioner
OAFS	Open access flexible sigmoidoscopy
CIBH	Change in bowel habits
TNM	Tumour, node and metastases classification
SD	Standard Deviation
A&E	Accident and Emergency department
TI	Townsend Index

Definitions

Colorectal Cancers:

All tumours originating from the mucosa of the colon or rectum and described histologically as an adenocarcinoma.

Colon cancers:

All tumours fitting the above criteria originating in any part of the colon and classified according to the specific site as follows:

Caecum, ascending colon, transverse colon, descending colon and sigmoid colon.

Rectal cancers[1]:

Any tumour where the lower margin of the tumour is within 15 cm of anal verge as defined by the consultant in the patient case notes, as per the definition from the Association of Coloproctology of Great Britain and Ireland [1].

Elective route of access:

Any patient referred to and seen in the outpatient services which include special colorectal clinic (RACRC), general outpatient clinics and open access nurse led flexible sigmoidoscopy service. These referrals may have originated

from general practitioners (letters or designated forms) or Inter-departmental (from specialties other than colorectal surgery).

The elective route of access has been further sub-divided into urgent and non-urgent categories (Flow diagram 1).

Urgent referral:

Any referral deemed to be urgent by a general practitioner (GP) or by a specialist colorectal consultant. These may include GP referrals via the designated colorectal referral forms appropriately annotated as urgent referrals, referrals by general practitioners using a letter and inter-departmental referrals from hospital consultants other than colorectal specialists (Flow diagram 1).

Non - urgent referral:

Any referral not prioritised as urgent in the designated forms and all referrals from any source prioritised as non-urgent by the specialist colorectal consultants (Flow diagram 1).

Emergency routes of access:

Any patient seen by the colorectal team on a non-elective basis. These could originate through the Accident and Emergency Department or from general

practitioners admitting acutely unwell patients as emergencies or by other consultant colleagues requesting an immediate consultation for their in-patients (Flow diagram 1).

Modified Dukes' staging (based on histological examination of the resection specimen after operation).

This is accepted as one of the standard pathological staging processes for colorectal cancer [1, 2].

- A Invasive adenocarcinoma not breaching the muscularis propria
- B Invasive carcinoma breaching the muscularis propria, but not involving regional lymph nodes
- C1 Invasive carcinoma involving regional lymph nodes (apical node negative)
- C2 Invasive carcinoma involving regional lymph nodes (apical node positive)
- D Presence of distant metastases (now accepted as Dukes' D, though not described in the original modified Dukes' staging)

TNM staging

This is now the accepted international standard pathological staging system

T Primary tumour

Tx Primary tumour cannot be assessed

T0 No evidence of primary tumour

T1 Tumour invades submucosa

T2 Tumour invades muscularis propria

T3 Tumour invades through muscularis propria into subserosa or into non-peritonealised pericolic or perirectal tissues

T4 Tumour perforates the visceral peritoneum or directly invades other organs or structures

N Regional lymph nodes

Nx Regional lymph nodes cannot be assessed

N0 No regional lymph node metastases

N1 Metastases in 1 to 3 pericolic or perirectal lymph nodes

N2 Metastases in 4 or more pericolic or perirectal lymph nodes

M Distant metastases

M0 No distant metastases

M1 Distant metastases

Correlation between the Dukes' staging and TNM staging:

	T Stage	N stage	M stage
Dukes' A	T1 / T2	N0	M0
Dukes' B	T3 / T4	N0	M0
Dukes' C	Any T	N1 / N2	M0
Dukes' D	Any T	Any N	M1

Dukes' A (early cancer) correspondence to colorectal cancer localised within the bowel with no nodal spread and absence of distant metastases.

Curative resection:

This was defined as removal of the primary tumour in patients with no evidence of distant metastases, in which there was no macroscopic or microscopic evidence of residual disease either locally or at distant sites on histological examination.

Rapid access colorectal clinic / Fast track colorectal clinics:

These are specialist clinics, which are designed to assess patients who are referred with high-risk symptoms with suspicion of colorectal cancer.

One stop clinic / Rapid access colorectal clinic with flexible sigmoidoscopy:

These are specialist clinics as defined above with the facility to perform immediate flexible sigmoidoscopy (endoscopic examination of the rectum and distal colon) during the same visit.

Open access flexible sigmoidoscopy clinic:

These are specialist clinics to which general practitioners directly refer patients with symptoms of rectal bleeding for flexible sigmoidoscopy. Once the procedure is performed patients are referred back to the general practitioners or referred to other specialists for opinion or further management. These services can be Doctor (consultant) led or Nurse led.

Nurse led flexible sigmoidoscopy clinic:

These are services provided by specially trained nurses who perform flexible sigmoidoscopy independently and can be accessed directly by general practitioners without a referral to a specialist colorectal consultant.

Trusts

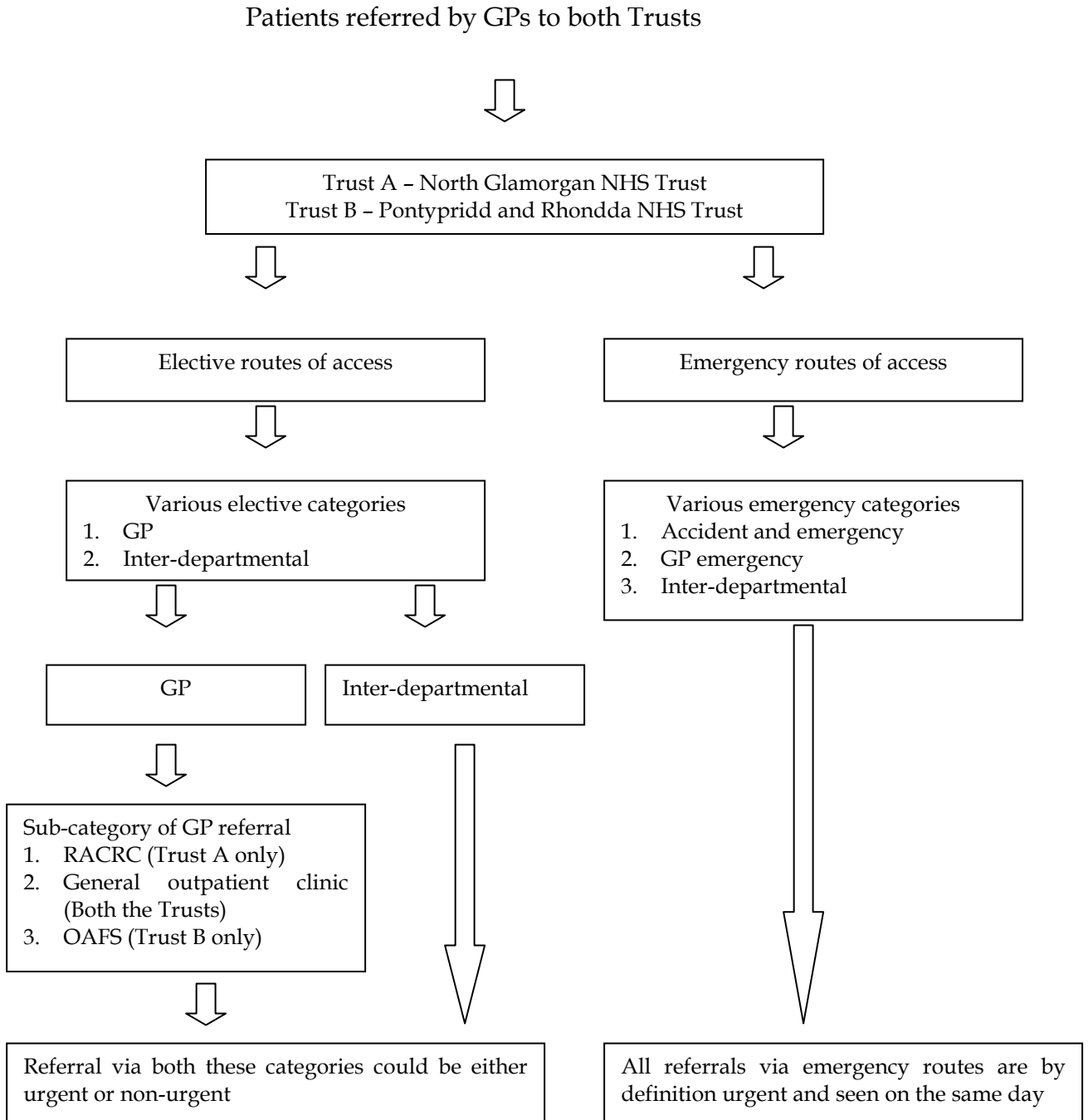
Trusts are organisations responsible for managing and/or delivering health services. There are a variety of Trusts, the two most common being Primary Care Trusts (PCTs) and NHS Trusts. PCTs are local organisations responsible for managing health services in a given local area. A PCT in Wales is referred

to as a Local Health Board (LHB). NHS Trusts manage hospitals, but can also provide services in the community [3].

Access mechanisms of referral in the models of health care delivery in present study:

Flow diagram 1 illustrates the access mechanisms for patients with colorectal cancer in the models of health care delivery being discussed in this study.

Access mechanisms of referral in the models of health care delivery in this study (Flow diagram 1)



Chapter 1

Introduction

1.1 General introduction

Survival in colorectal cancer patients is dependant on the stage of the cancer at diagnosis. Referral via an appropriate pathway to a specialist service is vital to the early detection of colorectal cancer. It is clear from the literature that there is neither a standard referral system nor a nationally agreed referral pathway in the UK to assess these patients. This thesis will attempt to evaluate two different models of service provision with regard to the diagnosis for patients suspected to have colorectal cancer. Such a study comparing the effectiveness of models in their entirety, one incorporating a rapid access colorectal clinic with flexible sigmoidoscopy as one of its components and the other, with a general surgical outpatient clinic has not been undertaken previously.

1.2 Aim

The aim of this thesis is to compare the clinical effectiveness of these two models of service delivery in South Wales with specific regard to the diagnosis, for patients suspected to have colorectal cancer.

1.3 Specific objectives

- a) To identify different characteristics of models of care for the diagnosis of colorectal cancer across the UK as published in the literature.

- b) To highlight these characteristics specifically in the North Glamorgan NHS Trust (Trust A) and the Pontypridd and Rhondda NHS Trust (Trust B) included in this study.
- c) To compare the impact of these two different models of service on the tumour stage at diagnosis.
- d) To correlate stages of cancer at diagnosis with the deprivation levels.

1.4 Hypothesis

The model of service delivery in Trust A picks up a higher percentage of early colorectal cancers (modified Dukes' A) than the model of service delivery in Trust B.

1.5 Chapters

Chapter 2 will provide the background to this study with specific reference to the aims and objectives set out above. It will discuss the referral systems in the two participating Trusts and describe the prioritization of referral letters from general practitioners prior to the first outpatient appointment. It will also highlight the high-risk criteria used. Finally, it will discuss the key differences in the two Trusts.

Chapter 3, the literature review, will concentrate on the current status of the diagnosis of colorectal cancer in the UK along with the referral models by

which urgent and non-urgent patients are assessed in various types of clinics. It will discuss the stage of cancer and delays in diagnosis with respect to the guidelines and standards laid down by the Department of Health.

Chapter 4 will explain the methods used to perform this study. It will describe the type of study, define the sample and specify the inclusion and exclusion criteria. It will also highlight issues around data protection, its sources, and the methodology of data analysis.

Chapter 5 is the results chapter and is divided into 4 sections. The first section discusses the overall cancers diagnosed in the two Trusts, the sample and the reasons for exclusion. It also compares the demographics of the sample with the Welsh data. It then compares the demographics of the samples from each of the two Trusts. The second section presents and analyses the results of the different routes of access and the waiting times for these different routes for the patients in the study. The third section presents the anatomical location of the cancers diagnosed in the study population in relation to their stage at diagnosis and routes of access to the specialist services and also correlates the deprivation levels of the population with the stage of cancer at diagnosis. Finally, the fourth section summarises the significant results of the present study.

Chapter 6 entitled 'Discussion', reviews the results of this study from each of the result sections above, in the light of available literature and published studies internationally, in the UK and from these Two Trusts. It will also briefly discuss the potential cost implications of these models of health care delivery.

Chapter 7 will present the conclusions drawn from this study.

Chapter 8 will discuss the possible future research and recommendation from this study.

Chapter 2

Background

2.1 Incidence, survival and mortality of colorectal cancer

Colorectal cancer is one of the most common malignant conditions with an annual incidence of approximately 35,000 cases per year (1, 4) and is the second most frequent cause of cancer death in the UK. Although, there have been many advances in diagnosis and treatment modalities in recent years, there has been only a moderate improvement in the survival (5). Survival from bowel cancer in the UK is worse than the USA or Europe owing to presentation of patients with advanced disease (6, 7). The death rate from colorectal cancer in Wales is amongst the highest in the United Kingdom (3). It is higher for colon cancer than rectal cancers. The mortality for colon cancers in 2000 was 26.2 (crude rate per 100,000) for men and 21.8 (crude rate per 100,000) and that for rectal cancers was 10.7 (crude rate per 100,000) for men and 7.7 (crude rate per 100,000) for women (3). Approximately 25% of patients in the UK and other countries present with locally advanced or metastatic disease (6-8).

2.2 Stage of colorectal cancer and survival

The system used for staging of colorectal cancer is the one described by Cuthbert Dukes in 1930 and later modified by Astler and Coller (1954). According to this system, modified Dukes' A denotes an early cancer. The TNM classification (as described in section on 'definitions') is currently accepted as a standard method of evaluating disease extent. Early colorectal cancer stage (Dukes' A) correspondence to T1 or T2 cancers with no nodal

disease and absence of distant metastases. Accurate pathological staging of the disease can be done only post-operatively and this informs the decision for any further adjuvant oncological treatment. Survival in colorectal cancer depends predominantly on the stage of the tumour at diagnosis, though there are several other less significant factors (9-11). Patients with Dukes' stage A (T1/T2,N0,M0) have a much better 5-year survival of over 80% as compared to those with Dukes' stage D (Any T, any N, M1) which is approximately 3% (1).

The current guidelines published by the Association of Coloproctology of Great Britain and Ireland (ACPGBI) place great emphasis on reducing the duration from presentation of symptoms to specialist assessment (4). This can be achieved by models care encompassing early referral, designated referral pathways and clear investigative and management protocols.

2.3 Early referral

In order to improve service provisions for colorectal cancer, it is important for patients to identify symptoms early and for general practitioners and hospital clinicians to be aware of guidelines. In the UK, 25 - 33% of colorectal patients present as an emergency admission with large bowel obstruction or other symptoms. The average general practitioner is likely to encounter one such patient every three years (3). These patients have poorer outcome than patients who present electively, along with high cancer-related and inter-current death

rates (12). A study published from Italy which looked at colorectal cancers diagnosed over 14 years highlighted that a patient's level of education regarding symptoms of colorectal cancer, the increased use of colonoscopy and a greater attention to symptoms were all significant factors in improving survival in colorectal cancers and resulted in an increase in the detection of localised (Dukes' A or T1/T2, N0, M0) colorectal cancers (13).

Symptoms relating to intestinal problems are very common which means that identifying the few patients who will turn out to have bowel cancer can be difficult. The ACPGBI guidelines for general practitioners aim to identify patients with a high risk of colorectal cancer. These referral guidelines facilitate referral of high-risk patients to specialist clinics for their assessment as per the Department of Health's Two-week standard (6, 14).

Early diagnosis demands health care delivery with clearly defined reliable referral pathways for patients suspected to have colorectal cancer, so that they can be prioritised and fast tracked to specialist services (1).

2.4 Screening

A significant survival advantage and diagnosis of early cancer can be achieved by screening asymptomatic populations (15). This has been demonstrated convincingly in cervical and breast cancers in the UK (16-18) and in colorectal

cancer in the USA (17). The national bowel cancer-screening programme is at present being set up in the UK and will achieve nation wide coverage by 2009 (19). The results of the pilot programme showed that nearly 48% of these screen detected cancer were modified Dukes' A (19). Initial results from a multicentre Medical Research Council (MRC) trial of screening with flexible sigmoidoscopy of people aged 55-65, followed by colonoscopy in those considered to be at high risk showed that cancers were found in 0.3% of those screened, 74% of which were Dukes' stage A or stage B, and adenomas were detected in 12% (3).

2.5 Stage at diagnosis

The pick up rate for modified Dukes' A cancers in outpatient clinics in the UK varies between 9 to 15% (20) with very little change over the last 20 years(21, 22), in spite of the introduction of the "Two Week Standard". The variability in the pick up rate may be related to the overall model of care provided rather than the individual clinicians concerned.

Specialist clinics with flexible sigmoidoscopy have reported a 23% pick up rate of with Dukes' A cancer (23) and those without flexible sigmoidoscopy have been shown to be less efficacious in this regard (24). Open access nurse led flexible sigmoidoscopy clinics alone have better patient acceptability but cancer

yield is poor when compared with doctor led service (one stop clinic). They also appear to have little impact on the utilisation of radiological resources (25).

The importance of diagnosis of colorectal cancers at an early stage is further discussed in detail in the review of literature.

2.6 Trusts

There are two Trusts in South East Wales covering a population of 330,000 providing secondary care service to Merthyr and Rhondda - Cynon - Taff valleys, Trust A (The North Glamorgan NHS Trust) and Trust B (The Pontypridd and Rhondda NHS Trust). Since this work was undertaken the two Trusts have merged (April 1, 2008) to form the Cwm Taf NHS Trust.

Trust A: The North Glamorgan NHS Trust

The North Glamorgan NHS Trust was established in April 1996 to provide acute, community and mental health services to the people in the Merthyr, Cynon and upper Rhymney valleys in South Wales. The Trust's catchment population is approximately 150,000.

