Evaluating a Model of Nurse-Led Care in a
Genitourinary Medicine Clinic

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KEVIN VINCENT MILES

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Abstract

The development of advanced practice roles for nurses working in the speciality of genitourinary medicine (GUM) is part of a wider process of change in nursing and the National Health Service. Despite the paucity of evidence of their effectiveness, there has been a steady growth of nurse-led GUM clinics over the past decade.

This thesis explores the impact of nurse-led GUM clinics for women in a central London GUM service. A process and outcome evaluation was conducted to demonstrate the effectiveness, acceptability and cost of nurse-led GUM clinics. 880 women were randomised to nurse-led or doctor-led clinics of whom 224 had their clinical records audited. A further (non-randomised) sample of 282 women completed a satisfaction survey, 20 completed an exit interview and 18 had their consultation observed. Staff completed 586 waiting time surveys. Staff interviews and focus group discussions identified the issues associated with the nurse-led clinic intervention. A cost analysis determined the average, incremental and marginal costs of nurse-led clinics.

The median documentation audit scores for specialist nurses (n=103) and senior house officers (SHOs) (n=121) were 92% and 85% respectively (p<0.0001). Specialist nurses performed equally to the SHOs with regard to requesting the correct diagnostic tests, preliminary diagnosis and treatment. The median satisfaction scores, out of a total of five, were 4.47 and 4.30 for the nurse-led and doctor-led groups respectively (p=0.05). There was no significant difference in the consultation times. Following the
introduction of nurse-led clinics, the average cost per patient rose from £8.80 to £8.88 with a marginal cost of £9.43 per patient.

The study concluded that trained, experienced specialist nurses supported within the multidisciplinary team were at least as effective in the assessment and management of female patients as SHOs. The model of nurse-led care was acceptable to patients and a cost-effective addition to existing services.
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<th>Description</th>
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<tbody>
<tr>
<td>BMA</td>
<td>British Medical Association</td>
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<tr>
<td>CI</td>
<td>confidence interval</td>
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<tr>
<td>CMB</td>
<td>Central Midwives Board</td>
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<td>GUM</td>
<td>genitourinary medicine</td>
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<td>GNC</td>
<td>General Nurses Council</td>
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<td>GP</td>
<td>general practitioner</td>
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<tr>
<td>NCCVD</td>
<td>National Council for Combating Venereal Disease</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NLC</td>
<td>nurse-led clinic</td>
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<td>OR</td>
<td>odds ratio</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<tr>
<td>s.d.</td>
<td>standard deviation</td>
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<tr>
<td>SHO</td>
<td>senior house officer</td>
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<td>SpN</td>
<td>specialist nurse</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
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<tr>
<td>UKCC</td>
<td>United Kingdom Central Council for Nursing, Midwifery and Health Visiting</td>
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<tr>
<td>VD</td>
<td>venereal disease</td>
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<tr>
<td>$\chi^2$</td>
<td>chi-square test</td>
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Chapter 1

Introduction

1.1 The Context for Change

The last few years have seen a number of changes to the structure of the National Health Service (NHS) in the United Kingdom (UK). This has created new demands and challenges for those providing health services. Health care providers are now expected to meet national standards of service excellence (Department of Health, 1997). They also need to develop new models of service that can deliver high quality, cost-effective care to meet the demands of NHS service-users. Nurses are to contribute to this modernisation agenda by undertaking a wider range of clinical tasks, including the right to make and receive referrals, admit and discharge patients, order investigations and diagnostic tests, run clinics and prescribe drugs (Department of Health, 2000a). Health care is to be planned and delivered according to best available evidence (Department of Health, 1996) and nurses, alongside other clinicians, are required to continuously improve quality and safeguard standards of care within a national framework of clinical governance (Department of Health, 1998).

Nurses, in general, have already begun the process of modernisation. New roles for nurses began to emerge more than a decade ago, as a result of a number of professional, management and policy changes (Shewan and Read, 1999). Nurses have extended their roles to take on tasks and roles previously, or normally, performed by
doctors. New role developments have led to the concept of 'nurse-led care', loosely defined to encompass roles at the interface between nursing and medicine (Read, 1999).

Nurses working in the speciality of genitourinary medicine (GUM) are now expected to follow this trend. The recently released National Strategy for Sexual Health and HIV proposes that nurses have an expanding role as specialists and consultants for the management of STIs (Department of Health, 2001). Although 'extended roles' for GUM nurses have been evident for some time (Rogers and Adler, 1987a), nurse-led care of persons with sexually transmitted infections (STIs) is still a relatively new concept in the UK. Descriptive accounts of nurse-led STI care have been reported (Allen, 1998; Sutton et al., 1999), although only one UK study has attempted to evaluate the effectiveness of nurses as first-line STI care providers (Harindra et al., 2001). Therefore, if GUM nurses are to continue developing their role, they now require evidence from high quality research to support their development in order to achieve the best possible outcomes for those they provide care for.

1.2 Setting the Scene for Nurse-Led GUM Care

The Mortimer Market Centre is a large central London GUM and HIV outpatient service. Of the total annual attendance of 60,000 patients, approximately 20,000 are seen in the women’s clinic. The women’s clinic provides specialist GUM services, including STI screening, HIV testing, health adviser and clinical psychology services, contraception advice and provision, young person services, and outreach work with partner organisations. The women’s clinic provided the setting for the nurse-led clinic intervention that was piloted over a period of twelve months.

In January 1999, two specialist nurses, each with over three years GUM nursing experience, were appointed to conduct nurse-led clinics. They had a two week induction and training period followed by regular clinical supervision with a consultant physician.
The specialist nurses’ defined role entitled them to work according to local protocols, to co-ordinate the comprehensive care of women who were undifferentiated from those seen by doctors. They worked autonomously without necessarily asking the advice of a doctor. They were able to elicit a sexual history, perform a genital examination, collect specimens and provide the preliminary diagnosis, results, selected treatments and health promotion for women presenting with various sexual health conditions and issues. They were required to work within the boundaries of their own knowledge and competence, and refer cases beyond their clinical expertise to the medical staff.

The nurse-led clinics ran alongside the traditional model of GUM care involving a doctor leading patient care supported by a team of staff nurses. In this model of care the doctor elicited the sexual history, and depending on the presenting problem and previous attendance history, performed the physical examination and collected the relevant specimens, or delegated these tasks to a staff nurse. The doctor then provided the preliminary diagnosis, results and treatments. The sexual health promotion aspects of care were dealt with by input from both the doctor and the staff nurses.

Senior house officers (SHOs) rotate through the service for a six month training period. The SHOs involved in the study commenced their GUM training rotation in February 1999. Following a one week induction period, the SHOs commenced doctor-led clinics as described above. The SHOs had a weekly group clinical supervision session in addition to individual supervision with a consultant physician. At the time of the outcome evaluation, the SHOs had more than four months GUM experience and covered approximately 35% of the women’s clinic workload. Similar to the specialist nurses, the SHOs had direct access to senior medical staff for referring cases beyond their clinical experience.

At the end of the twelve month pilot period, a decision was to be made as to whether nurse-led clinics would become a permanent feature of the women’s clinic
services. It is within this context that the study was set. Empirical data were required for the local decision-making process, although it was realised that the outcomes of the study would potentially hold implications for the conduct of GUM nursing practice across the UK.

