THE UNIVERSITY OF HULL

THE ROLE OF NURSE LED COLONOSCOPY AND ITS IMPACT ON THE NATIONAL HEALTH SERVICE

being a Thesis submitted for the Degree of Doctorate in Medicine

in the University of Hull

by

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DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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This thesis is the result of my own investigations, except where otherwise stated.

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The Role of Nurse Led Colonoscopy and its Impact on the National Health Service

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CONTENTS

ABBREVIATIONS:

ACPGBI, Association of Coloproctology Great Britain and Ireland

ASA, American Society of Anesthesiology

ASGE, American Society of Gastroenterology

BAE, Barium Enema

BSG, British Society of Gastroenterology

BNF, British National Formulary

CP, Consultant Physician

CRC, Colorectal Cancer

CS, Consultant Surgeon

DcBAE, Double contrast Barium Enema

DGH, District General Hospital

Doh, Department of Health

EMR, Endoscopic Mucosal Resection

ENB, English National Board

FOB, Faecal Occult Blood

FS, Flexible Sigmoidoscopy

GI, Gastrointestinal

IV, Intravenous

JAG, Joint Advisory Group on Gastrointestinal Endoscopy

Kg, kilogram

MAPH, Initials of the nurse colonoscopist in this thesis

Mcg, microgram

Mg, milligram

NC, Nurse Colonoscopist

NE, Nurse Endoscopist

NMC, Nursing and Midwifery Council

NP, Nurse Practitioner

NHS, National Health Service

NMTE, Non-Medically Trained Endoscopists

OPD, Out Patient Department

QALY, Quality Adjusted Life Years

RCP, Royal College of Physicians (of UK)

RCT, Randomised Controlled Trial

RS, Rigid sigmoidoscopy

SMR, Specialist Surgical & Medical Registrars

TI, Terminal Ileum

UC, Ulcerative Colitis

UK, United Kingdom

UKCC, United Kingdom Central Council for Nursing, Midwifery and Health Visiting

US, United States

WL, Waiting Lists

KEYWORDS:

Adenomatous polyps

Colonoscopy

Colonoscopy training

Colorectal cancer

Flexible sigmoidoscopy

Nurse endoscopy

Nurse practitioner

Nurse colonoscopist

Bowel cancer screening

CHAPTERS:

CHAPTER 1

INTRODUCTION

1.1 Role of nurse practitioners in gastroenterology

1.2 Role of nurse endoscopists

1.3 Colonoscopy in colorectal assessment

1.4 Role of nurse practitioner in colonoscopy

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1.1 Role of Nurse Practitioners and Nurse Specialists, in Gastroenterology:

The traditional remits of the provision of nursing care has significantly evolved over the last many years. The historic role played by the nurses has now extended beyond the conventional limitations and the scope of this is far-reaching and varied. Nursing care has now become specialised, especially with the advent of nurse practitioners (NP) or specialists.

Over the last two decades, the role of nurse specialists in gastroenterology has been substantial. Every aspect of gastroenterological care is seeing rapid development and expansion of specialist nurses.

This watershed change in gastroenterological practice is occurring amidst growing recognition of the changing roles of healthcare professionals, especially in United Kingdom (UK). In UK the provision of health care was significantly different to other countries, including financial and delivery aspects of care. There is also major discrepancy between the health resources and facilities available as opposed to the demand for the services. Amidst all these, there is considerable political pressure for nurses to extend their practice to encompass many functions formerly seen as the exclusive preserve of doctors. In fact, this sea change in nursing practice and responsibility is seen by the British government as one of the central means of effecting modernisation of the national health care (Milburn A, 2000). There are various reasons for this change in attitude and perceptions, especially among the

policymakers, including increasing waiting lists, Patients charter drawn in 1991, finite financial budget allocations for health service, possible overall savings on health care costs by employing specialist nurses, increasing demands by the public including demand for holistic care, two-week wait rule for suspected malignancies, reduced junior doctors working hours and also changing and complex training issues of health care personnel. The enormous challenges of providing healthcare in UK during 1990's and the growing public demands on the service led many National Health Service (NHS) trusts to create extended role for nurses. An important factor that aided this development was the publication in 1992 by United Kingdom Central Council (UKCC) for Nursing and Midwifery and Health Visiting of its *Scope of Professional Practice* (UKCC, 1992), in which nurses where encouraged to further develop their roles. This publication advised nurses to access educational resources to ensure their role as clinically competent practitioners, placing the responsibility on individual nurses to remedy any deficits in their clinical knowledge and skills. The Department of Health (DoH) produced a White Paper in 1998 (DoH, 1998), which introduced the concept of human resource strategy, which emphasised workforce planning, skills development, provision of managerial support and incorporated an overall aim to improve the quality of working life. Following the 'Agenda for Change', the government's recommendations for modernisation and rationalisation of the NHS pay scheme (DoH, 1999b), and the introduction of specialists and consultant nurse posts, a new career structure for nurses was unfolded. The DoH also implemented steps to promote the development of clinical academic career for nurses (DoH, 1999a). The various factors as mentioned all

contributed significantly to the creation of clinical nurse practitioners or nurse specialists. Castlidine (1998) described the essential criteria and qualities to be a clinical nurse specialist (**Table 1.1**), and characteristics of advanced practice nurse and extended role nurse are illustrated in **Table 1.2** (Read, 1998) and **Table 1.3** (Roberts-Davis, 1998).

At present there are hosts of various specialist roles in gastroenterology available for nurse practitioners, including stoma nurses, inflammatory bowel disease nurses, colorectal nurse practitioners, nutritionists, irritable bowel syndrome practitioners, anorectal physiologists with interest in biofeedback and also importantly in endoscopic services. The latter have developed over a period of years from the 1970's limited roles in upper GI endoscopy to flexible sigmoidoscopy (FS). Also nurse practitioners have been increasing performing therapeutic endoscopic treatments and have now started to perform colonoscopies.

Table 1.1

Criteria for clinical nurse specialist role
• Involvement in patient care • Educated to degree level, possible Masters Degree • Involved in research • Involved in educational programmes for healthcare team and patients • Co-ordinates care with other healthcare professionals or leads the organisation of the patients' total healthcare • Able to act in a consultant capacity • Concerned with the dissemination of practice in publications and conferences • Acts as a liaison between hospital and community • Has freedom and flexibility in role.

Table 1.2.

Characteristics of advanced practice
• Expands/adjusts the boundaries of practice • Pioneering • Sophisticated use of clinical knowledge and skill • Systemic assessment of patients leading to healthcare intervention • Independent clinical decision making • Demonstration of high levels of accountability, autonomy and risk taking • Grounded in nursing theory and practice when making decisions • Educational qualifications beyond registration (Sparacino, 1986)

Table 1.3.

Extended role nurse
• 70-80 percent of time is spent in clinical practice • Educated to Masters level • Performs comprehensive patient assessments based on completing medical and physical examination to arrive at a nursing and medical diagnosis • Identifies, orders and interprets specific diagnostic tests and procedures • Prescribes specific medication and therapeutic interventions • Independently performs selected invasive or non-invasive medical procedures • Authorises and co-ordinates admission, discharge and follow-up • Has advanced knowledge of educational theory to develop innovative educational programmes for patients and healthcare professionals • Provides expert knowledge to policy and procedure development • Provides leadership by advancing nursing knowledge through research related activities

1.2 Role of Nurse Endoscopists:

The role of nurse endoscopy is well established with growing evidence to support the effectiveness of it (Maule, 1994; Rosevelt et al., 1984; Jain et al., 2002; Cash et al., 1999; Schoenfeld et al., 1999a, 1999b and 1999c). In fact, nurse endoscopists have been utilized in performing Flexible sigmoidoscopy (FS) since the 1970's (Spencer et al., 1977 and 1978) and further studies have reiterated this (Cash et al., 1999). British Society of Gastroenterology Working Party (BSG, 1994 and 1995) and Society of Gastroenterology Nurse and Associates Practice Committee (1997) have supported the performance of sigmoidoscopy by non-physicians. Several studies has shown NE can perform endoscopy as well as experienced endoscopists, with similar effectiveness and patient satisfaction (Schoenfeld et al., 1999a) and with no differences in polyp detection rate or complications (Schoenfeld et al., 1999b). Maule (1994) reported that, although doctors inserted a flexible sigmoidoscopy to a slightly greater depth than the nurses, there was no difference in pick-up rate of adenomas and carcinomas. In this study, neither group had any complications. Significantly, more patients in the nurses' group returned for repeat screening at one year (45% vs's 30%). However, there was a selection bias due to symptomatic patients being seen by the doctor as opposed by the nurse (Maule, 1994; Lahad et al., 1994). Moshakis et al (1996) found that an independent blinded assessor scored a specially trained nurse within 15 % of the nurse's doctor trainer on various aspects of performance, with both achieving the aim of 60 cm insertion in over 70% of cases and reaching the descending colon in half, with no complications. Schoenfeld et al

(1999b) in a randomised trial, compared doctors with nurses performing flexible sigmoidoscopy as a screening test for colorectal cancer (CRC). In this study, both groups had a miss rate of around 20% for polyps, as discovered on a repeat endoscopy. In addition, although doctors reached greater depth of insertion there was no difference in complication rate.

It has been shown that nurse endoscopy is widely practised in UK (Good fellow et al., 2003; Pathmakanthan et al., 2001) and is not limited to one procedure or carried out solely for diagnostic purposes (Pathmakanthan et al., 2001), and the perceived benefits included reduction in waiting lists, reported good patient acceptability, improved care and safety. There is increasing acceptance among the patients and medical community with regard to role of NE in performing FS (Basnyat et al., 2002).

Since 1996, nurse practitioners have been performing FS in our unit, which has an established NE training programme for performing FS (Duthie et al., 1998).

1.3 Colonoscopy in colorectal assessment

The first successful total colonoscopy using the 'fibreoptic coloscope' was reported in 1967 by Overholt and Pollard. Since its first description, the role of colonoscopy has expanded considerably over the years. At present, colonoscopy has become the gold standard and definitive investigation of choice for colorectal assessment. Colonoscopy is more sensitive than radiological imaging and offers both diagnostic and therapeutic options.

The indications for colonoscopy are various, which are for patients with colorectal symptoms including rectal bleed, altered bowels, abdominal pain, associated weight loss or loss of appetite. Other factors include positive significant family history, polyp follow-up, previous colorectal cancer and surveillance for conditions like chronic ulcerative colitis (UC) to detect early malignant/dysplastic changes.

A good bowel preparation is essential for adequate assessment of the entire colon. Poor bowel preparation negates proper visualisation of colonic mucosa, and in addition prolongs intubation time (Kim et al., 2000). Bowel preparation usually includes sodium phosphate (e.g., Fleet), magnesium salts (e.g., Picolax) or polyethylene glycol (e.g., Kleen-prep). Various studies have been conducted to evaluate the efficacy of these preparations. A meta-analysis of sodium phosphate and polyethylene glycol showed that sodium phosphate had resulted in better preparation and better toleration by the patients (Hsu et al., 1998). Two studies

comparing magnesium salt with sodium picosulphate (Picolax) and polyethylene glycol showed sodium picosulphate as having better patient toleration and bowel preparation (Hamilton et al., 1996; Hawkins et al., 1996). Two other studies using sodium phosphate and sodium picosulphate, showed better with sodium phosphate in one study and a similar outcome for both preparations in the other study (Macleod et al., 1998; Yoshioka et al., 2000). Despite these earlier results, a recent prospective mulitcentre study by Bowles et al in 2004 showed that sodium phosphate was the least used and sodium picosulphate was the most commonly used followed by polyethylene glycol.

The endoscopy guidelines recommend the routine placement of peripheral intravenous cannulae prior to the procedure (Bell et al., 1991), and provision of oxygen for sedated patients. In most cases, a combination of sedation and analgesia is given prior to colonoscopy unless contraindicated or refused by patients. Midazolam is the drug of choice for short-term sedation (Ginsberg et al., 1992). Midazolam with pethidine for analgesia is the most commonly used combination in up to 58 % of patients (Bowles et al., 2004). The recommended dose of midazolam for sedation is usually 70 mcg/kg (that is 5 mg for 70 kg patient) and diazepam 10-20 mg (British National Formulary [BNF], 2002). In combined sedation with analgesia, it is important to note that analgesia is first given and then only the sedative should be given. This is to allow the safer titration of the sedative drug (Ben et al., 1990). There is also significant evidence that patient administered nitrous oxide/oxygen inhalation provides analgesia similar to opiates and

importantly results in less desaturation and faster recovery times (Harding et al., 2000; Saunders et al., 1994). Another controlled study has shown that the antispasmodic Hyoscine Butylbromide (Buscopan) is a useful adjunct as a premedication in colonoscopy and that it increases the speed of colonoscope insertion (Saunders et al., 1996).

A complete colonoscopy refers to the passage and examination of the entire colon, from rectum to caecum or terminal ileum. Various landmarks are widely used to denote a successful intubation utpo caecum, including ileocaecal valve, tri-radiate fold, transillumination, appendicular orifice, intubation of the terminal ileum, fluoroscopy and finger indentation of right iliac fossa. For a positive identification of caecum, one needs to visualise the ileocaecal valve (Cirocco et al., 1995). A complete colonoscopy is deemed to have been reliably performed only when ileocaecal valve is identified or terminal ileum is intubated (Cirocco et al., 1995; Bowles et al., 2004). As mentioned earlier, colonoscopy has now become the gold standard investigation of choice for colorectal assessment.

1.4 Role of Nurse Practitioner in colonoscopy

Since the report of the first successful total colonoscopy in 1966 by Overholt and Pollard, the role of colonoscopy as an investigation for colorectal assessment has expanded and has become the definitive investigation of choice. At present in UK, there is a widening disparity between the increasing demand for this service and the varying availability of the resources; either/both trained personnel and endoscopic facilities. The NHS faces staffing shortages (Goldacre, 1998; Bowles et al., 2004) and even if additional endoscopic facilities were provided there would still be inadequate number of trained personnel to combat the growing demand. The combination of reduced junior doctors' hours (NHS Management Executive, 1991) and Calman recommended shorter specialist training, in a report in 1993 by Working Group on Specialist Medical Training, result in further depleted manpower to perform service tasks. There is a consensus that increased number trained personnel might ameliorate the current waiting times (Moss, 2002). The current waiting times for colonoscopy (Goldacre, 1998; Bowles et al., 2004) presents as an unacceptable situation in this day and age. The pressures on health services to counter this are already stretched.

Screening for CRC, if implemented in UK, is going to put substantial pressures on the NHS, in addition to the near breaking point pressures that is already present. In US since 2002, a national screening programme for CRC has been implemented and colonoscopy is included as part of that screening tools (US Preventative Task Force,

2002). Currently in UK, the final results of two trials conducted by the Department of Health (DoH) and MRC evaluating the feasibility, effectiveness and cost-benefits of screening by faecal occult blood (FOB) and FS are awaited. Thompson et al. (2006) looked at screening from a UK perspective and reiterated that colorectal cancer is a major cause of morbidity and mortality with resultant substantial health care costs, and that in the present situation screening currently offers the best chance of improving outcomes from bowel cancer. It has been estimated that following FOB screening in normal risk individuals will lead to further 10,000 colonoscopy sessions in UK (National Screening Committee, DoH, 1998) or one session per week for each district general hospital serving a population of 250,000. Screening by FS for high-risk individuals, which is already taking place, will generate a further 13,000 colonoscopy sessions per annum (Atkin et al., 1998) or 1.25 sessions per week for a district general hospital serving a population of 250,000. The complimentary role of NE along with other medical endoscopists merits serious consideration in this present scenario and in context of potential future screening for CRC.

In 1995, East Yorkshire Trust developed two courses, which were the English National Board (ENB) Upper Gastro-Intestinal Course for Nurse Practitioners and ENB Flexible Sigmoidoscopy Course for Nurse Practitioners (Duthie et al., 1998). They were first of their kind in UK at the time. Since then, following the completion of supervised training, the role of the newly qualified nurse practitioner endoscopist progressively expanded. There has also been stringent auditing of the results of the

new nurse endoscopists (NE). As proficiency and skills among the new NE's increased, it was envisaged that due to growing demands of the health service there should be a scope for development of NE in colonoscopy. The training for this was started for one NE (MAPH) in our unit in 1998. Subsequently following the training and accreditation by the Joint Advisory Group (JAG), a single NE led colonoscopy service was started in our unit since November 2000. Nurse colonoscopy is in the initial stages with its role and acceptance still evolving. To date, no evidence has yet been published evaluating the outcome of nurse led colonoscopy practice. Our unit has one of the first UK recognized nurse colonoscopist (MAP) who was also the UK's first officially trained and recognized flexible sigmoidoscopist (Duthie et al., 1998).

1.5 Legal and ethical considerations in nurse led colonoscopy[§]:

In the present day scenario in healthcare, legal and ethical issues are becoming increasingly relevant. The legal structure concerning all sections of healthcare and its provision, including those governing nurses and nursing care is relatively complex. One of the important aspects of relationship between the law and nurses is accountability (Dimond, 1995). Nurses are accountable to patients, employer, to the profession and the public. There are four main areas of law that governs these arenas that includes civil law, employment law, Nursing and Midwifery Council (NMC) Code of Professional Conduct (2002) and criminal law (Palmer and Kaur, 2003). All the various factors are important in its own right and quite often overlap in their remits. There is also a strong interlink between the law and ethics so as to eventually ensure the adequate accountability and responsibility of the nurses.

Traditionally, all nurses employed in the National Health Service (NHS) are employed on 'Whitley Council terms and conditions of service'. However, things can be more complex when nurse practitioners are employed on a variety of different terms and conditions of service. Inspite of the various compounding factors, there is an essence in the relationship between the employee and employer in that the employee carries out specific duties for the employer on specified remuneration package. There are a number of statute laws arising out of this

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[§]General and Specific Referencing: (i) Palmer D, Kaur S. Core skills for nurse practitioners. Whurr Publication. 2003; chapter 7; (ii) http://www.thejag.org.uk, JAG Guidelines, 2004

essential aspect of this relationship (Palmer and Kaur, 2003). Young (1995) confirms that both the employer and employee have rights and duties that is an important factor that needs to be recognised. The employee's, in this instance the nurse's, rights are enshrined within the Employment Protection (Consolidation) Act 1978 and there have been further additions to the basic rights since then including the Trade Union and Employment Rights Act 1993.

Nursing and Midwifery Council (NMC) is the professional regulatory body for nurses and nursing and play a crucial and fundamental role in the development and maintenance of standards of the nurses and nursing practice. Previously, these matters were dealt by UKCC. Since April 2002, this role has now been taken over by NMC. All nurses have to be registered with the NMC before undertaking any employment within the NHS. The NMC Code of Conduct (2002) specifies that nurses are accountable for their own actions. Nurses must be aware of current practice and always act in the best interests of patients. NMC council also stipulates 'You must acknowledge any limitations in your knowledge and competence and decline any duties and responsibilities unless able to perform them in a safe and skilled manner' (UKCC, 1992).

At present, nurses are taking on increasingly responsible roles in the provision of health care. Nurse endoscopists are independently performing endoscopies, both diagnostic and therapeutic. UKCC (1992) supports the concept of development of professional practice, as long as "nurse concerned is competent for the purpose and

mindful of the personal professional accountability they bear for their actions". JAG Guidelines (2004) stresses that both nurses and other non-medical endoscopists, should be trained to the standards expected of a medical endoscopist.

In addition, JAG (2004) makes some general recommendations:

1. Nurses and other non-medical endoscopists are responsible themselves for ensuring their fitness to practice, and of doctors to ensure that responsibility is passed to a person fit to practise.