Trust B: The Pontypridd and Rhondda NHS Trust

Serving a population of 180,000, The Pontypridd and Rhondda NHS was established in April 1999 and aims to meet the physical and mental health care needs of the people in Rhondda Cynon Taff and Taff Ely.

These two Trusts have similar distributions of general population with respect to gender, age distribution and socio-economic status (26); however in one Trust all patients are assessed in general outpatient clinics with support from a nurse led flexible sigmoidoscopy service. The neighbouring Trust has a rapid access colorectal clinic with a flexible sigmoidoscopy service, where most of the patients are assessed. This is in addition to general outpatient clinics.

These two different models of service delivery may lead to differences in the stage at which colorectal cancers are diagnosed. Such a comparative study has not been undertaken previously. The detailed access mechanism to specialist services is discussed in 2.7.

2.7 Routes of access to specialist services

As seen from flow diagram 2, the primary mode of elective colorectal referrals to the specialist units in both Trusts is through outpatient clinics. In Trust A, designated rapid access colorectal clinics (with flexible sigmoidoscopy) as well as general outpatient clinics are used to assess patients with suspected

colorectal cancers. In Trust B, patients are seen in general outpatient clinics. In addition, there is an open access nurse-led flexible sigmoidoscopy service, which is also used to diagnose cancers.

Both Trusts also receive emergency referrals to the specialist units from Accident & Emergency and other departments within the hospital (flow diagram 3 and 4).

There is a further variation in the referral systems of the two Trusts. In Trust A, there is a special designated referral form (Appendix I), which is used by general practitioners to refer patients with colorectal symptoms. Its unique design allows classification by general practitioners of these referrals as urgent and non-urgent. A tick mark in the box at the top right hand corner would prioritise the referral as an urgent case, which results in the patient being appointed to the clinic within 14 calendar days. In addition to this referral route, GP letters are also received by Trust A (flow diagram 3), which need prioritisation by the specialists.

As seen from flow diagram 4, in Trust B, if a patient is referred via the designated referral form then it is not re-prioritised. Although the designated form is available in Trust B, it is not the preferred mode of referral by general

practitioners (personal communications) and hence the consultants in Trust B have to prioritise most of the referral letters received.

2.8 Development of RACRC in Trust A

The RACRC was established in Trust A in 1997 as a part of colorectal sub specialisation along with a multi-disciplinary team. Initially, the referral criteria were very general. However, a designated referral form was structured and disseminated to the general practitioners in 2000. This was based on a local audit to assess the sensitivity and specificity of the new high risk referral criteria from the ACPGBI (modified ACPGBI criteria as described in 2.10). Once the patients were reviewed in the RACRC, a strict criterion of rectal bleeding with age above 50 years was used to select patients for immediate on-site flexible sigmoidoscopy which was performed under consultant supervision (23). An initial audit highlighted cancer pick up rate of 23% from this services (23).

2.9 Development of OAFS in Trust B

A nurse led open access flexible sigmoidoscopy service was introduced in 1996 in Trust B after a senior endoscopy nurse practitioner was trained in accordance with approved guidelines. This service utilised minimal referral criteria (age > 45 years and fresh rectal bleeding). The acceptance of this clinic by general practitioners in the first year itself was 41% (25, 27, 28). A nurse

endoscopist role was developed to support the general outpatient clinics in assessing patients referred with rectal bleeding (personal communication). However, a previous study from Trust B has shown a low cancer yield with OAFS (25).

2.10 High-risk colorectal symptoms for an urgent referral

Only patients with new and persistent symptoms listed below should be referred to the fast-track system as per the guidelines from the Association of Coloproctology of Great Britain and Ireland (ACPGBI). These criteria are as follows:

1. Rectal bleeding WITH a change in bowel habit to increased frequency of defecation and/or looser stools and persistent for at least 6 weeks – All ages
2. Rectal bleeding persistently without anal symptoms – over 60 years
3. Change in bowel habits to increased frequency of defecation and /or looser stools persistent for at least 6 weeks – over 60 years
4. Patients with an easily palpable right iliac fossa mass
5. Patients with an easily palpable intraluminal rectal mass
6. Patients with an unexplained iron deficiency anaemia:
 - a. Haemoglobin below 11g/dl in men – All ages
 - b. Haemoglobin below 10g/dl in women – post-menopausal

A previous study carried out in Trust A (29), however showed that these criteria lacked sensitivity. This study reviewed 50 consecutive colorectal cancers diagnosed in 2000. According to the above criteria, 82% of these cancer patients would have been suitable for referral to the rapid access colorectal clinics. However, 18% of the cancers would have been missed, as they would not have been eligible for referral if these criteria had been applied. The authors recommended modifying the criteria, which increased the sensitivity to 94% (29).

Therefore, these criteria were modified as follows and have been used successfully in both Trusts. These modified criteria are:

- 1 Rectal bleeding with change in bowel habits (CIBH) - 6 weeks (all ages)
- 2 CIBH without rectal bleeding - 6 weeks (>50 yrs)
- 3 Rectal bleeding without anal symptoms (> 50 yrs)
- 4 A definite palpable abdominal mass (all ages)
- 5 A definite palpable rectal mass
- 6 Iron deficiency anaemia
- 7 Abdominal pain and weight loss

Both the Trusts have a policy of re-prioritising referral letters. Re-prioritisation of these referrals can either upgrade them to urgent or downgrade to non-

urgent. However, both Trusts do not re-prioritise referrals sent in on the designated forms.

All patients suspected with colorectal cancer (prioritised urgent letters and urgent designated forms) are expected to be seen within 14 calendar days of the GP referral in both the Trusts, as per the Department of Health regulations.

After initial assessment in the outpatient clinics, urgent investigations are arranged for patients suspected to have colorectal cancers. This process has inherent delays as seen in the flow diagram 1 from the time of referral from general practitioners to the diagnosis and staging of patients with colorectal cancers as shown below:

1. The time from referral from GP to 1st clinic appointment.
2. The time from receipt of referral in the Trust to the first out-patient appointment.
3. Time of the consultants for prioritisation of referrals by the GP.
4. The time first seen by specialist (consultant) to the date of the definitive diagnostic test.
5. The time from confirmation of diagnosis to completion of staging.

Multidisciplinary meetings (MDM) are an inherent part of all cancer services in the UK. They are composed of the surgical teams led by consultant colorectal surgeons, consultant radiologists, consultant pathologists, consultant oncologists, colorectal specialist nurses, and the palliative care team. All the colorectal cancers diagnosed are discussed in the MDM initially to assess pre-operative staging and formulate a treatment plan. The cases are discussed again to review the post-operative histology and plan further treatment and follow up. In both Trusts, colorectal cancers are discussed on a weekly basis and dealt with through the respective MDMs.

After definitive diagnosis, all patients have staging investigation to establish the stage of the disease and rule out distant metastases. After staging, patients are subjected to treatment, either curative or palliative (surgery or radiotherapy or chemotherapy or a combination of treatment). These aspects are beyond the scope of the present study.

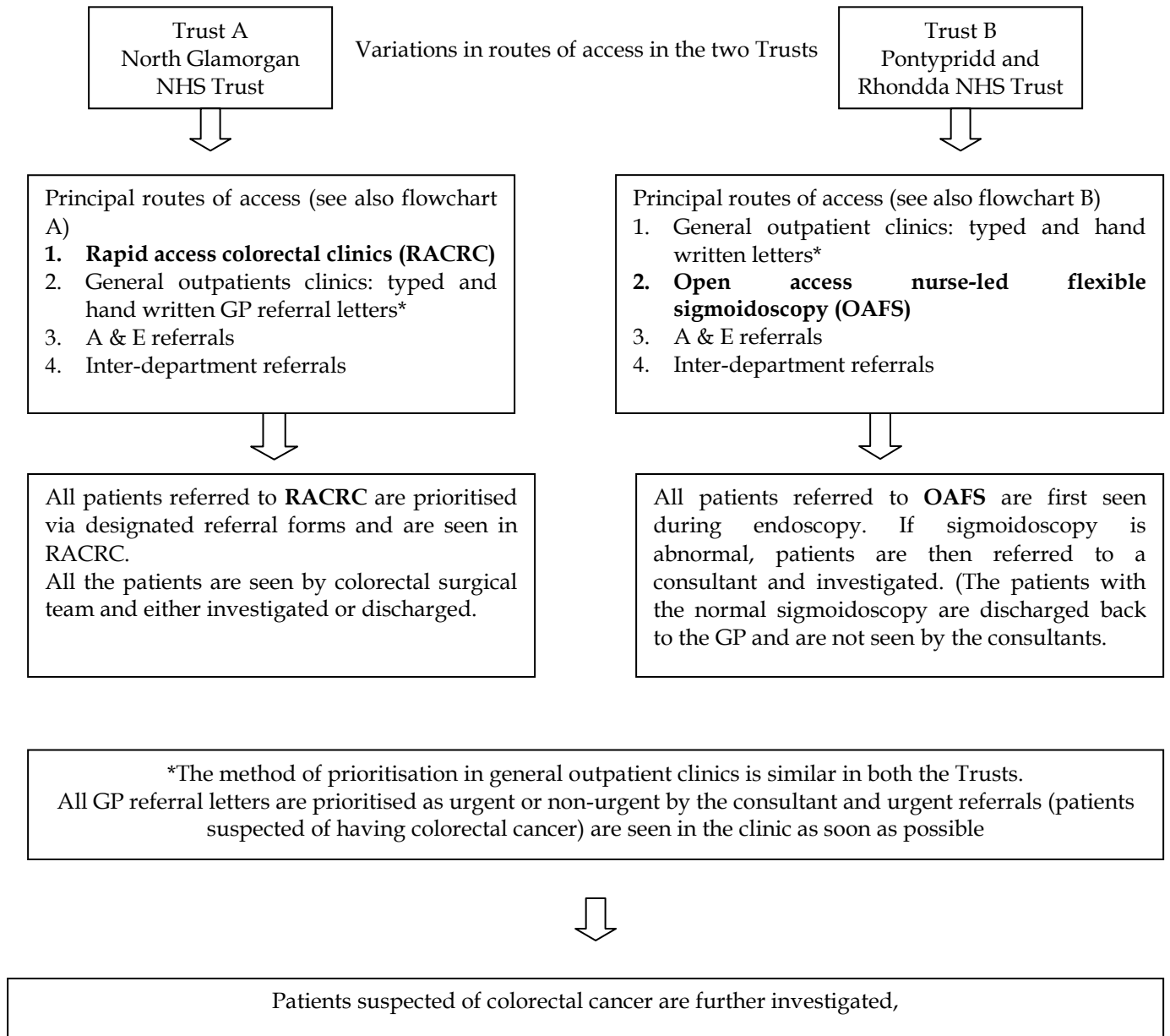
2.11 Key differences in the referral systems in the two Trusts

1. Trust A has a designated rapid access colorectal clinic (RACRC) with flexible sigmoidoscopy. (This does not exist in Trust B).
2. Trust B has an open access flexible sigmoidoscopy clinic (OAFS) run by a nurse specialist. (This does not exist in Trust A).

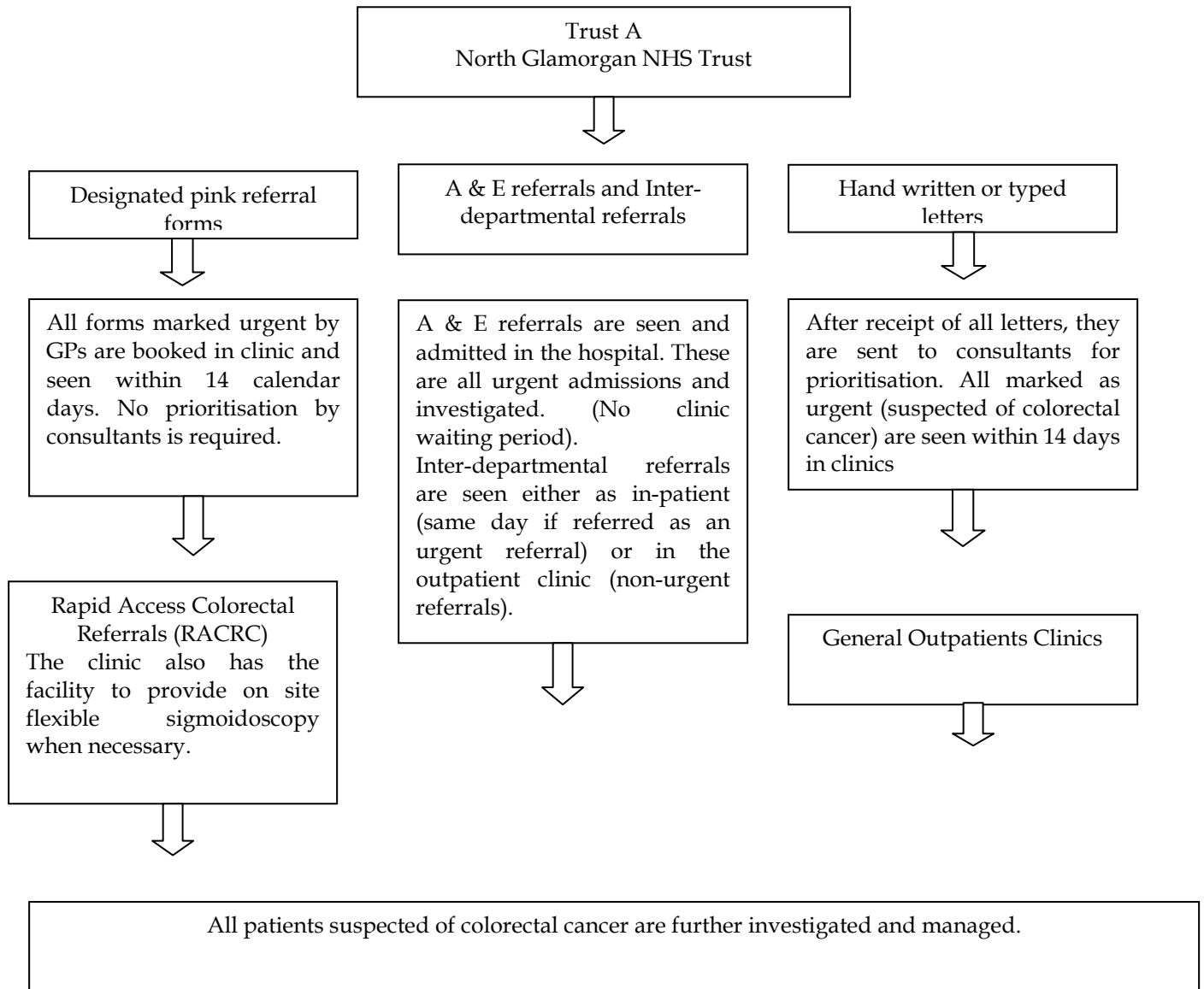
3. In Trust B, all patients referred to the specialist are assessed in general outpatient clinics. In Trust A, patients are assessed in RACRC. In addition, general outpatient clinics are used for assessment of any patients who have not been referred using the designated rapid access referral forms.
4. All patients referred via emergency routes of access are either assessed in the accident and emergency department or on the ward as in-patient if referred from other departments. This is similar in both the Trusts.
5. There are designated forms available in both Trusts. Whenever the designated forms are used, re-prioritisation by a specialist consultant is not required. (The use of these forms by general practitioners to refer patients varies in both the Trusts).
6. Both the Trusts receive a variable number of referrals via hand written or typed general practitioners' (GP) letters. All these are re-prioritised by specialist consultants.
7. Patients are also referred from non colorectal hospital consultants. These can be referred via either the elective routes of access and seen in the clinics or emergency as described earlier as in-patients. All these referrals via the elective routes of access are re-prioritised

Referral pathway in the two Trusts (Flow diagram 2)

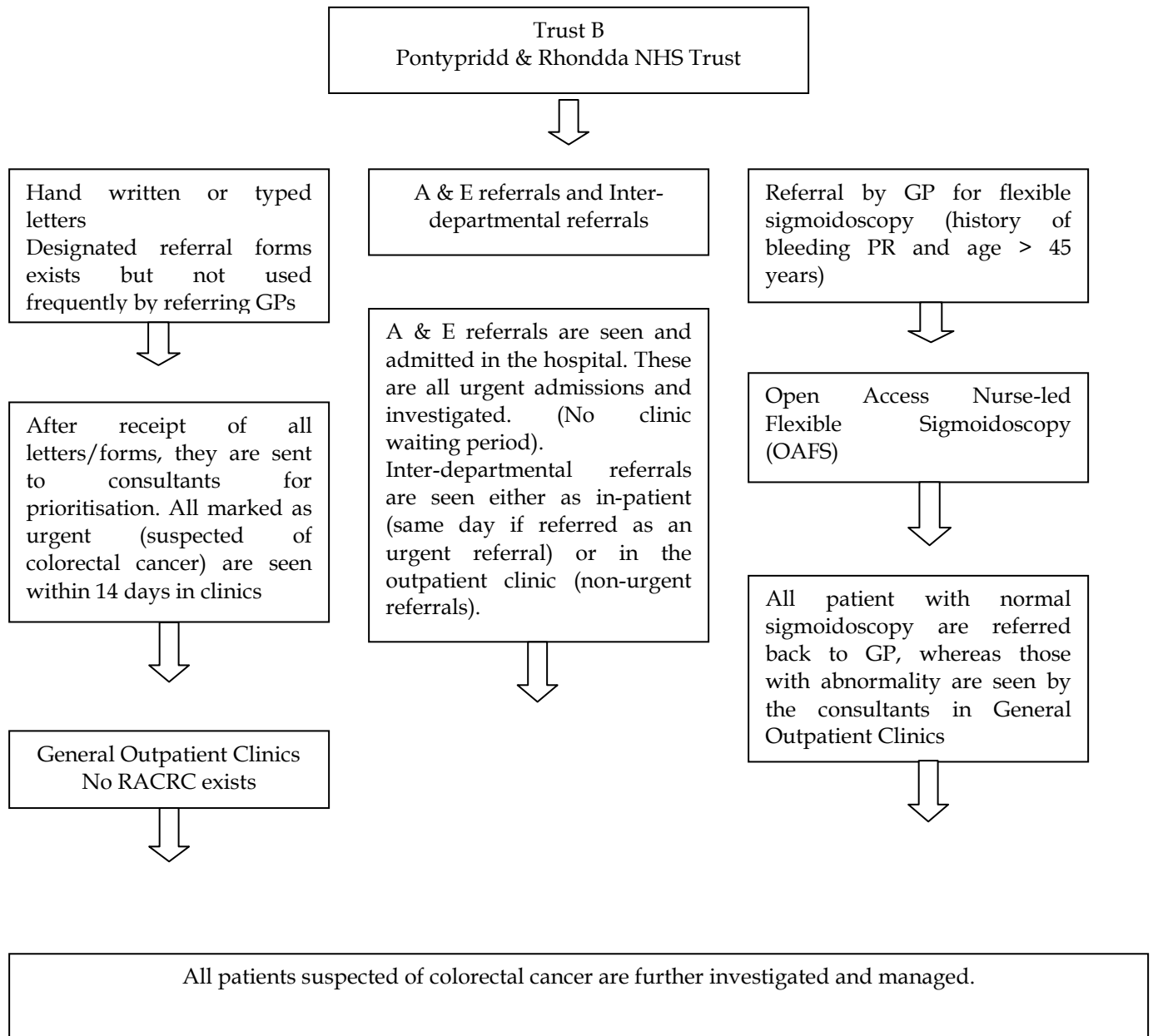
Patients referred by GPs to both Trusts



Patients referred by GPs to Trust A (Flow diagram 3)