1.3 Overview of Thesis

The primary aim of this thesis is to investigate the development of nurse-led clinics in the speciality of GUM. It begins by providing a historical overview of how nurses have contributed to the control and clinical management of sexually transmitted infections. The historical education of nurses is also presented, including the status of sexual health education in pre and post-registration nursing curricula. This provides the context and background for the development of advanced nursing roles in UK GUM clinics.

Chapter three provides an account of advanced nursing roles in GUM, as they exist today, from both an international and national perspective. Experiences from Amsterdam, Seattle and Sydney sexual health services are reported to show how nurse-led sexual health clinics compare in these different settings. Following this, the results of a postal survey explore the concept of nurse-led GUM care across England.

Chapter four reflects on the political context that has led to changes to nursing practice and the evolution of nurse-led interventions. It also examines the evidence for nurse-led care in the UK, first in the general nursing setting, then in the speciality of GUM.

Chapter five details the methodology used to study nurse-led GUM clinics at the Mortimer Market Centre. It describes and justifies the framework chosen for evaluating nurse-led GUM care before discussing the evaluation approaches, methods, study management and ethical issues.
Chapter six presents the findings of the process evaluation. The implementation and development of the nurse-led clinics are followed, in addition to the transition process of the specialist nurses. The chapter also explores the clinical activity and care processes involved in the nurse-led GUM clinics.

Chapter seven presents the findings of the outcome evaluation. Empirical evidence for the clinical effectiveness, acceptability and cost of nurse-led care is reported.

Chapter eight discusses the findings of the process and outcome evaluation. It provides possible explanations for the findings, discusses the limitations of the study and reflects on the implications and application of the findings for practice, at a local and national level. It concludes with recommendations for future research and development.
Chapter 2
The History of Nurses & Sexually Transmitted Infection Control

This chapter commences with a historical review of the nursing role in relation to the control and management of sexually transmitted infections. Following this, a historical review of the education of nurses with regards to sexually transmitted infections is presented. The chapter concludes by drawing conclusions with relevance to the development and evaluation of nurse-led GUM practice.

The terms venereal disease (VD), sexually transmitted disease (STD) and sexually transmitted infection (STI) are used interchangeably throughout this chapter, as are the terms VD clinic, ‘special’ clinic and genitourinary medicine (GUM) clinic. This generally reflects the changes in terminology over time.

2.1 The Role of the Nurse for the Care and Management of Sexually Transmitted Infections

2.1.1 Introduction

The history of sexually transmitted infections (STIs) and their associated control efforts in the United Kingdom during the nineteenth and twentieth centuries have been well researched (Waugh, 1971; Wyke, 1973; Waugh, 1973; Post, 1978; Adler, 1980; Adler, 1982; Roberts, 1982; Oriel, 1994). However, the historical involvement of nurses is less
clear. Therefore, this review presents the evolving role of nurses in the control and management of STIs over the last 150 years.

The review was conducted using journal and textbook publications and source documents from the Wellcome Institute for the History of Medicine Contemporary Medical Archives Centre and the Public Record Office in Kew, London. The findings of the historical review are presented in chronological order of events and/or publication.

2.1.2 Wet Nurses & Lock Hospitals: 19th Century

Early references to the term ‘nurse’ in conjunction with ‘venereal disease’ are not immediately identified with the nursing profession, as we now know it. The word ‘nurse’ originates from the Latin word *nutrire,* to nourish, or suckle. Nursing, as a profession, was not publicly recognised until 1860 when Florence Nightingale opened the first school of nursing at St Thomas’ Hospital, London (Dossey, 2000). This is possibly why one of the earliest references to the term ‘nurse’ is cited in the context of venereal disease transmission, rather than actual ‘nursing’ involvement in the treatment and management of venereal disease. Mahon (1808) reviewed writings of venereal disease transmission from the beginning of the 15th century until the middle of the 18th century. He quoted a number of authors who claimed they had evidence that the transmission of venereal disease occurred from the newborn to the nurse following breastfeeding, and vice versa. Nursing termed here, represented a woman who was employed to breast-feed another’s child.

Nonetheless, there is evidence of nursing involvement, as we now know it, in venereal disease management before the era of Nightingale. The following is an excerpt from the Manchester & Salford Lock Hospital minutes, 17th Sept 1827:
The women (patients) had a more permanent contact with the matron who was responsible for the day-day management of the hospital. She had to be a dependable character and had to ensure that the patients did not abuse the rules of the charity and benefited, physically and morally, from their stay. At first the hospital committee experienced difficulty in finding a trustworthy woman and in 1827 the matron had to be dismissed after it was discovered that ‘women of notoriously bad character had been found drinking in the kitchen’ and the matron had been ‘seen in a house of ill fame, singing in the company with very dissolute characters’ (Wyke, 1975).

Also before Nightingale, evidence of a nurse administering treatment for venereal diseases was cited in 1848 when a nurse was dismissed for over enthusiastic use of mercurial ointment (to treat syphilis), causing damage to the life of a patient (Waugh, 1971).

In Central London, after the first school of nursing was opened, St Peters Hospital for Stone (1860-1960) was recognised as one of the few institutions where the treatment of VD was carried out. The first record of nurses employed here was in 1864 followed by the employment of a Matron in 1876. At this time, the hospital was reported to have trouble retaining nurses due to poor wages and lack of educated women (Morson, 1960).

The London Lock Hospital in Dean Street Soho (1746-1952) also employed a matron and two nurses. ‘The matron received £15 and the nurses £6 per annum with a gratuity of £5 and £4 to be paid at Christmas if their services were satisfactory’ (Anon., 1906; p. 4). Male nurses supplied the needs of the few male inpatients from the 1890’s, whilst male orderlies looked after the outpatients department. In the early 1900s, the huge army of outpatients (20-30,000 per annum) overwhelmed the system, but the
rebuilding of Dean St in 1912 brought the departments up-to-date and allowed much of the treatment to be undertaken by nurses and orderlies. In general, the passage of sounds and prostatic massage were left in the hands of the male nurses (Innes Williams, 1996).

2.1.3 Moralising Against the Sexually Promiscuous: Early 1900’s

Following a presentation to the International Congress of Nurses in 1909, Dock, an American nurse, authored a manual for nurses with the chief purpose being ‘to reiterate the social significance of the venereal diseases and the crusade upon which women should enter in regard to them’ (Dock, 1910). This text, as with the vast majority of medical texts of the time, was obsessed with the notion of prostitution and its control:

The breeding place of all venereal diseases without exception is in the social institution called prostitution, or sexual promiscuity: in the debasement and degradation of what should be the highest and most revered of physical powers, those involved in the act of generation...Howsoever their derivation might be traced, prostitution is now as certainly the abiding place and inexhaustible source of this as of other germs of venereal disease, as is the marshy swamp is the abode of the malaria-carrying mosquito, or the polluted water supply of the typhoid bacillus (Dock, 1910; pp. 34-35).

Dock proposed to take the nurse reader through the medical, moral and legal aspects of venereal diseases, but the central aspect of her book regarded the social control of prostitution. In a chapter entitled ‘The Prevention of Venereal Disease’ the opening line was ‘Prostitution to be prevented... prostitution must be rooted out...’ (Dock, 1910; p. 129).
2.1.4 Midwives & Nosocomial Infection: A 1914 Case Study

Mahon’s (1808) writings drew attention to the (wet) nurse as a ‘vector’ for the transmission of syphilis. In 1914, in Corbett-Smith’s (1914) chapter about syphilis and ‘innocent contagion’, it was midwives who were held responsible for transmitting syphilis to the ‘innocent’:

Cases of infection by midwives are more common. Dr Duncan Bulkey records an epidemic of syphilis in a district in England, where a midwife continued her work although actively infected. Her victims numbered forty-one (Corbett-Smith, 1914; p.58).