2. Nurses and other non-medical endoscopists are accountable for their actions and omissions regarding the patient during an episode of endoscopy. Doctors do not accept responsibility for their actions, only their own delegation.

3. Endoscopy involves the use of skill and each practitioner will be judged against the standard of an 'ordinary skilled practitioner' professing to have that special skill.

In essence, nurses are individually accountable for their own practice. Incompetent or negligent practice from a nurse can result in their erasure from the professional register, in the same as way as for doctors. The same also applies for extended nursing roles, i.e., for nurse practitioners. In cases of litigation for negligence, the Bolam test applies with the benchmark of practice set as 'what would be seen as

reasonable practice by a group of competent peers'. In the NHS, the employing authority provides the crown indemnity where the employer is responsible for finance and management of medical negligence claims. This is different in the private sector where the employer might make similar arrangements with a medical defence organisation, but importantly the employee should make their own arrangements for this provision, e.g. with a medical defence union.

The British Society of Gastroenterology strongly recommends local written protocols and agreements for nurse endoscopists. Such documents would ensure good 'medical practice standards' and also help in cases of litigation. It is important to note that, medicolegal implications are the same for nurses as for doctors, in that the nurse's practice will be judged against similar standards of an experienced endoscopist regardless of the medical or nursing background (Duthie et al., 1998). Furthermore, the professional bodies responsible for recognition of nurse training courses are required to ensure that every training course provides a consistent and comprehensive level of training and there are strict guidelines that must be followed before a course can be approved (UKCC, 1994).

1.6 Aims of the study

The primary aims of the study were to evaluate and determine the:

(i) safety, efficacy and feasibility of nurse led colonoscopic practice

(ii) miss rates for colorectal cancer and adenomatous polyps in nurse colonoscopy

(iii) cost analysis of nurse led colonoscopic practice

(iv) effectiveness and safety of nurse colonoscopy in comparison to medically trained endoscopists

Chapter 2

Training for Nurse Colonoscopy Practice

2.1 Introduction

2.1.1 JAG Guidelines and recommendations for colonoscopy training

2.2 Nurse endoscopist's training and experience

2.2.1 Nursing experience

2.2.2 Courses for nurse endoscopy

2.2.3 Endoscopy training and experience

2.3 Review of performance of nurse endoscopist prior to colonoscopy and learning curve in colonoscopy

2.3.1 Methodology

2.3.2 Results

2.4 Discussion

2.1 Introduction

The role of nursing has evolved over the years, especially since the last few decades. This changing practice of nursing care has increasingly encompassed areas that had been traditionally the remit of medically qualified doctors. Nurse specialists or nurse practitioners have been increasingly taking the role of specialist practitioners in medical care in certain niche areas. This is particularly true in the case in the field of endoscopy, where nurse led flexible sigmoidoscopy has been present since the 1970's (Spencer et al., 1977 and 1978). In the UK, until very recently, nurses have not undertaken colonoscopy practice independently. Our unit has been one of the first in the UK to establish a nurse practitioner led lower GI endoscopy service. Our unit was one of the first in UK to set up a nurse led flexible sigmoidoscopy service in1995. Subsequent to this, a fully independent nurse colonoscopy practice was stated in our unit since November 2000. This was the first time ever in UK that such a service provision has been made available.

The training for flexible sigmoidoscopy has also evolved over the years and our unit was the one of the first centres in UK to put in place a structured training for flexible sigmoidoscopy training (Duthie et al 1998).

Clinical supervision and training is one of the fundamental aspects of health care profession, including for adequate career development, as a critical support mechanism for professionals and also to ensure that the highest possible standards

are achieved and maintained in the health service. Clinical supervision was identified as national initiative through the strategy document 'A Vision for the Future' (National Health Service Management Executive, 1993). One factor that led to this initiative was the concern arising from Allitt Inquiry in 1991, which highlighted the need for nurses to receive support within their day- to-day practice and argued that clinical supervision could actually assist in sustaining safe standards of clinical practice.

In the initial stages, especially in the early 1980's, endoscopic training, training was essentially poor and not well structured. This included both flexible sigmoidoscopy and colonoscopy training and assessments. The methods used were very basic consisting of audiovisual presentations and occasionally live demonstrations (Teague, 2000).

The Joint Advisory Group on Gastrointestinal Endoscopy (JAG) was set up in UK in 1999 (www.thejag.org.uk), with an aim to improve standards in provision and training of endoscopy services. The specific aim of JAG was to define the standards of training of all endoscopists no matter what their professional background. The Surgeons of UK, Radiologists and General Practitioners.

The COG guidelines from the Department of Health 1999 state: "Colonoscopy is a technically difficult procedure and is often performed poorly. People who wish to carry out colonoscopy should receive training, carry out sufficient numbers of the

procedure to attain competence and be able to demonstrate skill." The JAG has brought out guidance on various training aspects of endoscopists three times since its inception. (JAG, 1999, 2001 and 2004).

2.1.1 JAG guidelines and recommendations [†]

VARIOUS RECOMMENDATIONS AND GUIDELINES SET OUT BY JAG FOR TRAINING IN COLONOSCOPY (JAG, 2004), INCLUDES:

General Unit Facilities:

- Unit with adequate modern facilities, including endoscopy and imaging equipment
- Facilities for sedation, monitoring, resuscitation and recovery as recommended by BSG
- Adequately staffed unit, as laid down by BSG
- Training units should be approved by JAG

Specific for Colonoscopy:

- Training unit should undertake at least 400 procedures/year
- Training rotations for trainees shoul enable experience for trainees in units performing more than 800 procedures/year

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[†] General and Specific Referencing: Joint Advisory Group on Gastrointestinal Endoscopy (http://www.thejag.org.uk)

JAG is supported by various Royal Colleges, including those of Physicians of UK,

Training:

- Trainees must register with JAG
- Training to consist of in-service training, and attendance at JAG initiated courses or JAG compliant courses.
- Forms of therapeutic endoscopy should be taught only after acquiring competence in adequate diagnostic skills
- Trainees expected to maintain their skills and knowledge with commitment to continued medical education and professional development. Also to have knowledge of current surveillance protocols for gastrointestinal(GI) diseases
- Trainees to have good communication skills, and also to ensure good medical practice and patient care
- Diagnostic experience
    - trainees should have acquired prior basic endoscopic skills, either upper GI endoscopy or FS
    - Prior Basic Skills Foundation Course in Endoscopy or FS course
    - Trainees should be able to perform at least 100 procedures within the course of the year.
    - Caecal intubation rate should exceed 90 % in those patients without structuring or marked faecal contamination
    - TI intubation in at least 50% of procedures where indicated. (Recommended that trainees will need to perform more than 200 examinations to meet this criteria)
- Therapeutic experience

- trainees to be competent in techniques of hot biopsy, polypectomy and treatment of colonic bleeding
- Familiar with balloon dilatation of strictures and techniques to stop bleeding and treat angiodysplastic lesions.
- Some trainees may wish to gain higher training in advanced techniques of dye spraying, tattooing, endoscopic mucosal resection (EMR), and tumour debulkng and stenting.

Courses:

- Basic Skills in Colonoscopy, JAG approved
- Trainees wishing to undertake more advanced techniques should attend an advanced colonoscopy course approved by JAG
- Specific for nurses and other non-medical endoscopists
  - Formal university linked nurse endoscopy training courses, accredited by JAG. Attendance at these JAG compliant course are mandatory
  - Education for nurse and non-medical endoscopists are undertaken with an aim to achieve a common core standard of gastroenterology and endoscopy when compared with medical training
  - nurses and other non-medical endoscopists can act as endoscopy trainers for both doctors and nurses once they have achieved – expert practice; competency in role; and undertaken appropriate Training the Trainers (Endoscopy) course

Basic Skills in Colonoscopy Course includes:

- Three-day course with mixture of theory and practical hands-on skills training
- Theoretical aspects include -
  - Instrument design and function
  - Indications and contraindications
  - Complications, their avoidance and management
  - Informed consent
  - Safe sedation
  - Diathermy theory and practice
  - Accessories and sample handling
  - Equipment fault finding
  - Cleaning and disinfection
  - Unit management and organisation (including Modernising Agency Endoscopy Project details)
  - Additional topics – polypectomy and surveillance protocols
- Practical skills include –
  - control handling
  - Torque steering
  - Loop recognition and resolution
  - Each trainee undertakes 4 colonoscopies during the course under direct supervision of consultant trainer

Appraisal and Assessment:

- accurate logbook of experience
- portfolio of assessed cases
- currently three assessments methods are being piloted
    - Mini-CEX (clinical evaluation exercise)
    - DOPS (direct observation of procedural skills)
    - 360° assessment
- Trainers should have attended a 'Training the Trainers' course (Balfour, 2001), specific to endoscopic skills training when these are available.

General Recommendations for nurse endoscopists and other non-medical endoscopists:

- Trainee endoscopist, irrespective of their background, should ensure their endoscopy training is the same as that for any endoscopist
- Trainees' education should be at the level and depth to support clinical work and patient management
- Trainees are responsible to ensure their training is contemporary, evidence based and undertaken with national guidelines
- Mechanisms to ensure on-going assessment, updating and auditing of practice
- Use of professional portfolio to include a logbook is required to confirm learning needs and evidence of adequate training

In addition, good standards of colonoscopic procedures have also been recognised as (Wexner et al., 1998)

- Completion rate >90%'
- Majority of colonoscopies completed within 30 minutes
- Patient should experience no pain or mild pain in <60%
- Incidence of serious complications should be <0.2%

The JAG recommends trainees to perform 100 supervised colonoscopies in 1 year (JAG, 2004), and the American Society for Gastrointestinal endoscopy recommends a minimum of 100 supervised colonoscopies prior to assessment of competence including 20 polypectomies (American Society of Gastroenterology, 1991). In spite of the recommended number of minimum 100 colonoscopies under supervision in order to attain competence, it has been shown by several studies (Marshal, 1995; Tassios et al., 1999; Church et al., 2002; Harewood, 2005) that this minimum of 100 colonoscopies might be too low and that upto 200 procedures might be required so as to serve this specific purpose. In Australia the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy (1997a, 1997b) formulated the guidelines recommending a minimum of 100 supervised but unassisted colonoscopies, including 30 snare polypectomies with a completion rate at the end of training which should be in excess of 85%.

2.2 Nurse endoscopist's training and experience

The nurse (MAPH) started training in flexible sigmoidoscopy from October 1994. MAPH completed FS training by April 1995 and independent FS practice was started by the nurse in the same month. Subsequent to this, fully independent nurse colonoscopy service was started in our unit from November 2000.

At the time of starting training in FS in 1994, there were no well established training models for training in either FS or colonoscopy. MAPH started to be trained in the traditional medical model of apprenticeship training. It was decided at the time, partly empirically and partly based on training model as described by Maule et al (1994), that MAPH was to undertake 35 training cases each of observing, withdrawing and then performing FS under supervision. Following this, MAPH started doing fully independent FS service in our unit in April 1995. As a result of the experience gained in training the nurse endoscopist, our unit set up the first UK accredited training programme in FS (Duthie et al, 1998).

MAPH started performing colonoscopies from November 2000. Prior to this, MAPH did not have any colonoscopic experience. This was due to the substantial experience MAPH had with FS, including therapeutic procedures, and also due to lack of any established training model or national accreditation criteria that existed at the time. The first 100 colonoscopies were supervised. MAPH's experience in

endoscopy prior to November 2000 was solely based on FS and none in upper GI scopies.

2.2.1 Nursing experience

MAPH experience prior to starting nurse colonoscopy in 2000 was as following:

- 1983 to 1986: Nursing training, RGN course, Hull
- 1986 to 1987: Staff nurse ICU, HRI
- 1988 to 1989: Staff nurse in surgical ward
- 1989 to 1990: Charge nurse and set up urology ward at Kingston hospital
- 1990 to 1994: Junior charge nurse at colorectal ward, ward 11, castle hill hospital
- 1994 to 1999: Family history clinics, support colorectal cancer patients; flexible sigmoidoscopy training and practice

2.2.2 Courses for nurse endoscopy

Three courses were undertaken by MAPH as part of training in FS:

1. English National Board 906 course – Gastrointestinal Endoscopy and Related Procedures, January 1995
2. English National Board 9N81 course– Colorectal Endoscopy course for nurses, Specialist Practice Module; January 1998
3. English National Board DO3 Course– Management and Care of Clients Requiring Sigmoidoscopy and Biopsy; September 1998

English National Board 906 course – Gastrointestinal Endoscopy and Related Procedures

- Post graduate diploma level 'Short courses'
- January - February 1995, Fazakerley Hospital, School of Health Studies, Edge Hill University, Liverpool
- Four week sessions from Jan to Feb. 1995
- Part-time student

Learning outcomes:

1. Identify the principles of health education and promotion within the client group

2. Critically analyse Health and Safety rules, and regulations and the hazards involved in the environment with radiological X-ray, lasers and electrosurgical equipment
3. Be cognizant with the socioeconomic factors and influences affecting the resourcing of patient/client-care and rehabilitation
4. Explore in depth physiology of healthy individual relating specifically to inter-relations of nervous, vascular and digestive systems
5. Analyse the pathophysiological basis for dysfunction of the digestive system and its application to the susceptible client with gastrointestinal problems
6. Examine the nature of specialist nursing role/skills relating to the holistic care of clients within the gastrointestinal endoscopy suite
7. Use an analytical and reflective approach to the nursing care of clients undergoing diagnostic and therapeutic interventions of the upper and lower gastrointestinal tract
8. Use an analytical and reflective approach to the needs of dying clients and their relatives
9. Demonstrate specialist skills in measurement and data recording

The course module involved various aspects as follows:

- Demographic effects on enterology
- Anatomy of the upper and lower gastrointestinal tract
- Physiology of the gastrointestinal system
- Gastroenterology, biliary tract – relevant aspects

- Oesophageal pathology and treatment
- Oesophageal motility
- Pathologies of upper and lower gastrointestinal tract
- Gastric haemorrhage
- Endoscopic supporting equipment
- Use of gluteraldehyde
- Sterilisation and disinfection
- Cleaning and maintenance of scopes
- Servicing of scopes
- Microbiological aspects of endoscopy
- Peg tubes
- ERCP and associated instrumentation
- Combined procedures
- Insertion of sengstaken tubes
- Use of lasers as therapeutic tool
- Radiology – barium studies, cholangiogram
- Future technology
- Consent and negligence
- Accountability
- Planning of care
- Assessment of hospital policy
- Health education
- IT skills workshop

- Quality and standards
- Audit
- Research appreciation and dissemination

English National Board 9N81 course– Colorectal Endoscopy course for nurses, Specialist Practice Module

- Two semesters in January to July 1998
- Faculty of Health department, University of Hull
- Part time student

Course involved:

- Structure and function of abdomen and large bowel
- Pathologies of large bowel
- Anorectal anatomy and physiology, functional aspects and measurement
- Colon cancer – screening, treatment and surgery
- Pharmacologiocal treatment of GI disease
- Liver – structure, function, applied physiology and pathology
- Inflammatory bowel disease
- Anaesthesia and laparoscopic surgery
- Radiology of GI tract
- Interventional radiology

- Benefits of non-sedation endoscopy
- Principles of electrosurgery
- Endoscopy – principles, safety and practice
- Practical sessions in endoscopy
- Patient examination – practical session
- Epidemiology
- Health promotion
- Protocol writing and practice development
- Learning methods
- Writing for publication; Manuscript workshop
- Clinical Audit and project management

English National Board DO3 Course– Management and Care of Clients Requiring Sigmoidoscopy and Biopsy, September 1998

This course involved four modules undertaken by the University of Hull, Department of Nursing and Applied Health Studies at the Faculty of Health. Each of the modules had a taught lecture style teaching strategy that covered 7.5 days and also had tutorial support covering 1.5 hrs per student throughout each module. In addition, problem based learning method was also incorporated into the courses. The part-time students were encouraged to set aside 6-12 hours of private study for reading each week during the duration of the course. During the relevant modules, the trainee needed to working in an area where nurse endoscopy is required.

The four modules were:

1. Conscious sedation for nurses
2. Developing and updating nursing practice
3. Colorectal techniques by endoscopy in practice
4. Colorectal techniques by endoscopy for nurses

Conscious sedation

This module was designed to develop professional knowledge and competence in the safe administration of conscious sedation and to provide opportunities to examine the legal, ethical and moral issues of nurse(s) prescribing and administering medicines.

There were five learning outcomes:

1. Administer conscious sedation safely to patients
2. Discuss and apply Clarke's Sedation Scale to patients undergoing conscious sedation
3. Demonstrate techniques of monitoring of patients under conscious sedation
4. Identify complications of conscious sedation and commence intervention according to agreed clinical protocols
5. Identify the need and use of reversal agents

The assessment method included a 3000 word seminar paper and 50 supervised cannulations.

The content of this module involved:

- Conscious sedation: an overview
- Complications of conscious sedation
- Pharmacology, drug absorption and secretion
- IV cannulation
- Conscious sedation case scenarios
- Administration of medicine
- Patient group directions
- Sedation effects
- Oxygen saturation monitoring
- Respiratory physiology
- Pathways and physiology of pain
- Advanced life support
- Cardiac monitoring
- Reflective diaries

Developing and updating nursing practice

This module's aim was to explore the legal, ethical and professional issues related to the development and extension of professional practice.

Learning outcomes

1. Analyse the legal, ethical and professional issues relating to the expansion and extension of nursing practice
2. Discuss the impact of extended professional roles on the NHS, profession and society
3. Examine the role of the specialist nurse
4. Understand and critically evaluate the legal responsibility and accountability in obtaining informed consent
5. Demonstrates accountability in relation to trainee's practice
6. Critically applies current research findings and incorporates these into practice
7. Critically apples the principles of audit and quality in clinical practice

The assessment method used included a 3000 word critical incident analysis and 500 word research abstract.

The contents of this module involved:

- Scope of professional practice
- Code of conduct
- Professional accountability
- Guideline for practice
- Models for care
- Clinical effectiveness and evidence based care

- Informed consent
- Standards for record keeping and documentation
- Professional judgement and clinical decision making
- Legal aspects of care
- Research process
- Reflection in action and on action
- Clinical supervision
- Writing for publication
- Health promotion
- Role of nurse practitioner
- Presentation skills
- Reflective diaries
- Lifelong learning

Colorectal techniques by endoscopy in practice

This module aim was to enable the student to examine a broad range of issues relating to colorectal endoscopy

Learning outcomes:

1. Discuss and apply knowledge of anatomy and physiology of gastrointestinal tract in performing flexible sigmoidoscopy and rigid sigmoidoscopy

2. Demonstrate diagnostic skills and limited therapeutic skills in relation to identifying normal and abnormal colonic pathology
3. Demonstrates the techniques of flexible sigmoidoscopy whilst performing flexible sigmoidoscopy
4. Apply knowledge of infection control to performance of flexible sigmoidoscopy
5. Perform safely per rectal examinations
6. Demonstrates techniques of cold biopsy, safely and a critical understanding of the limitation of the technique
7. Demonstrates techniques of polypectomy, safely and a critical understanding of the limitation of the technique
8. Demonstrates techniques of banding of haemorrhoids, safely and a critical understanding of the limitation of the technique
9. Apply and evaluate local protocols in relation to the performance of flexible sigmoidoscopy

The assessment method was a 3000 word case study and supervision of endoscopy procedures.