Patients referred by GPs to Trust B (Flow diagram 4)



2.12 Research problem

Survival in colorectal cancer patients is dependant on the stage of the cancer at diagnosis. Referral via an appropriate pathway to a specialist service is key to the early detection of colorectal cancer. It will be clear from the review of literature that there is neither a standard referral system nor a nationally agreed referral pathway in the UK to assess these patients. This thesis will attempt to evaluate two different models of service provision with regard to the diagnosis for patients suspected to have colorectal cancer. A previous study by Arumugam *et al* compared RACRC in Trust A with OAFS with Trust B (25). However, these were only components of the two models of health care delivery. A study comparing the effectiveness of entire models on the pick up rate of early cancer, one with a rapid access colorectal clinic incorporating immediate flexible sigmoidoscopy, as one of its components, and the other, a general surgical outpatient clinic, has not been undertaken previously. Hospitals/ Trusts in the UK use a combination of routes of referral which make each one virtually unique. Most commonly, patients are seen in either general outpatient clinics or rapid access colorectal clinics (one stop access) with different referral pathways, forming different models of service delivery. A comparison between some of these different models in their entirety may help delineate systems with better diagnosis rates for early cancers.

This study is based on the hypothesis that the model of health care delivery in Trust A has a better pick up rate of early stage colorectal cancers as compared to the model in Trust B.

Chapter 3

Review of literature

3.1 Scope of literature review

Given the aims of this research project, the review of the literature will concentrate on the current practices in the diagnosis of colorectal cancer in the United Kingdom and the models of health care delivery (including the various types of clinics and referral pathways etc.), by which patients suspected of colorectal cancer are being assessed. This study is mainly concerned with different referral pathways. The literature review will exclude studies concerned with the screening of asymptomatic patients for colorectal cancer as well as the various aspects of investigation, treatments (operative or radio-chemotherapy) or follow up.

The review will begin by highlighting the prevalence and incidence of colorectal cancer in the UK, as well as the stage of cancer and survival data in the UK along with guidelines and standards laid down by the government to improve the detection of early cancer. It will then discuss the main issue of the referral systems in the UK and attempt to discuss published studies on various types of outpatient services. Finally, it will stress on reasons for delays in diagnosis of colorectal cancer and factors impacting on the stage of the cancer at diagnosis.

3.2 Literature review method

A review of literature was performed using Medline, Ovid and Cochrane databases in the English language publications relating to colorectal referrals and staging. The keywords used to search the databases were colorectal cancer, rapid access clinic, one stop clinic, referral, stage, early cancer, prioritisation, open access flexible sigmoidoscopy, waiting times, delays, two week standard and Dukes' A. Although there was no date restriction on the studies considered, only those studies with references published on search databases were considered for the review.

3.3 Colorectal cancer in the UK

In the UK, about 35,000 people are diagnosed with bowel cancer every year with little change in the national 5-year mortality rate of 40% over the past many years. In England and Wales, colorectal cancer is the second commonest cause of cancer related death in the UK after lung cancer in terms of both incidence and mortality (1, 3, 4). The incidence of colorectal cancers in England and Wales is 52.85 per 100,000 and mean age of presentation is 71 years. In the UK, male incidence rates have increased by an average of 1% each year for the last 20 years, but in women, the rates have changed very little (30).

In Wales, colorectal cancer is the second most common cancer in males and the third most common cancer (after breast and lung) in women. In the 5-year

period 1986-1990, there was an average of 870 new registrations per annum for colorectal cancer in both men and women, which was higher than any of the other regions (30, 31).

Survival from bowel cancer in the UK is poorer than in Europe, perhaps because approximately one quarter of the UK patients are diagnosed with incurable disease or have delayed treatment (6, 7, 30, 32). A study by Gatta *et al* looked at the 5-year survival for the colorectal cancer across Europe. In Europe, only Netherlands, Sweden, Switzerland and France had 5-year survival greater than 50% in both sexes. This was compared with the available data from US, Japan and Australia where it was between 50 - 60% (32). The death rate from colorectal cancer in Wales is amongst the highest in the UK (3). The mortality for colon cancers in 2000 was 26.2 (crude rate per 100,000) for men and 21.8 (crude rate per 100,000) and that for rectal cancers was 10.7 (crude rate per 100,000) for men and 7.7 for women (crude rate per 100,000) (3).

3.4 Stage of colorectal cancer and survival

Tumour stage at diagnosis is one the most important prognostic factors for survival of patients with colorectal cancer along with vascular invasion and tumour ploidy (33). Several studies have shown that survival in colorectal cancer is directly related to the stage at diagnosis (1, 30, 34). Data from the Birmingham registry between 1977 and 1981 indicated that, after curative

resection the 5 year-age-adjusted survival for colon cancer was 85%, 67% and 37% for Dukes' A, B and C cancers stage (1). Other factors include the number and location of affected lymph nodes (10) and presence of hepatic metastases (11). Wrigley *et al* have shown that socio-economic factors and cultural differences also play a significant role in survival after colorectal cancer (9). The reasons for these, however, are not clear (3). There have been improvements in the 5-year survival from colorectal cancer over the last 25 years for both colon and rectal cancer in both the sexes. This is due to earlier diagnosis and better treatment; nevertheless, the overall picture in the UK is still disappointing (30). As mentioned in 3.3, the poor survival in the UK as compared to the rest of the Europe relates to late presentation or delay in treatment (30).

Patients diagnosed and treated at an early stage have a better 5-year survival as compared to those with advanced disease (35). Approximately 25% of patients in the UK and other countries present with locally advanced or metastatic disease (6-8). A study from Rome by Barillari *et al* divided the patients diagnosed with colorectal cancer in groups according to the duration of symptoms. Their study showed that asymptomatic patients appeared to present with less advanced disease (higher incidence of T1N0M0) and thus had better survival (36). Interestingly, the study also highlighted that the duration of intestinal symptoms did not appear to be related to the stage and prognosis

of tumours (36), as the other groups with symptoms varying from < 3 months to more than a year had no correlation between the site of cancer or the stage. A study by Kiran *et al* also showed no significant difference in Dukes' staging in patients with symptoms lasting less or more than 6 months (37). Adams *et al* showed that if elderly patients survived their operation, they had a better prognosis than younger patients (38, 39). Patients aged < 40 years have a poorer prognosis as they are usually diagnosed with advanced disease (40-42). However, a literature review performed by O'Connell *et al* showed that if young people are diagnosed early (Dukes' A or B), they have a better 5-year survival (43). People with colorectal cancer tend to develop non-specific symptoms leading to emergency presentation with advanced disease (3). These patients are also associated with high post-operative mortality and a poor 5-year survival (12). A study by Scott *et al* highlighted that (44) 5-year survival rate was lower for colorectal cancer presenting as emergency when compared to elective presentations (29% versus 39 %).

3.5 Guidelines

Guidelines for the management of colorectal cancer have been published by the Association of Coloproctology of Great Britain and Ireland (ACPGBI) in co-operation with the British Society of Gastroenterology (BSG) and the Royal College of General Practitioners (1). The guidelines state that "*the high incidence of this disease, together with the fact that improvement in mortality in recent years has*

been modest, highlights the need for research into prevention, earlier diagnosis and better treatment” (1, 4). In the absence of clearly defined screening protocols, the path to earlier diagnosis clearly involves the time from presentation to specialist assessment being as short as possible.

Questions have been raised regarding the sensitivity (accuracy of diagnosing colorectal cancer) and specificity (accuracy of ruling out colorectal cancer) of the referral guidelines published by ACPGBI and the Royal College of Surgeons and modifications have been suggested to make the guidelines more effective (29, 45). The ACPGBI referrals criteria have sensitivity between 80 – 90 %, which can be increased to over 90% by bringing down cut off age to 50 years instead of 60 years (29).

3.6 Early referral

A high percentage of colorectal cancers present as emergency admissions (6-8). Waldron *et al* looked at the presentation in patients aged less and greater than 70 years and found that older patients > 70 years are more likely to present as emergencies (58% versus 41%) (46). A study from a district general hospital by Scott *et al* also confirmed a high incidence (30%) of colorectal cancers presenting as an emergency admission (44). These patients have more advanced tumours (Dukes stage B and C, 96% versus 88% of those admitted electively). The mortality (19 versus 8 %) was higher in the emergency group.

They had shorter history but longer stay in the hospital (median stay 16 versus 13 days). Hence, these patients require far greater resource provision from the hospital and the community (44). Cancer patients presenting as emergency presentation are less well and may have complications of the disease as presenting symptoms e.g. intestinal perforation or obstruction (44). Avoidance of emergency presentation by pre-emptive detection and conversion to elective care would be a rational solution to this problem (44).

A referral made to a non-surgical specialty can significantly delay diagnosis of cancer. This has been recognised with lung cancer. A study by Billing *et al* raised concerns that respiratory physicians spent on an average 109 days prior to referral to surgeons (47). Similarly in the Wessex audit on the colorectal cancer, initial referral to physicians led to significant longer delay to treatment (1).

3.7 Wessex and Trent/Wales audit

An audit of colorectal cancer management was conducted in the Trent and Wales regions in 1992-1993 and another prospective audit was conducted in Wessex from 1991 to 1994. Both these audits looked at the management of colorectal cancer patients including referral, diagnosis, clinical management and follow up. These audits highlighted that 65% of the delay in patients having elective surgery for rectal and sigmoid cancer occurred before referral

to a hospital and 20% during the process of diagnosis and treatment. These audits also highlighted the fact that there was a 15% delay from referral to patients being actually seen at specialist clinics (5). There was a longer time to treatment for patients primarily referred to physicians in comparison with those referred to surgeons (1). They also raised concern that the time to referral, diagnosis and treatment had not changed for the preceding twenty years. However, the delay in the waiting time for an outpatient appointment could be affected by introduction of the government's "Two Week" standard (1).

3.8 "Two Week" standard

In an attempt to improve the healthcare services for cancer patients, the Department of Health introduced the "Two Week Rule" with effect from 1st July 2000. According to this rule *'everyone with suspected cancer will be able to see a specialist within two weeks of their GP deciding that they need to be seen urgently and requesting an appointment'* (6, 14). This has led to changes in the practices of various surgeons and Trusts across the country (48) to reduce the waiting times from referral to the specialist clinic (14, 49). However, no steps have been taken to counteract the delay prior to referral to a specialist, which has been shown to be significant (5, 20) as highlighted by Trent/Wales and Wessex audits.

A study from Canada looking at the delay in the management of cancers has also shown that the delay has mainly been from referral to treatment which was 29 days rather than first clinics appointment which was only 11 days (50). This was due to shortage of operating room time, lack of other resources such as diagnostic tests or preference of allied health personnel and circumstance of the patient. A similar delay after the outpatient referral to diagnosis has been shown in the Trent/Wales and Wessex audits and by a study from the Porstmouth (1, 20). In view of this, the government has recently added additional targets of 62 days for the time between referral by general practitioners to the commencement of the first definitive treatment, and also of 31 days for the time between diagnosis (decision to treat) to the initiation of treatment (51). However, this literature review has not concentrated on this area, as this is beyond the scope of this study.

Over the past two years, numerous studies have raised questions regarding the appropriate working of the 'Two Week Rule'. This rule necessarily relies on the appropriateness of the referrals (20). A patient referred urgently on the basis of ACPGBI criteria will be fast tracked through the system and will be seen within two weeks. However, if the system is clogged with unnecessary or inappropriately marked urgent referrals then this may in turn prolong waiting times for non-urgent referrals (52) .

3.9 Routes of access to specialist colorectal services

There are predominately two routes of access: elective and emergency.

3.9.1 Elective route of access

The elective route is for those patients who have colorectal symptoms and are referred to outpatient diagnostic services such as RACRC, general outpatient clinic, OAFS etc. This route is predominantly used by general practitioners but also used by consultants from other specialities who have patients with colorectal symptoms.

There are three traditional routes of access for general practitioners as defined by ACPGBI, which are based on the colorectal referral criteria (1) for elective referrals:

- 1) Fast track clinics (Two-week standard) – for higher risk criteria e.g. rectal bleeding or change in bowel habits persisting for more than six weeks as described in the Background.
- 2) Urgent appointment in general outpatient clinic – persistent low risk symptoms but with other worrying factors such as positive family history.
- 3) Non-urgent appointment in general outpatient clinic – for patients with low risk symptoms who do not qualify as an urgent referral.

The two Trusts included in this study have similar routes of referral in place but there is an overlap. Trust A, as defined earlier, has a RACRC and at the same time urgent and non-urgent referrals are seen in the general outpatient clinics. In Trust B, the majority of referrals are seen in the general outpatient clinics as urgent or non-urgent, but in addition there is a nurse-led flexible sigmoidoscopy service.

3.9.2 Emergency routes of access

The emergency routes of access are predominately used by general practitioners when faced with acutely unwell patients who need immediate hospitalisation. This route is also used by patients who self present at accident and emergency departments as well as by hospital specialists other than colorectal surgeons who may have inpatients requiring emergency colorectal care.

3.10 Types of outpatient clinics in the UK

An extensive literature search has identified 3 types of clinics in which patients are being assessed.

1. One stop clinic / rapid access colorectal clinic with or without flexible sigmoidoscopy service
2. Open access flexible sigmoidoscopy service

3. General outpatient clinics (no facility for immediate flexible sigmoidoscopy)

3.11 One stop clinics

The rapid access or fast track proctology clinic has been reported as early as 1993 (53). In this report, it was a weekly walk in coloproctology clinic started in London. The review of its first year showed reduction in waiting times, improved patients' and general practitioners' satisfaction and raised awareness of colorectal disease. The first one stop or open access clinic was developed in the USA for patients suspected to have breast cancer with the facility of mammography at the same time as the first clinical examination (54). Since then, there are increasing examples of such clinics in the UK, involving a whole range of surgical and non-surgical specialities (55-59).

In recent years, rapid access or one stop colorectal clinics have become the gold standard in colorectal departments. These clinics offer immediate flexible sigmoidoscopy where the facilities are available (3, 23, 24, 49, 60). Specialist colorectal clinics e.g. fast track or rapid access are demonstrating earlier diagnosis with shorter waiting times (23, 61, 62). A study by Jones *et al* showed that one stop clinics had better acceptance even if carried out in the evening. This pilot clinic led to reduction in waiting time for flexible sigmoidoscopy from 119 to 63 days. Once this pilot project ended, the waiting list went back

up again to 108 (62). Davies *et al* have shown that fast track services reduce emergency admission to hospitals (63). The results of this study showed a similar trend; however, the difference did not achieve statistical significance ($p = 0.06$).

Studies on RACRC have shown that these clinics are associated with a higher cancer detection rate and short waiting times for specialist assessment (48). Chohan *et al* highlighted that fast track clinics (RACRC) have sped up the process of assessment of patients suspected to have colorectal cancer with better (14%) cancer yield (64). These types of services have also been shown to have better patient satisfaction (49). Overall, these clinics have led to improved clinical effectiveness with variable pick up rates of colorectal cancer between 1.7% to 14% (3, 23, 48, 49, 64).

Walsh *et al* have shown that the “Two Week Standard” has reduced clinic waiting times, but may not have had a major impact on patient outcomes; as there were no time limits for investigations or treatments (14). A review by Carter *et al* in 1993 suggested that the diagnostic delay at hospital level had increased from one week to six weeks (65). There has been evidence that this delay between the time patients are seen at clinic and the time that treatment begins has not been affected by the two week rule (14, 20). Potter *et al* showed that the average diagnostic delay may be more than one month (66), as also

shown by other studies (64). A study from Canada highlights that although there is median wait of 11 days from referral to first visit, the time from first visit to treatment is only 20 days (50). This issue is being addressed in the revised National Cancer Standard where targets have been set for diagnostic and treatment times as well as referrals times (51). Accordingly, there is now a 31 day standard for the commencement of treatment from date of diagnosis of cancer, and an overall target of 62 days from the date of urgent referral from general practitioners to the start of treatment.