2.1.5 Post Royal Commission: 1916

On the 12th July 1916, regulations made by the Local Government Board (LGB) were sent with a memorandum by the Medical Officer of the LGB on the organisation of medical measures against venereal diseases, to: 1) Councils of Counties and County Boroughs 2) Governing Bodies of Hospitals, and 3) Boards of Guardians. Regarding Section 8 of ‘Outpatients work at the clinic’, it was noted that ‘A nurse will always assist at the clinic for women.’ (Local Government Board, 1916) Although the role and responsibilities of the medical officer of the clinic were discussed, the role of the nurse was not made explicit.

In the early 1900’s there was an abundance of medical texts describing the venereal diseases. The vast ranges of remedies were presented and many authors wrote numerous editions. The content of these texts were very similar and a 1917 book written by a doctor ‘more especially for nurses and midwives’ was also a duplicate of the medical texts of the time (Watson, 1917). Although the book intended to provide
suitable instruction to nurses, of the 54 total pages, the term ‘nurse’ was only used in the preface and conclusion where the education of nurses was discussed:

In their turn [doctors and medical students], when they have acquired a thorough grounding, must pass on that part of their knowledge which is appropriate, to the nurses and midwives, who possess vast opportunities for educating women and disseminating knowledge of these diseases and their terrible results (Watson, 1917; p. 46).

Although the role of the nurse was recognised for the control of VD, the level of knowledge for these nurses was clearly controlled by the medical profession. Gender disparities and the suitability for women to view illustrations of the genitalia was apparent, in that fifteen of the sixteen illustrations in the book are of extra-genital lesions, with only one drawing of the male urethral anatomy and none of female genitalia. There are eight pages dedicated to the management of male gonorrhoea and one to female.

2.1.6 National Council for Combating Venereal Disease: Post World War 1

In February 1919, the Medical Committee of the National Council for Combating Venereal Disease (NCCVD) considered the effective method of providing facilities for early preventative treatment of VD. Such early treatment facilities were to be attached to public conveniences, in large towns, or clinics:

All such treatment centres would be under the direct supervision of a Medical Officer, whose attendance it would be possible to secure at any time of the night or day. The staff would consist of trained orderlies and nurses who would
administer early treatment [urethral/vaginal irrigation] as first aid, passing on all necessary cases to the Medical Officer (NCCVD, 1919a).

However, at the same meeting, although sympathetic to the initiative of the nurse, the nursing role was restricted in so far as providing advice to patients:

The Honorary Adviser of the National Union of Trained Nurses had written reporting to the National Council [NCCVD] the case of a member of their union, a Health Visitor, who, when in attendance on an infant suffering from some form of venereal disease had advised the father to seek treatment. The Doctor to whom the father went had complained to the Health Authority of the action taken by the nurse... With regard to the special case the committee registered their sympathy with a public servant being penalised in performance of her duty. It was agreed to inform Miss Eden, that provided the nurses makes no diagnosis she is quite within her rights in advising medical supervision when she sees suspicious symptoms (NCCVD, 1919a).

The role of the nurse in ‘early treatment centres’ later extended so they were able to render early treatment on an ‘emergency’ basis. However, the patient was then to be referred to the medical officer of the centre and ‘under no circumstances what ever should any further treatment of any sort be given for the same risk of infection by such a nurse’(NCCVD, 1919b).

Following the Royal Commission (Royal Commission on Venereal Diseases, 1916) the organisation of specialist venereal clinics became topical. These clinics were to employ nurses, preferably male, but in most civilian hospitals at the time, male nurses
were difficult to obtain, and, as a rule female nurses were to attend both male and female patients (Bayly, 1920).

In 1923, the Report of the Committee of Inquiry on Venereal Diseases recognised the importance of educating the community in an effort to prevent disease (Ministry of Health, 1923). The report stated the duty to give repeated personal instruction and warning to patients attending venereal clinics ‘must always devolve mainly on the doctors, but that it might well be supplemented by trained social workers...’ (point 24: p. 8). Although the mere suggestion of another professional giving advice had moved on from the 1917 VD act preventing anyone otherwise than by duly qualified medical practitioner ‘to offer to give or give any advice in connection with the treatment thereof’ (Venereal Disease Act, 1917), nurses did not feature in this report.

2.1.7 Recognising Nurses to Aid VD Control: 1920's

In a text for nurses and others engaged in the treatment of venereal diseases, it was acknowledged that:

By its influence on family life the nursing profession could be of much more assistance in the fight against venereal diseases that it has been in the past (preface) ... the study of venereal disease still received little attention in a doctor’s training, and even less in a nurse’s (Turner Warwick, 1928; p. 6).

At this point in time, ‘a nurse engaged in the treatment of venereal diseases was perhaps more the guardian of human happiness and efficiency than of human life, and must realise the importance of the work she is undertaking’ (p. 7). Turner Warwick (1928) discussed the duties of the nurse towards patients with VD, stating that the nurse must be careful not to infect herself and to warn patients of cleanliness with regards to baths
and WC seats. At this time, the health promotion potential of the nurse was coming into recognition; a significant turning point for the GUM nursing role. Turner Warwick (1928) stressed the attitude towards the patient and the need to refer patients in the community to treatment centres. However, he also stressed that:

Nor must she [the nurse] take to herself the task of telling a patient that he has venereal disease, even if the patient suspects the condition and has asked her opinion... If, however, he has no medical adviser, she may be able to help further by suggesting one with experience in the diagnostic and treatment of VD or by referring him to a venereal clinic (Turner Warwick, 1928; p. 28).

The medico-legal issues and role of patient consent were also raised. The following example was in the context of the nurse acting as an impartial witness:

A mistress cannot demand the examination of a servant. This request is occasionally made in cases of suspected pregnancy by the worried mistress, the doctor being asked to examine the breast during real or pretend examination of the chest... if the nurse plays the part of the impartial witness... her position is a very insecure one legally (Turner Warwick, 1928; p. 31).

Turner Warwick (1928) presented the nursing role in the intravenous treatment of syphilis with arsenic. ‘The nurse must see that the injection needles are kept in order. They must be sharp... the surgeon inserts the needle into the vein, and when satisfied that it is correctly placed in the lumen, he may ask the nurse to release the tourniquet’ (p. 73-74). Although many treatments and procedures were described in the text, who actually carried out the various tasks was not explicit. The ‘surgeon’ conducted the
urethral irrigations, but the nurse or attendant was to be 'guided' as to whether to perform posterior irrigation for prophylaxis. It appeared acceptable for a nurse to irrigate for prophylaxis reasons, but in an acute case of gonorrhoea it was the doctor's duty to carry out the irrigation. In 'sub-acute' cases of gonorrhoea in women 'the nurse may carry out the following treatment once a day: - the vulva is thoroughly cleansed with potassium permanganate... a Cusco's speculum is passed into the vagina... irrigation of the cervical canal may be carried out...' (p. 155). Although this demonstrated some progress in the role of the nurse, confusion was still apparent, as was a clear-cut rationale for who did what and when.