The contents of this module involved:

- Anatomy and physiology of the large bowel
- Bowel preparation
- Benefits of non-sedation endoscopy

- Colon cancer: Screening, Treatment and Surgery
- Reconstructive bowel surgery
- Structure and function of abdomen and large bowel
- Nutritional screening and assessment
- Pathologies of large bowel
- Benign diseases
- Inflammatory bowel disease
- Virtual endoscopy
- One stop rectal bleeding clinic
- Genetics of GI disease and cancer
- Constipation
- Anorectal functioning and measurement
- Principles and safety of electrosurgery
- Interventional radiology
- Pharmacological treatment of GI disease
- Radiology of GI tract
- Reflective diaries

Colorectal techniques by endoscopy for nurses:

This module was designed to develop the knowledge and understanding of a range of clinical issues and procedures related to the practice of colorectal endoscopy.

Learning outcomes:

1. Discuss application of nursing models and nursing process to the screened patient group
2. Demonstrate the workings of flexible sigmoidoscope and accessories
3. Identify reasons for failure to perform flexible sigmoidoscopy and likely outcomes
4. Evaluate and resolve, within agreed guidelines, problems with equipment used in flexible sigmoidoscopy
5. Critically reflect on potential complications associated with flexible sigmoidoscopy, take appropriate actions and give sound rationale for these actions

The assessment method included a 3000 word critical literature review and observation of endoscopy procedures.

Indicative content of the module:

- Endoscopy principles, safety and practice
- Holistic medicine and complimentary therapies
- The nurse practitioner in endoscopy
- Ethics in practice
- Counselling knowledge and cancer care
- Nutritional screening and assessment
- Oncological nursing care
- Protocol writing and practice development

- Radiotherapy, principles, side-effects and treatments
- Epidemiology
- Psychosocial aspects of malignant disease
- Clinical Audit and project management
- Establishing a nurse practitioner clinic
- Reflective diaries

2.2.3 Endoscopy training and experience

FS training: started October 1994

- Observe – 35 cases, started 3 October 1994, completed 1 November 1994
- Withdraw – 35 cases, started 9 November 1994, completed 10 January 1995
- Perform full procedure – 35 cases, started 11 January 1995, completed 12 April 1995

Started doing FS independently: 12 April 1995.

Individual personal logbook kept by trainee for the first 178 cases, in addition to the computer endoscopy database entry, till 15 May 1996, after that procedures only logged in the endoscopy database system (MicroMed).

Courses completed:

- English National Board 906 course – Gastrointestinal Endoscopy and Related Procedures, January 1995
- English National Board 9N81 course– Colorectal Endoscopy course for nurses, Specialist Practice Module; January 1998
- English National Board DO3 Course– Management and Care of Clients Requiring Sigmoidoscopy and Biopsy; September 1998

Competency gained and assessed in the examination of the anus, rectum and sigmoid colon:

Undertaken as part of ENB 9N81 course.

- Insertion of rigid sigmoidoscope – 35 cases., 28/8/98 to 4/12/98

  Aim: gain experience in doing per rectal examination and safely insert the RS

  Objective: digitally examine the anus prior to insertion of the rigid sigmoidoscope (RS); safely insert the scope whilst observing the lumen of rectum; comment on the anatomy and physiology of the rectum viewed through the scope

- Removal of rigid sigmoidoscope – 35 cases, 14/1/99 to29/4/99

  Aim: gain experience in the safe removal of RS

  Objectives: safely remove the rigid scope observing the lumen of rectum; safely discard the disposable instrument; leave the patient clean and comfortable; comment on the anatomy and physiology of the rectum viewed through the scope

- Perform rigid sigmoidoscopy – 35 cases., 7/5/99 to 13/1/2000

  Aim: gain experience in safe performance of examination of anus, rectum and sigmoid colon

Objectives: Visually examine the anal area and detect any abnormalities; digitally examine the anus to assess sphincter tone and detect any abnormalities that may defer the use of RS; safely perform the rigid sigmoidoscopy whilst observing the lumen of rectum; comment on the anatomy and physiology of the rectum viewed through the scope with the medical staff and be able to reassure the patient.

Conscious sedation and IV cannulation

- Undertaken as part of ENB DO3 Course
- 35 cases, 2 September 1998 till 24 January 2000
- supervised

Training in therapeutic flexible sigmoidoscopy

- 15 cases, started in 22/4/1998 till 31/3/99
- supervised
- training in performing polypectomy

2.3 Review of performance of nurse endoscopist prior to colonoscopy and learning curve in colonoscopy

As discussed previously, MAPH did not have any colonoscopic experience prior to undertaking colonoscopy from November 2000. However, he was a fully established flexible sigmoioscopist by then.

We decided to determine and review the performance of MAPH prior to doing any colonoscopy. In addition, we aimed to determine the success rate and hence the learning curve in MAPH's initial colonoscopic practice.

2.3.1 Methodology

A review of all flexible sigmoidoscopies performed by MAPH from October 1994 to October 2000 was undertaken. This was conducted retrospectively and data was collected from the endoscopy database that existed at the time. Various outcome measures were determined, including indications, type of FS, level reached, findings, complications and any medications used during the procedure.

A randomised controlled trial was also conducted in 1996, to assess the outcome of FS between MAPH (nurse) and a established medically qualified endoscopist (doctor), which was a consultant surgeon at the unit. 215 patients were randomised

to either group, of which 16 patients did not attend for FS procedure. This resulted in 199 cases, randomised to 86 (nurse) and 113 (doctor). Various outcome measures were determined, including indications, level reached, depth of insertion, findings, complications, patients understanding of the procedure. Also, patients' symptoms of pain and its severity, vasovagal symptoms, bloatedness, nausea and vomiting were also assessed.

Finally, the success rate of MAPH in performing colonoscopies were undertaken from the very first colonoscopy in November 2000 upto January 2003. These included 435 cases, with 218 males and 217 females with median age of 62 (range 21-92) years. The success rate was calculated using Cussum summative scoring system. This system is well established and validated, and used by the BSG and JAG for assessing performance status in colonoscopies. As per the guidelines issued by JAG, 43 cases were excluded in the calculation for Cussum scoring and this resulted in 392 cases. The excluded cases included incompletes colonoscopies due to significantly poor bowel prep or due to disease limitations. In order to assess the learning curve, the 392 cases were divided into groups of 50 cases each and Cussum score calculated. Also, Cussum score of the entire 392 cases were calculated.

2.3.2 Results

Flexible sigmoidosopy experience:

The review of all consecutive endoscopies undertaken by the NE prior to starting doing colonoscopies showed that there were 2082 FS performed from October 1994 upto October 2000. There were 935 males and 1147 females with a mean age of 55.09 yrs (range 2 – 99 yrs; Std Deviation – 17.25).

The indications for undertaking FS were for various reasons as showed in table 2.1, with several cases having more than one indication. The nature of cases were planned FS (1941 cases), Planned follow-up FS (139), unplanned repeat FS (2) and no cases of emergency FS were done.

The level reached during the FS procedure is depicted on table 2.2 and the findings in table 2.3. None of the patients required any sedation or analgesia during the FS procedure. Complications encountered as a result of the procedure were 6 cases (0.3%) of vasovagal episode and 5 cases (0.2%) had abdominal pain recorded as a complication.

Table 2.1, Indications for flexible sigmoidoscopy:

	No of cases, (%)
Rectal Bleeding	1091 (52.4%)
Anaemia	61 (2.9%)
Abdominal pain	401 (19.3%)
Abdominal mass	8 (0.4%)
Change in bowel habit	712 (34.2%)
Polyp on Barium enema	41 (2.0%)
Colitis/Crohn's on Barium enema	2 (0.09%)
Equivocal Barium enema	30 (1.4%)
Positive haemoccult test	21 (1.0%)
Colitis/crohn's assessment	26 (1.2%)
Polyp follow-up	96 (4.6%)
Cancer follow-up	47 (2.3%)
Post colorectal surgery	70 (3.4%)
Surveillance for UC	8 (0.4%)
Surveillance for family h/o CRC	18 (0.9%)
Surveillance FAP	3 (0.14%)
Screening	7 (0.3%)
Other	408 (19.6%)
Total	3050

Table 2.2, Level reached:

	No of cases, (%)
Terminal ileum (neo)	24 (1.2%)
Ascending colon	2 (0.1%)
Hepatic flexure	1 (0.05%)
Transverse colon	200 (9.6%)
Splenic flexure	380 (18.3%)
Descending colon	729 (35%)
Sigmoid colon	683 (32.8%)
Rectum	57 (2.7%)
Not recorded	6 (0.3%)
Total	2082

Table 2.3, Findings

	No of cases, (%)
Normal	984 (47.3%)
Polyp	368 (17.7%)
Polyposis coli	1 (0.05%)
Diverticular Disease	503 (24.2%)
Possible cancer	55 (2.6%)
Cancer	38 (1.8 %)
Stricture	29 (1.4%)
UC	21 (1.0%)
Crohn's	1 (0.05%)
Unspecified colitis	65 (3.1%)
Proctitis	29 (1.4%)
Angiodysplasia	1 (0.05%)
Melanosis coli	14 (0.7%)
Spasm	12 (0.6%)
Other	279 (13.4%)
Total	2400

Results of the randomized control trial:

215 patients were recruited for taking part in the RCT to evaluate the performance between the doctor and nurse. Sixteen cases failed to attend for the FS, resulting in 199 cases with 133 cases in the doctor group and 86 in nurse group. Patient demographics is shown in table 2.4.

The depth of insertion of the scope and time taken for FS are shown in table 2.5 and there were no significant statistical difference between the groups. Table 2.6 reveals level reached during FS. Again there were no significant differences between doctor and nurse. The findings encountered during FS is shown in table 2.7.

Table 2.8 reveals patients' understanding of the explanation given and nature of FS procedure, with no significant difference between doctor and nurse. Various categories of patients' experience were determined. Tables 2.9 and 2.10, shows the pain experienced by patients and its severity respectively. Tables 2,11, 2.12 and 2.13 shows vasovagal symptoms, nausea/vomiting and post procedure bloatedness respectively. Statistical analysis did not reveal any significant differences. In addition, there were no recorded complications in either of the two groups.

Table 2.4, Patient demographics

	Doctor	**Nurse**
Male	45 (40%)	39 (45%)
Female	68 (60%)	47 (55%)
Age (Mean)	55.7 y	54.7 y

Table 2.5, Depth of insertion and time taken

	Doctor	**Nurse**
Depth of insertion (cms) [‡]	59.18	58.43
Time taken (minutes) [†]	5.44	5.43

[‡] p=0.561

[†] p=0.835

Two sample t-test

Table 2.6, Level reached, no of cases (%)

	Doctor	**Nurse**
Rectum	0 (0)	3 (3.5)
Sigmoid	33 (29.2)	22 (25.6)
D.Colon	23 (20.4)	31 (36)
Sp.Flex	30 (26.5)	15 (17.4)
T.Colon	25 (22.1)	13 (15.1)
Ileum	2 (1.8)	2 (2.3)

p=0.216, Chi-squared test

Table 2.7, Findings on Flexible sigmoidoscopy, no of cases (%)

	Doctor	**Nurse**
Normal	39 (34.5)	22 (25.6)
Haemorrhoids	16 (14.2)	23 (26.7)
Diverticular disease	23 (20.4)	13 (15.1)
Polyps	22 (19.5)	12 (13.9)
IBD	4 (3.5)	2 (2.3)
Cancer	2 (1.8)	1 (1.2)
Other	4 (3.5)	3 (3.5)
> 1 finding	3 (2.7)	10 (11.6)

Table 2.8, Patients understanding of the FS procedure, no of cases

	Not understood	Confused	Understood little	Fully Understood
Nurse			3	83
doctor	1	2	10	100
total	1	2	13	183

p=0.183, Chi-squared test

Table 2.9, Pain perception

	Yes	No
Doctor	99 (87.6%)	14 (12.4%)
Nurse	72 (83.7%)	14 (16.3%)

p=0.449, Two sample t-test

Table 2.10, Severity of pain perception, no of cases (%)

	Mild	Moderate	Severe, but tolerable	Severe, procedure stopped
Doctor	39 (34.5)	32 (28.3)	35 (31)	7 (6.2)
Nurse	28 (32.5)	25 (29.1)	28 (32.5)	5 (5.8)

p=0.492, Chi-squared test

Table 2.11, Patient experience – Vasovagal symptoms

	None	Dizziness	Feeling Faint	Sweaty	Two symptoms	All symptoms
Doctor	84 (74.3%)	6 (5.3%)	4 (3.5%)	17 (15%)	1 (0.9)	1 (0.9)
Nurse	64 (74.4%)	4(4.6%)	3(3.5%)	14(16.3%)	1(1.2%)	0(0)

p= 0.876, Chi-squared test

Table 2.12, Patient experience – Nausea/Vomiting

	None	Nausea	Vomiting
Doctor	102 (90%)	11 (10%)	0
Nurse	76 (88.4%)	9 (10.4%)	1 (1.2)

p = 0.495, Chi-squared test

Table 2.13, Post procedure bloatedness, no of cases

	None	Mild	Moderate	Severe
Doctor	27 (23.9%)	43 (38%)	29 (25.7%)	14 (12.4%)
Nurse	17 (19.8%)	29 (33.7%)	25 (29.1%)	15 (17.4%)

p=0.561, Chi-squared test

2.4 Discussion

Historically, medical training has predominantly been done using the conventional apprenticeship model. Training in endoscopy has also been traditionally undertaken using the same apprentice modelling. Prior to 1998, there has been no reported or well recognised structure to endoscopy training (Duthie et al, 1998). JAG was established only in 1999.

In addition to the standard type of training undertaking colonoscopies under direct supervision, there exist simulator types of training to acquire and improve the technical skills. These include both inanimate models, using mannequins etc and also computer based simulated trainers (Torkington et al., 2000; Goldiez, 1995). Several models are available including 'Simbionix', 'AccuTouch', 'GI-Mentor', 'HT Immersion Medical Colonoscopy Simulator', 'Simendo' and training with these computer based simulators have been shown to enhance and improve the acquisition of colonoscopic skills (Clark et al., 2005; Cohen J et al., 2006; Ahlberg G et al., 2005; Mahmood and Darzi, 2003; Ferlitsch A et al., 2002; Sedlack et al., 2004).

Historically, backgrounds for learner support and self-reliance can be found in the theory of cognitive apprenticeship (Collins, Brown, and Newman, 1989); Vygotsky's (1978) socio-cultural theory; and the related principle of scaffolding (Bruner, 1978). Scaffolding can be defined as providing learner support, and fading

this support so that students will gradually become self-reliant. One of these views on pedagogy that may prove useful in the new context is cognitive apprenticeship theory. Cognitive-apprenticeship theory has its roots in traditional societies where apprentices worked under a master craftsperson to learn how to become skilled practitioners (Wilson and Cole, 1996). A major principle in cognitive apprenticeship is that in collaboration and conversation with an expert, students gradually learn to speak the language of an expert, and learn how to solve problems as an expert would solve them. This theory also provides a good background for the problem setting as it takes notice of the situated nature of knowledge. It is not just assumed that conceptual knowledge can be abstracted from the situations in which it is learned and used (Brown, Collins, and Duguid, 1989), but also that it should be used in context.

The British society of Gastroenterology supports the development of nurse endoscopy with the provision that appropriate training is available [19]. At present there exists, as mentioned above, various courses authorised by the JAG that is designed to achieve and maintain the skills needed at various levels. Once a nurse practitioner completes all the training requirements, JAG would then accredit the trainee and then the nurse practitioner can independently perform colonoscopies. In our unit, the nurse practitioner completed the colonoscopy course in 2000 and obtained accreditation as a nurse colonoscopist (NC) and also subsequently has become a colonoscopy trainer. Sedation and analgesic requirements are also independently prescribed and administered by NC according to clinical guidelines

and strict protocol. The NC had previously undergone a structured English National Board approved sedation module, which included training and assessment of sedation on various aspects of theory, prescription, administration, resuscitation and management of complications.

Nurse led FS has been well established since the late 1970's (Spencer et al., 1977 and 1978). However, the concept of nurse colonoscopy is relatively new. Our unit was the first ever fully established nurse led colonoscopy service. The concept of nurses taking on traditional medical roles is ever increasing, however most of these areas have a dearth of well structured and approved training models. This is particularly the case in nurse endoscopy. In fact, there were no existing nationally validated and approved training regimes in nurse endoscopy. The experience and training imparted to the nurse endoscopist (MAPH) since 1994, resulted in UK's first approved training programme for nurse FS. For the purpose of this chapter and to identify the learning curve of MAPH in doing colonoscopies meant that this would not be comprehensive as there were no existing formal accreditation criterias at the NE training. In addition, MAPH didn't have any formal colonoscopy training or colonoscopic experience before he undertook colonoscopies independently, apart from supervised first 100 cases. The unit and the hospital trust felt that MAPH's FS experience and results at the time would be satisfactory enough in order to proceed to performing colonoscopies.

This chapter, with the above constraints, determined the various outcomes and results of MAPH's endoscopic experience prior to MAPH started doing colonoscopy service independently, from of October 1994 and October 2000.

The results show that MAPH had a substantial level of FS experience prior to starting colonoscopies. The FS were undertaken for all types of indications and the level reached were acceptable. On comparison in the RCT, there were no significant differences in any of the outcomes measures of level reached, depth of insertion, time taken, patients' understanding or their experience of symptoms due to FS. No complications were seen during the RCT trial, and on review of the 2082 cases, there were no significant complications at all.

The results of Cusum score revealed that MAPH was fairly consistent in the success rate achieved in the 392 cases. Looking at the learning curve over groups of 50 cases also reiterates this fact. This shows that there was no real learning curve, even at the time of starting colonoscopies. This might be due to the fact that MAPH was a good endoscopist with a good repertoire of endoscopic skills, knowledge and innate ability for doing scopies. However, this doesn't automatically translate that nurse colonoscopy will be always produce good results nor that it is a fait accompli due our results. The jury is still out on the concept of nurse colonoscopy and whether it it would be a good thing for nurses to undertake colonoscopy as part of provision for medical care. In spite of this, there is no denying the fact that the flood gates are open from the point of nurses being trained and doing colonoscopies. This is

especially since it is shown that nurse colonoscopy could provide an acceptable colonoscopic service based on our results (chapter 3 and 5 of this thesis). This is further reinforced by problems with of service constraints, government targets, colorectal screening pressures, perceived reduction in junior doctors training level and hours. Considering all this, NC concept is well worth reviewing on a long-term basis and also across various regions.

Further work should be undertaken to evaluate, whether the nurse colonoscopy is sustainable in its ability to deliver acceptable and safe results, and on a consistent basis. It is important that stringent audit standards are maintained and regular assessment and validation of the performance is undertaken so as to maintain the level of satisfactory results.

This review on training of the NE shows that nurses can be trained to a acceptable level of endoscopic training and he results of nurses doing endoscopies or colonoscopies can be good and maintained.

CHAPTER 3

EVALUATION OF EFFICACY, FEASIBILITY, SAFETY AND MISS RATE OF NURSE LED COLONOSCOPY

3.1 Introduction

The role of colorectal assessment is ever-increasing resulting in substantial additional pressures on health services to provide it. Colonoscopy is considered to be the gold standard investigation for colorectal assessment. At present, the health services in United Kingdom (UK) are finding it increasingly difficult to provide the optimum colonoscopy service due to many reasons including lack of trained personnel to perform colonoscopy. These pressures will be even more considerable with the probable advent of screening for colorectal cancer, both as a potential initial diagnostic tool in itself and as subsequent definitive investigation when other screening methods reveal a positive result.

The current waiting times for colonoscopy in UK is considerable (BSG, RCP and ACPGBI – Joint Position Statement; Mayor, 2001; Cantor, 2000) and this is similar even when other alternative investigative methods including flexible sigmoidoscopy (FS) and double contrast Barium enema (DCBaE) are considered (Mayor, 2001; Cantor, 2000). This invariably leads to undesirable and decreased standards of care for the patient.