The two-week standard had been used as a safety net by general practitioners to refer patients to specialist clinics. This has led to controversies on the effectiveness on the current referral system caused predominantly by a large number of inappropriate referrals flooding rapid access clinics (48). At least half of those referred as urgent cases do not fit the national guidelines (3). Some general practitioners do not follow the national guidelines correctly, as a result of which 18% of cancer patients were found to have been sent as non urgent in a report by the Commission for Health Improvement / Audit Commission (3).

Questions have been raised on the utilisation of these services as a large number of cancer patients are still sent to hospitals by other routes of access (67). 26% of the cancers diagnosed in the study by Barrett *et al* presented as emergency admissions of this 10% were admitted after being seen in the fast

track clinic. The percentage of cancers diagnosed by routes other than clinics has been reported as high as 75% (68).

3.12 Open access flexible sigmoidoscopy clinic

Open access flexible sigmoidoscopy was reported for the first time in Northern Israel (69). There were 225 patients referred for flexible sigmoidoscopy during the first year. Adenomatous polyps or colorectal cancers were detected in 27% of these referrals. Their cancer yield was 11.4% which was better than their pick up rates from barium enema examinations. A study by MacKenzie *et al* compared open access endoscopy service to consultant led outpatient clinics. There was a significant trend for patients in the consultant led service to have more investigations leading to more cost per patient. There was no difference in the time taken to diagnose cancer in the two groups. This study further recommended referral to open access endoscopy service for colonoscopy or flexible sigmoidoscopy so that patients could have their investigations at one hospital attendance (70). Open access endoscopy services have illustrated their effectiveness when compared to consultant-led clinic in terms of diagnosing colorectal cancers or requesting other large bowel investigations (70).

A similar study from both the Trusts participating in the current study has shown that though open access endoscopy services may help in reducing the delay in diagnosing colorectal cancer, they appear to have little impact on stage

of cancer at diagnosis (25, 71). In 1994, a study showed that nurses can carry out screening flexible sigmoidoscopy as accurately and safely as experienced gastroenterologists (72). Nurse endoscopists have been widely used in the USA and Australia for screening colorectal cancer (72-74). In the UK, there has been a role expansion of nurses as endoscopists over the past decade (28, 75-77).

Open access nurse led flexible sigmoidoscopy services have not been shown to be cost effective and do not lead to a reduction in the numbers of other diagnostic tests such as barium enema being performed (71). This study by Vellacott *et al* demonstrated that this service does lead to a decrease in the number of outpatient visits for patients. This study did not support the proposition that direct access flexible service should be made nationally available; however, its recommendation was that if facilities were already available, then it may have some benefit for both patients and general practitioners (71). Another study from Australia has supported that nurse led clinics have been shown to be clinically effective along with better patient satisfaction (74). Jain *et al* suggested that although nurse led diagnostic services have not been shown to be cost effective, this may be a cost effective way for screening colorectal cancer in an asymptomatic population (78).

In summary, open access clinics (doctor led or nurse led) have been found to be superior to conventional consultant led clinics; reducing waiting times for

consultation (49, 70). In addition, they appear to be more accessible, with better acceptability in comparison to conventional consultant led outpatients clinics (49).

3.13 General surgical outpatient clinics

This is a standard form of clinic routinely used to assess patients. With wider use of rapid access clinics for urgent and cancer referrals, these clinics are increasingly being used for non-urgent and potentially benign referrals. These clinics have a low pick up rate of cancers due to nature of referrals e.g. 2.2% (20). The waiting times for the first clinic appointment in these clinics vary significantly (61, 64); from 44 days for an urgent referral to 1 year for a non-colorectal benign referral to a specialist colorectal unit (79), though with the recent government targets reducing waiting times for all referrals, this is likely to reduce (51). To counteract this problem of long waiting periods, “paper clinics” have been established in various hospitals, in which the case notes with requested investigations are reviewed by consultants and a plan is derived. This actually decreases unnecessary follow up appointments (68, 80).

3.14 Prioritisation

There are various mechanisms across the UK for triaging urgent and non-urgent referrals. The standard mode of referral is a letter from a general practitioner (81), which goes through the process of prioritisation by specialist

consultants and is marked as urgent or non-urgent based on ACPGBI guidelines. This process has inherent delays as well as difficulties in accurate prioritisation due to incomplete information in the referrals letters. A previous study by Basnyat *et al* has shown that referral letters from general practitioners often do not contain enough relevant information to allow for appropriate prioritisation by hospital consultants (27). In an attempt to solve this problem, some units have developed a designated referral form based on ACPGBI high risk criteria for colorectal cancer (23, 25). This allows general practitioners to prioritise patients to be seen urgently in specialist clinics e.g. rapid access rectal bleeding or colorectal clinics with or without immediate flexible sigmoidoscopy (23) .

In a similar manner, a surgical unit at Crewe has developed a scoring system based on the number of symptoms and symptom complexes to produce a computer generated numerical score. This scoring system helps to identify patients with a high likelihood of colonic cancer (82).

For emergency referrals, the process of prioritisation is absent as these are acutely unwell patients being referred via one of the emergency routes of access e.g. accident and emergency, emergency admission to the hospital via GP etc.

3.15 Delays to diagnosis

A major factor that contributes to the low incidence of early cancers is the delay that can occur at three different levels: the patient, the general practitioner and the hospital (65); the longest delay possibly being between the time that the patient notices symptoms and his/her presentation to the general practitioner. Holliday *et al* in 1979 highlighted that the mean delay from onset of symptoms to diagnosis for colonic cancer was 30.5 weeks and that of rectal cancer was 38 weeks (83). Similarly, delay in the presentation of rectal cancer has been found in other studies (84). Most of these delays occurred outside the hospital, attributed to patients and family doctors. There has been no change in “help seeking” for the symptoms for colorectal cancer in the last 15 years (85). Nearly 50% of the delay is due to patients’ ignorance of their symptoms. In one study, nearly 90% of patients discussed their symptoms with relatives but only 22% approached a physician (65). A study in Italy has shown that patients’ level of knowledge and awareness of colorectal symptoms may have an influence on whether they seek professional help early (13).

General practitioners who examine their patients do refer them early to specialists (86). A study of 500 consecutive patients showed that half did not have rectal examination by the general practitioner and 31% had no examination at all. Amongst those examined, the diagnosis was incorrect in half of them (87). Further delays on the part of general practitioners could be

due to failure to perform recto-sigmoidoscopy / proctoscopy or even digital rectal examination (88).

One of the causes of delay in diagnosis at the hospital could be the result of inappropriate referrals by general practitioners, referring patients with significant colorectal symptoms as a non-urgent referrals or referring patients to a non-surgical speciality (65). The delays at the hospital can also be due to mis-diagnosis by a GP. Hence, prioritisation of these referrals is important (27).

The other cause of delay at the hospital could be due to referrals to other departments (66), diagnostic delay and administrative delay. According to Potter *et al* 34% of patients, have to wait more than one month due to these reasons. A study comparing the duration involved in the management pathway for patients diagnosed with colorectal cancer in 1998 and 2003 showed that there is an increase in the number of patients being referred as urgent to specialists in 2003 as compared to 1998. However, the proportion of patients receiving treatment within 31 days of diagnosis or 62 days of urgent referral has not changed in these 5 years (89).

There is no correlation between the duration of history and stage of tumour at diagnosis (37, 90, 91). Emergency presentation is associated with shorter history and more advanced disease (44) along with a higher mortality (92).

3.16 Staging

Clinical outcome, including survival following treatment of colorectal cancer, is affected by the local extent of the disease, lymph nodes status and the presence of metastases (1). One of most commonly systems used for staging of colorectal cancer is the one described by Cuthbert Dukes' (1930) and later modified by Astler and Coller (1954). This staging system describes stage A when the tumour is confined to the bowel wall, stage B when the bowel wall has been breached, stage C when lymph nodes are involved and stage D when there are distant metastases (1, 2). In recent years, TNM staging has become the standard system and the correlation between these two systems has been outlined in the Definitions. Patients with early disease (modified Dukes' A, T1/T2,N0,M0)

Komuta *et al* have shown that early stage of cancers is more common in asymptomatic patients and can be identified only by screening (15, 17, 93). A study published from Nottingham looked at the stage migration of colorectal cancers over a period of 10 years after the introduction of haemoccult screening. This study was divided as pre 1989 and post 1989. It highlighted that changing awareness of colorectal cancer and its symptomatology amongst patients and general practitioners led to significantly increased proportion of Dukes' A cancers diagnosed (94). This was especially true for rectosigmoid (9.9 % to 28%) cancer but not for colonic cancers (10.9% to 11.5%).

The national bowel cancer-screening programme is at present being set up in the UK and will achieve nation wide coverage by 2009 (19). The results of the pilot programme showed that nearly 48% of these screen detected cancer were Dukes' A (19). A multicentre UK trial of screening with flexible sigmoidoscopy of people aged 55-65, followed by colonoscopy in those considered to be at high risk, picked up cancers in 0.3% of those screened, 74% of which were Dukes' stage A or stage B, and adenomas were detected in 12% (3). However, the effect of the screening on the stage of cancer at diagnosis is beyond the scope of this study.

In the Trent/ Wales audit, Dukes' A cancer accounted for only 10% of all the colorectal cancers diagnosed. A study by Flashman *et al* has shown that the pick up rate of patients with Dukes' A cancers in the general outpatient clinics and specialist clinics varies between 9 to 15% (20). Studies from other countries like New Zealand and Italy have also shown proportions of patients diagnosed with Dukes' A cancer to be 4 - 18 % (95, 96). Miller *et al* compared the colorectal cancer data from different periods between 1969 - 1976 and 1989 - 1995. This study showed the resectability of cancers increased, stay in hospital and 30 day mortality declined. Despite apparent earlier presentation and improved surgical resectability, the proportion of patients with localised disease (Dukes' stage A and B) had not changed significantly (21). Another study from the UK performed in 1995 compared data available between 1966 -

1971 and 1979 - 1983. There was no difference in the Dukes' staging of colorectal cancer in the study groups (22). Similarly, there has been no change in the proportion of patients diagnosed with early cancer in 20 years in Australia and also in the UK (21, 22). It is difficult to pick up early cancer without screening. It is also a problem in countries such as China where analysis of over 2000 patients showed a very low incidence of Dukes' A cancer (97).

Specialist clinics with flexible sigmoidoscopy have reported a significant improvement in the proportion of patients diagnosed with Dukes' A cancer from 11% to 23% after sub-specialisation in surgical speciality (23).

Specialist clinics without flexible sigmoidoscopy are considered to be unsafe (24) and have shown to be less efficacious in identifying Dukes' A cancers and the pick up rate appears to be similar to other clinics (45, 49). Open access nurse led flexible sigmoidoscopy clinics alone have better patient acceptability but cancer yield is poor when compared with doctor led services (one stop clinic). At the same time, they also seem to have little impact on the utilisation of radiological resources (25). However, in this study, the RACRC and the OAFS are not strictly comparable, as the doctor led service (RACRC) used the ACPGBI guidelines and was set up specifically to diagnose cancers and the

nurse led (OAFS) service was an evaluation service for patients with rectal bleeding.

Cancer patients referred via fast track clinics are seen more quickly than those sent via standard modes of referral. However, these patients sometimes appear to present with more advanced disease, raising a question again regarding the appropriateness and prioritisation of these referrals from primary care(64). A study by Trickett *et al* showed that patients referred by general practitioners to allied medical specialities or the emergency department present with advanced disease while those referred to either fast track clinics or general outpatient clinics (urgent or non-urgent) have early disease (98). However, this study did not differentiate between urgent and non-urgent referral. A study by Lamah *et al* did not show any difference in stage distribution of colorectal cancer diagnosed through the different modes of referrals (49).

This review of the literature has not revealed any study correlating different types of the referral with its categories (urgent and non-urgent) on the stage of tumour at diagnosis nor has it revealed any comparisons between models of care in their entirety.

3.17 Summary of review

From the literature review, it is evident that colorectal cancer is a major health concern in the UK. Even in the presence of clearly defined guidelines from ACPGBI and standards from the Department of Health, the pick up rate of early cancers (Dukes' A) still remains low throughout the UK. This is due to the fact that referral practices vary widely throughout the UK with no standard model.

One-stop open access clinics have already been shown to be more accessible, acceptable and more effective than conventional consultant led general outpatient clinics. In spite of these differences, many health care delivery service models are unable to incorporate one stop clinics, probably due to lack of resources. Studies so far, have not compared the impact of prioritisation and modes of referrals on the stage of cancer at diagnosis. There is no evidence of a systematic nationally accepted protocol to assess urgent referrals.

Individual components of models of health care delivery have varied effects on the diagnosis and management of patients suspected of colorectal cancer. The cumulative effect these components could be beneficial or detrimental, but has not been studied before. The present study compares two different models of health care delivery in two adjacent Trusts in South Wales, with regards to the stage at diagnosis. The next chapter will discuss the methods of this study.

Chapter 4

Methodology

4.1 Introduction

This chapter explains the methods used in this study.

4.2 Study design

This is a retrospective study performed using secondary data (i.e. data that had already been recorded). The sample in this study consisted of patients diagnosed with colorectal cancer in the two adjacent Trusts in South Wales. These patients were selected based on inclusion and exclusion criteria mentioned below.

4.3 Inclusion criteria

All patients diagnosed with colorectal cancers between 1st January 2001 and 31st December 2003 were eligible for inclusion.

4.4 Exclusion criteria

1. All patients who were deemed unsuitable for surgery due to severe co-morbidities were excluded. These included only those patients where either staging was not performed, or if staging was carried out, it did not reveal distant metastases. These patients were excluded because, without a resection specimen in these cases, staging information was not available. If any of these patients who were excluded due to severe co-morbidity, were found to have metastatic disease, they were included as Dukes' D.

2. All patients diagnosed to have cancer within a polyp treated only with endoscopic resection
3. Patients found to have cancer in an appendicectomy specimen.
4. Patients referred to the consultant surgeons as private patients, as they were not referred via the referral system within the National Health Service. (All these patients bypassed the system for their first specialist appointment.)

4.5 Study groups

The patients selected belonged to either of two study groups based on the hospital at which they received treatment;

Trust A: The North Glamorgan NHS Trust

Trust B: The Pontypridd and Rhondda NHS Trust

4.6 Identification of colorectal cancer patients

Patients included were identified from the colorectal cancer databases at each Trust. All patient details were further cross-checked and re-confirmed with multidisciplinary meeting (MDM) records, surgical department patient data, and finally re-confirmed with the cancer services co-coordinators' data for completeness in each Trust.

4.7 Sample representativeness

Representativeness is the extent to which the sample of a study compares with a wider population. It is evident from literature that the mean age of incidence of colorectal cancer in scientific published papers could not be directly compared with the present sample. This could be due to studies from different geographical locations or lack of adequate demographic detail in some of the published studies (32, 99) . It could be also due to studies involving a particular site of colorectal cancer e.g. sigmoid colon or rectum (100). The Welsh Cancer Intelligence and Surveillance Unit collates data for all colorectal cancers diagnosed in Wales. Comparison with this data would better indicate representativeness of the study sample. However, the study sample is derived using rigorous inclusion and exclusion criteria, whereas the Welsh data includes all patients with a diagnosis of colorectal cancer.

The present study compares differences between two distinct service models of the health care delivery in adjacent geographical locations and therefore the study sample does not need to reflect the demographics of the general Welsh population. Results, therefore, relate specifically to patients who meet the criteria for inclusion in this study.

This study has, therefore, not attempted to fully assess representativeness of the sample with the general population, but has compared the data from the

two participating Trusts to establish demographic similarities. The main measures of comparison that have been used are the mean age and gender distribution.

4.8 Outcome measures

In this study the primary outcome is the stage of colorectal cancer at the time of diagnosis.

4.9 Sample size

As this is a retrospective observational study, the sample size is fixed (the number of cancers diagnosed during the period). The findings of this study, however, can provide evidence to inform a larger and more representative multi-centre prospective study. Such a definitive study would perform an initial power calculation to determine the sample size needed to detect a clinically important difference in the primary outcome of a given magnitude at a pre-determined significance level.

4.10 Data collection

Data collection for this study has two components:

1. Patient level clinico-pathological data from a review of patients' records

2. Organisational level data regarding the structures of the two models of health care delivery collated from discussions with both sets of clinicians and managers involved as well as by direct observation

4.11 Data sources

Data used for analysis in this study were collected from following areas in each Trust:

1. Colorectal cancer database
2. Pathology records
3. Multi-disciplinary meeting records
4. Patients' case notes
5. Medical records department
6. Human resources department
7. Surgical Directorate Management
8. National Public Health Service for Wales, Wales Statistics (www.wales.gov.uk) for deprivation levels

4.12 Clinico-pathological data

Clinico-pathological data were collected under following headings:

1. Patient demographics - from patients' records (case notes).
2. General Practitioners' details - from patient records (case notes).

3. Clinic Details- from referral letters to the consultant surgeons.
4. Symptomatology on presentation - from the referral letter as well as from the notes made at the time of the patients' first appointment at the specialist clinic.
5. Investigations carried out to confirm diagnosis and pre-operative stage of cancer - from formal radiological and pathological (biopsy) reports within the case notes and from the radiology department records.
6. Histo-pathology with tumour stage - from formal report on each patient filed in the patient case notes.
7. Operation details - from the operation note and MDM records.

Details of data collection proforma are as shown in Appendix II.

The data obtained were used to compare the stage of patients with colorectal cancer at the time of diagnosis between the two Trusts with respect to the modes and the priority of referral.

4.13 Delays and checkpoints

Data were also collected to highlight the various delays or check points in the two different models of health care delivery. Time intervals between the various steps in the referral pathway were identified as follows:

1. waiting period from referral from GP to 1st clinic appointment

2. waiting period from referral received in the Trust to 1st specialist outpatient appointment
3. waiting period from 1st appointment to the date of the definitive diagnostic test
4. Time from confirmation of diagnosis to final staging

4.14 Townsend Index

The Townsend index provides a material measure of deprivation & disadvantage. It is a composite score based on four different variables (101).