2.1.8 The Nurse as Almoner and Technician: 1940's

By 1944 the role of the 'lady almoner' was made explicit as the person who traced and brought to treatment (under Government Regulation 33B) the sexual contacts of those infected with VD (Milner, 1944). The almoner was often a trained VD nurse commonly referred to as the 'nurse almoner'. However, the Institute of Hospital Almoners advocated that the almoner should not be a nurse, but be a woman trained specifically in the social aspects of disease (Manchée, 1945).

In a 1948 text addressed to nursing students and practitioners, the nursing role was described as a 'mechanical role in the management of the sick' (Stokes and Taylor, 1948). The nurse was encouraged to consider the sanitary and public health point of view and look upon the medical and nursing problems involved, rather than 'lose herself in the maze of moral and social controversy'. The nurse was now taking on more technical aspects of care, such as the preparation of common drugs, the care of glassware, needles and syringes and the recognition and emergency treatment of various drug reactions. The nurse was encouraged to be observant in the examination of patients and understanding of diagnostic tests, although this was still regarded as the
responsibility of the physician. The role of administering treatment was now being handed to the nurse. In a section entitled ‘The Nurse as Technician and Operator’, Stokes and Taylor (1948) wrote that studies showed nurses’ ability to draw blood and give intravenous and intramuscular injections safely and satisfactorily, was ‘equal of the trained medical men’ (p. 269). Despite providing this information, the authors made it clear that the nurse, with the knowledge the text presented, should not proceed to treatment without the authority of a physician. In addition to the task-related role of nurses, the sociological aspect of care was emphasised with the nurse becoming a listener and more understanding towards the patient. Finally, ‘it was the clinic nurse who set the tone of the clinic; who saw that the physicians had the necessary materials; that the patients were not kept waiting...’ (p. 344).

Although Stokes and Taylor’s (1948) text illustrated the evolving role of the VD clinic nurse, Batchelor and Murrell’s (1951) text reverted to the replication of medical texts seen earlier in the century. Although the specific roles for nurses within the clinic were barely mentioned, the medical authors made it clear what was not the role of the nurse:

The question of how much the patient should be told about their condition depends upon each individual case, and the nurse should refer all questions on the subject to the doctor-in-charge (Batchelor and Murrell, 1951; p. 196).

In 1952, a Venereologist Group Committee conducted a questionnaire regarding the use of social workers (Anon., 1952). This led to recommendations that social workers be an integral part of the VD service. This was followed by a circular issued by the assistant secretary to the British Medical Association (BMA) regarding social workers in VD centres (Claxton E.E., 1953). Two letters were then received by the BMA stating that
the sister-in-charge of the VD clinic carried out all social work duties (Crumbie, 1953; Tinkler, 1953). At the same time a letter, also concerned about the introduction of more social workers into clinics, was received by an Essex County Hall Health Department (Anon., 1953). It was felt that the (nurse) health visitor would be more appropriate.

2.1.9 Retaining VD Nurses in the Speciality: 1950's

Around the same time, the BMA and Royal College of Nursing (RCN) recognised the need to retain nurses in VD clinics. The provision of an extra allowance for nurses working regularly in VD clinics was considered necessary, not because these nurses were engaged in the management of infective disorders, but ‘in the interest of venereal services as a whole’. The pay award to retain nurses in the speciality was justified by the unique role of the trained VD nurse:

> It is necessary too that she can perform semi-specialised operations such as giving injections, taking blood specimens and passing vaginal speculae, painlessly and with a speed that can only be imperative so that patients are not kept waiting... in addition she has to have a knowledge of clerical procedures... handling of confidential notes and of pathological specimens and the recording of their results (British Medical Association & Royal College of Nursing Liaison Committee, 1952).

The origins of the salary increase appear to have come from recommendations to the Ministry of Health by the Venereologist Group of the BMA (Claxton E.E., 1950). The Venereologist Group of the BMA corresponded with the RCN for a £20 per annum allowance for VD nurses (Claxton E.E., 1951). The RCN responded suggesting that ‘the
general feeling was that there did not appear to be a case for nurses in VD service being remunerated on a different scale from nurses in any other specialised field' (Goodall, 1951).

However, the correspondence from the RCN occurred after the Ministry of Health had set out detailed agreements reached by the Nurses and Midwives Whitley Council as part of the general revision of hospital nurses' salaries (Ministry of Health, 1950). The Nurses and Midwives Council Circular No. 5 revised rates of remuneration for ward sisters, charge nurses, staff nurses and enrolled assistant nurses employed in fever hospitals, in sanatoria, tuberculosis hospitals and in the treatment of venereal diseases. Additional payment to nurses employed in the treatment of venereal diseases, in addition to the salary appropriate to the corresponding grade, was an allowance at the rate of £20 per annum (Nursing & Midwifery Council, 1950). The correspondence of the time highlighted the need to offer additional payment to sanatoria and fever nurses so to retain these nurses in the specialities where stigma and fear of disease led to low recruitment. There was no reasoning or mention as to why venereal disease nurses were entitled an additional allowance, only an assumption that there were similar recruitment and retention issues to that of the fever and tuberculosis units.

During the same period in time, the medical venereologists were facing similar retention problems. Between 1953 and 1957, Ministry of Health correspondence recorded the difficulties recruiting consultants to the venereal disease speciality. Following the substantial decrease of VD in the 1950’s and subsequent reduced attendance at clinics, there was a decreased interest in venereology leading to a suggestion that the speciality be combined with dermatology. This was opposed, as was the suggestion that general practitioners take on the treatment and management of venereal diseases. The council of the Medical Society for the Study of Venereal Diseases (MSSVD) prepared a memorandum entitled ‘Venereology and the Future’ for
the Ministry of Health (King, 1955). This lengthy memo provided justification of the separate existence of the speciality of venereology. Nurses, however, did not feature in this document.

In the States, the picture of nurse involvement in the control of venereal diseases was somewhat different. At a 1954 conference for nurses on the public health aspects of venereal diseases in North Carolina, the fluctuating pattern of nursing service in VD was acknowledged. Following the high incidence of VD post World War 1 (WW1), public health nurses were actively involved. Towards the end of WW1 funds were cut and the extent of nursing input changed. The faltering interest in VD was not revived until 1935 when VD control intensified, therefore needing more personnel. However, there was a shortage of nurses and the 'VD investigator' assumed a greater responsibility for activities previously undertaken by nurses. Post WW2 the incidence of VD decreased, VD investigators were not required, and nurses resumed this role. The conference was then in a position to discuss how nursing should plan meeting challenges in the control of VD, the focus being more orientated towards community case finding (Working conference for nurses on the public health aspects of venereal disease control, 1954). By 1956, planning for the venereal disease content of basic nursing curriculum in Boston was based on the nurse's core functions of case finding, case holding and follow-up, nursing care, teaching, and interviewing of the patient (Morris, 1957).

Back in the UK at the Seamen's Dispensary, Liverpool (1924-1991), all of the non-medical staffing of the clinic consisted of male orderlies until 1955. Two State Enrolled Nurses (male) were then employed, but a Charge Nurse was not appointed until 1957 and a record clerk until 1963. Before this, the nurses did all the clerical duties, a very different picture to what was happening in the States (Arya and Plumb, 1992).
2.1.10 Health Promotion & the Nurse - A Formal Affiliation: Mid-1950’s

By 1956, the role of giving advice to patients had moved from the remit of the doctor, to the nurse. Although the nursing staff to a large extent were responsible for ‘nursing technique’, preparing syringes and assisting the doctor during examination, teaching patients about the prevention of VD and explaining the doctor’s recommendations became the sister’s duty (Ryle-Horwood, 1956).