The role of nurse endoscopy is well established with growing evidence to support the effectiveness of it (Maule, 1994; Rosevelt et al., 1984; Jain et al., 2002; Cash et al., 1999; Schoenfeld et al., 1999a, 1999b, 1999c). In fact, nurse endoscopists have been utilized in performing FS since the 1970's (Spencer et al., 1977, 1978) and further studies have reiterated this (Cash et al., 1999). British Society of

Gastroenterology and Society of Gastroenterology Nurse and Associates have supported the performance of sigmoidoscopy by non-physicians (BSG, 1995; Society of Gastrointestinal Nurses and Associates Practice Committee, 1997). Several studies has shown NE can perform endoscopy as well as experienced endoscopists, with similar effectiveness and patient satisfaction (Schoenfeld et al., 1999a), and with no differences in polyp detection rate or complications (Schoenfeld et al., 1999b). There is increasing acceptance among the patients and medical community with regard to role of NE in performing FS (Basnyat et al., 2002). Since 1996, nurse practitioners have been performing FS in our unit, which has an established NE training programme for performing FS (Duthie et al., 1998).

Nurse colonoscopy is in the initial stages with its role and acceptance still evolving. To date, no evidence has yet been published evaluating the outcome of nurse led colonoscopy practice. Our unit, has one of the first UK recognized nurse colonoscopist (MAP) who was also the UK's first officially trained and recognized flexible sigmoidoscopist (Duthie et al., 1998). A single NE led colonoscopy service was started in our unit since November 2000. The purpose of this study was to determine the outcome and effectiveness of the single nurse practitioner led colonoscopy service.

3.2 Patients and Methods:

All patients who underwent colonoscopy by the NE at our unit between November 2000 and January 2003 were evaluated using the endoscopy database. Four hundred and thirty five patients underwent elective, consecutive colonoscopies for both diagnostic and therapeutic reasons, and were reviewed retrospectively (382 cases) and prospectively (53).

The NE, prior to November 2000, completed a nine-month colonoscopy training course and in addition had subsequent registration as a colonoscopy trainer. The indications for colonoscopic procedures included symptomatic (221), follow-up (166) and family screening (48). There were no differences in the case mix of the referrals between consultant and NE. A colonoscopy trainer supervised the initial 100 procedures, as per the national guidelines (JAG, 1999). The first 157 cases were timed for the length of the procedure from anus to anus. The NE undertook the time measurement of these initial procedures as part of self-assessment process. A complete colonoscopy was deemed to be done when the colonoscope was intubated upto the caecum or TI. This was confirmed by visual inspection of the features of the caecum including tri-radiate fold, appendicular orifice, ileocaecal valve and intubation of TI. The TI was confirmed by the appearance of the intestinal villi, and when required with a confirmatory water-insufflation test.

Sedation and analgesic requirements were independently prescribed and administered by NE according to clinical guidelines and strict protocol. The NE had previously undergone a structured English National Board approved sedation module, which included training and assessment of sedation on various aspects of theory, prescription, administration, resuscitation and management of complications. Sedation and analgesia was given using peripheral intravenous route with Midazolam plus Fentanyl (389), Midazolam alone (21) and Fentanyl alone (1). Six patients refused sedation and in 18 cases sedation was not given. One patient required additional usage of 20 milligram of Hyoscine Butylbromide. The dosages given per patient with Midazolam (benzodiazepine) was 70 microgram/kilogram (maximum administered 5 milligram) and for Fentanyl (opioid) with 50 – 100 microgram. The elderly and ASA III cases were given decreased doses. Among the sedation 'not given' or 'refused' cases, eight has had previous colorectal resections. Once the colonoscopy is completed, patients would be rested in the recovery room for approximately 30 minutes after which they would be discharged home along with an accompanying adult and a further follow-up appointment made with referring doctor.

Following the initial evaluation, all 435 cases that underwent colonoscopy by the NC had further review over a follow-up period from November 2000 to January 2004 (minimum 12 – maximum 39 months) for any missed malignancies, and any subsequent polyps detected elsewhere in the colon that was not initially detected by

the NE. This review was conducted using the hospital's colorectal cancer database, histopathology database and endoscopy records of any subsequent procedures. Also case notes of any required patients were assessed. During the follow-up period, 87 patients had repeat colonoscopy of which 59 were complete colonoscopies. A colonoscopy is deemed to be complete provided either the caecum or terminal ileum (TI) has been intubated. The repeat colonoscopies were indicated as part of routine follow-up, clinical/radiological need or as a result of new symptoms. No repeat colonoscopies were undertaken for the sole purpose of finding a missed polyp or cancer following an initial complete colonoscopy. Ethical considerations would have proved too difficult in doing a back-to-back colonoscopy due to the nature of possible colonoscopy related complications involved.

There were 218 males and 217 females with median age of 62 (range 21-92) years. The results showed that time taken to complete the procedure (121 cases), anus to anus, was a median of 15 minutes (IQR: 12-20; range 5-60) in the initial 157 cases. The remaining 36 cases had incomplete procedures due to technical difficulty (13), poor bowel preparation (17) and disease limitations (6).

Of the first 100 cases, assistance from the consultant supervisor was required in 12 cases. Despite receiving assistance, eight of these had incomplete intubations of the TI due to technical difficulty and the final levels reached were remained the same as when the initial difficulty was encountered by the NE (3 splenic flexure; 2 TV colon; 1 hepatic flexure; 1 sigmoid colon; 1 caecum). Of the remaining four cases, assistance was required in one case for polypectomy and three cases for completion of intubations to TI from right side of colon.

Of the 435 cases, 352 had complete intubations upto the caecum or the TI (**Table 2.1**). The reasons for failure to intubate the caecum or TI are shown in **Table 2.2**. The technical difficulty includes inability to complete either due to NE technical ability or due to patients inability to tolerate the procedure. All the patients with incomplete procedures were organized to have either repeat colonoscopy at a later date; Barium enema or sent back to the referring clinician. This was decided following consideration of the primary indications, urgency of the case, the level

Table 3.1, Intubation levels reached (n=435):

Level reached	**No. of cases**
Terminal Ileum	193
Caecum	159
Ascending colon	4
Transverse colon	49
Descending colon	6
Sigmoid	19
Rectum	5

Table 3.2, Reasons for failure to complete (n=83):

	No. of cases
Technical difficulty	40
Poor Bowel Preparation	30
Disease limitations	13

reached and reasons for failure. The overall completion rate was 90.1 %, including those cases with technical difficulty.

The various primary colonoscopic findings (197 cases) are shown in **Table 2.3**. Sixty-four of these had additional pathologies **(Table 2.4)**. There were four cases of miscellaneous primary findings, including melanosis coli (1), non-dilating stricture of sigmoid colon (1), ulcer at TI (1) and possible crohn's at TI (1). The site of the primary pathology found during the colonoscopy is listed in **Table 2.5**. There were two cases of diverticular disease in which the site was not recorded.

Malignant cases (25), included annular lesions (7), polypoid (6), stricture (5), ulcerative (3) and description not recorded (4); of the latter group 3 were in the rectum and one in the descending colon. During the same colonoscopy, five patients with malignancy had 10 polyps found at a separate site, whilst two patients had five polyps detected at around the same site as the malignancy. One of the patients in the latter group had a proximal synchronous cancer detected at the same time.

Eighty-nine patients had the finding of a polyp as the primary pathology, of which 32 cases had additional polyps detected at the same time. These included polyps around the same area (7 cases), elsewhere in colon (23) and at the same site as well as distant site (2). In addition, nine patients had polyps detected along with other primary findings apart from a primary polyp finding. The NE performed

Table 3.3, Primary Colonoscopic findings (n=435):

Findings	**No. of cases**
Normal	238
Polyps	89
Malignant	25
Diverticular Disease (Div. Dis)	41
Inflammatory Bowel Disease (IBD)	38
Miscellaneous	4

Table 3.4, List of additional findings on colonoscopy (n- 64):

Additional findings	No. of cases
Polyps	34
Div. Dis	18
IBD	1
Polyp + Div. Dis.	3
Polyp + IBD	1
Polyp + Div. Dis. + IBD	2
Polyp + Malignancy + IBD	1
Div.Dis.(sigmoid) + Sigmoid stricture	1
Div. Dis + Melanosis coli	1
Melanosis coli	1
Lipomatous lesion	1

Table 3.5, Site of the primary pathology (n-197):

Site of primary pathology	No. of cases
Rectum	32
Recto-sigmoid junction	2
Sigmoid	83
Descending colon	23
Splenic flexure	3
Transverse colon	11
Hepatic flexure	4
Ascending colon	15
Caecum	6
Terminal ileum	5
Pan-colon	11
Not recorded	2

therapeutic polypectomy in 54 patients (12.4 %) by either snare polypectomy (39 cases) or by hot biopsy forceps (15). In remainder of patients, 50 (11.5 %) had a conventional polyp biopsy.

There were no complications apart from five patients (1.1%) who had vasovagal episodes, all of which resolved spontaneously on stopping the procedure. None of the patients required the use of any reversal agents following sedation. There were no cases of mortality within the 30-day post colonoscopy period. In those cases where sedation was not given (18 patients), 10 of them had complete intubations and the findings included polyp (5), IBD (1) and normal appearance (4). The remaining cases (8) had failed intubations due to poor bowel prep. In the group of patients who refused sedation (6 patients), complete intubaton was achieved in four patients with findings of normal (3) and IBD (1). The remaining two cases had incomplete intubations due to poor bowel prep (1) and due to technical difficulty (1). In the sedation 'not given' group, seven of the eighteen patients had previous colorectal resections (3 Right Hemicolectomy, 2 Left Hemicolectomy and 2 Anterior Resection). One out of the six patients who refused sedation had a previous Sigmoid Colectomy. All the cases in whom sedation was not given was due to their significant past cardiac/respiratory medical history, and all were offered an alternative investigation by way of flexible sigmoidoscopy and Barium enema or the colonoscopy to performed by an experienced consultant. All 18 patients went on to have colonoscopy performed by the NE.

For the purpose of evaluation of any missed CRC or polyps, review was conducted using the hospital's colorectal cancer database, histopathology database and endoscopy records of any subsequent procedures. Also case notes of any required patients were assessed. The follow-up period was over a minimum 12 up to maximum of 39 months.

During this period, there were no malignancies that were missed at the initial colonoscopy and then detected over the follow-up period.

Evaluation of any missed adenomatous polyps over the follow-up period revealed that five patients had 6 polyps detected elsewhere in the colon on subsequent endoscopies during follow-up period. One of these patient's had two polyps detected, with the other four patients each having the finding of a single polyp detected during the follow up period. The mean time to detection of these polyps was 17.2 months (range 6-30). The size of the polyps ranged from 3mm-20mm, four of these were present in the left colon/rectum and one in the proximal ascending colon. Four of them had histology of tubular adenoma with mild-moderate dysplasia. The remaining two were tubulo-villous adenomas, one with moderate dysplasia and the other with severe dysplasia. The latter was of 20 mm size and detected at 14 months after the initial scope. None of the polyps had any malignancies, either invasive or focal.

3.4 Discussion

Since the report of the first successful total colonoscopy in 1966 by Overholt and Pollard, the role of colonoscopy as an investigation for colorectal assessment has expanded and has become the definitive investigation of choice. At present in UK, there is a widening disparity between the increasing demand for this service and the varying availability of the resources; either/both trained personnel and endoscopic facilities. The NHS faces staffing shortages (Goldacre, 1998) and even if additional endoscopic facilities were provided there would still be inadequate number of trained personnel to combat the growing demand. The combination of reduced junior doctor's hours (NHS Management Executive, 1991) and Calman recommended shorter specialist training (Working Group on Specialist Medical Training, 1993) result in further depleted manpower to perform service tasks. There is a consensus that increased number trained personnel might ameliorate the current waiting times (Moss, 2002). The current waiting times for colonoscopy (BSG, RCP and ACPGBI – Joint Position Statement; Mayor, 2001; Cantor, 2000) presents as an unacceptable situation in this day and age. The pressures on health services to counter this are already stretched.

Screening for CRC, if implemented in UK, is going to put substantial pressures on the NHS, in addition to the near breaking point pressures that is already present. In US since 2002, a national screening programme for CRC has been implemented and colonoscopy is included as part of that screening tools (US Preventative Services

Task Force, 2002). Currently in UK, the results of two trials conducted by the Department of Health and MRC evaluating the feasibility effectiveness and cost benefits of screening by faecal occult blood (FOB) and FS are awaited. It has been estimated that following FOB screening in normal risk individuals will lead to further 10,000 colonoscopy sessions in UK (National Screening Committee, DoH, 1998) or one session per week for each district general hospital serving a population of 250,000. Screening by FS for high risk individuals, which is already taking place, will generate a further 13,000 colonoscopy sessions per annum (Atkin et al., 1998) or 1.25 sessions per week for a district general hospital serving a population of 250,000. The complimentary role of NE along with other medical endoscopists merits serious consideration in this present scenario and in context of potential future screening for CRC.

Our results show that NE colonosopy is feasible and has good results. This series has revealed that nurse colonoscopy is time efficient, even taking into consideration the initial learning curve that is required for performing both diagnostic and therapeutic procedures. The assistance required by the NE for the initial 100 cases were only in a small number of cases. NE undertook colonoscopy for a wide mix of cases and performed both diagnostic and therapeutic procedures. The overall completion rate was 90.1%. This is in keeping with the national Joint Advisory Group's (JAG) criteria for colonoscopic procedures, which recommends complete intubations in at least 90% of the procedures. A previous survey has shown that the completeness of colonoscopy was highly variable, ranging from 55-97% (Report by

the Endoscopy Section Committee of the British Society of Gastroenterology, 1987; Bowles et al., 2004).

There were no significant complications seen, including any bleeding or bowel perforations even when therapeutic polypectomies and conventional biopsies are performed. There was no mortality case in our series. Other much larger series have shown colonoscopic complications of bleeding varying from 0.2 - 1% (Gibbs et al., 1996; Rosen et al., 1993; Macrae et al., 1983) and a perforation rate to be from 0.09 - 0.2 % (Macrae et al., 1983; Araghizadeh et al., 2001; Anderson et al., 2000). There is a reported perforation related postoperative mortality of 12% and morbidity of 43% (Garbay et al., 1996), with risk of perforations or bleeding is higher when therapeutic procedures or biopsies are undertaken (Rosen et al., 1993; Macrae et al., 1983; Araghizadeh et al., 2001; Anderson et al., 2000). Overall mortality following colonoscopy has been reported in upto 0.02% cases (Anderson et al., 2000). The cause of deaths has been attributed to perforation or sedation related (Macrae et al., 1983; Anderson et al., 2000). No sedation related complications were seen nor were there any need for sedation reversal in our series.

Colorectal cancer (CRC) represents a major health care burden in United Kingdom (UK) with being the second commonest cancer in UK, and the second commonest cause of cancer death (16,000 deaths in 1993 survey). There are 30,000 new cases of CRC every year (Office for National Statistics, 1999), and up to a third of cases

present as emergencies with a proportionately lower survival rates. The overall five-year survival for CRC is around 40 %.

CRC presents a similar picture in United States (US), with 135,400 new cases every year and 56,700 deaths per annum resulting in 11 % of all cancer deaths (American cancer Society 1996). It has estimated to cost six billion UD dollars in annual treatment costs and there is an approximate 758,000 person-life years lost. There is six percent lifetime risk for developing CRC, with equal risk for males and females.

All these factors represent the true magnitude of the problem of CRC. Almost all CRC arises from adenomatous polyps. Prospective data from the National Polyp Study (Winawer et al 1992, 1993) show that some adenomatous polyps slowly develop into CRC in 5 to 7 years. It has also been proven, by studies done by National Polyp Study and multiple other case control and cohort studies (Winawer et al 1992, 1993, 1997; Mandel et al., 1993) that identification and removal of adenomatous polyps is associated with reductions in CRC incidence and mortality. Hence accurate identification of any CRC and adenomatous polyps is crucial.

This study evaluated primarily any missed CRC or adenomatous polyps over a relatively long follow-up period following the initial colonoscopy performed by NC.

Our study revealed that there were no missed malignancies that were detected in the follow-up period. The assumption is that patients with any sort of symptoms would

have re-presented either to the general practitioner or picked up at subsequent outpatient follow-up and resultant investigation would have detected any malignancies. This review is limited for patients who have moved their existing residence to another region or those who are asymptomatic during the review period. Ethical issues and the present scope of this study prevented us from conducting a personal review of all patients or undertaking a non-invasive investigation like faecal occult blood testing. It has been shown in an earlier study by Singh et al (2006) that the risk of developing colorectal cancer remains decreased for more than 10 years following the performance of a negative colonoscopy.

This review also showed that only a very small number of additional adenomatous polyps were detected elsewhere in the colon over the follow-up period. None of these polyps had either any invasive or focal malignancy. Obviously, these polyps could be either a synchronous or metachronous polyps. This would still only present as a small number of polyps even if it were assumed that all of them were synchronous. But this definitely cannot be attributed as the true miss rate of synchronous polyps in our series, as it would have required a back-back colonoscopy to be performed at the same time. Other studies have shown a colonoscopic polyp miss rate varying from 4.6 %-31% (Hixson et al., 1991; Warneke et al., 1992; Bensen et al., 1999; Rex et al., 2003). Again the ethical issues and a potential complication of the simultaneous tandem colonoscopy led to inability of detecting the actual miss rate. Colonoscopy has potential, albeit small, complication rate including recognised serious complications of perforation,

bleeding and mortality. In addition, this review would have excluded any patients who have moved their residence to another locality.

It has been previously shown that there were no differences in detection of adenomatous polyps between experienced nurse endoscopists and gastroenterologists during screening flexible sigmoidoscopy and they can perform the procedure as safely and effectively as the latter (Schoenfeld et al., 1999b).

Our review represents a large study involving consecutive cases evaluating the miss rate for NC. The miss rate for NC has not been looked at previously in any other studies. The large number of cases has further strengthened the study over a relatively long follow-up period.

There are few weaknesses, in the fact that this represents a single nurse colonoscopist's case series, but this has been unavoidable as NC concept is still relatively new with very scarce number of existing independent other NC's. Ideally, true miss rate can only be established by doing a tandem colonoscopy or histological evaluation from resected specimens. Due to the above mentioned reasons, ethical issues and potential complications make it difficult to achieve.

Colonoscopy rarely misses polyps equal or more than 10 mm, but the miss rate increases significantly in smaller sized polyps (Van Rijn et al., 2006). Using current colonoscopic technology, there are significant miss rates for adenomas < 1 cm even

with meticulous colonoscopy (Rex et al., 1997). There are few ways of reducing false negatives and increasing pick up rate during colonoscopy. Using zoom chromoendoscopy, the rate of detecting colonic polyps can be increased at the cost of a longer retrieval time (Stergiou et al., 2006) and it also established that simultaneous radiological imaging could increase the pick up rate.

Future studies might be able to assess the miss rate more accurately by possibly doing a simultaneous digital recording of the initial colonoscopic assessments. Also there is a scope for multi centre randomised controlled trial evaluating the miss rates of NC's compared with medical endoscopists.

With the advent of service orientated NE led FS and the current nurse colonoscopy service; there exists an important consideration in terms of training for the junior doctors who are going to be the future providers of health care. There is a perception felt in some quarters of the medical community that training of the junior doctors will be hampered by this trend of NE's being trained and performing endoscopies. There are arguments to be made for either side. On one hand, NE have a shorter training period of 9 months and once they are fully trained and if registered as a trainer, they can then assist in training of junior doctors. This is already happening in our unit where the NE has two dedicated teaching lists for a colonoscopy fellow. Also junior doctors can benefit from undertaking the same training modules as for the NE. The current waiting lists pressures on the clinicians can have a detrimental effect on junior doctors training. By making more trained personnel available and

thereby reducing the waiting lists, these pressures can be eased and an extra person can be utilized for teaching purposes. On the other hand, training of more and more NE to perform endoscopies reduces the already limited training resources that traditionally existed for junior doctors. More importantly, there is no benefit in training more NE to perform in a certain hospital setting if there are no adequate endoscopy facilities to fully appreciate it. Overall, consideration should be given to the availability of the facilities and the need for further trained personnel to utilise this. The present increasing national demand for colorectal assessments should be taken into account as well. There has to be a fine balance between providing better health care without compromising training requirements of junior doctors. There might be a need for further evaluation of the impact on junior doctors training resulting from NE service.