1. Unemployment as a percentage of those who are economically active
2. Non-car ownership, as a percentage of all households
3. Non-home ownership as a percentage of all households
4. Household overcrowding

The five Townsend Index categories are Most Affluent, Next Affluent, Median, Next Deprived and Most Deprived. The higher the Townsend Index score, the more deprived & disadvantaged an area is considered to be. Scores can also be negative denoting affluent areas. If all the 9309 electoral wards of England and Wales were pooled and sorted in rank order according to the above criteria and then divided into five quintiles, then the top 20% will represent the most affluent areas down to the most deprived in the bottom 20%.

For the population of this study, the percentage of population belonging to each category of the Townsend Index was obtained from the website of the National Public Health Service for Wales.

4.15 Data protection and Caldicott guidelines

Data protection regulations and Caldicott guidelines were followed to maintain the confidentiality of patients' clinical data. All patient details such as name and date of birth were anonymised to maintain patient confidentiality. Data were only used for research purposes and a master list correlating patient identification details was kept in a locked drawer and was accessed for data validation, if required. On completion of the research, the master list was destroyed.

4.16 Ethical approval

This study involved reviewing notes of patients who were diagnosed to have colorectal cancer. All colorectal cancer patients included in this study have had their treatment prior to the commencement of this study. The study did not affect the treatment or continuing care of any of the patients. The study did not involve patients and their identity nor did it involve patient participation. The patients were not contacted at any stage of the study. Given this and the fact that patient level data were anonymised meant that the study could be regarded as an audit.

The proposal was submitted to the South East Wales Local Research and Ethics Committee who agreed that the study could be regarded as an audit. The proposal was also reviewed and approved by the Ethics Committee of the (then) School of Care Science, University of Glamorgan, now re-designated as Faculty of Health, Sports and Science, University of Glamorgan.

4.17 Statistical analysis

The clinical and pathology data were entered in to SPSS Version 11.5 for statistical analysis. Chi-squared tests were used for categorical data to test for statistical significance e.g. for stage of tumour at diagnosis in relation to various clinics and to compare different routes of access. Independent t-tests were used for continuous data e.g. waiting times for the first clinic appointment. A p value of < 0.05 was considered statistically significant.

Chapter 5

Results

5.0.1 Introduction to results

The results from this study have been presented in four sections.

The first section deals with the cancers diagnosed in the two Trusts, the sample along with the reasons for exclusion. It also compares the demographics of the sample with the Welsh data. It then discusses the demographics of the two Trusts in terms of age and gender.

The second section presents and analyses the results of the different routes of access and the waiting times for these different routes for the patients in the study.

The third section presents the anatomical location of the cancers diagnosed in the study population in relation to their stage at diagnosis and route of access to the specialist services

Finally, the fourth section summarises the significant results of the present study.

5.0.2 Challenges encountered in conducting this research

The first problem was to identify all cases of colorectal cancer in the two Trusts and then to identify those cases eligible for inclusion in this study. There was

no single source or database from which these patients could be identified in either of the Trusts. Hence data were collected from various sources: MDM records, histopathology database, records from cancer services departments and operative logs. This resulted in a number of disparate lists, which required time to compile and eliminate duplication.

In some of the cases identified from the MDM records, case notes had to be examined to confirm malignant pathology.

The patients included in the study were being followed up not only for cancer follow-up with surgical teams, but also with oncologists for their further treatment, as well as with other specialists for concomitant illnesses. This made retrieval of some of case notes particularly difficult. Another problem was to obtain all the volumes of case notes, as old volumes had been moved to off-site storage areas.

The presence of multiple volumes of case notes with improper filing of contents e. g. operation notes, histology records etc made identification of appropriate documents time consuming and tedious.

Results - section 1

Sample demographics

5.1.1 Introduction

This section presents the details of the overall cancers diagnosed in the two Trusts, the sample of this study and the exclusion criteria. It then discusses the demographics in terms of age and gender.

5.1.2 The sample

The research sample consisted of all patients diagnosed with colorectal cancer in the two Trusts subject to the study's inclusion and exclusion criteria. Details of data collection and validation have been described in Methodology.

Table 5.1.1: Colorectal cancer included and excluded in the two Trusts

Colorectal cancer	Trust A	Trust B
Total colorectal cancers diagnosed	220 (100%)	245 (100%)
Colorectal cancers included in this study	187 (85%)	217 (88.57%)
Colorectal cancers excluded from this study.	33 (15%)	28 (11.43%)

As seen from Table 5.1.1, there were 220 patients diagnosed with colorectal cancer identified in Trust A from 2001 to 2003. The rigorous exclusion criteria left only 187 patients who had full staging and were eligible for inclusion. In Trust B, 245 colorectal cancers were identified in the period of which 28 were excluded.

Table 5.1.2 presents the details of patients included and excluded. There were no obvious differences ($p = 0.25$) between the two Trusts in the numbers and the types of cases excluded from the study.

Table 5.1.2: Reasons for exclusion of colorectal cancers in Trust A & Trust B

Reasons for exclusion	Trust A	Trust B
Referred as a private patient to a specialist	7	6
Patients with co-morbidity who were unfit for surgery and in whom staging was not carried out ^a	10	8
Patients with co-morbidity who were unfit for surgery in whom staging was carried out but did not show distant metastases ^b	12	11
Malignancy in polyps	2	3
Malignancy in appendicectomy specimen	1	0
Total	33	28

^a These patients were excluded as no staging information was available.

^b These patients were excluded as without resection, staging information was not available.

5.1.3 Sample representativeness

The gender and age comparison between the study sample and the all Wales data is tabulated below in 5.1.3 and 5.1.4 respectively.

As can be seen from the table 5.1.3 below, the male to female ratio in the study samples was dis-similar to that for all colorectal cancer patients in Wales. One possible explanation for this is that the study included only those patients who met the rigid inclusion criteria whereas, the all Wales data represent all the colorectal cancers diagnosed, with or without staging.

Table 5.1.3: Gender comparison between the sample and all Wales data (102)

Gender	Sample Trust A	Sample Trust B	All Wales ^a
Male	121 (64.70%)	125 (57.6%)	1037 (54.32%)
Female	66 (35.29%)	92 (42.3%)	872 (45.68%)
Total	187	217	1909
Male: Female	1.8 : 1.0	1.35 : 1.0	1.2 : 1.0

^a Data based on the Welsh Cancer Intelligence and Surveillance Units' information 2002

Table 5.1.4: Mean age comparison between the sample & all Wales data (102)

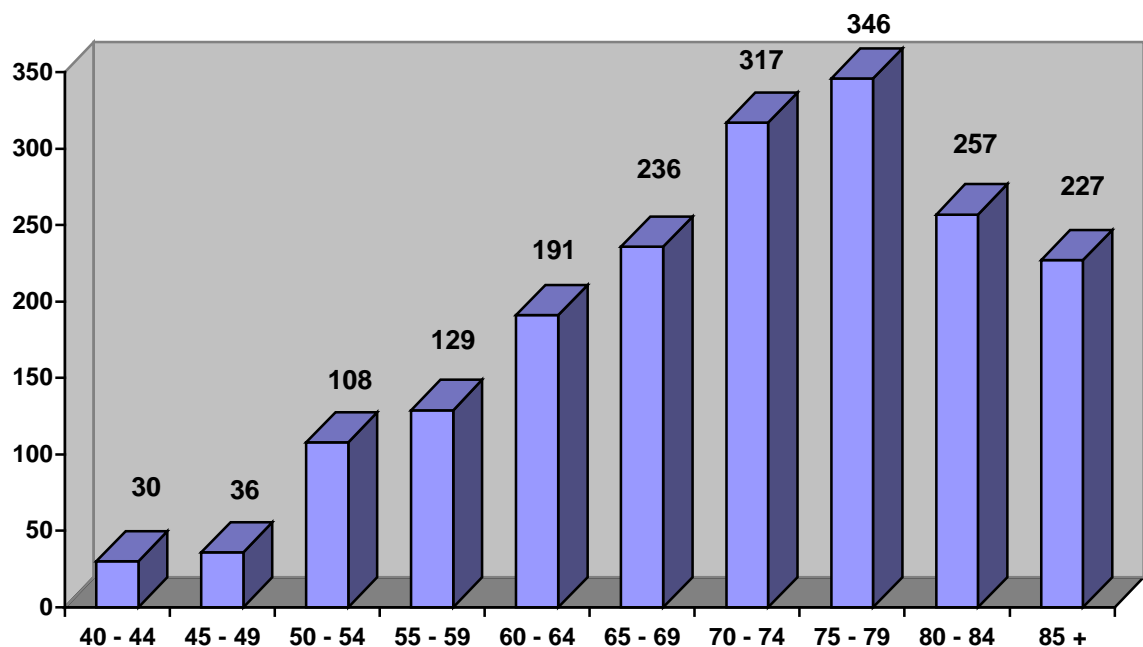
Population under study	Sample Trust A	Sample Trust B	All Wales ^a
Sample Size	187	217	1909
Mean age (SD)	70.97 (10.22)	68.94 (12.00)	70.05 ^b

^a Data based on the Welsh Cancer Intelligence and Surveillance Units' information 2002

The mean ages from all Wales data (102) are compared to mean ages of the study samples in Table 5.1.4. There is no significant difference in the mean age of the patients in Trust A as compared to Trust B ($p = 0.07$). As seen from the table above, the mean age of the sample from Trust A is closer than the sample from Trust B to that of the all Wales Data.

In Figure 5.1.1, the age distribution of colorectal cancers for all colorectal cancer patients in Wales) are presented for the year 2002. The majority of these patients were in their 6th and 7th decade.

Figure 5.1.1: Age distribution of colorectal cancers in Wales for the year 2002



The proportion of cancer patients in their 6th and 7th decade in Trust B was similar to that for all Wales. However in Trust A, there was another peak between 60 – 65 years.

5.1.4 Gender distribution

Male to female ratio of the sample in the Trust A is 121: 66 (1.83: 1.0) and that of in the Trust B is 125: 92 (1.35: 1.0). There was no statistical significance in the distribution of male and female in these study population in the two Trusts (p = 0.14).

Table 5.1.5: The distribution of sample by gender

Gender	Trust A (n = 187)	Trust B (n = 217)	p value
Male	121 (64.70%)	125 (57.60%)	0.14
Female	66 (35.29%)	92 (42.39%)	

5.1.5 Age distribution

The sample distribution by age group in the two Trusts can be seen from the table 5.1.6 below.

Table 5.1.6: Sample distribution by age group

Age range	Trust A (n = 187)		Trust B (n = 217)	
30 - 34	-	-	1	0.46%
34 - 39	-	-	2	0.92%
40 - 44	2	1.07%	4	1.84%
45 - 49	0	0.00%	5	2.30%
50 - 54	10	5.35%	16	7.37%
55 - 59	13	6.95%	19	8.76%
60 - 64	29	15.51%	20	9.22%
65 - 69	22	11.76%	44	20.28%
70 - 74	36	19.25%	33	15.21%
75 - 79	36	19.25%	35	16.13%
80 - 84	24	12.83%	19	8.76%
85 - 90	9	4.81%	11	5.07%
> 90	6	3.21%	8	3.69%
Total	187		217	

This data is shown as histograms (Figures 5.1.2 and 5.1.3) below.

Figure 5.1.2: Age distribution in Trust A

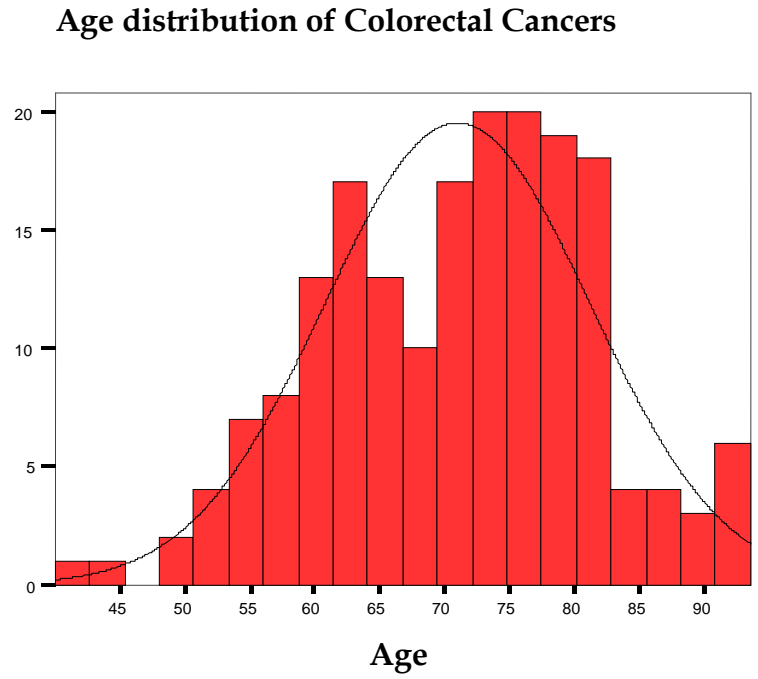
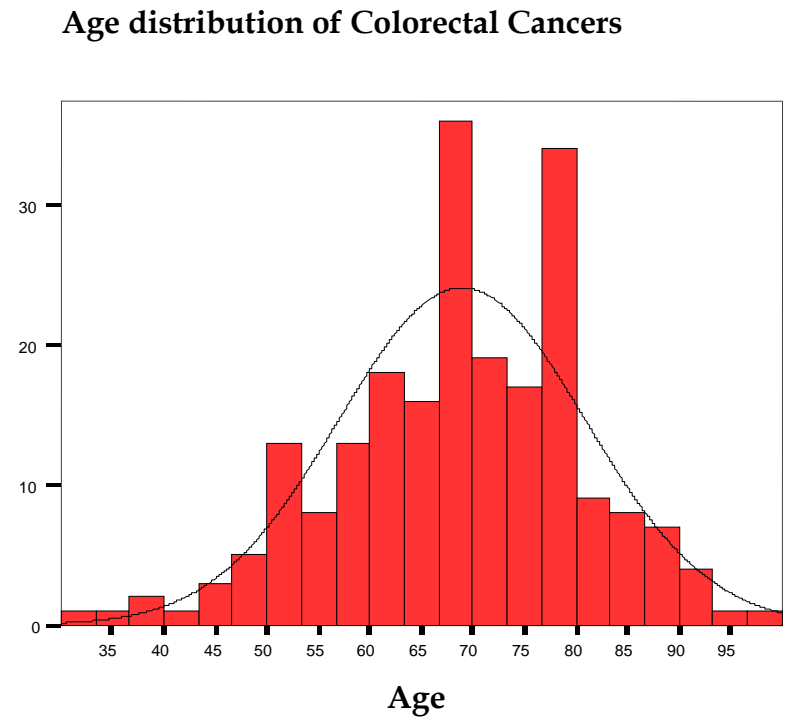


Figure 5.1.3: Age distribution in Trust B



The graph shows some skewness in distribution due to the fact that colorectal cancers naturally are more common in the older population.

5.1.6 Mean age

The mean age of the sample in the Trust A is 70.97 (SD 10.23, range 40 - 93) and that of the Trust B is 68.94 (SD 12.00, range 30 - 100). The difference in the means in the two Trusts was not statistically significant ($p = 0.07$)

The table 5.1.7 shows the mean age as per the gender distribution in the two Trusts. There was no statistical significant difference ($p = 0.51$, independent t-test) in males; however, the mean age of females in the Trust A was significantly higher ($p = 0.04$, independent t-test) than that of Trust B.

Table 5.1.7 Comparison between mean ages of male and female in sample

	Trust A	Trust B	p value
Sample	Mean age (SD)	Mean age (SD)	
Male	69.63 (9.23)	68.80 (10.55)	0.51
Female	73.43 (11.50)	69.14 (13.78)	0.04

Results – Section 2

Routes of access and waiting times

5.2.1 Introduction

This section presents and analyses the results of the different routes of access and the waiting times for these different routes for the patients in the study.

5.2.2 Cancers diagnosed via elective and emergency routes of access

As shown in Flow chart 1 (Definitions), there are primarily two routes of access, elective and emergency. As seen from table 5.2.1, the percentage of patients seen via the elective route of access in Trust B was more than Trust A. In contrast, the emergency workload in Trust A was higher than Trust B. These differences were statistically significant ($p = 0.011$).

Table 5.2.1: Distribution of patients diagnosed with colorectal cancer as per routes of access

Routes of Access	Trust A	Trust B	p value
Elective	101 (54%)	144 (66.35%)	0.011
Emergency	86 (46%)	73 (33.65%)	
Total	187	217	

5.2.3 Cancers diagnosed via elective routes of access

The elective routes of access were rapid access colorectal clinics, open access flexible sigmoidoscopy service, general outpatient clinics and inter-departmental referrals. Table 5.2.2, shows the distribution of the cancers diagnosed via these defined elective routes.

Table 5.2.2: Distribution of cancers based on elective routes of access

	Trust A		Trust B	
Elective	Frequency	Percentage	Frequency	Percentage
RACRC	69	68.32%	-	-
General outpatient clinic	16	15.84%	101	70.14%
OAFS	-	-	13	9.03%
Inter-departmental referrals	16	15.84%	30	20.83%
Total	101		144	

For further sub-analysis, the above elective category has been grouped into inter-departmental referrals and GP referrals (RACRC, OAFS and general outpatient clinic). This data is shown below in table 5.2.3. There was no significant difference in the distribution of the elective routes of access in the two Trusts ($p = 0.32$).

Table 5.2.3: Distribution of cancers based on GP or inter-departmental referrals within the elective routes of access

Elective	Trust A	Trust B	p value
GP referrals	85 (84.16%)	114 (79.17%)	0.32
Inter-departmental referrals	16 (15.84%)	30 (20.83%)	
Total	101	144	

5.2.4 Cancers diagnosed via the GP referral category within the elective route of access

As seen from table 5.2.3 above, there were 85 and 114 patients in this category in Trust A and B respectively. These were prioritised as urgent or non-urgent by the general practitioners as can be seen in Table 5.2.4 below.