However, the underutilisation of nurses was also acknowledged. It was with great foresight that Ryle-Horwood, a State Registered Nurse holding a Venereal Disease certificate\(^f\) from the Royal College of Nursing, stated:

> It is obvious that, at the moment, the total potential contribution of nurses to venereal disease control is far from being realised. Until even more interest in these problems can be obtained from the authorities responsible for nursing and allied training, so that they can utilise every opportunity, we are losing a vast part of the services of a profession which could be a vital force in attaining our ultimate objective – the eradication of venereal diseases from this country (Ryle-Horwood, 1956; p. 4).

During the 1960’s the momentum for a less restrictive environment in which the nurse could provide education and advice to patients was sustained. However, the nurses’ role to assist the doctor was still explicit:

> Whilst the patient is undressing the nurse should make sure that the trolley contains everything the doctor will require for his examination... when the

\(^f\) no account of this course and qualification was located from RCN records
examination is completed... the nurse changes the sheet in readiness for another
patient (Catterall, 1964; p. 119).

The doctor will sit on a stool at the foot of the table... the nurse will stand on his
right with the instrument trolley next to her. She will hand the instruments to the
doctor as though she were assisting in an operation (Catterall, 1964; p. 120).

With regard to the management of male patients, the text by Catterall (1964) also
clarified the nurses' role in the collection of specimens. Nurses collected urethral swabs,
and although digital examination of the prostate and pelvis was usually carried out by
the doctor, 'in certain cases the nurse may be requested to do the test' (p. 129). The
nurse prepared the patient and assisted the doctor during urethroscopy, lumbar puncture
and proctoscopy. The nurse was also able to dispense treatment prescribed by the
doctor.

Another text for nurses in the VD speciality was published two years later
(Schwartz.B., 1966). The introduction quoted: 'techniques that are an everyday part of
the nurses work are omitted in order to allow more details to be given of methods
peculiar to the investigation and treatment of the VD patient'. Apart from this, the term
'nurse' and the role of the nurse was not mentioned in any other part of the book,
therefore adding little to the development of GUM nursing practice.

2.1.11 Nurses Hindering Role Progress: 1972

The nursing texts of the 1950's and 60's had progressed to promoting the information
and advice giving role of the nurse. In a 1972 text written by a senior nursing officer,
this role had reverted to the pre-1950s attitude, suggesting that only the doctor could
give the patient information:
Nurses are frequently asked by patients when they can have sexual intercourse again. They should refer the patient back to the doctor, who will tell him when he can resume normal relationships...(Elliot and Ryz, 1972; p. 53).

Plump (1973) also reiterated this particular point of resuming sexual intercourse post infection:

Patients often talk to nursing staff about their condition and its prognosis. Although such questions are dealt with sympathetically and intelligently, we have an inflexible rule never to advise a patient about resuming sexual relations. This decision is for the doctor alone to make for he, after all, bears the ultimate responsibility (Plump, 1973).

Elliot and Ryz (1972) even suggested that the nurse collude to prevent a patient, usually a woman, from knowing her true diagnosis. An example being that if a wife discovered she had gonorrhoea, this would clearly point to adultery and wreck their marriage.

The remainder of Elliot and Ryz’s (1972) book lends itself to the nurse being the doctor’s assistant, although for male patients the nurse usually took the tests. However, for the first time in any of the VD texts, Elliot & Ryz (1972) described microscopy as a role of the nurse. There was, quoted by the authors, ‘no specific training needed for the use of this instrument and a nurse can master the essential techniques of microscopy within one or two weeks.’ (p. 95).
2.1.12 Progress - Clarity in Roles: Mid-late 1970's

Although throughout the 1970's nurses were still required to work as doctors' assistants (DHSS, 1974), the movement for nurses to take on more proactive and multifaceted roles in the VD clinic had begun:

In the space of one session, the nurse (he or she) can, depending on the size of the clinic, be acting as receptionist, clerk, child-minder, social worker, laboratory technician, doctor's assistant, family planning adviser, statistician, dispenser, marriage counsellor and telephonist (Harris, 1974).

The psychosocial role of the nurse was highlighted and also recognised by patients. The nurse was often perceived as 'an emotional dustbin, someone on whom to unburden their guilt, shame, embarrassment, remorse or aggression' (Shaw, 1973). The education and counselling function of the VD nurse was also clarified and the nurse was even allowed to give advice about contraception. The nurse could take specimens from men, perform microscopy, assist in research projects and 'need no longer be merely a chaperone' (Schofield, 1976). The microscopy role of the VD nurse was later supported by the development of a self-instructional training package at Sheffield VD clinic in conjunction with the Joint Board for Clinical Nursing Studies (Marson and Shaw, 1979).

In 1978, Adler et al. reported on the facilities and diagnostic criteria in sexually transmitted disease clinics. In this study, ninety-five consultants from 189 GUM clinics in England and Wales were surveyed. It was reported that consultants often delegated some of the duties normally carried out by medical staff to appropriately trained nurses. These delegated duties ranged from seeing and advising the patient, examining and diagnosing to prescribing treatment. For example, in thirty five clinics nurses were
allowed to prescribe treatment, in seventeen of them this was so when a doctor was not present. If the doctor was absent, the nurse would confirm treatment over the telephone before instituting treatment. Such practices were deemed acceptable as long as the nurses were adequately trained.

2.1.13 Inconsistency of Roles Between Clinics: 1983

In promoting a career in venereology nursing, Kahl (1983) stated that the nurses’ work was dependant on not only the size of the clinic, opening hours, diagnostic facilities and number of staff, but also the consultant’s overall policy as to the extent of nurse involvement:

In a very small clinic a nurse might deal single-handed with reception work, statistics, contract tracing and transport of laboratory samples as well as preparing patients for medical examination, assisting doctors, counselling and treating patients. In a very big clinic a team of receptionists, secretaries, medical health workers and perhaps a laboratory technician will help doctors and nurses to diagnose, treat and otherwise assist in the smooth running of the clinic. If the clinic is run on traditional outpatient lines, the nurse prepares the patient for doctor’s examination, chaperones for the doctor, collects blood and urine samples, stains and reads microscopic slides and treats patients. In a progressive clinic, nurses are allowed to extend their skills and knowledge and to work as a team with the doctors. They are directly involved with the patients: perform routine examinations, initiate additional tests, collect all diagnostic material, read microscopic slides, plan with patients follow-up visits for treatment and sometimes conduct interviews and discuss any problems with the patient. (Kahl, 1983).
Kahl (1983) quoted that greater responsibility and direct involvement with patients made the nurse's work very satisfying and enjoyable.

2.1.14 Researching the Role of the GUM Nurse: 1987-1993

In 1987, Rogers and Adler conducted the first comprehensive review to define the duties and delegated tasks nurses in GUM clinics could perform, or already performed. Nurses and doctors were represented in stratified randomised samples of ninety six clinics across England and Wales. The duties of nurses were grouped under five headings: clerical and administrative, statistical returns, patient care, clinical duties (the extended role of the nurse), and advisory. The 'extended role' of the nurse consisted of taking sexual histories, examining patients and taking genital tests, performing microscopy, and prescribing treatment. These duties represented 21.8% of the working week for senior nurses and 22.5% for other nurses (Rogers and Adler, 1987a).