The trained NE led service has its limitations in that there is the need for a consultant to be present in the hospital to deal with any emergencies, although in our study there were no significant complications. This would also make it difficult for the NE to do emergency lists or out of hours services unless an on-call consultant is in place. There could be a place for NE in providing elective colonoscopy service and complementing clinician's work-load and reducing waiting lists (WL). The experienced NE can also work in the OPD and do family screening clinics, cancer follow-ups and form part of the multidisciplinary teams, which the NE (MAP) is already performing, to ensure better utilization of this excellent and often unused resource. NE can also free up time for the clinician to do other important tasks. By

increasing the availability of the trained personnel might eventually lead to improved health related quality of life for patients.

Nurse endoscopists who are well trained have already been shown to have excellent results which are comparable to consultants in providing upper and lower gastro-intestinal endoscopy service (Maule, 1994; Rosevelt et al., 1984; Jain et al., 2002; Cash et al., 1999; Schoenfeld et al., 1999a, 1999b, 1999c). Our unit was the first in UK to establish a NE training for FS and also have a recognized colonoscopy training course for both medical and nursing staff (Duthie et al, 1998). The British Society of Gastroenterology supports the development of nurse endoscopy provided that appropriate training is available (Report of BSG Working Party, 1994), and medico-legal implications of NE will be similar to standards and practice of an experienced medical endoscopist.

Our series represents the work of a single NE led colonoscopy service and has shown good results. In future, for the good results and standards of care to be maintained elsewhere, there remains the need for continued and well structured training programmes for NE, good supervision and regular auditing once the NE is registered and independently performing. Further multi-center randomised controlled trial, comparing consultant endoscopists and NE, is needed to determine the full potential and implications of nurse colonoscopy in the NHS. With this in mind we are considering conducting a multi-center RCT between NE's, consultant gastroenterologists and colorectal surgeons.

As compared to yester-years, the present day delivery and needs of medical care has changed substantially. In future, this changing trend will be more acute. There is immense pressure on health services to keep up with this ever-increasing demand. Current resources to provide this are scarce and limited, and there remain an imperative need for the best use of the available resources. As a response to this, the health delivery systems need to adapt to in ways as to provide the best utilization of the resources, especially personnel, to combat this challenging environment. Nurse practitioners form an integral part of this utilization. The results of this study have shown that nurse practitioner endoscopist can provide excellent results in providing colorectal assessment by way of colonoscopy service.

In conclusion, nurse led colonoscopy service provides both diagnostic and therapeutic options along with good results of high completion rate, minimal complications, time efficiency. The results show that nurse colonoscopy is a viable, safe and effective method in providing colorectal assessment. This review also concludes that nurse colonoscopy practice may provide good diagnostic results with minimal miss rate for CRC and adenomatous polyps. The results also seems to be favourable when compared with other existing recognised miss rates of medical endoscopists.

CHAPTER 4

COST ANALYSIS OF NURSE LED COLONOSCOPY PRACTICE

4.1 Introduction

Colonoscopy provides for an essential investigation in the armoury of colorectal assessments and is considered as the gold standard of investigation, especially from colorectal cancer point of view.

Colonoscopy is associated with significant costs and the overall costs are deemed to be substantially higher when considering colorectal cancer screening. The screening has recently been started in UK, with initial pilot projects across 10 sites in England and currently the national screening programme is being rolled out all across UK. In the US, the national screening programme has been well established since last few years. The need for provision of increased colonoscopy services has got significant current implications on a national scale. This is even more with the advent of screening for colorectal cancer in UK. In US, a national population based screening is already in place. The UK Colorectal Cancer Screening Pilot Group recently published that screening on a national scale is feasible and leads to a reduction in mortality from colorectal cancer (UK Colorectal Cancer Screening Pilot Group, 2004). They have however reiterated the importance of increased colonoscopy service as the current pressures on endoscopy services is overstretched, and that introduction of screening must go hand in hand with improved provision of endoscopy services. It has been estimated that following faecal occult blood screening in normal risk individuals will lead to further 10,000 colonoscopy sessions in UK or one session per week for each district general hospital serving a population

of 250,000 (National Screening Committee London: Department of Health, 1998). Screening by flexible sigmoidoscopy for high risk individuals, which is already taking place in UK, will generate a further 13,000 colonoscopy sessions per annum or 1.25 sessions per week for a district general hospital serving a population of 250,000 (Atkin et al., 1998). Colonoscopy done by the non-medical community might be able to provide an increase of this service.

Basnyat et al., (2002) had shown that nurse led FS service was more cost effective than a consultant led service. There seems to be similar possible cost savings for NC when compared with medical consultant colonoscopist. However, the true cost of nurse led colonoscopy service is yet to be established and an economic evaluation into this practice has never been done before.

The purpose of this study was to determine the cost analysis for nurse led colonoscopy practice and to see if this offers any cost savings when compared with a medical consultant colonoscopist. We also aimed to assess the training costs involved in colonoscopy and compare this between NC and consultant colonoscopist.

4.2 Methods

A single nurse led independent colonoscopy service was started in our unit since 2000. We did a basic economic evaluation and cost analysis of this full-time single nurse colonoscopist in our unit and compared the data with a typical full-time medical consultant colonoscopist working in the same unit.

We identified several cost factors that needed to be considered when calculating cost analysis for both NC and consultant colonoscopists. These included gross annual salary, which was calculated at mid point of the scale (DoH, NHS Reference costs 2003 and National Tariff 2004); annual leave; study leave, statutory days; no. of contracted hours; no. of colonoscopy sessions undertaken, no. of colonoscopies per session, colonoscopy session duration. Using these, hourly rate for both consultants and NC were determined and also the labour costs involved for performing each colonoscopy. A comparative study was made between the nurse colonoscopist and the consultant colonoscopist and any cost benefits were determined.

In addition, we undertook a comprehensive comparative review of results of NC and other established medical consultant colonoscopists. This review consisted of 5870 consecutive colonoscopies performed in our unit over a three year period from January 2001 to December 2003, with 2578 colonoscopies for consultants and 591 cases for NC. The review for the purpose of cost analysis particularly looked at complications from each group, as this would had implications for any cost savings.

A review of therapeutic procedures undertaken during the colonoscopies was also undertaken.

We also reviewed training costs involved in colonoscopy, which also involved looking at all factors involved in the training of a nurse colonoscopist in order to perform independent colonoscopic service.

For the purpose of cost analysis and to ensure its credibility, we closely liased with the chief health economic and policy adviser (AndrewTaylor) at Hull Primary Care Trust and also took advice from Health Sciences department (Professor David Torgerson) at University of York.

4.3 Results:

Cost savings:

For the purpose of this study, the total number of working days available in a year was deemed to be 261 days, and was calculated deducting the fifty-two weekends. Using the various factors mentioned in the methods section, we did the cost analysis. **Table 4.1** shows the leave/days-off in a year and **table 4.2** shows details of the work-days, contracted hours and the salary per hour for both consultant colonoscopist and NC. We estimated the gross annual salary, at mid point of the scale, based on the 2004-2005 NHS salary scale, as £ 75,654 for consultant and £ 29,515 for Nurse Colonoscopist.

In our unit, Consultant colonoscopist undertook 2 colonoscopy sessions per week and NC did 3 colonoscopy sessions per week. The duration of each session and the number of colonoscopies performed per session was similar for both consultant colonoscopist and NC **(Table 4.3)**. This table shows the labour cost of NC doing a colonoscopy at 10.62 £ and consultant at 26.14 £. This amounts to more than double the cost per colonoscopy for the consultant colonoscopist. The resultant cost saving for NC was 15.52 £ per single colonoscopy.

Table 4.4, depicts the incremental annual cost savings of a single NC performing colonoscopies.

Table 4.1, Leave/ days-off in a year:

	Consultant colonoscopist	**Nurse colonoscopist**
Annual leave	32	27
Study leave	10	10
Statutory days-off	8	8
Total no. of days-off	**50**	**45**
Working days available	**211**	**216**

Table 4.2, Work-days and hours details [‡,#]

	Consultant colonoscopist	**Nurse colonoscopist**
No. of contracted hours/week	40	37.5
Average no. of work hours/day	8	7.5
Total days-off	50	45
Working days available annually	211	216
No. of work hours available annually	1688	1620
Salary per hour	44.82 £	18.20 £

[‡] Note: the total annual working days possible is 261 days, obviously for both groups.

[#] Note: Annual salary (at mid-point of scale): Consultant – 75,654 £; NC – 29,515 £

Table 4.3, colonoscopy and cost details

	Consultant	**Nurse colonoscopist**
No. of Colonoscopies done per session	6	6
No. of hours per whole colonoscopy session	3.5	3.5
Time per single colonoscopy episode	0.58 hours	0.58 hours
Hourly salary rate	44.82 £	18.20 £
Labour costs per single colonoscopy	**26.14 £**	**10.62 £**

Table 4.4, Incremental annual cost savings of a single NC performing colonoscopies:*

No. of colonoscopies per annum	Annual cost savings
200	3104 £
350	5432 £
450	6984

* Note: Cost saving with NC = £ 15.52/colonoscopy

The review of comparative case series of colonoscopies of 5870 cases did not reveal any significant difference in complication rate between NC and medical consultants. Hence, there was no need for further complex cost benefit analysis in order to factor in cost implications and quality of life issues when considering any cost savings. In addition, there was no difference in the number or nature of therapeutic procedures undertaken between both these groups of colonoscopists. In addition, we undertook a separate study of 435 consecutive colonoscopies by the NC, which revealed a 90 % adjusted colonoscopy completion rate and this was in keeping with the national JAG requirements. All of this showed that there were no significant differences in the colonoscopy outcomes between the NC and medical consultants that would have had implications for any cost saving analysis.

Training costs:

The training requirements and courses recommended by JAG are similar for both medical and nurse endoscopy trainees, apart from one additional course required by nurses and other non-medical trainee endoscopists are required to undertake. The course involved is a formal university linked nurse endoscopy training courses. It usually involves 4 modules over a 9 month period, taken over 2 semesters. The JAG approved courses are run by the university, including at Hull University. On clarification with the Hull University, it was informed that exact cost of this course has not yet been calculated but is estimated to be around 1500 £ approximately. The Raven department of education at the Royal College of Surgeons of England, who is

responsible for co-coordinating and running of the upper and lower GI endoscopy courses in England, was also contacted to in order to establish the costing involved in training a colonoscopist. They were also unsure as to the actual extend of the costs involved.

There are two skills courses that are mandatory for colonoscopy trainees, which are Foundation course in GI endoscopy or Basic skills in flexible sigmoidoscopy and Basic Skills in Colonoscopy. The fees for the former two courses are 350 £ each and the latter course is 650 £, making it a total of 1000 £. These courses are funded by the DoH and are hence free for any trainee, both nurses and doctors, within the NHS. For trainees outside NHS, the above fees are payable.

There were fixed factors in training for colonoscopy that remained similar for both groups. These included costs of teaching, i.e. practical, theory and supervision and endoscopy unit's costs of training, equipment and overheads.

4.4 Discussion

Economic evaluation and any resultant benefits play a major role in today's health care services and its delivery. This is especially reflective when considering the rising care of health care costs, inequality of healthcare amongst people and regions, increasingly ageing population, increased disease pickup rate due to earlier diagnosis and better investigative modalities, rising insurance costs, general taxation and scarcity of resources – money, personnel, equipment and facilities. All this exerts a major pressure on the providers of healthcare to ensure the 'best value for money' that is available and to devise ways to positively improve the financial burden.

Nurse colonoscopy service is a new concept and has not been assessed if it provides an overall cost saving. Till date, no other study has evaluated this. This was a pilot and a basic study of cost analysis of nurse colonoscopy.

This study's stated aim was to determine the cost analysis of nurse colonoscopy service. This has proved more difficult than initially envisaged, in spite of the best efforts. There were various confounding and complex factors identified that made this difficult. These included the fact that nurse colonoscopy service is very recent introduction in the health service, including UK and elsewhere in the world, and hence there were no existing systems already in place that would reflect a true long standing nature of the cost structure. Our unit had one of the first ever fully

independent NC service. Secondly, this study only looked at the cost benefits when considering a single nurse colonoscopist, and hence extend of any true actuarial benefits would have been difficult to estimate exactly. Thirdly, to identify accurate cost-benefit and cost-utility analysis would have required a multi-centre study over a very long period of time and this was beyond the scope of this study and scarcity of other centres providing NC service was minimal.

Similarly, there were several training cost factors that were variable and complex, which made an accurate quantification of these difficult. For a true reflection of overall costs, one need to also consider training costs involved not only during nurse colonoscopy training period, but also training costs during period of qualifying as a nurse and compare it with the training costs at medical school for doctors and subsequent periods as a junior doctor. This aspect has never been previously assessed and was beyond the scope of this study. Also the training period time-frame for a junior doctor would be extremely variable. Secondly, it was also difficult to determine the costs of secondment and their replacement with 'back-fill' costs during the nurse colonoscopist training period. There would also have been an overall national 'back-fill' costs that also applicable to doctors in training as well. Thirdly, training colonoscopy sessions would entail decreased full lists during training, and occasional over-running of the list. These were variable, and possibly similar for both medical and nurse trainee colonoscopists. In addition to all these, there were other fixed factors that would have remained similar for medical and nurse trainees, including costs of teaching (i.e., practical, theory and supervision),

skills courses, equipment costs, usage of unit facilities. The training requirements stipulated by JAG were similar for doctors and nurses, excluding the formal university linked nurse endoscopy trained course and this was taken into account for calculation of NC training costs. The two JAG approved mandatory skills courses were free and was paid for by London Workforce development scheme run by the DoH.

We had consulted Health Economist consultant at Hull Primary Care Trust and also liaised with department of Health Sciences at University of York regarding all these issues in order to see if further would be possible to elucidate and quantify the factors better. The final opinion was that considering the pilot nature of this study, various issues identified above including very variable confounding factors, that there was limited else that could be realistically be achieved.

In addition, we were unable to identify if the cost savings identified in this study for nurse colonoscopy service were in fact saved or redeployed elsewhere for any additional improvements. This is an important consideration to make (Drummond et al., 1997) as any freed resources or savings could be consumed by ineffective or unevaluated programmes with resultant increased overall healthcare system costs. Again, this latter aspect was beyond the breadth of this study to be assessed.

Inspite of the above constraints and limitations of the study, our basic cost analysis does show that there is cost savings in nurse colonoscopy practice, especially if considered over a period of time. This is further more, if the numbers of nurse colonoscopists are increased. In addition, the training costs spent on training a NC could be recouped within a very short duration of time. There are also seems to be perceived direct benefits to employing health trust as the nurse colonoscopist would more than likely continue to provide many years of service commitment to the same trust, where as junior doctors might more than likely move to other trusts in the following years. However, this perceived advantage is negated when one considers the NHS as a whole entity.

For the purpose of economic evaluation by cost analysis and cost-utility studies, any increased complication or misdiagnosis rate by NC would negatively impact any cost benefits due to higher costs involved with this. It has been already been shown in chapters two and five of this thesis that nurse led colonoscopy is safe, feasible and effective. The complicate rate for NC was extremely small and importantly, there were no significant difference in complication rate between NC and medical consultants, nor were there any significant difference in therapeutic procedures undertaken between the two groups. The overall results, including completion rate were better than that of a recently done regional survey on medical community by the British Society of Gastroenterologists (Bowles et al., 2004). In addition, it has been shown that NC offers good diagnostic results with minimal miss rate for CRC and adenomatous polyps (Chapter 3 and 4 of this thesis). The expert opinion from

health economists at Hull PCT and York University was that, considering the above factors, no further economic evaluation for cost savings for this study is required.

With the advent of CRC screening in UK, there would be significantly increased demands for colonoscopy and subsequent need for trained personnel to undertake this. NC could be considered as significant additional manpower resource to mitigate the work burden with added possible cost savings. Additional trained personnel by the way of NC's , provided enough equipment and unit facilities are present, may significantly reduce waiting lists. Also, one could envisage the possibility of earlier diagnosis, subsequent better disease outcomes and improved patient satisfaction. Future long-term work could determine the true effects of these in a cost-benefits and cost-utility analysis and also assess quality adjusted life years (QALY) saved. Our study also identified several confounding areas that would have to address in further studies. In addition, a mulitcentre and randomized control trial would be scope for future work in economic evaluation of NC practice.

In conclusion, this pilot study despite limitations and confounding factors does show that there are cost savings to a nurse colonoscopy practice when compared with consultant medical endoscopists. This saving could represent major gains when considering long-term and increased number of nurse colonoscopists. However, this is not a definitive study on economic evaluation on this subject and would need further long-term studies in future to accurately identify this.

CHAPTER 5

COMPARISON OF EFFICACY BETWEEN NURSE COLONOSCOPIST AND MEDICALLY TRAINED COLONOSCOPISTS

5.1 Introduction:

Nurse led endoscopy service has been in existence from 1970's (Spencer et al., 1977, 1978) and has since then become increasingly prominent. Nurse led flexible sigmoidoscopy has now become well established with proven efficacy, safety and comparable other parameters including patient satisfaction in relation to medical endoscopists (Maule et al., 1994; Maruthachalam et al., 2006; Basnyat et al., 2002; Schoenfeld et al., 1999a; Schoenfeld et al., 1999b; Pathmakanthan et al., 2001). British Society of gastroenterology (BSG) Working Party (1994) supported the role of nurses offering gastrointestinal endoscopy and American Society of Gastrointestinal Endoscopy (ASGE) (1998) recommends utilisation of non-physicians in performing screening flexible sigmoidoscopy.

Nurse led colonoscopy offers a relatively newer concept, which has been gaining increasing acceptance (Vance M, 2005). We undertook an earlier study that showed nurse colonoscopy could offer a safe, reliable and effective colonoscopic service. (Chapter 2 of this thesis. Presented at ACPGBI meeting 2004, ASCRS 2004).

However till to-date, there has been no evidence to directly compare colonoscopy service between a nurse colonoscopist and other medically trained established endoscopists.

We aim to compare the effectiveness of nurse colonoscopy service in relation to other medical endoscopist, including consultant surgeon, consultant physician and specialist registrars providing a colonoscopy service. This will help to establish the real difference, if any, between these groups and whether any one group offers a distinct advantage over the other.

5.2 Patients and Methods:

We reviewed a prospectively collected database of all patients undergoing colonoscopy in our tertiary colorectal unit over a three-year period between January 2001 and December 2003. For the purpose of this study we categorised the groups into consultant physicians (CP), consultant surgeons (CS), single nurse colonoscopist (NC), Specialist medical and surgical registrars (SMR) and also included cases done by non-medically trained endoscopists (NMTE) doing independent colonoscopy over the same period.

In total, over this period there were 9306 cases done for lower gastrointestinal endoscopy. Of this group all cases of flexible sigmoidoscopy were excluded with a resultant caseload of 5927 colonoscopies. Further 57 cases were also not considered for this study, including cases that did not have a clearly recorded endoscopist category. This resulted in 5870 colonoscopies that form the final number of cases for this study.