Analysis of this data demonstrates that general practitioners accessing the specialist colorectal service using the elective route, in Trust A prioritised more patients as 'urgent' and this reaches statistical significance ($p = 0.03$)

Table 5.2.4 Prioritisation by GPs when accessing the elective route

Prioritisation as per GP	Trust A	Trust B	p value
Urgent	76 (89.41%)	88 (77.19%)	0.03
Non-urgent	9 (10.59%)	26 (22.81%)	
Total	85	114	

When GP referrals are received in either Trust, they can be re-prioritised by the specialist consultants.

Table 5.2.5 Urgent GP referrals re-prioritised by hospital consultants

Re-prioritisation by consultants	Trust A	Trust B	p value
Urgent	74 (97.36%)	75 (85.22%)	p = 0.007
Non-urgent	2 (2.64%)	13 (14.78%)	
Total	76	88	

As seen from the table 5.2.5, almost 97.36% (74/76) of the urgent referrals by the general practitioners were sent in using designated referral forms and therefore were seen as urgent in Trust A. The remaining 2.64% (2/76) patients had been sent in on referral letters rather than the designated form and were re-prioritised by the specialist consultants and seen as non-urgent. In Trust B, all GP referrals including those marked urgent were re-prioritised which led to 85.22% (75/88) being seen as urgent and 14.78% (13/88) as non-urgent. This achieved statistical significance ($p=0.007$). This suggests that the presence of a designated referral form is vital for general practitioners to refer patients urgently to the specialist consultants.

Table 5.2.6 Non-urgent GP referrals re-prioritised by hospital consultants

Re-prioritisation by consultants	Trust A	Trust B	p value
Urgent	4 (44.44%)	4 (14.38%)	p = 0.07
Non-urgent	5 (55.56%)	22 (84.61%)	
Total	9	26	

When one analyses the referrals sent in as non-urgent by general practitioners, nearly half (4/9, 44.44%) were re-prioritised as urgent in Trust A compared to 14.38% (4/28) in Trust B. Thus, only 5 (55.56%, 5/9) patients who were deemed non urgent by both general practitioners and specialists in Trust A turned out to have cancer compared to 22(84.61%, 22/26) in Trust B. This

result has been tabulated in Table 5.2.6 above. These differences do not reach statistical significance ($p = 0.07$).

5.2.5 Cancers diagnosed via emergency routes of access

The emergency routes of access were accident and emergency referrals, GP emergency referrals for direct admission to hospital and inter-departmental referrals requesting an immediate review of in-patients.

Table 5.2.7: Distribution of cancers based on emergency routes of access

	Trust A		Trust B	
Emergency	Frequency	Percentage	Frequency	Percentage
A & E	9	10.47%	21	28.77%
GP emergency	26	30.23%	31	42.46%
Inter-departmental referrals	51	59.30%	21	28.77%
Total	86		73	

As seen from Table 5.2.7, there was significant difference in the number of referrals via A & E route of access in Trust B as compared to A and similar difference was also observed in cancers diagnosed via the inter-departmental referral route. Analysis of these results using Chi-square test shows that it achieves statistical significance ($p < 0.001$)

5.2.6 Overall waiting times

The overall waiting times for the first clinic appointment with the specialist in the hospital were 9.37 days (SD = 15.93) in Trust A and 18.32 days (SD = 30.93) in Trust B. This difference was statistically significant ($p < 0.001$)

5.2.7 Waiting times for patients accessed through the elective route

The following sections present the results of the analysis of the waiting times for those patients who had been referred via the elective route of access. Patients referred in through the emergency route of access had zero days waiting time.

The mean waiting time for all 101 patients referred via elective routes of access in Trust A was 16.68 days (SD = 18.08). This was significantly lower ($p = 0.02$) than Trust B (27.54 days, SD = 34.63)

Table 5.2.8 shows the mean waiting times for first clinic appointment for patient assessed via elective routes i.e. GP referrals and inter-departmental category. The mean waiting times for both GP referrals and inter-departmental referrals was significantly less ($p = < 0.05$) in Trust A as compared to Trust B.

Table 5.2.8: Mean waiting times based on GP or inter-departmental referrals within the elective routes of access

	Trust A	Trust B	
	Mean clinic waiting time (SD)	Mean clinic waiting time (SD)	p value
GP Referrals	18.18 days (19.04)	27.76 days (32.37)	0.01
Inter-departmental referrals	8.88 days (8.67)	26.70 days (42.63)	0.03

5.2.8 Waiting times for patients accessed through the elective route as re-prioritised by consultants

The mean waiting time for the first clinic appointment depends on re-prioritisation by the specialist consultants. Every patient referred to the hospital deemed urgent by the GP, is seen as urgent in the clinic unless re-prioritised by the consultants.

As seen from the Table 5.2.9, there was no significant difference in the mean waiting times for the first clinic appointment for cancer patients referred via the elective routes of access and re-prioritised urgent by the specialist consultants. Similarly, there was no significant difference amongst non-urgent referrals as re-prioritised by specialist consultants (Table 5.2.10). Trust A appears to see patients referred via inter-departmental category earlier than Trust B, however, no significant difference is achieved which may be due to small number of these referrals in the present study.

Table 5.2.9: Mean waiting times for referrals via elective routes of access re-prioritised as urgent by hospital Consultants

	Trust A	Trust B	
Re-prioritised urgent by consultants	Mean clinic waiting time (SD)	Mean clinic waiting time (SD)	p value
GP Referrals	15.26 days (11.27)	14.12 days (12.26)	0.54
Inter-departmental referrals	7.53 days (7.06)	22.19 days (39.61)	0.07

Table 5.2.10: Mean waiting times for referrals via elective routes of access re-prioritised as non-urgent by hospital Consultants

	Trust A	Trust B	
Re-prioritised non-urgent by consultants	Mean clinic waiting time (SD)	Mean clinic waiting time (SD)	p value
GP Referrals	55.67 days (46.91)	57.77 days (41.68)	0.92
Inter-departmental referrals	29 days (29.0)	56 days (56.34)	0.69

5.2.9 Waiting times for patients accessed through the various elective routes as re-prioritised urgent by consultants

Analysing the urgent category within the various categories of elective route of access showed that patients referred to the RACRC in Trust A are seen within

14 days and patients referred to the OAFS in Trust B are seen within 34.5 days.

This difference is statistically significant ($p < 0.001$).

Table 5.2.11: Mean waiting times for referrals via various elective routes of access re-prioritised as urgent by hospital Consultants

	Trust A	Trust B	
Re-prioritised urgent by consultants	Mean clinic waiting (SD)	Mean clinic waiting (SD)	p value
GP Referrals			
1. RACRC	14.0 days (9.93)	-	< 0.001
2. OAFS	-	34.5 days (13.69)	
3. General outpatient clinic	21.56 days (18.17)	13 days (11.24)	0.05
Inter-departmental referrals	7.53 days (7.06)	22.19 days (39.61)	0.07

As can be seen from Table 5.2.11, patients referred through the elective inter-departmental route are also seen earlier in Trust A, though this difference does not reach statistical significance ($p = 0.07$). Cancers diagnosed via the general outpatient clinic were seen earlier in Trust B as compared to Trust A. This is due the fact that general outpatient clinic is the main clinic in Trust B to assess urgent referrals.

Results – Section 3

Tumour stage

5.3.1 Introduction

This chapter presents the anatomical location of the cancers diagnosed in the study population in relation to their stage at diagnosis and route of access to the specialist services. This section also briefly discusses the relationship between deprivation levels (Townsend index) and the stage of cancer at diagnosis.

5.3.2 Anatomical location of cancers

Table 5.3.1 shows the anatomical location of the cancers diagnosed in this study. This distribution of cancers across the large bowel was not significantly different in the two Trusts ($p = 0.29$).

Table 5.3.1: Anatomical location of cancers in the two Trusts

Anatomical location	Trust A	Trust B
Caecum	27 (14.4%)	38 (17.5%)
Ascending colon	13 (7.0%)	19 (8.8%)
Transverse colon	21 (11.2%)	23 (10.6%)
Descending colon	11 (5.9%)	6 (2.8%)
Sigmoid colon	43 (23.0%)	61 (28.1%)
Rectal	68 (36.4%)	67 (30.9%)
Multiple	4 (2.1%)	3 (1.4%)
Total	187 (100%)	217 (100%)

5.3.3 Distribution of cancers according to modified Dukes' stage

As seen from Table 5.3.2, there was no significant difference in the number of modified Dukes' A cancers diagnosed in the two Trusts ($p = 0.81$).

Table 5.3.2: Distribution of Modified Dukes' A and Non-A cancers

Modified Dukes' stage	Trust A	Trust B	p value
A	26 (13.90%)	32 (14.74%)	0.81
Non A	161 (86.10%)	185 (85.26%)	
Total	187 (100%)	217 (100%)	

The above results appear to reject the hypothesis of this research. However, the subsequent part of this section drills down into the data to identify the stage of cancer at various steps of the access mechanism as shown in flow diagram 1.

5.3.4 Distribution of modified Dukes' Stage as per anatomical location of tumour

Table 5.3.3 shows the distribution of modified Dukes' stage as per the anatomical location of the tumour. There were no statistical differences in the distribution of Dukes' A and non-A cancers at any of the anatomical locations in the two Trusts.

Table 5.3.3: Distribution of stage of cancer as per anatomical location

Anatomical location	Trust A		Trust B		p value
	Dukes' A	Dukes' non-A	Dukes' A	Dukes' non-A	
Caecum	3	24	2	36	0.38
Ascending colon	0	13	0	19	NA
Transverse colon	1	20	1	22	0.94
Descending colon	0	11	1	5	0.16
Sigmoid colon	7	36	13	48	0.52
Rectal	15	53	15	52	0.96
Multiple	0	4	0	3	NA
	187		217		

5.3.5 Distribution of gender and modified Dukes' A cancers

As seen in Table 5.3.4, amongst 26 modified Dukes' A cancers diagnosed in Trust A, there were 57.69% males (15/26) and 42.31% females (11/26). In Trust B, there were 62.50% male (20/32) and 37.50% female (12/32). This difference showed no statistical significance ($p = 0.71$).

Table 5.3.4: Distribution of modified Dukes' A cancers and gender

	Trust A	Trust B	p Value
Male	15 (57.69%)	20 (62.5%)	0.71
Female	11 (42.31%)	12 (37.5%)	
Total	26 (100%)	32	

5.3.6 Mean age of the modified Dukes' A cancers diagnosed

The overall mean age of patients with modified Dukes' A cancers diagnosed in Trust A was not significantly different ($p = 0.54$) from Trust B (68.29 days, SD = 8.01 in Trust A v. 69.78 days, SD = 10.61 in Trust B).

5.3.7 Mean age of the modified Dukes' A cancers diagnosed in relation to gender in the two Trusts

Table 5.3.5: Mean age of the Dukes' A cancers in relation to gender

	Trust A	Trust B	p value
	Mean Age (SD)	Mean Age (SD)	
Male	68.25 days (6.84)	68.05 days (10.47)	0.94
Female	68.35 days (9.72)	72.67 days (10.67)	0.32

As seen from the Table 5.3.5, there was no statistical difference in the mean ages of males and females diagnosed with modified Dukes' A cancers in the two Trusts.

5.3.8 Stages of cancers diagnosed in relation to the various routes of access

This section presents data on the cancer stage at diagnosis in relation to the route by which these patients accessed the specialist services. The results are presented for the elective and emergency routes with detailed breakdown of the different categories within each route of access.

5.3.8.1 Stages of cancers diagnosed via the elective routes of access

As seen from Table 5.3.6, there was no statistical difference ($p = 0.56$) in the number of modified Dukes' A cancers diagnosed via the elective routes of access in the two Trusts.

Table 5.3.6: Stage of cancers diagnosed via elective routes of access

	Trust A	Trust B	p value
Dukes' A	22 (21.78%)	27 (18.75%)	0.56
Dukes' non-A	79 (78.22%)	117 (81.25%)	
Total	101 (100%)	144 (100%)	

5.3.8.2 Stages of cancers diagnosed via the emergency routes of access

As seen from Table 5.3.7, there was no statistical difference ($p = 0.55$) in the number of modified Dukes' A cancers diagnosed via the emergency routes of access in the two Trusts.

Table 5.3.7: Stage of cancers diagnosed via emergency routes of access

	Trust A	Trust B	p value
Dukes' A	4 (4.66%)	5 (6.85%)	0.55
Dukes' non-A	82 (95.34%)	68 (93.15%)	
Total	86 (100%)	73 (100%)	

5.3.9 Stage of cancers diagnosed via different categories of the elective routes of access

As presented earlier, the elective routes of access have been classified into two categories i.e. GP referrals and inter-departmental referrals for the purpose of analysis. Tables 5.3.8 and 5.3.9 illustrate the stage of modified Dukes' cancers diagnosed via these routes of access respectively. There was no significant difference between the two Trusts, in the modified Dukes' A cancers diagnosed via the GP route of access ($p = 0.94$) and the inter-departmental elective route of access ($p = 0.21$).

Table 5.3.8: Stage of cancers diagnosed via GP category of the elective route of access

	Trust A	Trust B	p value
Dukes' A	19 (22.35%)	25 (21.92%)	0.94
Dukes' non-A	66 (77.65%)	89 (78.08%)	
Total	85 (100%)	114 (100%)	

Table 5.3.9: Stage of cancers diagnosed via inter-departmental category of the elective routes of access

	Trust A	Trust B	p value
Dukes' A	3 (18.75%)	2 (6.67%)	0.21
Dukes' non-A	13 (81.25%)	28 (93.33%)	
Total	16 (100%)	30 (100%)	

5.3.9.1 Sub-analysis of the stage of cancer in relation to the different referral mechanisms within the GP category of the elective route of access

The RACRC in Trust A picked up a total of 69 patients with colorectal cancer (see Table 5.2.2). Of these, 13 patients (18.84%) were at the modified Dukes' A stage. Comparison between the two Trusts is not possible as the RACRC is not available in Trust B.

Similarly in Trust B, the OAFS service picked up a total of 13 cases of colorectal cancer (see Table 5.2.2), of which 4 (30.76%) were at Dukes' stage A. This service is unique to Trust B and hence comparison between Trusts is not possible.

However, both Trusts picked up colorectal cancers from the general outpatient clinics, 16 in Trust A and 101 in Trust B. Of these 6 (37.50%) were at Dukes' stage A in Trust A compared with 21 (19.80%) in Trust B. This is shown below

in tabular form (Table 5.3.10). These differences did not reach statistical significance ($p = 0.14$).

Table 5.3.10: Stage of cancers diagnosed via general outpatient clinic of GP elective route of access

	Trust A	Trust B	p value
Dukes' A	6 (37.50%)	21 (19.80%)	0.14
Dukes' non-A	10 (62.50%)	80 (79.20%)	
Total	16 (100%)	101 (100%)	

5.3.9.2 Sub-analysis of the urgency of the referral in relation to the stage of the cancers diagnosed

As detailed in the previous section, the elective route can be accessed urgently or non-urgently depending on the type of referral. Thus, cancers diagnosed via the elective routes of access could have been seen as either urgent or non-urgent. Analysis of the cancers diagnosed through urgent referrals, showed 21 Dukes' A cancers out of 93 (22.58%) in Trust A compared to 11 out of 105 (10.47%) in Trust B (Table 5.3.11). This difference achieved statistical significance ($p = 0.02$).

Table 5.3.11: Stage of cancers diagnosed via urgent elective routes of access

	Trust A	Trust B	p value
Dukes' A	21 (22.58%)	11 (10.47%)	0.02
Dukes' non-A	72 (77.41%)	94 (89.23%)	
Total	93 (100%)	105 (100%)	

5.3.9.3 Sub-analysis of the urgent referrals within the elective route of access

As detailed earlier in section 2 of chapter 5, urgent referrals could either be from the GP or the inter-departmental category within the elective route of access. On Sub-analysis (Tables 5.3.12 and 5.3.13), there was no difference in modified Dukes' A cancers diagnosed in either category (p = 0.08 for GP Category and p = 0.93 for inter-department category).

Table 5.3.12: Stage of cancers diagnosed via GP category of urgent elective routes of access

	Trust A	Trust B	p value
Dukes' A	18 (23.07%)	10 (12.65%)	0.08
Dukes' non-A	60 (76.93%)	69 (87.35%)	
Total	78 (100%)	79 (100%)	

Table 5.3.13: Stage of cancers diagnosed via Inter-departmental category of urgent elective routes of access

	Trust A	Trust B	p value
Dukes' A	3 (20.0%)	1 (3.8%)	0.93
Dukes' non-A	12 (80.0%)	25 (96.2%)	
Total	15 (100%)	26 (100%)	

5.3.9.4 Sub-analysis of the urgent referrals from the GP category

To establish precisely what was causing the significant difference noted in the urgent elective route of access (Table 5.3.11), the urgent referrals from the GP category have been further sub-analysed. Urgent referrals from general practitioners into the elective route of access could be seen either in RACRC, general out-patient clinics or OAFS. Further sub-analysis showed that the pick up rate of modified Dukes' A via RACRC was 19%. None of the four cancers diagnosed via OAFS from urgent referrals were early cancers (Dukes' A). The percentage of modified Dukes' A cancers diagnosed via general out-patients clinic in Trust A were significantly higher than that of Trust B ($p = 0.004$), as shown in table 5.3.14.