In 1988, the Monks report (Department of Health, 1988) highlighted the considerable rise of the workload of GUM clinics and the potential inefficient use of doctor consultation time. This report recommended that staffing levels and roles, especially those of nurses and doctors, should be examined.

This recommendation was pursued with research conducted in 1993 (Allen and Hogg, 1993). In this study, 98 nurses from 20 clinics were interviewed about their qualifications, grade, length of time working in GUM, job satisfaction, training, and roles and responsibilities. The role of nurses varied from clinic to clinic and even within clinics. Microscopy, cryotherapy, venepuncture, female examination and 'extended' roles were asked about specifically. More than half of the nurses interviewed said that the nursing staff in their clinic could take on more responsibilities. The main reason preventing nurses from taking on more responsibilities, such as counselling, taking sexual histories, taking tests on new and follow-up patients, doing cytology smears,
giving test results and educating patients, was the clinic consultant who governed what
nurses did, or did not do, in the clinic. The second reason was simply lack of time, and
finally, some nurses felt that they were not sufficiently trained or experienced enough to
take on the extra responsibilities. However, only 39% of the medical staff thought that
nurses could take on more responsibilities compared with 56% of the nurses. When
asked whether nurses could run specific clinics without the medical staff being present,
67% of nurses and 62% of doctors thought this possible. The study recommended that
serious consideration should be given to the extension or introduction of nurse-run
clinics or sessions. This suggestion was supported by a majority of both nursing and
medical staff, particularly by younger doctors in training grades.

2.1.15 Medics Hindering Nursing Role Development: 1997

Four years later, despite the findings and recommendations by Allen and Hogg (1993),
resistance from medical staff regarding the move to integrate nurse-led clinics for the
first line management of STIs was recognised by a commissioned review of the work of
twenty one London clinics (Weatherburn et al., 1997). The authors of this review
remarked that the development of nurse-led clinics was likely to ‘depend on doctors
attitudes to nursing rather than nurses’ choice’ (p.14). In the face of this resistance,
nurse-led services were soon to feature in the routine services of London clinics, such as
St Mary’s Hospital at Paddington (Allen, 1998).

2.2 The Education and Training of Nurses for the Management
of Sexually Transmitted Infections

2.2.1 Introduction

The second section of this chapter provides a historical overview of the education of
nurses working in the field of sexually transmitted infections. The review commences
post World War 1 when nurses, and their subsequent education, were recognised as important components in combating the upsurge of venereal diseases (VD). Following through to the end of the 20th century, the review traces the numerous attempts to provide education for nurses in general, and more specifically, nurses working directly in the GUM speciality. The review concludes with a summary of the findings placed within the context of this thesis.

2.2.2 The Beginnings of Nurse Education for VD Control: Post WW1

One of the earliest attempts to educate nurses on the venereal diseases was by the Central Midwives Board in 1916 who issued a series of leaflets giving nurses factual information about gonorrhoea and syphilis (Central Midwives Board for England, 1916).

Later in the same year, the National Council for Combating Venereal Diseases (NCCVD) received a letter from the National Union of Trained Nurses about the teaching of nurses in venereal diseases. The Medical Committee of the NCCVD considered it ‘desirable that nurses should receive special instruction on venereal diseases, especially as regards the dangers of infection’. It was decided that this resolution should be conveyed to the National Union of Trained Nurses, and that they should be asked to convey this to the Matrons with whom they were in touch (NCCVD, 1916). However, VD being a new concept for nurse education, there appeared to be little direction in providing this instruction to nurses.

In January 1917, the NCCVD Medical Committee received a letter from Miss Hay Cooper asking whether it would be possible for VAD nurses to be given some instruction as to the dangers of venereal diseases in the infectious stage. It was agreed

* Voluntary Aid Detachment: nation wide voluntary movement, much favoured by middle class women, at the beginning of World War 1
that a copy of this letter should be sent to the British Red Cross Society asking whether it would be possible to make arrangements for such instruction (NCCVD, 1917).

A year later at the January 1918 meeting, the Medical Committee found 'it desirable to obtain the personal co-operation of nurses in this campaign [against VD], and that adequate instruction should be given to the nurses by the members of the medical staff in regard to the precautions which should be taken by nurses' (NCCVD, 1918a).

At the next meeting in February 1918, hospitals requested a sample syllabus for medical staff to teach nurses. It was felt that 'the most important thing to emphasise was the prevention of accidental infection by the nurses possessing suitable knowledge as to the dangers involved in nursing such cases' (NCCVD, 1918b).

In March 1918, 'Mr Clarkson reported the syllabus was practically complete...a single lecture giving the main points of the dangers of infection and one longer syllabus which would serve for two lectures dealing with the medical aspect and also the wider social aspect of the problem' (NCCVD, 1918c).

The matter was not addressed in the minutes again until April 1919 when the Medical Committee considered advocating a special course of VD training and certification for nurses (NCCVD, 1919b).

2.2.3 A Course of VD Information for Nurses: 1920

In January 1920, there was evidence of hospitals already providing VD instruction to nurses, and those arranging to give instruction (NCCVD, 1920a). Later that year, the Medical Committee was still discussing a course for nurses and discussed whether the Institute of Hygiene could provide this (NCCVD, 1920b). The Institute suggested four lectures: 1) dealing with the sociological aspect of VD, 2) a lecture on syphilis, 3) a
lecture on gonorrhoea, 4) a lecture particularly directed towards the incidence and prevention of both diseases with special reference to children (NCCVD, 1920c).

From here on, the momentum for training nurses diminished until it was raised again in February 1923:

Dr Fairfield asked whether the council could take any action in regard to the training of nurses in venereal diseases as it was apparent that a number of the hospitals were not using the VD clinics as training ground for their staff. It was agreed that a circular letter should be sent to the hospitals drawing their attention to the necessity for training their nurses... (NCCVD, 1923a).

2.2.4 Nurses as Barriers to Progression: 1920's

It was not only the degrees of bureaucracy that delayed the instruction of nurses in the venereal diseases, but also nurses themselves. Clarkson & Cantab (1922) wrote of the existing stigma within the nursing profession:

It should be realised that the stigmatic position which is so frequently adopted towards patients suffering from venereal disease is one which is as entirely inconsistent with the tradition of the nursing profession as it is uncharitable and ignorant (Clarkson & Cantab, 1922; p. 360).

In April 1923, of 191 letters sent to treatment centres across England and Wales, only 20 replies were received regarding the training of nurses. Seven of these were merely acknowledgements (NCCVD, 1923b). In the same meeting a letter had also been sent to the Ministry of Health asking if the training of nurses could be made a definite part of the Ministry’s venereal disease scheme. The Ministry of Health felt that they were
unable to do anything and suggested writing to the General Nursing Council (GNC). The next meeting of the NCCVD Medical Committee reported approaches to the College of Nursing, the Royal British Nursing Association and the Queen Victoria Jubilee Nursing Institute in an attempt to get venereal diseases on the nursing curriculum (NCCVD, 1923c). The GNC responded saying they would include the physiology of the reproductive system in the nursing training syllabus (NCCVD, 1923d). Later in the year the Medical Committee felt that this was not sufficient for addressing venereal diseases and were to take the matter up again in two months (NCCVD, 1923e). Of the existing minutes of the NCCVD Medical Committee that continued until 25th March 1926, there was no further mention of nurse training.