The cases were retrospectively retrieved for analysis from a prospectively collected database and this included all consecutive cases in the above subgroups. The parameters assessed were patients' demographics of age and sex, indications, type of referral (i.e., planned, unplanned, emergency), intubation level reached, completion rate, reasons for failure to completely intubate, findings, procedures underatken and complications. The findings included primary findings and any secondary findings

and the site of the findings. Any procedures undertaken were noted. Complete intubation was deemed to have been achieved when either the caecum or terminal ileum (TI) was intubated.

Sedation details of the whole 5870 series were not able to be collected due to the deficiencies of initial recording of the database. However, we undertook review of sedation details across all groups in another review. This included 1848 consecutive colonoscopies from January 2007 to June 2007. Four of these cases did not have the endoscopist's name or category recorded, hence was excluded from the final review.

5.3 Results:

We reviewed a total of 5870 consecutive cases over a three-year period from January 2001 to December 2003. Colonoscopies were performed by CP (1180 cases), CS (1398), NMTE (40), NC (591) and SMR (2661) (**Table 5.1**). The M : F ratio was 2848 : 3022. The mean age was 60.41 years (range 18 to 101). The sex and age distribution matched evenly among the five subgroups as shown in **table 5.2 and table 5.3** respectively.

Majority of the nature of the colonoscopic referrals were performed for planned first colonoscopy done for the first time, in 4330 cases, and planned follow-up colonoscopy in 1479 cases with remainder of cases as depicted in **table 5.4**. **Table 5.5** shows the breakdown of these referrals for colonoscopy as per each endoscopist subcategory.

Colorectal symptoms accounted for majority of indications for colonoscopy in 3457 cases and polyp follow-up was the second commonest indication in 1034 cases. The remainder of indications, as shown in **table 5.6**, included colorectal cancer (CRC), colorectal cancer follow-up, family screening, inflammatory bowel disease, radiological indications, faecal occult blood positivity, diverticular disease and others. There were 33 cases of indications for colorectal cancer, which included very obvious or highly suspicious cases of cancer on the basis of clinical, radiological or flexible sigmoidoscopy.

Table 5.1: Endoscopist category, n: 5870

Endoscopist Category	No. of cases
Consultant physicians (CP)	1180
Consultant surgeons (CS)	1398
Non medically trained endoscopists (NMTE)	40
Nurse Colonoscopist (NC)	591
Specialist Registrars, surgical & medical (SMR)	2661

Table 5.2: Sex distribution, n 5870

Males – 2848, Females – 3022

Endoscopic category	Sex	No. of cases
Consultant physician	F	654
Consultant physician	M	526
Consultant surgeon	F	677
Consultant surgeon	M	721
NMTE	F	21
NMTE	M	19
Nurse Colonoscopist	F	308
Nurse Colonoscopist	M	283
Specialist Registrar	F	1362
Specialist Registrar	M	1299

Table 5.3: Age distribution by endoscopists' category, n : 5870

Endoscopist category	Mean	Min age	Max age
Consultant physician	59.22	18	93
Consultant surgeon	61.94	19	101
NMTE	57.21	35	87
Nurse Colonoscopist	60.20	22	100
Specialist Registrar	60.23	19	101

Table 5.4: Nature of colonoscopy referrals, overall, n : 5870

Planned/unplanned	No. of cases
Planned - first Colonoscopy	4330
Planned - follow-up Colonoscopy	1479
Unplanned repeat Colonoscopy	57
Emergency Colonoscopy	4

Nature of colonoscopy referrals

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Endoscopist Category	Unplanned repeat Colonoscopy	1.8%	1.6%			
	Planned - follow-up Colonoscopy	14.7%*	26.8%*	40.0%	47.2%	24.0%*
	Planned - first Colonoscopy	83.4%*	71.3%*	60.0%	52.8%	76.0%*
	Emergency Colonoscopy	1%	2%			

The table shows the nature of colonoscopy referrals in each group. Analysis of the differences using the chi squared statistic (excluding emergency colonoscopies due to the limited sample size falling into this category) shows that there is a significant difference between the groups at the 95% confidence level, $\chi^2(8)=280.8$, $p<0.01$.

Table 5.5: Nature of colonoscopy referrals, n : 5870

Endoscopist Category	Nature of colonoscopy	No. of cases
Consultant physician	Unplanned repeat Colonoscopy	21
Consultant physician	Planned - follow-up Colonoscopy	174
Consultant physician	Planned - first Colonoscopy	984
Consultant physician	Emergency Colonoscopy	1
Consultant surgeon	Unplanned repeat Colonoscopy	23
Consultant surgeon	Planned - follow-up Colonoscopy	375
Consultant surgeon	Planned - first Colonoscopy	997
Consultant surgeon	Emergency Colonoscopy	3
NMTE	Planned - follow-up Colonoscopy	16
NMTE	Planned - first Colonoscopy	24
Nurse Colonoscopist	Planned - follow-up Colonoscopy	279
Nurse Colonoscopist	Planned - first Colonoscopy	312
Specialist Registrar	Unplanned repeat Colonoscopy	13
Specialist Registrar	Planned - follow-up Colonoscopy	635
Specialist Registrar	Planned - first Colonoscopy	2013

Table 5.6: Indications for colonoscopy, n : 5870

Indications	**No. of cases**
Colorectal symptoms	3457
Polyp follow-up	1074
Colorectal cancer	33
Colorectal cancer follow-up	434
Family screening	336
Inflammatory bowel disease	375
Radiological indications	59
Faecal occult blood positivity	18
Diverticular disease	6
Others	35
Not recorded	43

The 434 cases of CRC follow-up includes, mostly post cancer surgery surveillance. Of the 375 cases of inflammatory bowel disease (IBD), majority were accounted by ulcerative colitis (UC) in 364 with the remaining for crohn's. Radiological indications included cases referred for colonoscopy on the basis of computerised tomography, barium enema, ultrasound scan or PET scans. **Table 5.7** shows the 'other' category of indications that were recorded at the time of endoscopy, of which 7 cases were accounted by post surgery (non-cancer cases or no obvious evidence of previous CRC). **Table 5.8** shows the various indications as per each endoscopic subcategory.

Of the total 5870 cases, 4902 cases achieved complete intubation upto caecum (3190) and TI (1712) with incomplete intubations in 968 cases (**Table 5.9**), and the various levels of incomplete intubations are as shown in **table 5.10**. **Table 5.11** and **table 5.12** show the various levels of intubations achieved by the endoscopists in complete and incomplete cases respectively. Sigmoid colon (226 cases) was the furthest intubation level in most of the incomplete cases.

The overall various reasons for incomplete intubations are shown in **table 5.13** and **table 5.14** depicts the breakdown of these reasons among the endoscopists. There were 31 cases of 'other' reasons, with all of these cases recording as that further intubations were not performed due to pathology encountered. However, there was no mention if the pathologies in these 31 cases prevented the passage of scope beyond it due to any disease limitation, i.e., as in impassable stricture etc.

Table 5.7: 'Other' indications recorded for colonoscopy, n : 35

Other indications	No. of cases
Post surgery	7
Proctitis	2
Stricture	1
Fistula	3
Endomucosal resection of polyp	5
Slow transit constipation	3
Gastric cystic fundic polyps	3
Angiodysplasia	2
Rectal Prolapse	1
Review of right colon	1
Peutz-Jeughers syndrome	1
Signet ovarian carcinoma	1
Cherpes Syndrome	1
Peri-appendiceal inflammation	1
Pulmonary embolism	1
High CRP	1
Gram -ve septicaemia	1

Table 5.8: Indications and endoscopic category, n : 5870

Indications	CP	CS	NMTE	NC	SMR
Colorectal symptoms	793	800	20	256	1588
Polyp follow-up	172	262	5	157	478
Colorectal cancer	1	18	-	2	12
Colorectal cancer follow-up	57	118	4	61	194
Family screening	59	62	5	58	152
Inflammatory bowel disease	75	74	4	36	186
Radiological indications	8	20	1	9	21
Faecal occult blood positivity	2	2	-	8	6
Diverticular disease	0	3	-	-	3
Others	6	12	1	2	14
Not recorded	7	27	-	2	7

The individual comparisons are shown in the table below.

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Indication s	Colorectal symptoms	67.2%*	57.2%*	50.0%	43.3%	59.7%*
	Polyp follow-up	14.6%*	18.7%*	12.5%	26.6%	18.0%*
	Colorectal cancer	1%	1.3%		.3%	.5%
	Colorectal cancer follow-up	4.8%*	8.4%	10.0%	10.3%	7.3%
	Family screening	5.0%*	4.4%*	12.5%	9.8%	5.7%
	Inflammatory bowel disease	6.4%	5.3%	10.0%	6.1%	7.0%
	Radiological indications	.7%	1.4%	2.5%	1.5%	.8%
	Others	.7%	1.2%	2.5%	1.7%	.9%
	Not recorded	.6%	1.9%		.3%	.3%

* = significant difference at 95% confidence level compared to the NC group.

Table 5.9: Level of intubation, n : 5870

Level reached	No. of cases
Caecum	3190
Terminal ileum	1712
Incomplete	968

Table 5.10: Incomplete levels of intubation, n : 968

Level reached	No. of cases
Ascending colon	185
Hepatic flexure	135
Transverse colon	170
Splenic flexure	95
Descending colon	80
Sigmoid colon	226
Rectum	43
Not recorded	34

Table 5.11: Complete intubations and endoscopist category, n : 4902

Level reached	CP	CS	NMTE	NC	SMR
Caecum	763	766	26	198	1437
Terminal ileum	253	373	8	273	805

Level reached

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Level reached	Caecum	75.1%	67.3%	76.5%	42.0%	64.1%
	Terminal ileum	24.9%	32.7%	23.5%	58.0%	35.9%

The table shows the percentage reaching Terminal ileum in each group. Analysis of the differences using the chi squared statistic shows that there is a significant difference between the groups at the 95% confidence level, $\chi^2(4)=160.2$, $p<0.01$.

Level reached. The table below shows the summary statistics of the comparisons between the NC group with the other groups.

5.11 completion levels	χ^2	Degrees of freedom	P value	Significant at 95% confidence level?
NC vs. CP	153.9	1	P<0.001	Yes
NC vs. CS	88.2	1	P<0.001	Yes
NC vs. NMTE	15.2	1	P<0.001	Yes
NC vs. SMR	79.1	1	P<0.001	Yes

Table 5.12: Incomplete colonoscopies, level reached, n : 968

Level reached	CP	CS	NMTE	NC	SMR
Ascending colon	36	50	-	6	93
Hepatic flexure	24	26	1	23	61
Transverse colon	30	47	2	26	65
Splenic flexure	22	28	-	15	30
Descending colon	16	28	1	13	22
Sigmoid colon	29	62	2	28	105
Rectum	2	9	-	7	25
Not recorded	5	9	-	2	18
Total	**164**	**259**	**6**	**120**	**419**

Table 5.13: Reasons for incomplete intubations, n : 968

Reasons	No. of cases
Impassable Stricture	140
Poor Bowel Preparation	211
Technically Difficult	218
Patient Intolerance	276
Other	31
Planned Limited	26
Not recorded	66

Table 5.14: Reasons for incomplete intubations as per endoscopist category, n : 968

Reasons	CP	CS	NMTE	NC	SMR
Impassable Stricture	19	40	2	16	63
Poor Bowel Preparation	29	51	1	34	96
Technically Difficult	39	64	-	25	90
Patient Intolerance	56	56	1	29	134
Other	8	14	-	2	7
Planned Limited	2	13	-	4	7
Not recorded	11	21	2	10	22

		Group			
		CP	CS	NC	SMR
		Col %	Col %	Col %	Col %
Reason for incomplete intubations	Impassable Stricture	11.6%	15.4%	13.3%	15.0%
	Poor Bowel Preparation	17.7%*	19.7%*	28.3%	22.9%
	Technically Difficult	23.8%	24.7%	20.8%	21.5%
	Patient Intolerance	34.1%*	21.6%	24.2%	32.0%*
	Other	4.9%	5.4%	1.7%	1.7%
	Planned Limited	1.2%	5.0%	3.3%	1.7%
	Not recorded	6.7%	8.1%	8.3%	5.3%

* = significant difference at 95% confidence level compared to the NC group.

All the 26 cases with reasons cited by the endoscopist as 'planned limited' was, however planned initially for a full colonoscopy. Sixty-six cases did not have any reasons recorded by the endoscopist for failure of complete intubation. The overall non-adjusted completion rate among all endoscopist sub-groups combined was 83.5 %, with an overall adjusted completion rate of 90 %. Calculation of adjusted rate included incomplete cases of technically difficulty, patient intolerance, 'other' reasons and 'planned limited' reasons. The latter two categories were included for the above mentioned reasons including the fact that endoscopists didn't expressly state that pathology encountered in the 'other' group prevented further colonoscopic intubation and likewise in 'planned limited' cases the initial indication showed a clear expression for performing a complete colonoscopy. The incomplete cases of impassable stricture, poor bowel preparation and 'not recorded' reasons were excluded from the adjusted completion rate calculation. The adjusted completion rate among the subgroups was CP (91 %), CS (89 %), NMTE (97 %), NC (89 %) and SMR (90 %) (**Table 5.15**).

The colonoscopic examinations revealed no abnormality in 2967 cases, and primary pathologies encountered included mainly of polyp (1219 cases), malignancy (261), diverticular disease (728) and UC (314) with remainder of primary pathologies seen as in **table 5.16**. There were 45 cases of stricture, excluding diverticular stricture, where the endoscopist was not entirely certain of its benign/malignant nature. In addition, there were 39 cases when the endoscopist was unsure of the pathology.

Table 5.15: Completion rate among various endoscopist subgroups

	Overall completion rate	**Adjusted completion rate**
Consultant Physicians	86.1 %	**91 %**
Consultant Surgeons	81.5 %	**89 %**
Non-medically trained endoscopists	85 %	**97 %**
Nurse colonoscopist	80 %	**89 %**
Specialist Registrar	84.3 %	**90 %**

Overall Completion rate

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
completio n rate	complete	86.4%	81.5%	85.0%	80.0%	84.3%
	not complete	13.6%	18.5%	15.0%	20.0%	15.7%

The table shows the completion rate in each group. Analysis of the differences using the chi squared statistic shows that there is a significant difference between the groups at the 95% confidence level, $\chi^2(4)=17.9$, $p<0.01$.

The table below shows the summary statistics of the comparisons between the NC group with the other groups.

Overall Completion rate	χ^2	Degrees of freedom	P value	Significant at 95% confidence level?
NC vs. CP	10.8	1	P<0.001	Yes
NC vs. CS	0.56	1	P=0.454	No
NC vs. NMTE	0.56	1	P=0.444	No
NC vs. SMR	6.4	1	P=0.012	Yes

Completion rate - adjusted

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Adjusted completion rate	complete	91.2%	89.0%	97.0%	89.0%	90.0%
	not complete	8.8%	11.0%	3.0%	11.0%	10.0%

The table shows the adjusted completion rate in each group. Analysis of the differences using the chi squared statistic shows that the difference between the groups is not significant, $\chi^2(4)=6.6$, p=0.157.

The table below shows the summary statistics of the comparisons between the NC group with the other groups.

Completion rate - adjusted	χ^2	Degrees of freedom	P value	Significant at 95% confidence level?
NC vs. CP	1.8	1	P=0.176	No
NC vs. CS	0.00	1	P=0.999	No
NC vs. NMTE	2.9	1	P=0.089	No
NC vs. SMR	0.53	1	P=0.466	No

Table 5.16: Primary Pathology findings, n : 5870

Primary Diagnosis	No. of cases
Normal	2967
Polyp	1219
Malignancy	261
Diverticular disease	728
Diverticular stricture	10
Ulcerative colitis	314
Crohn's disease	65
Proctitis	63
Stricture	45
Familial adenomatous polyposis	12
Angiodysplasia	21
Endoscopist Unsure	39
Others	48
Not recorded	78

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Primary	Normal	54.5%	47.6%	67.5%*	53.1%	49.5%
Diagnosi	Polyp	16.5%*	22.5%	7.5%*	22.0%	21.6%
s	Malignancy	4.4%	6.0%	2.5%	3.4%	3.9%
	Diverticular disease	12.4%	11.7%	7.5%	10.5%	13.3%
	Diverticular stricture	.1%	.2%	5.0%		.2%
	Ulcerative colitis	5.7%	3.9%	7.5%	6.8%	5.6%
	Crohn's disease	1.9%	.4%		.5%	1.3%
	Proctitis	.6%	1.1%	2.5%	.8%	1.3%
	Stricture	.2%	1.4%		1.5%	.5%
	Familial adenomatous polyposis	.2%	.1%			.3%
	Angiodysplasia	.8%	.3%			.3%
	Endoscopist Unsure	.9%	.3%		.8%	.7%
	Others	.7%	1.0%		.3%	.9%
	Not recorded	1.1%	3.5%		.2%	.6%

* = significant difference at 95% confidence level compared to the NC group.

Seventy-eight cases had no record entered of any finding. There were 48 'other' primary findings as shown in **table 5.17**. The breakdown of the primary findings for each endoscopist group is shown on **table 5.18**, and the sites of these primary findings are shown in **table 5.19**. The cases of 'not recorded' sites included malignancy (10 cases) and crohn's disease (2). Five cases had angiodysplastic lesions in two sites.

Secondary pathologies were found in 629 cases (**Table 5.20**), including finding of polyp in 419 cases. This involved synchronous polyp at the same site (200) and elsewhere (195) in the colon as compared to primary polyp finding in the same patients. Nine patients with a primary diagnosis of malignancy had four cases with polyps at the same site and five cases with polyps elsewhere in the colon. In addition, six patients had a synchronous malignancy found along with primary diagnosis of malignancy. The 'other' secondary findings were melanosis coli (5 cases), pseudopolyps (2) and lipoma at the caecum (1). The secondary pathology found and site of these as per the endoscopist subgroups are depicted on **table 5.21** and **table 5.22** respectively.

Therapeutic and diagnostic procedures were undertaken in 1086 cases (**Table 5.23, Table 5.24**). For the whole series of 5870 colonoscopies, there was no significant difference in the complication rate between NC and medical consultant colonoscopists (CP and CS).