Table 5.3.14: Stage of cancers diagnosed when GPs accessed the elective route via urgent referrals

	Trust A		Trust B	
	RACRC	General outpatient clinics	General outpatient clinics	OAFS
Dukes' A	13 (19.12%)	5 (50.0%)	10 (13.33%)	0 (0%)
Dukes' non-A	55 (80.88)	5 (50.0%)	65 (86.67%)	4 (100%)
Total	68	10 (100%)	75 (100%)	4 (100%)

The above data (Table 5.3.14) shows that there was a significantly higher pick up rate of early colorectal cancer (Dukes' stage A) in Trust A compared with Trust B, when general practitioners sent patients into the specialist service using an urgent referral through the elective route. The possible reasons for this will be discussed in the next chapter.

5.3.9.5 Sub-analysis of the non-urgent referrals within the elective route of access

There was no sub-analysis done on the cancers diagnosed from non-urgent referrals due to the small number in Trust A (8 out of 101).

5.3.10 Relationship between the deprivation levels (Townsend Index) and stage of cancer at diagnosis

The mean Townsend index for study population was +0.64 (SD + 2.44) with a range of - 6.00 to + 7.00. Table 5.3.15 shows the distribution of patients and the population of the catchment areas of the study according to Townsend Index (TI) categories. As seen from this Table, more than 85% of population in the valleys belong to median to deprived category and there is no clear correlation between deprivation levels and incidence of colorectal cancer.

Table 5.3.15: Distribution of patients and the population of the catchment areas of the study according to Townsend Index (TI) categories

Category of TI	Population distribution	Cancer distribution
Most Affluent	7.94%	18 (4.5%)
Next Affluent	4.76%	59 (14.6%)
Median	20.63%	159 (39.1%)
Next Deprived	39.68%	87 (21.5%)
Most deprived	26.98%	81 (20.0%)

The mean Townsend index was higher for patients who were sent in as urgent referrals (TI = +1.13, SD 2.1), compared to patients who presented as non-

urgent referrals (TI = +0.34, SD 2.6). This difference achieves statistical significance ($p < 0.005$)

Table 5.3.16 illustrates that the index was higher for patients with modified Dukes' D cancers as compared to the earlier stages. However, this was statistically insignificant.

Table 5.3.16: Townsend Index and modified Dukes' Stage

Modified Dukes' stage	Mean TI	SD
A	+0.78	2.65
B	+0.54	2.42
C	+0.43	2.43
D	+1.13	2.2

Results – Section 4

Summary of significant findings

Summary of significant findings

1. More of the cancers diagnosed in Trust B were seen as elective
2. Of the cancers diagnosed from general practitioners referrals, more patients were sent in as 'urgent' to Trust A
3. Of the cancers diagnosed from urgent GP referrals, more patients were seen as 'urgent' in Trust A (less re-prioritisation by consultants).
4. Of the cancers diagnosed from urgent GP referrals, more patients were re-prioritised as 'non-urgent' in Trust B
5. Higher percentage of cancers diagnosed via A & E in Trust B and inter-departmental emergency referrals in Trust A
6. Overall waiting times for the first clinic appointment (applicable only to 'elective') was less in Trust A
7. Waiting times for both categories of elective route of access (the GP and the inter-departmental) were less in A
8. No difference in waiting times once the patient was deemed urgent by either Trust
9. Higher pick up rate of early colorectal cancer (Dukes' stage A) in Trust A compared with Trust B, when general practitioners sent patients into the specialist service using an urgent referral through the elective route.
10. The majority of population of the catchment areas of this study belong to the more deprived areas.

11. Patients from deprived areas are more likely to present as an urgent referral.
12. Townsend index was higher for modified Dukes' D cancers, but this was not statistically significant.

Chapter 6

Discussion

6.1 Introduction

Colorectal cancer is one of the most common malignant diseases in the western world. It affects men and women equally and the incidence increases with age (2). Colorectal cancer is the third commonest cause of cancer related death (after breast and lung cancer) in the UK (1). There are over 34,000 new cases of colorectal cancer diagnosed in the UK every year and approximately 17,000 deaths (1).

Survival in colorectal cancer is directly related to the stage at diagnosis (34, 35). There is strong evidence that asymptomatic patients present with less advanced disease and thus have better survival (36, 93, 103). This is the basis for the colorectal cancer screening programme that has recently been introduced in England and is due to start in Wales shortly.

Approximately 25% of patients in the UK present with locally advanced or metastatic disease (6-8). Patients with colorectal cancer occasionally tend to develop non-specific symptoms leading to emergency presentation with advanced disease (3). Therefore, it is important to have effective mechanisms in place to assess and diagnose these cancers early.

Routes of access play a crucial role in early diagnosis. It is well known that a referral made to a non-surgical speciality can significantly delay diagnosis (47,

104). There are different models of health care delivery to allow access from the primary care sector into the specialist colorectal services in the secondary care sector. There are several components that are constituents of a given model of health care delivery. Differences exist in each of these components such as the presence or absence of strict referral criteria, designated referral pathways, prioritisation protocols in the specialist units and in the resources available to assess patients with high risk symptoms. There are several publications which have looked at the impact of many of these individual components (3, 20, 23, 25, 48, 49, 64, 68, 70, 71, 98, 105). However, there have been no studies looking at the impact of whole models in their entirety.

The aim of the present study was to compare the clinical effectiveness of two service models in terms of diagnosis of early colorectal cancers (modified Dukes' A).

6.2 Sample representativeness

In the present study, the percentage of the patients excluded from each of the two participating Trusts was not significantly different. The reasons for exclusion were also similar. There were two main reasons for exclusion from this study. One was lack of staging information because of unsuitability for surgery due to severe co-morbidities. Another reason was that in some unfit patients where, although pre-operative staging was carried out, it did not show

any metastatic disease. These patients were obviously not Dukes' D cancers but whether they were Dukes' A could not be ascertained. These patients were excluded because, without a resection specimen in these cases, staging information was not available. According to the 2001 census (26), the two valleys that form the catchment area of the two Trusts in this study (Merthyr and Rhondda Cynon Taff) were amongst the top 5 areas in the UK with high proportion of the general population suffering from long term illnesses.

This study tries to identify similarities of the study sample with all Wales data in terms of mean age and gender. This does not attempt to prove that study sample is representative of Welsh population. This is because the all Wales data includes all patients diagnosed with colorectal cancer whereas the study sample has been derived after the application of rigorous exclusion criteria, as described in Methodology.

6.3 Sample demographics

The incidence of rectal cancer peaks in the 60 - 69 years age group and increases with advancing age (2, 106). The figures are similar for colon cancer. The reported incidence of the disease in patients below 40 years varies from 2% - 4% (107-109). The mean age of presentation was similar in the two Trusts which was also in keeping with the available data from the UK literature (22). A previous study performed in Trust A has also shown similar age distribution

(23). The gender distribution in the previous study published from Trust A also showed similar trends (23).

6.4 Routes of access

There were significant differences in the presentation of cancers to both secondary care Trusts. Trust A had a larger number of patients presenting via the emergency route of access when compared to the Trust B. A trend similar to the pattern in Trust A has been shown in the another study published in British Journal of Surgery in 1992 (92). This could be due to patient education, patients' perception of their symptoms, available medical facilities e.g. access to GP or out of the hours service, socio-economic status or profession (13, 110). A study by Cockburn *et al* concentrated on healthy adults with symptoms of rectal bleeding (85). The study showed that of those patients who experienced rectal bleeding, one third never sought medical advice. A similar study looking at the management of colorectal cancer highlighted that social influences such as profession, type of education, marital status and availability of health insurance had a significant influence on treatment delay, as did the level of clinical experience of the physician first contacted (84). Delays in patients accessing health care can also be associated with past anxiety or depression as highlighted in a study by Robertson *et al* (111).

The catchment area for Trust A is more deprived than that of Trust B in terms of unemployment, long term illness and also educational qualifications (26). These factors do contribute in the decision making of patients such that they tend to approach the hospital directly (thus accessing the emergency route) instead of their own general practitioners. Another explanation for the differences in the utilisation of the emergency route of access between the two Trusts, might be a wide variation in the way general practitioners manage rectal bleeding or inconsistent knowledge among general practitioners about the existing guidelines (112).

6.5 Elective routes of access

As discussed in the Results chapter (section 2), the elective route of access is used either by general practitioners to refer patients to the specialist services or by other hospital consultants. There was no difference in the percentage of the cancers diagnosed via either GP or inter-departmental category between the two Trusts.

The Department of Health introduced national urgent referral guidelines in 2000, based on higher risk symptoms and signs for colorectal cancer – “the Two Week rule”. All units are now required to see at least 95% of patients who meet these criteria for urgent referral within two weeks (14 calendar days). These referral guidelines were revised by the colorectal unit in Trust A and were

adopted by Trust B as well , as discussed in chapter 2 (23). These guidelines were incorporated into simple forms which helped general practitioners to prioritise patients for early referral to the rapid access clinics (Appendix I). In Trust A, they were made available to general practitioners through meetings conducted by the consultant surgeon at regular intervals to educate as well as to highlight the importance of the guidelines. Trust A has also published its unique education programme, arranged by the colorectal unit in conjunction with the Local health Board for general practitioners to gain insight into referral pathways and secondary care mechanisms(113). Trust B has not had a similar programme for the dissemination of the referral form and this is the most likely explanation for the difference in the utilisation of these designated forms seen in Section 5.2.4.

In Trust B, an audit of the appropriateness of general practitioner letters was conducted in 1997 (27). It was found that the overall standard of these letters was poor with inadequate information (unpublished data, presented at local and regional meetings). Hence, all the general practitioners of the catchment areas of Trust B were visited and educated regarding colorectal cancer and rectal bleeding. This was performed prior to the introduction of the designated form. There are large proportion of patients are referred with use of letters by general practitioner to Trust B. The standard of these letters at present is beyond the scope of this study, but as highlighted earlier, there may be need to

re-visit the general practitioners of the Trust B to emphasize the use of the designated referral form.

There are significantly more patients sent in as urgent by general practitioners in Trust A (Table 5.2.4). This could be the result of general practitioners' awareness of the referral guidelines or presence of the designated referral form. These referrals once received in the two Trusts are re-prioritised by the specialist consultants as either urgent or non-urgent. In Trust A, the majority of referrals to RACRC were on designated referral forms and hence did not require re-prioritisation by specialist consultants and were seen as urgent (Table 5.2.5).

The standard mode of referral is a letter from general practitioners (81) and this is the preferred method for general practitioners to access the specialist service in Trust B. All these GP referrals including those marked urgent were re-prioritised and a significant number of referrals were downgraded as non-urgent (Table 5.2.5). This suggests that the presence of a designated referral form is important for general practitioners to refer patients urgently to the specialist consultants.

A surgical unit at Crewe has developed a scoring system based on the presence of symptoms and symptom complexes to produce a computer generated

numerical score to identify patients with a higher likelihood of colorectal cancer (82) though this is not yet been accepted widely. In order to avoid the controversies around prioritisation, a study by Scott *et al* suggested that all patients referred to specialist clinics should be seen on an urgent basis until a more accurate method of identifying the highest risk patients is implemented (114). This could lead significant impact on non-urgent referrals (79).

As seen in Table 5.2.6, analysis of patients referred as non-urgent by general practitioners showed that a higher proportion were re-prioritised as urgent in Trust A, though this difference does not achieve statistical significance. Though these data suggest that Trust A is better at identifying urgent cases, there may be a significant increase in the workload and may actually reflect an inefficient service. In fact, a previous study from Trust A has highlighted that increase in the number of urgent colorectal referrals affects the waiting time of non-urgent colorectal and non-colorectal referrals (52). The possible effect of such consultant re-prioritisation on the management of these patients is outside the scope of this study.

6.6 Emergency routes of access

There is a variation of 25% to 42% in the proportion of colorectal cancers diagnosed via emergency routes of access in the published literature (44, 46, 67, 83, 92). This study has shown that the figures for Trust A and Trust B were

46% and 34% respectively. The higher proportion of access through the emergency route in Trust A may be due to socio-economic factors as discussed in 6.1 and 6.3 above.

A study from South Thames District Health Authorities has shown that emergency presentation is higher for rectal cancer as compared to colon cancer (115), though this has not been demonstrated in the present study. As discussed earlier in section 5.2.7, there are three main categories of emergency routes of access. There were a significantly lower percentage of cancers diagnosed via A & E in Trust A as compared to Trust B. This could be a reflection of the availability of the designated referral form and the RACRC for the elective route of access.

Conversely, a higher percentage of cases were diagnosed via the inter-departmental referral route in Trust A. This difference was not seen in the inter-departmental category of the elective route. This suggests that the same socio-economic factors highlighted above, may have the effect of increasing the overall emergency workload in Trust A, across all departments. Interestingly, many of the cancers referred from these sources are right-sided colonic cancers (16 right colonic cancers in Trust A versus 4 in Trust B). The probable explanation for this is that right sided cancers often present with anaemia, which may manifest with symptoms of lethargy, fainting, shortness of breath

etc. necessitating admission under the care of physicians rather than colorectal surgeons (116, 117).

Colorectal cancer patients admitted as emergencies tend to have more advanced disease and hence higher mortality and morbidity and therefore require far greater resource provision (44). Earlier referral appears to be useful in preventing this emergency presentation (44, 118) and related complications (119). It may not, in itself, significantly influence survival. However, this is beyond the scope of present study.

6.7 Waiting time for first clinic appointment

The overall waiting times in the present study was significantly less in Trust A due the fact that Trust A diagnoses larger number of cancers via the emergency route of access. The waiting time for the emergency route is zero as patients are seen and assessed the same day.

The mean waiting time for the first outpatient clinic for cancers diagnosed via the elective route was significantly less in Trust A . On further sub-analysis of the categories within the elective route of access, the mean waiting times for the GP referral and Inter-departmental category were both significantly less in Trust A. This difference is explained by the fact that the elective route of access

includes urgent and non urgent referrals. As seen in section 5.2.4, Trust A has a significantly higher percentage of urgent referrals.

Further analysis showed that the urgent category within the elective route of access showed no differences between the two Trusts. This is explained by the fact that in order to meet government regulations, once patients have been categorised as urgent they need to be seen within two weeks(1, 6, 14). As can be seen from Section 5.2.9, patients referred to the RACRC in Trust A are seen within 14 days and patients referred to the OAFS in Trust B are seen within 35 days. This difference is statistically significant ($p < 0.001$). However, RACRC and OAFS are two distinct type of clinics. RACRC is run by consultants to assess and rule out or diagnose colorectal cancer in patients with high risk symptoms. OAFS on the other hand is only an evaluation service to identify the cause of the rectal bleeding and not used primarily as a service to diagnose cancers (personal communications). Patients referred through the elective inter-departmental route are also seen earlier in Trust A, though this difference does not reach statistical significance ($p = 0.07$). Cancers diagnosed via the general outpatient clinic were seen earlier in Trust B. This is due the fact that general outpatient clinic is the main clinic in Trust B to assess urgent referrals.

Thus, the significant difference seen in the waiting times for the overall elective route of access is explained by the fact that the RACRC is more expeditious

than the OAFS and the specialists in Trust A see inter-departmental referrals earlier than in Trust B. A referral made to a non-surgical specialty can significantly delay diagnosis of colorectal cancer. This has been well recognised with colorectal and other cancers (1, 47).

An audit published from Trust A, highlighted that colorectal sub-specialisation has resulted in a significant delay in the management of patients with non-colorectal diseases and showed that routine colorectal referrals had to wait for nearly 84 days for their first appointment (52). The results from the present study have further highlighted these concerns in both Trusts. This is due to the fact that non-colorectal and routine colorectal referrals are normally seen and dealt in general outpatient clinics along with general surgical referrals. A similar difference in waiting times for urgent and non-urgent referrals was seen across the whole of the UK for various cancers (120). A study by Oslon *et al* has highlighted further delay amongst patients undergoing elective surgery for non-cancer related causes. However, this is beyond the scope of this study (121).

The two-week standard had been used as a safety net by general practitioners to refer patients to specialist clinics. This has led to large number of inappropriate referrals flooding the clinics (48). At least half of those referred

as urgent cases do not fit the national guidelines (3). This has also been true in the present setting (52).

6.8 Modified Dukes' stage

Patients with early disease (modified Dukes' A) have been shown to have 5-year survival of 95%. Survival decreases with later cancer stages (2, 122). Hence, it is important to diagnose colorectal cancers early.

The overall pick up rate of Dukes' A colorectal cancers in the study sample was more than the overall UK pick rate (13.9% in Trust A and 14.7% in Trust B compared to 10% for the UK (30). This is in spite of the exclusion of malignancies identified in polyps. Thus both the Trusts in this study have very good pick-up rates for early cancers. In the Trent/ Wales audit, modified Dukes' A cancer accounted for only 10% of all the colorectal cancer diagnosed. Pick up rate of Dukes' A cancer in the published literature varies between 4% to 18% across the world (5, 20, 95, 96). In the present study, the percentage of Dukes' A cancers diagnosed in the two Trusts was not statistically different. This result appears to reject the hypothesis of the present thesis. However, models of health care delivery have various components as shown in Flow diagram 1 and the specific pick up rate of Dukes' A cancers will be different for individual components.

A study published by Shankar *et al* performed in Trust A highlighted increases in the modified Dukes' A cancer after initiation of sub-specialisation (23). It went from 11% in 1993 to 23% in 2000. In the present study, it is 13.90% in Trust A. This is due to exclusion criteria, as the present study excluded cancers diagnosed in the endoscopically resected polyps, whereas the study by Shankar *et al* (2000) included endoscopically resected polyps as Dukes' A cancers (23). It could be also due to better staging facilities now being available. In 2000, X-ray chest and ultrasound of the liver were standard staging modality for metastatic assessment whereas in the present study it was computed tomography of the chest, abdomen and pelvis. There is evidence to show that with better staging modalities and protocols, more distant metastases will be identified (123, 124), thus reducing the overall proportion of early cancers detected.