2.2.5 Still No Curriculum in Sight: 1932-1950

Nearly ten years later, correspondence regarding the training of nurses on venereal diseases recommenced, this time between the Central Midwives Board (CMB) for Scotland and the British Social Hygiene Council. In May 1932, the CMB (Scotland) considered giving practical teaching to pupil midwives on the subject of venereal diseases in pregnant women (Central Midwives Board for England, 1932a). They followed this up in November 1932 with a letter to the British Social Hygiene Council regarding more adequate VD training for midwives (Central Midwives Board for Scotland, 1932).

Around the same time, the CMB (for England and Wales) also wrote to the British Social Hygiene Council regarding difficulties in obtaining proper teaching for pupil midwives in England and Wales (Central Midwives Board for England, 1932b). In March 1933, the British Social Hygiene Council discussed the practical training of VD for midwives (British Social Hygiene Council, 1933a). This was followed up in 1933
with a letter to a Dr Fairburn to assist with 'a regional plan of approved places of instruction of VD for midwives' (British Social Hygiene Council, 1933b).

Twelve years later the British Social Hygiene Council wrote to the CMB:

Considering various problems in the training of nurses and health visitors... without in any way criticising their training in this respect, I should be grateful if your Board would consider whether it is sufficient to make them competent to advise on these problems... (British Social Hygiene Council, 1945).

The CMB responded to the Chairman of the British Social Hygiene Council advocating the importance of a midwife 'having a sound knowledge of VD and its social implications' (Central Midwives Board for England, 1945).

Five years later, the matter of VD training for midwives had made little progress. A letter from the Secretary of the CMB stated: 'Instruction on venereal diseases should be given in both periods of training... in the second period of training the emphasis is much more practical...' (Central Midwives Board for England, 1950). Demonstrations and visits to VD clinics were advocated.

In 1956, *Aids to the Nursing of Venereal Diseases* (Ryle-Horwood, 1956) was published by a State Registered Nurse (SRN) with a VD certificate from the RCN. The author wrote that the RCN offered courses for SRNs working or willing to work in a VD clinic for three months. However, Ryle-Horwood (1956) quoted that 'sufficient nurses would not be recruited unless a special effort was made to interest student nurses in the subject' (p. 2).
2.2.6 A Course Sustained at Last: 1970's

Despite the periodic attempts to educate nurses on venereal diseases over a seventy year period, there appeared to be no programmes that were sustained in the teaching of venereal diseases until the 1970's. In 1971, the Joint Board of Clinical Nursing Studies (now the English National Board (ENB) for Nursing, Midwifery and Health Visiting) organised a Venereal Diseases Panel to discuss a course in VD for nurses (Joint Board of Clinical Nursing Studies, 1971).

A twenty four week course for registered and enrolled nurses to fulfil a specified role in 'special clinics' for venereal and other sexually transmitted diseases was initiated (Joint Board of Clinical Nursing Studies, 1972). This course included planned teaching with clinical experience in a 'special clinic' and laboratory, with visits into the community for contact tracing. The planned teaching consisted of task orientated skill development, preparation and assisting procedures, and administration procedures. The specific nursing skills taught included taking specimens, staining and microscopy techniques, culture techniques, venepuncture, examination and interpretation of urine specimens, and making and interpreting clinical observations and taking appropriate action. The nurse was taught to prepare and assist for genital/rectal examination, proctoscopy, urethroscopy, cytology and lumbar puncture. Administration procedures included contact tracing, taking charge of the clinic and general administration procedures.

By 1979, there were four centres conducting the course with forty places available per year and one hundred and thirty one certificates had been issued (Joint Board of Clinical Nursing Studies, 1979).

In 1980, a further short course in STD nursing was planned (Joint Board of Clinical Nursing Studies, 1980). The course, later to be known as the ENB 932, was
launched in 1982 and targeted nurses with three years minimum experience in the speciality (Joint Board of Clinical Nursing Studies, 1982).

2.2.7 Researching the Training Requirements of GUM Nurses: 1987

In the mid 1980's, a study exploring the role and training of nurses in GUM found that training was generally on-the-job in addition to the ENB six month course (ENB 275) (Rogers and Adler, 1987b). In addition to this long course, the ENB continued to run a short five day update course (ENB 932). Rogers and Adler (1987b) advocated that student nurses required more teaching about STDs and that specific training and updating of nurses working in GUM clinics be instituted. These recommendations were made as the General Nursing Council had, at this point of time, laid down no specific guidelines concerning the time or content of nurse teaching in sexually transmitted diseases.

2.2.8 The Curriculum Status in 1999

In 1999, the Genitourinary Urinary Nurses Association (GUNA) surveyed ninety universities in the UK. They identified forty five universities offering over 120 courses relevant to GUM nurses. The majority of these courses were ENB certificate courses in GUM, family planning and HIV/AIDS.

2.3 Conclusion

Historical research helps us to understand the process of change and provides one way of investigating the dynamics and direction of change (Rafferty, 2000). Researching the historical contribution nurses have made to the field of sexually transmitted infections offers an understanding of the process and politics of innovation and change towards advanced GUM nursing practice.
This historical review has shown how milestones in the evolving role of the nurse have often correlated with the changing epidemiology of STIs and subsequent demand for services and trained personnel. For instance, the rise in STIs following WW1 and WW2 correlated with calls for the greater involvement of nurses in STI control. Again, as the incidence of STIs rose in the late 1960’s and 1970’s, so too did the greater involvement and broadening role of the nurse.

In spite of the fact that the many texts and policies reiterated over time what nurses could and could not do, there has nonetheless, been a repeating pattern in which nurses have been called upon to take on new roles and responsibilities during times of crisis and need. When existing systems have failed to retain control over epidemics, the nursing profession has been recruited to become more involved, take on new tasks and assume enhanced roles.

In the final years of the historical review, the beginnings of this pattern have become apparent once again. Recent Public Health Laboratory Service (PHLS) reports indicate that GUM clinics are experiencing increasing workloads associated with the rising numbers of STI diagnoses and the provision of other sexual health services, such as HIV testing, counselling and advice (PHLS, 2000; PHLS, 2001). Despite such warnings, some of the final references in the historical review illustrate how the medical profession continues to be a barrier to the progression of the nurses role in GUM services (Kahl, 1983; Allen and Hogg, 1993; Weatherburn et al., 1997). This underlying theme of professional domination is not unique to GUM. Nursing has often been seen as subordinate to, and dominated by, the medical profession and for many years nurses practising in direct contact with patients have had little or no authority over their work (Wainwright, 1994).

With regard to the history of nursing education and training, efforts to initiate forums for educating and training nurses about sexually transmitted infections have
fluctuated over the past eighty five years. This has occurred despite the varying levels of commitment from individuals, professional nursing bodies and other national organisations. From the cited evidence, there appears to have been a number of contributing factors to suggest why no campaign was successful in securing a sustained programme of STI education until the 1970’s. First, lack of momentum, continuity and bureaucracy appeared to be key to the delay in initiating education programmes. In the surviving NCCVD correspondence, there were often lengthy gaps between raising the issue of nurse education, making decisions and taking action. Although it was difficult to pinpoint reasons for these delays from the evidence, it is likely that the lack of momentum and continuity in particular, could have resulted from the other priorities that organisations, such as the NCCVD, were committed to addressing during recorded STI epidemics. Second, after decisions were made it appeared that the capacity to follow through with appropriate action was simply not available. For example, in 1916 when the NCCVD suggested it was desirable for nurses to be educated about the venereal diseases, it took some time before they decided what content should be included in the education proposals and who should conduct the education. Finally, nurses themselves proved to be a barrier to further education. The stigma within the nursing profession, as suggested by Clarkson & Cantab (1922), was one example, and the complacency of the General Nursing Council who suggested physiology of the reproductive system in the nursing training syllabus was adequate, yet another. Ryle-Horwood (1956) also quoted that nurses’ interest in the subject needed to increase in order to improve recruitment into training programmes.