Table 5.17: 'Other' primary findings and site, n : 48

Findings	Site	No. of cases
Solitary Rectal Ulcer Syndrome	Rectum	6
Isolated Ulcer	Cæcum	1
	Descending colon	1
	Transverse colon	1
	Not recorded	2
Pouchitis	Pouch	1
Apthous ulcer	Terminal ileum	1
Defunctioned colitis	Not recorded	1
Melanosis coli	Not recorded	26
Lipoma	Caecum	1
	Hepatic flexure	1
	Not recorded	3
Pseudopolyps	Not recorded	2
Worm infestation	Not recorded	1

Table 5.18: Primary Pathology findings as per endoscopist category, n : 5870

Primary Diagnosis	CP	CS	NMTE	NC	SMR
Normal	643	665	27	314	1318
Polyp	195	315	3	130	576
Malignancy	52	84	1	20	104
Diverticular disease	146	164	3	62	353
Diverticular stricture	1	3	2	-	4
Ulcerative colitis	67	54	3	40	150
Crohn's disease	23	5	-	3	34
Proctitis	7	16	1	5	34
Stricture	2	20	-	9	14
Familial adenomatous polyposis	2	1	-	-	9
Angiodysplasia	10	4	-	-	7
Endoscopist Unsure	11	4	-	5	19
Others	8	14	-	2	24
Not recorded	13	49	-	1	15

Table 5.19: Site of the main primary findings

Primary findings	Site	No. of cases
Polyp	Rectum	259
	Sigmoid	404
	Descending colon	116
	Splenic flexure	32
	Transverse colon	113
	Hepatic flexure	41
	Ascending colon	224
	Caecum	2
	Multiple sites (throughout colon)	1
	Not recorded	27
Malignancy	Rectum	93
	Sigmoid	67
	Descending colon	7
	Splenic flexure	5
	Transverse colon	15
	Hepatic flexure	10
	Ascending colon	53
	Caecum	1
	- Not recorded	10
Diverticular disease	Sigmoid	434
	Descending colon	15
	Throughout left colon	176
	Transverse colon	6
	Throughout middle and left colon	30
	Ascending colon	8
	Scattered throughout entire colon	30
	Not recorded	29
Ulcerative colitis	Rectum (proximal extent)	28
	Sigmoid (proximal extent)	69
	Descendingcolon (proximal extent)	50
	Splenic flexure (proximal extent)	35
	Transverse colon (proximal extent)	26
	Hepatic flexure (proximal extent)	9
	Ascending colon (proximal extent)	26
	Pan-colon	68
	Not recorded	3
Crohn's disease	Terminal ileum	24
	Terminal ileum & Caecum	9
	Caecum and ascending colon	5
	Transverse colon	4
	Splenic flexure	1
	Sigmoid	2

	Multiple sites - Not recorded	18 2

(Table 5.19, continued) Site of the main primary findings

Primary findings	**Site**	**No. of cases**
Diverticular stricture	Sigmoid Descending colon	9 1
Proctitis	Rectum	63
Stricture (other stricture of unsure aetiology)	Rectum Sigmoid Descending colon Splenic flexure Transverse colon Hepatic flexure - Ascending colon	9 20 4 1 6 1 4
Familial adenomatous polyposis	Pan-colon	12
Angiodysplasia	Transverse colon Ascending colon Caecum Terminal ileum More than one site (i.e. two sites)	1 13 1 1 5

Table 5.20: Secondary Pathology findings, n : 629

Secondary Diagnosis	No. of cases
Polyp (synchronous with primary polyp finding)	
Same site	200
New site	195
Polyp (synchronous with primary malignancy finding)	
Same site	4
New site	5
Polyp (new finding)	15
Malignancy (synchronous with primary malignancy finding)	6
Diverticular disease	160
Diverticular stricture	2
Ulcerative colitis	21
Crohn's disease	2
Proctitis	6
Stricture	1
Angiodysplasia	2
Others	8
Endoscopist unsure	2

Table 5.21: Secondary Pathology findings as per endoscopist category, n: 629

Primary Diagnosis	CP	CS	NMTE	NC	SMR
Polyp	65	141	1	8	204
Malignancy	2	-	-	-	4
Diverticular disease	40	43	2	11	64
Diverticular stricture	1	-	-	1	-
Ulcerative colitis	3	6	1	1	10
Crohn's disease	-	-	-	-	2
Proctitis	-	-	-	-	6
Stricture	-	-	-	-	1
Angiodysplasia	-	1	-	-	1
Others	2	2	-	2	2
Endoscopist Unsure	-	1	-	-	1

The comparisons by each secondary diagnosis are shown in the table below

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Secondary Diagnosis	Polyp	57.5%*	72.7%*	25.0%	34.8%	69.2%*
	Diverticular disease	35.4%*	22.2%*	50.0%	47.8%	21.7%*
	Other	7.1%	5.2%	25.0%	17.4%	9.2%

* = significant difference at 95% confidence level compared to the NC group.

Table 5.22: Site of secondary findings, n: 629

Site	CP	CS	NMTE	NC	SMR
Rectum	19	33	-	3	68
Sigmoid	54	98	3	11	96
Descending colon	7	17	1	1	46
Splenic flexure	1	1	-	1	13
Transverse colon	10	18	-	-	28
Hepatic flexure	5	2	-	-	2
Ascending colon	10	20	-	-	30
Caecum	-	-	-	-	1
Terminal ileum	-	-	-	-	2
Descending colon + Sigmoid	3	1	-	-	5
Transverse colon + Sigmoid	1	-	-	-	-
Pan-colon	-	1	-	-	-
Not recorded	3	3	-	7	4

Table 5.23: Total count of procedures performed, n: 1086

Procedure	No. of cases
Conventional polyp biopsy	200
Hot biopsy of polyp	374
Snare polypectomy	501
Coagulation (angiodysplasia lesions)	11

Table 5.24: Procedures performed as per endoscopist category, n: 1086

Procedure	CP	CS	NMTE	NC	SMR
Conventional polyp biopsy	21	43	-	50	86
Hot biopsy of polyp	32	89	2	15	236
Snare polypectomy	107	165	1	39	189
Coagulation	7	2	-	-	2

The comparisons between the individual procedures is shown below

		Group				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Procedure	Conventional polyp biopsy	12.6%*	14.4%*		48.1%	16.8%*
	Hot biopsy of polyp	19.2%	29.8%*	66.7%	14.4%	46.0%*

Snare polypectomy	64.1%*	55.2%*	33.3%	37.5%	36.8%
Coagulation	4.2%	.7%			.4%

* = significant difference at 95% confidence level compared to the NC group.

Complications

The following table shows the number (%) of patients who developed complications as a results of the colonoscopy.

Cases (% of cases)	Major complications	Minor complications	Total complications
CP	0	3 (0.3%)	3 (0.3%)
CS	3 (0.2%)	5 (0.4%)	8 (0.6%)
NC	0	3 (0.5%)	3 (0.5%)
SMR	4 (0.2%)	4 (0.2%)	8 (0.4%)

There are no significant differences between the levels of **major** complications between the groups overall and no significant differences between any of the groups compared with the NC group.

There are no significant differences between the levels of **minor** complications between the groups overall and no significant differences between any of the groups compared with the NC group.

There are no significant differences between the levels of **total** complications between the groups overall and no significant differences between any of the groups compared with the NC group.

Cases (% of cases)	Major complications	Minor complications	Total complications
CP & CS combined	3 (0.1%)	8 (0.3%)	11 (0.4%)
NC	0	3 (0.5%)	3 (0.5%)

The differences between the CP&CS combined groups compared to the NC group are not significant for Major, Minor or total complications.

Investigation into gender & age differences.

The results show that there are significant gender and age differences between the groups and further investigation into the affect of these differences has been carried out.

Analysis has been carried out to identify gender and age differences in the main outcome measure, completion rate. The tables below show both the completion rate and adjusted completion rate by gender and age.

	Completion rate	Adjusted completion rate
Female	82.0%	88.8%
Male	85.1%	93.2%

As expected the completion rates are higher amongst men than women. There are significant differences for both the overall completion rate and the adjusted rate between males and females at the 95% confidence level. (Overall $\chi^2(1)=10.8$, $p<0.001$ and adjusted $\chi^2(1)=31.9$, $p<0.001$)

	Completion rate	Adjusted completion rate
Under 25	84.50%	90.20%
25-34 years	86.20%	90.60%
35 – 44 years	89.50%	92.80%
45 – 54 years	88.50%	92.50%
55 -64 years	85.90%	91.50%
65 – 74 years	80.30%	90.30%
75+ years	77.20%	88.90%

Completion rates were higher in the younger age groups. There is a statistically significant difference at the 99% confidence level($\chi^2(6)=82.9$, $p<0.01$) between the age groups for the overall completion rate but the difference between the age groups for adjusted completion rate is not statistically significant ($\chi^2(6)=11.6$, $p=0.07$).

With these gender and age differences evident, it is worthwhile investigating the differences in completion rates between the groups taking into account the gender and age differences between them. Weighing each group by gender gives a sample in each group balanced for both gender and age as shown below.

		Group - weighted				
		CP	CS	NMTE	NC	SMR
		Col %	Col %	Col %	Col %	Col %
Gende	Female	51.5%	51.5%	51.5%	51.5%	51.5%
r	Male	48.5%	48.5%	48.5%	48.5%	48.5%

		Group – weighted				
		CP	CS	NMTE	NC	SMR
Age group	Under 25	2.4%	2.4%	2.5%	2.4%	2.4%
	25 - 34	4.6%	4.6%		4.6%	4.6%
	35 - 44	10.4%	10.4%	10.9%	10.4%	10.4%
	45 - 54	15.4%	15.4%	16.1%	15.4%	15.4%
	55 - 64	22.3%	22.3%	23.4%	22.3%	22.3%
	65 - 74	25.4%	25.4%	26.6%	25.4%	25.4%
	75+	19.6%	19.6%	20.5%	19.6%	19.6%

Using the weighted sample we investigate the levels of completion within each group.

5.15 Completion rate – comparing the sample and the weighted sample for gender & age

	Completion rate	Completion rate **weighted**	Adjusted completion rate	Adjusted completion rate **weighted**
CP	86.4%*	86.3%*	91.2%	91.7%
CS	81.5%	81.3%	89.0%	89.6%
NMTE	85.0%	85.1%	97.0%	96.8%
NC	80.0%	79.7%	89.0%	89.3%
SMR	84.3%*	84.2%*	90.0%	90.6%

*=significant difference at the 95% confidence level compared to the NC group.

The table shows the completion/adjusted completion rate in each group with the groups weighted for gender and age. Analysis of the differences on the weighted sample shows that there is still a significant difference between the groups at the 99% confidence level, $\chi^2(4)=20.2$, $p<0.01$.

Analysis of the adjusted completion rate on the weighted sample shows that there is not a significant difference between the groups $\chi^2(4)=9.3$, $p=0.54$.

This tells us that despite the differences in gender and age between the groups, the results based on the completion/adjusted completion rates remain the same.

Review of Sedation related study and results

Age results for the 1844 patients

	Mean age	Std Deviation
CP	59.9	15.5
CS	55.6	17.4
NC	58.1	16.7
SMR	59.2	14.6

Complications

The following table shows the number (%) of patients who developed complications as a results of the colonoscopy from the 1844 patients.

	Complications
CP	3 (0.5%)
CS	0 (0%)
NC	1 (0.5%)
SMR	3 (0.4%)

There are no significant differences between the groups overall or between any of the individual groups compared to the NC group.

Overall Completion rates (not adjusted completion rates)

Cases (% of cases)	COMPLETE COLONOSCOPY	INCOMPLETE COLONOSCOPY	NOT RECORDED
CP	511 (90.6%)*	37 (6.6%)*	16 (2.8%)
CS	291 (84.3%)	48 (13.9%)	6 (1.7%)
NC	190 (85.6%)	32 (14.4%)	0
SMR	580 (81.3%)*	114 (16.0%)*	19 (2.7%)

*=significant difference compared to the NC group at the 95% confidence level

Analysis of the differences using the chi squared statistic shows that there is a significant difference between all the groups at the 95% confidence level, $\chi^2(6)=34.1$, $p<0.01$.

There are also significant differences between the CP and NC groups and SMR and NC groups.

Sedation/Analgesia

	CP	CS	NC	SMR
F+M	510 (90.4%)	287 (83.2%)	189 (85.1%)	621 (87.1%)
F+M+B	3 (0.5%)	3 (0.9%)	3 (1.4%)	7 (1.0%_)
F+B				1 (0.1%)
F	10 (1.8%)	21 (6.1%)	10 (4.5%)	55 (7.7%)
M	15 (2.7%)	8 (2.3%)	1 (0.5%)	7 (1.0%)

E	1 (0.2%)	1 (0.3%)	2 (0.9%)	
P	1 (0.2%)	1 (0.3%)		
P+K		1 (0.3%)		
NOT GIVEN	19 (3.4%)	23 (6.7%)	17 (7.7%)	22 (3.1%)
NOT RECORDED	5 (0.9%)			

The table above shows the type of sedation/analgesia used. Due to the small sample sizes in some cells it has been necessary to recode into 'other sedation' category.

	CP	CS	NC	SMR
F+M	510 (90.4%)*	287 (83.2%)	189 (85.1%)	621 (87.1%)
F	10 (1.8%)*	21 (6.1%)	10 (4.5%)	55 (7.7%)
M	15 (2.7%)*	8 (2.3%)	1 (0.5%)	7 (1.0%)
NOT GIVEN	19 (3.4%)*	23 (6.7%)	17 (7.7%)	22 (3.1%)*
OTHER	10 (1.8%)	6 (1.7%)	5 (2.3%)	8 (1.1%)

*=significant difference compared to the NC group at the 95% confidence level

Analysis of the differences using the chi squared statistic shows that there is a significant difference between all the groups at the 95% confidence level, $\chi^2(12)=47.0$, $p<0.01$.

There are significant differences between the CP and NC groups and the NC and SMR groups in the use of some sedation/analgesia.

5.4 Discussion:

Colonoscopy is considered as the gold standard investigation for colorectal assessments (Ee HC et al., 2002; Cappell et al., 2002). Its scope and demand for this is ever increasing, especially considering the earlier detection of colorectal cancers and the imminent advent for colorectal cancer screening (Price et al., 2005). Colonoscopy has been shown to be feasible and effective as a screening tool for assessing CRC (Hunt et al., 1998; Gilbert et al., 2001; Stephenson et al., 1993). Nurse endoscopy is already well established and nurses have been performing independent flexible sigmoidoscopy since the 1970's. They have to shown to be safe and effective, providing good comparable results with other medical endoscopists and offers excellent patient satisfaction (Maruthachalam et al., 2006; Basnyat et al., 2002; Schoenfeld et al., 1999a, 1999b; Pathmakanthan et al., 2001). Nurse led colonoscopy is a much newer concept (Vance, 2005) and the efficacy and safety of nurse led colonoscopy have now been established following a previous large case series study done at our unit (chapter 2 of this thesis). This study looked at the efficacy of nurse colonoscopy as compared with other endoscopists.

This large study compared results of colonoscopy among various groups of endoscopists including nurse colonoscopist. The sex and ages were evenly matched across the subgroups, with majority of cases done as planned first colonoscopy for investigation into primarily colorectal symptom assessment.

The overall adjusted completion rate was 90 %. The adjusted completion rate among various endoscopist subgroups groups were also around 90 % or higher, including 89 % for NC. Joint Advisory Group (JAG) on Gastrointestinal Endoscopy recommends a 90 % intubation of caecum and 50 % of TI intubations in required cases. (Joint Advisory Group recommendation, 1999, 2004). The calculation of the adjusted completion rate was done according to JAG recommendations, where cases of disease limitations or poor bowel preparation were to be excluded from the adjusted rate. We also excluded cases where the reasons for incomplete intubations were not recorded. The incomplete cases included for this adjusted rate were cases of technical difficulty, patient intolerance, 'other' and 'planned limited' reasons. The final adjusted rate shows that both the overall and group completion figures, including that of NC were in keeping with recommended national guidelines. This is shown to be favourable when compared with other published series, including variable completion rates of 55 – 97 % in a British Society of gastroenterology (BSG) survey (Endoscopy Section Committee of the British Society of Gastroenterology survey 1987) and also another large national survey showing 76.9 % caecal completion rate, with a low adjusted rate of 56.9 % (Bowles et al., 2004). In addition, our series shows an approximate of around 50 % of TI intubations. In the NC group this figure was much higher, but the exact reason of this was not obvious.

The majority of colonoscopies were normal and the pathologies encountered revealed a wide spectrum of cases. The diagnostic findings in the NC group were

comparable to other groups in this study. There were no colonoscopy related complications recorded in this study, in any of the sub-groups including NC. Both diagnostic and therapeutic procedures were performed in this series; however there was no record of any procedures undertaken by NC. However an earlier case series study of the NC in our unit showed that the NC had safely performed a substantial number of procedures with no immediate or delayed complications (Chapter 2 of this thesis).

This current study represents a very large consecutive case series over 3 years of 5870 colonoscopic procedures. It is one of the largest case series studies in the world comparing various established endoscopists and nurse colonoscopist. It also represents a large series on nurse colonoscopy cases. Till to date, there has been no published similar large volume of work either as a comparative series or as individual NC series. This study was undertaken in a colorectal tertiary unit, which was also the first in UK to introduce a national training programme for nurse endoscopy training (Duthie et al., 1998) and the NC reviewed in this study was one of the first nurse colonoscopist in UK. The unit is now currently one of the national endoscopy training centres for medical, nursing and non-medical trainees.

There were few weaknesses noted in this study and the results should be interpreted accordingly. First of all this was retrospective study, although on a prospectively collected database. The strength of the evidence would have been greater if it was a randomised controlled trial. This comparative study involves a single NC's series in

the nurse colonoscopy subgroup and comprises 10 % caseload of the whole study. This is primarily due to the fact that, nurse colonoscopy is a relatively new concept and there were no other established independent NC's that could be included at the time of this study. Due to the nature of data recording and collection, there were neither sedation details for the whole series nor the time taken to undertake the procedures and as such we are unable to analyse these. However, an earlier study of the NC series showed that this NC routinely performed independent sedations with no significant complications and colonoscopy by the NC was time efficient (chapter 2 of this thesis). This series did not look at delayed complications of colonoscopy, i.e., occurring due to delayed presentation of perforations. The main complications of colonoscopy are perforation (0.07 – 0.2 %), bleeding (0.001 – 1.24 %) and mortality (unto 0.07 %) (Eckardt et al., 1999; Jentschura et al., 1994; Sieg et al., 2001; Waye et al.,1992; Wexner SD et al., 2001; Nelson et al., 2002; Anderson et al., 2000; Farley et al., 1997; Puchner et al., 1996; Tran et al., 2001; Bowles et al., 2004) (**Table 5.25**). We had reviewed, in an earlier study of 435 colonoscopies done by NC, and this did not reveal any immediate or delayed complications over a 30-day period (chapter 2 of this thesis). Finally, the confirmation of any missed pathologies would have ideally required a tandem colonoscopy, however ethical considerations and the retrospective nature of this study did not deem this possible. Again, our earlier single NC case series of 435 cases did not reveal any significant missed pathology.

Table 5.25: Summary of previous studies of colonoscopy complications

(Bowles et al, 2004)

Reference	Prospective/retrospective	No of colonoscopies	Bleeding (%)	Perforation (%)	Mortality (%)
Eckardt	Prospective	2500	0.24	0.08	0
Jentschura	Prospective	29 695*	0.24	0.10	0.015
Sieg	Prospective	8416	0.001	0.005	0.001
Waye	Prospective	2097	1.24	0.10	0
Wexner	Prospective	13 580	0.07	0.07	0.007
Nelson	Prospective	3196	0.22	0	0
Anderson	Retrospective	10 486	N/A	0.19	0.019
Farley	Retrospective	57 028	N/A	0.075	0
Puchner	Retrospective	10 000	0.05	0.09	0.02
Tran	Retrospective	26 162	N/A	0.08	0.004
Bowles	Prospective	9223	0.07	0.13	0.07

*15 159 colonoscopies, 14 536 rigid sigmoidoscopies.

This study shows that nurse colonoscopy have comparable results to that of other established endoscopists. The overall results of the centre also show better results

than the national average and are comparable to the JAG recommended guidelines. Nurse colonoscopy has now been shown to be equally effective and has enormous implications for the service provision in UK, especially with ever increasing demand for colonoscopic colorectal assessment (Bowles et al., 2004 Endoscopy Section Committee of the British Society of Gastroenterology, 1987; Working Party of BSG, 1991 and 2001). This demand will be substantially higher with the advent of screening for colorectal cancer (Cairns S et al., 2001 Rhodes JM, 2000). It has also been shown in a previous study of ours that nurse colonoscopy may offer substantial cost savings and this again implications on a national scale, especially with the current financial crisis and record deficits affecting the NHS. This resource of nurse colonoscopy service can also be utilised as a significant teaching and training resource (Duthie et al., 1998). This has already become established practice within our unit.