The overall pick up rate of modified Dukes' A colorectal cancer diagnosed in the Wales as per the Trent /Wales audit was 10% which is less when compared with the two Trusts (5). This could be due to the fact that there has been an exclusion of cases where the staging was not carried out in the present study. This could influence the percentage of the Dukes' A cancers diagnosed. The other reason could be use of the modified ACPGBI criteria used by the two Trusts as discussed in the Chapter 2 Background (2.10). The reduction in the age group of patients from 60 years to 50 years could be the reason for the high

percentage of early colorectal cancers diagnosed as flexible sigmoidoscopy is performed ten years earlier in symptomatic patients in the study group.

6.9 Modified Dukes' stage and routes of access

Asymptomatic patients present with less advanced disease, thus have better survival. Early cancer diagnosis in these patients is best achieved by screening the population (37). A study by Waldron *et al* suggested that 66% of patients who present as emergency have potentially curable disease (46). Introduction of a fast-track service to meet the two-week target has resulted in a trend towards fewer emergency presentations with colorectal cancer (63). Colorectal cancers diagnosed via direct surgical referral tend to be at an earlier stage compared to those referred via accident and emergency (98). These findings are supported by the present study in that there were larger numbers of Dukes' A cancers diagnosed via elective routes as compared to emergency routes. This was equally true for both the Trusts. Chohan *et al* highlighted that there was a higher incidence of metastatic disease in patients referred as fast track referrals (64). This was in contrast to the study performed by Lamah *et al* which showed that only one of 70 patients diagnosed via fast track service had metastatic disease (49).

6.10 Modified Dukes' stage and various categories of elective routes of access

There was no significant difference in the Dukes' A stage in the two Trusts in patients diagnosed via various elective category of referral i.e. GP and inter-departmental. However, there were higher percentage of Dukes' A cancers diagnosed via inter-departmental category of elective route in Trust A (18.75%) as compared to Trust B (6.67%). Although, this appears to be a trend, there is no statistical significance, possibly due to small numbers.

Elective referrals to the specialist service could be either urgent or non-urgent. Analysis of the cancers diagnosed through urgent referrals (Section 5.3.9.2), showed that there were significantly higher numbers of Dukes' A cancers diagnosed in Trust A (21/93) compared with Trust B (11/105). Detailed sub-analysis of the urgency of the referral in relation to the elective routes of access shows that 19% of cancers diagnosed via RACRC were Dukes' A cancers. OAFS did not diagnose any Dukes' A cancer. This may be explained by the fact that RACRC utilised the modified ACPGBI criteria (29) for classification of urgent referrals whereas OAFS is based on only simple criteria like age > 45 years and rectal bleeding. The differences could also be explained by the fact that RACRC is accessed by a designated referral form. Though a previous study from Trust B has shown that the general practitioners have accepted the nurse-led OAFS (28), this study seems to suggest that in the present

circumstances with specific government guidelines, GP acceptance may need to be re-assessed. Furthermore, OAFS has not been shown to be a particularly expeditious service (Section 5.2.9) and that may be an explanation as to why general practitioners are not using it for urgent cases. A study published in 2000 from these two Trusts compared the RACRC with OAFS (25) and showed similar stage migration in terms of Dukes' A cancer diagnosed via both these services. This has not been supported by the present study. However, the study published in 2000 did not look into whether the referrals were urgent or non-urgent. Studies in the literature have published varied results of cancers diagnosed via their fast track clinics. A study by Walsh *et al* picked up 15% Dukes' A cancers via fast track clinics (14). A Study by Chohan *et al* produced contradictory finding of higher pick up of cancers with metastatic disease (Dukes' D) as compared to Dukes' A which was 12% (64).

Continuing with the sub-analysis of the urgent referrals within the elective route of access, a significantly higher proportion of early cancers in this study were diagnosed from urgent referrals via general outpatient clinics in Trust A as compared to B (Table 5.3.14). This difference is explained by the fact that the vast majority of urgent referrals are seen in RACRC rather than the general outpatient clinic in Trust A. All the urgent referrals are seen in the general outpatient clinic in Trust B. However, this study has not looked at the overall

workload of any of these services and therefore, cannot comment on the efficiency of these individual services.

General outpatient clinics are a standard form of access for patients with a wide range of problems. With the use of rapid access clinics for urgent cases with suspected cancer referrals, the general clinics are mainly used for non-urgent and benign referrals leading to low pick up rate of cancers in these clinics (20). This is true for Trust A. However, in Trust B, where the general surgical clinic forms the backbone of the access mechanism, increased usage of a designated referral form with strict criteria by the referring general practitioners could improve the pick up rate of early cancers.

In summary, there appears to be no significant difference in the overall pick-up rate of Dukes' A colorectal cancers between the two models of health care delivery. However, detailed sub-analysis of the urgency of the referral in relation to the stage of the cancer diagnosed shows that there was a significantly higher pick up rate of early colorectal cancer (Dukes' stage A) in Trust A compared with Trust B, when general practitioners sent patients into the specialist service using an urgent referral through the elective route (Table 5.3.14). The fact that the differences are so subtle is hardly surprising when comparing two systems of health care delivery, both of which are performing well above the national average in terms of the diagnosis of early colorectal

cancer. This is especially true, when examined in the context of the particularly high levels of socio-economic deprivation in the catchment population where these health care delivery systems operate.

6.11 Deprivation levels (Townsend Index) and stage of colorectal cancer

This study highlights that there is a wide variation of the Townsend index in patients diagnosed with colorectal cancer. The two Trusts in this study serve a particularly deprived area of Wales as shown by the fact that more than 85% of this population belonged to median and deprived categories. The overall range of the Townsend index for the whole of the Wales varies from -8.23 to + 11.88 and that of the catchment population is -8.23 to +9.59.

People with colorectal cancer tend to develop non-specific symptoms leading to emergency presentation with advanced disease (3). This study highlights that patients with high Townsend scores are more likely to be referred as an urgent referral to the clinic or via Accident and Emergency department or as a GP emergency referral. Hence in turn, they are also likely to have significant risk of having an urgent/emergency operation and consequently have poorer outcomes (1).

There is increasing evidence of variation in treatments being provided to cancer patients in different socio-economic groups (125). Women with breast cancer living in deprived areas have been found to be more likely to receive a mastectomy than breast-conserving therapy in comparison with those living in affluent places in the UK (125). Similarly, variations in chemotherapeutic regimes have been seen in the management of colorectal cancer in the USA. However, this is beyond the scope of this study.

A Scottish audit showed that there was no consistent evidence that patients from deprived communities present with more advanced disease for colorectal cancer (126). In the present setting, patients with modified Dukes' D stage do have a higher Townsend index as compared to the other stages but statistical significance has not been achieved (Table 5.3.16).

6.11 Potential cost implications

Cost is another major issue in the management of patients with colorectal cancer. Cost per patient should ideally be calculated from the time of referral to the diagnosis, treatment and include the after-care of the patient. These costs vary widely and are affected by various factors, for e.g. blood transfusion (127), screen detected or asymptomatic patients etc. Costs have been reported to be

significantly less for Dukes' B and Dukes' A cancers, in both the pre-diagnosis phase and 12 months after diagnosis (128).

Life time costs of managing colorectal cancer diagnosed in the early stages is lower than when the cancer is a diagnosed at a late stage (129). The cost of the hospitalisation has been reported to account for 61% to 65%, as compared to 2% for diagnosis and staging. Most of the studies do not take in to account non-medical costs, such as the patient's time associated with travel to, waiting for or seeking medical care (70, 130). These can account for a substantial amount, almost 20% of medical costs in the initial period of care (diagnosis and primary treatment) and nearly 40% in the terminal phase (130, 131).

RACRC with flexible sigmoidoscopy may use more resources as compared to general outpatient clinics, in terms of more medical and nursing staff, use of consumables, overheads etc. The cost effectiveness of such a service would depend not only on the number of cancers diagnosed, but also on the overall number of referrals seen. The stage at which cancers are diagnosed also affects the cost of post-operative care. Hence, a high number of early cancers diagnosed from a fast track service may result in long term overall savings. There is evidence in the published literature to suggest that open access sigmoidoscopy or colonoscopy services reduces costs when compared to consultant-led clinics, with no differences in the colonic diseases diagnosed

(70). The cost per cancer patient diagnosed via various routes of access is beyond the scope of this study.

6.12 Strengths of this study

This is a unique study, which has compared two distinct models of health care delivery. The literature review has shown that various individual components of different models of health care have been studied in isolation. However, no previous study has compared whole models in their entirety. This study was aimed to assess the pick up rate of Dukes' A cancers and a very systematic approach has been undertaken to identify the differences in the two Trusts with a view to correlating the various steps in the process of health care delivery with the stage of colorectal cancer at diagnosis.

6.13 Limitations of this study

The study has good data collection, but it does not take into consideration the overall number of patients seen in the various categories of routes of access during the period of this study. That information would help to assess the efficiency of each of these components with regard to the pick up rate of early colorectal cancers as a proportion of the total number of patients seen in the clinic.

The sample size of this study could have been increased by collecting data over a longer period. A larger sample size may have shown up more significant differences and strengthened this study further.

Both the Trusts in this study have a higher pick up rate of early colorectal cancer than the national average. This could be a limitation of this study in that it has attempted to compare two exceptionally good models of health care delivery and therefore, the differences seen have been subtle.

This study has not taken into consideration detailed impact from the socio-economic status of the catchment population. Future studies may need to consider this issue in depth.

Chapter 7

Conclusions

It is safe to conclude from this study that there appears to be no difference between the two systems of health care delivery in their overall ability to pick up early colorectal cancers. However, detailed analysis of the constituent components of each model has shown specific differences.

This study has shown that the combination of a rapid access clinic with flexible sigmoidoscopy in association with the modified ACPGBI criteria incorporated in a specially designed referral form does reduce waiting times and results in a higher pick up of early colorectal cancers. There is conclusive evidence that there was a significantly higher pick up rate of modified Dukes' stage A colorectal cancer in Trust A compared with Trust B, when general practitioners gain access to the specialist service using an urgent referral through the elective route.

There is no significant difference in the waiting times for the first clinic appointment for the patients deemed urgent in either of the Trusts.

It is also possible to conclude that both these models of health care delivery are exceptionally good as the pick up rate of early colorectal cancers is higher than the national average in both the Trusts. This difference in the pick up rate of early cancers could be due to the modified ACPGBI criteria adopted in these two models of health care delivery.

This study demonstrates that patients with colorectal cancer from deprived areas are more likely to be referred as urgent referrals as well as require urgent intervention. They may have poorer outcomes in terms of stage of disease at diagnosis as well as postoperative mortality, though, due to sample size, statistical significance has not been achieved.

Finally, this study suggests that the presence of a dedicated specialist service is probably more important than any specific model of health care delivery for the early diagnosis of colorectal cancer.

Chapter 8

Recommendations

8.1 Recommendations

- General practitioner education should be instituted to highlight referral criteria to increase the appropriateness of referrals. This is particularly true for Trust B.
- Use of the designated referral form by general practitioners should be made mandatory. Both Trusts still get a lot of referrals through letters, but this is a particular issue in Trust B.
- Trust A should carry out regular audits of the appropriateness of the urgent referrals to the RACRC to optimise the elective workload.
- Trust A should carry out audits of the referrals through the emergency route of access to optimise the emergency workload.

8.2 Recommendations for future research

- Studies to compare both these models with other systems which are performing below the national average in terms of picking up early colorectal cancers may help to clarify the effectiveness of some of the specific components.
- Detailed studies should be undertaken regarding the cost implications of both these models of health care delivery.
- Future research could study the impact, if any, of the socio-economic status of the study population in relation to specific models of health care delivery and their correlation with pick up rates of early colorectal cancer.

Chapter 9

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APPENDIX I

North Glamorgan NHS Trust
REFERRAL FORM FOR THE COLORECTAL CLINIC

PART A (to be completed by the referring GP)

Patient Name: NHS No: Hosp No:

DOB: Patient Address.....

..... Patient Tel No:

Date of referral.....Date referral received.....Date seen in colorectal clinic.....

PLEASE TICK THIS BOX IF YOU FEEL THAT THIS PATIENT IS AT HIGH RISK OF BEING DIAGNOSED AS HAVING COLORECTAL CANCER SO THAT THE PATIENT CAN BE SEEN WITHIN 10 WORKING DAYS

[Empty box for high risk assessment]

Because of one or more of the following high risk criteria for urgent referral:

- 1. Rectal bleeding WITH a change in bowel habits to looser stools and/or increased frequency of defaecation persistent for 6 weeks. All Ages []
2. Change in bowel habit as above WITHOUT rectal bleeding and persistent for 6 weeks. Over 50 years []
3. Rectal bleeding persistently WITHOUT anal symptoms. Over 50 years []
4. A definite palpable abdominal mass. All Ages []
5. A definite palpable rectal mass. All Ages []
6. Iron deficiency anaemia: Below 10grams in post-menopausal women All Ages [] Below 11grams all men If this is the reason for referral, please mention Hb.....on (date).....
7. Abdominal pain with significant weight loss. Over 50 years []

If none of the above criteria apply, but you still want the patient to be seen in the colorectal clinic, please indicate below and a routine appointment will be sent to the patient.

Rectal bleeding [] Diarrhoea [] Constipation [] Weight loss [] Abdominal pain []

Other Comments:

.....

Relevant medication: Anticoagulants [] Other

Relevant Family History:

Relevant Past Medical History:

Referring GP Address

When you have filled in this form return it urgently to the Medical Records Dept. at Prince Charles Hospital for your patient to be seen at the colorectal clinic. If you have ticked the top box and selected one of the high risk criteria, the patient will be sent an appointment within 2 weeks. Otherwise, a routine appointment will be sent. There is no need to send any additional information or letter.

Prof P N Haray - Consultant Surgeon Mr A G Masoud - Consultant Surgeon
Mr. A. Joseph - Associate Specialist
Medical Records Phone: 01685 728315 Fax: 01685 728480

APPENDIX I

PART B (to be completed at Colorectal Clinic)

Additional History

.....

.....

Examination:

General

.....

Abdomen

.....

PR – Inspection

.....

PR – Palpation

.....

Proctoscopy

.....

.....

Sigmoidoscopy

.....

.....

Any Procedures

.....

Investigations

FBC

USS

Flex. Sigmoidoscopy

U&E

Ba enema

Other.....

LFTs

Colonoscopy

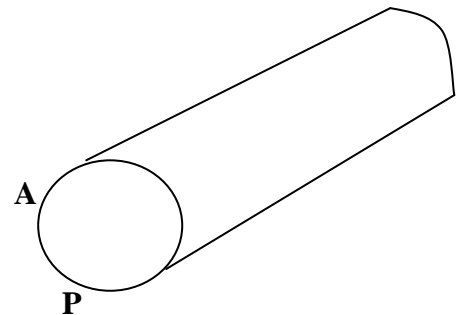
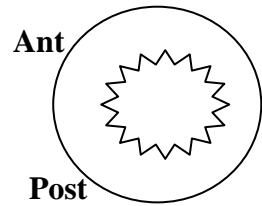
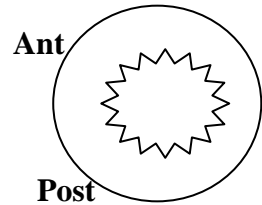
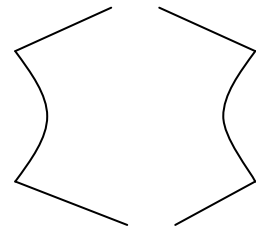
Provisional Diagnosis

Plan

.....

Seen by:Consultant/Assoc. Specialist/SPR Date:

Patient Sticker



Appendix II

Proforma for Data Collection

Patient's demographics

- 1 Hospital Number: _____
- 2 Unique identifier: _____
- 3 Post code: _____
- 4 Date of birth: _____
- 5 Age: _____ years.
- 6 Sex: Male Female

General Practitioners (GP) details

- 7 GP: _____
- 8 GP surgery: _____

Clinic Details

- 9 Date of referral by GP: _____
- 10 Date of referral received in the hospital: _____
- 11 Date 1st seen in the clinic: _____
- 12 Waiting period from GP referral to 1st clinic appointment _____ days
- 13 Route of access Elective Emergency
- 14 Referral prioritisation by GP Urgent Non-urgent
- 15 Referral prioritisation by specialist Urgent Non-urgent

Appendix II

- 16 Modes of referral
- a. RACRC
 - b. General outpatient clinic
 - c. OAFS
 - d. Inter-departmental
 - i. Physician
 - ii. Surgeon
 - iii. Other _____
 - e. Accident & Emergency

- 17 Type of referral
- a. Designated referral form(pink form)
 - b. Letter Typed Hand written

Symptomatology

- | | | | | |
|----|--|----------|-----|----|
| 18 | Rectal bleeding with CIBH - 6 weeks | All ages | Yes | No |
| 19 | Change in Bowel Habits (CIBH)
without rectal bleeding - 6 weeks | >50 yrs | Yes | No |
| 20 | Rectal bleeding without anal symptoms | > 50 yrs | Yes | No |
| 21 | Palpable abdominal mass | All ages | Yes | No |
| 22 | Palpable rectal mass | | Yes | No |
| 23 | Iron deficiency anaemia | | Yes | No |
| 24 | Abdominal pain & weight loss | | Yes | No |
| 25 | Date of diagnosis: | | | |

Appendix II

Investigations

- 26 Distant Metastasis
- a. Liver
 - b. Lung
 - c. Bone
 - d. Other

Histopathology

- 27 Synchronous tumour: Yes No
- 28 Anatomical localisation _____
- 29 Stage A non-A
- 30 T Stage
- 31 N Stage
- 32 M stage

Operation details

- 33 Surgery performed Yes No
- 34 Resection/surgery Curative Intent Palliative Intent
- 35 Mode of operation Elective Emergency
- 36 Type of operation:
- 37 Stoma Yes No
- 38 Stoma Permanent Temporary