A further multicentre randomised controlled study would be able to evaluate the results further and this may possible give further credence to the present study findings. A detailed cost analysis and effectiveness study in future might be able to assess the actual cost benefits and any possible 'quality adjusted life years' saved if nurse colonoscopy resource is increasingly used. This might be increasingly relevant in the present day cash-strapped NHS

In conclusion, our large comparative study shows that nurse colonoscopy provides effective and safe results that are comparable to other medically trained

endoscopists. In addition, the NC results are favourable to the recommended national JAG guidelines.

CHAPTER 6

GENERAL DISCUSSION – ROLE OF NURSE LED COLONOSCOPY

6.1 Discussion

Historically, nurses have always played an extremely important role in human society. The provision of nursing care has always been pivotal in the provision and implementation of health care. This role was not always universally accepted as fundamental among the medical society and for quiet a long time, nurses were perceived to have been subservient to other medical professionals and nursing care had to play second fiddle rather than as an equal part of a coherent and vital cog in a multidisciplinary health care team.

Since last few decades, the concept and the provision of nursing care has progressively improved dramatically. There have always been pioneers among nurses in healthcare community. Throughout history, especially in the latter half of twentieth century, nurses have been given increasing role in healthcare, especially in areas where previously thought to be the sole fiefdom of medically trained personnel.

In the last 50 years, nurses have become increasingly specialized, especially in endoscopic services. These included a wide variety of procedures, including bronchoscopy, cystoscopy, upper gastrointestinal endoscopy and flexible sigmoidoscopy. They underwent appropriate training and performed various endoscopic procedures, initially under supervision and then independently. They also started to perform more complex and difficult cases, and even therapeutic

procedures, once the initial fear and trepidation by the medical fraternity was overcome, and more so as the confidence and better results became evident.

In UK, the provision of health care is relatively different to other countries, including financial and delivery aspects of care. There is also major discrepancy between the health resources and facilities available as opposed to the demand for the services. In fact, this sea change in nursing practice and responsibility is seen by the British government as one of the central means of effecting modernisation of the national health care (Milburn, Secretary of State's Address, 2000). There are various reasons for this change in attitude and perceptions, especially among the policymakers, including increasing waiting lists, Patients charter drawn in 1991, finite financial budget allocations for health service, possible overall savings on health care costs by employing specialist nurses, increasing demands by the public including demand for holistic care, increased clinical workload due to two-week wait rule for suspected malignancies, reduced junior doctors working hours and also changing and complex training issues of health care personnel. An important factor that aided this development was the publication in 1992 by United Kingdom Central Council (UKCC) for Nursing and Midwifery and Health Visiting of its *Scope of Professional Practice 1992*, in which nurses where encouraged to further develop their roles.

The role of nurse endoscopy is well established with growing evidence to support the effectiveness of it (Maule, 1994; Rosevelt et al., 1984; Jain et al., 2002; Cash et al., 1999; Schoenfeld et al., 1999a and 1999bl). In fact, nurse endoscopists have been utilized in performing Flexible sigmoidoscopy (FS) since the 1970's (Spencer et al., 1977 and 1978) and further studies have reiterated this (Maule, 1994). British Society of Gastroenterology Working Party 1995 and Society of Gastroenterology Nurse and Associates Practice Committee 1997 have supported the performance of sigmoidoscopy by non-physicians. Several studies has shown NE can perform endoscopy as well as experienced endoscopists, with similar effectiveness and patient satisfaction (Rosevelt J et al., 1984) and with no differences in polyp detection rate or complications (Jain et al., 2002).

It has been shown that nurse endoscopy is widely practised in UK (Goodfellow et al., 2003; Pathmakanthan et al., 2001) and is not limited to one procedure or carried out solely for diagnostic purposes (Pathmakanthan et al., 2001), and the perceived benefits included reduction in waiting lists, reported good patient acceptability, improved care and safety. There is increasing acceptance among the patients and medical community with regard to role of NE in performing FS (Basnyat et al., 2002).

Since 1996, nurse practitioners have been performing FS in our unit, which has an established NE training programme for performing FS (Duthie et al., 1998).

Since the first description of the 'fibreoptic coloscope', reported in 1967 by Overholt and Pollard, colonoscopy has expanded considerable over the years. At present, colonoscopy has become the gold standard and definitive investigation of choice for colorectal assessment. Colonoscopy is more sensitive than radiological imaging and offers both diagnostic and therapeutic options.

At present in UK, there is a widening disparity between the increasing demand for this service and the varying availability of the resources; either/both trained personnel and endoscopic facilities. Screening for CRC, if implemented in UK, is going to put substantial pressures on the NHS, in addition to the near breaking point pressures that is already present. In 1995, East Yorkshire Trust developed two courses, which were the English National Board (ENB) Flexible Sigmoidoscopy Course for Nurse Practitioners and the ENB Upper Gastro-Intestinal Course for Nurse Practitioners (Duthie et al., 1998). They were first of their kind in UK at the time. A nurse endoscopist (NE) was trained in our unit in 1998 to perform flexible sigmoidoscopy and subsequently following further training, was accredited by Joint Advisory Group (JAG) as an independent nurse colonoscopist (NC). A single nurse led colonoscopy service was started in our tertiary colorectal unit from November 2000. Our unit has one of the first UK recognized nurse colonoscopist (MAP) who was also the UK's first officially trained and recognized flexible sigmoidoscopist (Duthie et al., 1998).

Nurse led flexible sigmoidoscopy has already been shown extensively by various studies to safe, effective with good results across various parameters that is comparable among other medical endoscopists. However, nurse colonoscopy is in the initial stages with its role and acceptance still evolving. To date, no evidence has yet been published evaluating the outcome of nurse led colonoscopy practice. The aim of the study was to determine the safety, efficacy and feasibility of NC. We also aimed to assess whether there were any significant miss rates for CRC and polyps. The cost analysis of a nurse led colonoscopy practice was assessed. The final aim was to compare the results and effectiveness of NC with other medically trained established colonoscopists.

The study was subdivided into three sections in order to achieve the aims of this study. Firstly, in order to determine the safety, efficacy and feasibility of NC, we reviewed 435 consecutive elective colonoscopies performed by NC from November 2000 to January 2003 and evaluated various parameters including completion rate, time taken to complete colonoscopy, pathologies encountered, therapeutic and diagnostic procedures undertaken, sedation and analgesic details and complications. Secondly, we undertook follow-up of all these 435 cases over a minimum 12 months to maximum of 39 months to assess the miss rates of CRC and adenomatous polyps. This was done using colorectal cancer database, central histopathology database, further endoscopy records and any required clinical case notes. The cost analysis was determined using various cost factors involved, including contracted hours, hours worked, leave details, annual salary, and colonoscopy sessions and number of

procedures in each section. Finally, we evaluated the effectiveness and safety of NC when compared with other medical colonoscopist by reviewing consecutive 5870 colonoscopies performed over a three-year period from January 2001 and December 2003.

Our results show that NE colonoscopy is feasible and has good results. This series has revealed that nurse colonoscopy is time efficient, even taking into consideration the initial learning curve that is required for performing both diagnostic and therapeutic procedures. The assistance required by the NE for the initial 100 cases were only in a small number of cases. NE undertook colonoscopy for a wide mix of cases and performed both diagnostic and therapeutic procedures. The overall completion rate was 90.1%. This is in keeping with the national Joint Advisory Group's (JAG) criteria for colonoscopic procedures, which recommends complete intubations in at least 90% of the procedures. A previous survey by the Endoscopy Committee of BSG in 1998 and Bowles et al., (2004) has shown that the completeness of colonoscopy was highly variable, ranging from 55-97%.

There were no significant complications seen, including any bleeding or bowel perforations even when therapeutic polypectomies and conventional biopsies are performed. There was also no mortality in our series. Other much larger series have shown colonoscopic complications of bleeding varying from 0.2 - 1% (Gibbs et al., 1996; Rosen et al., 1993; Macrae et al., 1983) and a perforation rate to be from 0.09 - 0.2 % (Macrae et al., 1983 Araghizadeh et al., 2001; Anderson et al., 2000). There

is a reported perforation related postoperative mortality of 12% and morbidity of 43% (Garbay et al., 1996). The risk of perforations or bleeding is higher when therapeutic procedures or biopsies are undertaken (Rosen et al., 1993 Macrae et al., 1983; Araghizadeh et al., 2001; Anderson et al., 2000) Overall mortality following colonoscopy has been reported in upto 0.02% cases (Anderson et al., 2000). The cause of deaths has been attributed to perforation or sedation related (Macrae et al., 1983; Anderson et al., 2000). No sedation related complications were seen nor were there any need for sedation reversal in our series.

Our study revealed that there were no missed malignancies that were detected in the follow-up period. The assumption is that patients with any sort of symptoms would have re-presented either to the general practitioner or picked up at subsequent outpatient follow-up and resultant investigation would have detected any malignancies. This review is limited for patients who have moved their existing residence to another region or those who are asymptomatic during the review period. Ethical issues and the present scope of this study prevented us from conducting a personal review of all patients or undertaking a non-invasive investigation like faecal occult blood testing. It has been shown in an earlier study by Singh et al., (2006) that the risk of developing colorectal cancer remains decreased for more than 10 years following the performance of a negative colonoscopy.

This review also showed that only a very small number of additional adenomatous polyps were detected elsewhere in the colon over the follow-up period. None of

these polyps had either any invasive or focal malignancy. Obviously, these polyps could be either a synchronous or metachronous polyps. This would still only present as a small number of polyps even if it were assumed that all of them were synchronous. But this definitely cannot be attributed as the true miss rate of synchronous polyps in our series, as it would have required a back-back colonoscopy to be performed at the same time. Other studies have shown a colonoscopic polyp miss rate varying from 4.6 %-31% (Hixson et al., 1991; Warneke et al., 1992; Bensen et al., 1999; Rex et al.,2003). Again the ethical issues and a potential complication of the simultaneous check colonoscopy led to inability of detecting the actual miss rate. Colonoscopy has potential, albeit small, complication rate including recognised serious complications of perforation, bleeding and mortality. In addition, this review would have excluded any patients who have moved their residence to another locality.

The overall adjusted completion rate was 90 %. The adjusted completion rate among various endoscopist subgroups groups were also around 90 % or higher, including 89 % for NC. Joint Advisory Group (JAG) on Gastrointestinal Endoscopy recommends a 90 % intubation of caecum and 50 % of TI intubations in required cases. (Joint Advisory Group recommendation, 1999, 2004). The calculation of the adjusted completion rate was done according to JAG recommendations, where cases of disease limitations or poor bowel preparation were to be excluded from the adjusted rate. We also excluded cases where the reasons for incomplete intubations were not recorded. The final adjusted rate shows that both the overall and group

completion figures, including that of NC were in keeping with recommended national guidelines. This is shown to be favourable when compared with other published series, including variable completion rates of 55 – 97 % in a British Society of gastroenterology (BSG) survey (Endoscopy Section Committee of the British Society of Gastroenterology survey 1987) and also another large national survey showing 76.9 % caecal completion rate, with a low adjusted rate of 56.9 % (Bowles CJA et al). In addition, our series shows an approximate of around 50 % of TI intubations. In the NC group this figure was much higher, but the exact reason of this was not obvious.

The diagnostic findings in the NC group were comparable to other groups in this study. There were no colonoscopy related complications recorded in this study, in any of the sub-groups including NC. Both diagnostic and therapeutic procedures were performed in this series; however there was no record of any procedures undertaken by NC. However an earlier case series study of the NC in our unit showed that the NC had safely performed a substantial number of procedures with no immediate or delayed complications.

This whole study represents a large consecutive series of work evaluating and determining various aspects and results of NC practice. Currently, there is a dearth of results of nurse colonoscopy practice on its own or when compared with other medically trained endoscopists. The work was undertaken in a busy tertiary colorectal unit and represents the largest volume of workload evaluating all aspects

of nurse led colonoscopy practice. The miss rate for NC has not been looked at previously in any other studies. The large number of cases has further strengthened the study over a relatively long follow-up period. The comparative study reviewed substantial number of cases of 5870 consecutive colonoscopies over a 3-year period.

There are few weaknesses identified in the study and as such the results need to be interpreted accordingly. Our work represents a single nurse colonoscopist's case series, but this has been unavoidable as NC concept is still relatively new with very scarce number of existing independent other NC's. There were no other established independent NC's that could be included at the time of this study.

Ideally, true miss rate of CRC or especially polyps can only be established by doing a tandem colonoscopy or histological evaluation from resected specimens. Due ethical issues and potential complications of the simultaneous tandem colonoscopy led to inability of detecting the actual/true miss rate. Colonoscopy has potential, albeit small, complication rate including recognised serious complications of perforation, bleeding and mortality. In addition, this review would have excluded any patients who have moved their residence to another locality. With regard to miss rate for CRC, it is not normally a routine practice to do repeat colonoscopy if initial colonoscopy is deemed to be normal, and hence the review was limited for patients who are asymptomatic during the review period. Ethical issues and the present scope of this study prevented us from conducting a personal review of all patients or undertaking a non-invasive investigation like faecal occult blood testing. It has been

shown in an earlier study by Singh et al., (2006) that the risk of developing colorectal cancer remains decreased for more than 10 years following the performance of a negative colonoscopy.

Colonoscopy rarely misses polyps equal or more than 10 mm, but the miss rate increases significantly in smaller sized polyps (Van Rijn et al., 2006). Using current colonoscopic technology, there are significant miss rates for adenomas < 1 cm even with meticulous colonoscopy (Rex et al., 2003; Cutler et al., 1997). There are few ways of reducing false negatives and increasing pick up rate during colonoscopy. Using zoom chromoendoscopy, the rate of detecting colonic polyps can be increased at the cost of a longer retrieval time (Stergiou et al., 2006) and it also established that simultaneous radiological imaging could increase the pick up rate. Future studies might be able to assess the miss rate more accurately by possibly doing a simultaneous digital recording of the initial colonoscopic assessments.

One of the limitations of the comparative case series was the retrospective nature of study, although it was of a prospectively collected database. This comparative study involves a single NC's series in the nurse colonoscopy subgroup and comprises 10 % caseload of the whole study. The strength of any evidence would have been greater if it was a randomised controlled trial.

With the advent of service orientated NE led FS and the current nurse colonoscopy service; there exists an important consideration in terms of training for the junior

doctors who are going to be the future providers of health care. There is a perception felt in some quarters of the medical community that training of the junior doctors will be hampered by this trend of NE's training and performing endoscopies. There are arguments to be made for either side. On one hand, NE have a shorter training period of 9 months and once they are fully trained and if registered as a trainer, they can then assist in training of junior doctors. This is already happening in our unit where the NE has two dedicated teaching lists for a colonoscopy fellow. Also junior doctors can benefit from undertaking the same training modules as for the NE. The current waiting lists pressures on the clinicians can have a detrimental effect on junior doctors training. By making more trained personnel available and thereby reducing the waiting lists, these pressures can be eased and an extra person can be utilized for teaching purposes. On the other hand, training of more and more NE to perform endoscopies reduces the already limited training resources that traditionally existed for junior doctors. More importantly, there is no benefit in training more NE to perform in a certain hospital setting if there are no adequate endoscopy facilities to fully appreciate it. Overall, consideration should be given to the availability of the facilities and the need for further trained personnel to utilise this. The present increasing national demand for colorectal assessments should be taken into account as well. There has to be a fine balance between providing better health care without compromising training requirements of junior doctors. There might be a need for further evaluation of the impact on junior doctors training resulting from NE service.

The trained NE led service has its limitations in that there is the need for a consultant to be present in the hospital to deal with any emergencies, although in our study there were no significant complications. This would also make it difficult for the NE to do emergency lists or out of hours services unless an on-call consultant is in place. There could be a place for NE in providing elective colonoscopy service and complementing clinician's workload and reducing waiting lists (WL). The experienced NE can also work in the OPD and do family screening clinics, cancer follow-ups and form part of the multidisciplinary teams, which the NE (MAPH) is already performing, to ensure better utilization of this excellent and often unused resource. NE can also free up time for the clinician to do other important tasks. By increasing the availability of the trained personnel might eventually lead to improved health related quality of life for patients.

Screening for CRC, if implemented in UK, is going to put substantial pressures on the NHS, in addition to the near breaking point pressures that is already present. In US since 2002, a national screening programme for CRC has been implemented and colonoscopy is included as part of that screening tools (US Preventive Task Force, 2002). Currently in UK, the results of two trials conducted by the Department of Health and MRC evaluating the feasibility, effectiveness and cost-benefits of screening by faecal occult blood (FOB) and FS are awaited. Thompson et al. (2006) looked at screening from a UK perspective and reiterated that colorectal cancer is a major cause of morbidity and mortality with resultant substantial health care costs, and that in the present situation screening currently offers the best chance of

improving outcomes from bowel cancer. It has been estimated that following FOB screening in normal risk individuals will lead to further 10,000 colonoscopy sessions in UK National Screening Committee 1998 or one session per week for each district general hospital serving a population of 250,000. Screening by FS for high-risk individuals, which is already taking place, will generate a further 13,000 colonoscopy sessions per annum (Atkin et al., 1998) or 1.25 sessions per week for a district general hospital serving a population of 250,000. The complimentary role of NE along with other medical endoscopists merits serious consideration in this present scenario and in context of potential future screening for CRC.

There are several things that could be considered for improving the understanding of nurse led colonoscopy practice. Randomised controlled multi center trials involving greater number of NC's would give a greater level of evidence in assessing the full implications of NC practice.

The cost analysis showed that the labour cost of NC doing a colonoscopy was at 10.62 £ and consultant at 26.14 £. This amounts to more than double the cost per colonoscopy for the consultant colonoscopist. The resultant cost saving for NC was 15.52 £ per single colonoscopy. The savings could be substantially more if considered over a period of time and also if the number of nurse colonoscopists are increased. In addition, the training costs spent on training a NC could be recouped

within a very short duration of time. The pilot study despite the various limitations and confounding factors did show that there are cost savings to a nurse colonoscopy practice when compared with consultant medical endoscopists. Future work could determine the true effects of these in a cost-benefits and cost-utility analysis and also assess quality adjusted life years (QALY) saved. Our study also identified several confounding areas that would have to address in further studies. In addition, a mulitcentre and randomized control trial would be scope for future work in economic evaluation of NC practice.

Another factor that needs to be considered is assessing patient's satisfaction for NC practice and this study could also be extended to take into account the perceptions of medical community for the concept of NC led practice. It is also important to assess the actual training implications especially for junior medical staff

Our series represents the work of a single NE led colonoscopy service and has shown good results. In future, for the good results and standards of care to be maintained elsewhere, there remains the need for continued and well structured training programmes for NE, good supervision and regular auditing once the NE is registered and independently performing.

As compared to yester-years, the present day delivery and needs of medical care has changed substantially representing a seismic shift in the paradigm of provision of medical care. In future, this changing trend will be more acute. There is immense

pressure on health services to keep up with this ever-increasing demand. Current resources to provide this are scarce and limited, and there remain an imperative need for the best use of the available resources. As a response to this, the health delivery systems need to adapt to in ways as to provide the best utilization of the resources, especially personnel, to combat this challenging environment. Nurse practitioners form an integral part of this utilisation. The results of this study have shown that nurse practitioner endoscopist can provide excellent results in providing colorectal assessment by way of colonoscopy service.

The study concludes that nurse led colonoscopy service provides good results of high completion rate, minimal complications, time efficiency and offers both diagnostic and therapeutic options. It has also been proved that nurse colonoscopy is a viable, safe and effective method in providing colorectal assessment. Nurse colonoscopy practice can provide good diagnostic results with minimal miss rate for CRC and adenomatous polyps. The results are favourable when compared with other existing recognised miss rates of medical endoscopists. NC also offers cost savings when compared with medical consultant colonoscopists, with possible greater savings in the long-term. Finally, NC offers comparable colonoscopy results to that of other established medically trained endoscopists.

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