Finally, after nearly seventy years of attempting to introduce and maintain nursing education for the control and management of STIs, the Joint Board for Clinical Nursing Studies (now the English National Board) initiated a number of courses during the 1970’s. These courses still exist today. However, with relevance to advanced GUM
nursing care, there is little evidence to suggest that the ENB course curricula have been modified to reflect the recent changes to GUM nursing practice. One explanation for this may be a result of the poor understanding of the process of nurse-led care in GUM.

This historical review of nursing roles and education therefore serves its place in the context of this thesis. The importance of acknowledging history should not be underestimated. Unless sound evidence is produced, followed by effective dissemination and lobbying, there is the possibility that the pattern of nurse utilisation seen over the past century will continue to emerge to a point in which the nurses’ role will only develop and be accepted through crisis and necessity. Without appropriate action now, it could take another STI epidemic before the full potential of today’s GUM nurse is truly integrated into services.

The potential of nurses as quasi-independent practitioners to manage people with STIs has been acknowledged (Allen and Hogg, 1993). However, for better integration and utilisation of nurses in the management of STIs, it is clear that attitudes need to change and old demarcations specifying what nurses can and cannot do need to be broken down. Empirical evidence for the effectiveness, safety, cost and service user acceptability of nurses performing new roles will assist in the wider acceptance and utilisation of the skills that GUM nurses possess.
Chapter 3

Nurse-Led GUM Care: An International & National Account

Chapter two presented the historical contribution that nurses have made to the control of sexually transmitted infections in this country. This provided the context and background for the development of new, advanced GUM nursing roles. However, the number and type of new nurse-led clinic developments in this country have not been defined. Nurse-led GUM services are known to exist in other countries, but their relevance to the UK has not been explored. This chapter therefore provides a current account of nurse-led GUM clinics from both an international and national perspective. The aim of researching both perspectives was to compare and contrast nurse-led developments in other countries and settings with those located in England. The findings of this chapter will also have bearing on the generalisability and recommendations that result from the study reported in this thesis.

The chapter commences with an outline of nurse-led care in three GUM clinics in three different countries. This data was collated during a Florence Nightingale travel scholarship and is presented as individual case studies. The second section of the chapter presents the results of a postal survey of nurse-led clinics across England. The chapter concludes with clear reasons why evaluation of nurse-led GUM services in the UK is required.
3.1 International Experiences of Nurse-Led Clinics

A study tour to explore the models of nurse-led care in three different countries was undertaken in 2000. Three centres were visited: Amsterdam STI Clinic in The Netherlands, Harbourview STI Clinic in Seattle, USA and the Sydney Sexual Health Centre in Australia. These sexual health services were chosen for the study tour as it was known that they all had well-established models of nurse-led care. Further to this, each centre had initiated nurse-led clinics for different reasons, had different approaches to care and different mechanisms to monitor care. Although the sites visited did not represent the state of services within the respective country visited, they did nonetheless explore approaches to nurse-led care existing within different health care systems.

Amsterdam was the only clinic where English was not the first language spoken. This is why the detail of information presented here is less than that of the other two clinics visited.

3.1.1 Amsterdam

Background to service

There are an estimated 110,000 sexually transmitted infections (STIs) in the Netherlands each year. These are managed in various ways. STI control is largely decentralised with an estimated 80% of all STIs being diagnosed and managed by general practitioners. Approximately 10% of STIs are managed in the six open access STI clinics, open access teaching hospital clinics and community health services. The final 10% are managed in dermatology clinics, gynaecology clinics, family planning clinics and targeted services for gay men and prostitutes.

The Amsterdam Main STI clinic (GGD) originated in the 1920's as an exclusive service for seamen. In the 1940’s, the clinic expanded its remit to include female
prostitutes before it became an open access clinic for any person. GGD is now the only free, open access STI clinic in central Amsterdam. In 1999 the clinic saw 17,400 clients.

Nurses at GGD became the first-line, primary care providers during the 1970’s as a response to the increase in STIs, resulting high workload and shortage of trained STI doctors. Nurse-led clinics have been in place ever since.

Process of care

The nurses’ role in the management of STIs is a comprehensive one. Each nurse coordinates all aspects of care apart from ‘difficult’ cases, such as pelvic pain, genital warts or genital herpes. In these cases a doctor is called to confirm the clinical diagnosis and/or perform a bi-manual pelvic examination. Chaperones are only used at the request of patients and in appropriate situations, such as sexual abuse.

Each consultation room is set up for the examination of both men and women to enable each patient to have all of their care managed from one room. All details of the patient - their sexual history, the tests performed, the physical examination, microscopy, diagnosis and treatment - are entered directly onto a computer during, or after, the consultation.

Once the nurse has taken the sexual history, performed the examination and taken the appropriate tests, a technician performs the microscopy in an onsite laboratory. Once the technician has entered the results on to the computer, a doctor reviews these and enters the diagnosis and treatment accordingly. The nurse will take this as the named prescription for treatment and will give the patient their results and medication as required. Partner notification, pre-HIV test discussion and health promotion work is primarily carried out by the nurse seeing the patient.
The boundaries of care for the nurses are set by:

1) *Legal restrictions* e.g. nurses cannot legally prescribe in The Netherlands.

2) *Evolved process* – e.g. boundaries with respect to counselling clients are discussed during group supervision sessions. Knowing when to refer a client may represent a boundary of care.

3) *Clinic protocol* – agreed at local level e.g. clinic policy states that bi-manual pelvic examination is to be performed by a doctor.

The medical director sets the guidelines/protocols of care for medical staff and a ‘quality management’ nurse has developed protocols for the nursing staff in conjunction with the medical director and clinic co-ordinator.

**Role of doctor**

There are no routine doctor-led clinics. The doctors’ role is to diagnose, prescribe treatment and consult on difficult cases. Doctors only see patients at the request of a nurse.

Junior doctors rotate through the GUM clinic every six months. The nurses provide some of their training. The new doctors learn how to take sexual histories and conduct the consultation by observing the nurse-led clinics.

**Role preparation & continuing professional development**

Although STI experience is not an essential prerequisite for employment at GGD, degree level nurses or nurses trained as Social Nurses (public health focus and counselling, partner notification roles) are preferred. When a new nurse is employed at GGD, they commence an intensive eight week in-house training programme. Two clinical teaching sessions are conducted each week to facilitate training and continuing
professional development in addition to one-to-one teaching and mentoring of new nurses. Mentoring continues throughout the initial few weeks until the new nurse is confident and competent in their role.

At present there is no competency accreditation process for practitioners, although this is currently being addressed.

Monitoring and evaluation

No evaluation comparing nurse-led and doctor-led care has been conducted.

### 3.1.2 Seattle

#### Background to service

The 1970's saw a significant shift in the type of clinician providing care in North America. Physician Assistants (PAs) emerged as a new class of health care provider and nurses were able to take on extended roles as Advanced Registered Nurse Practitioners (ARNPs).

In 1973, a satellite STI service was initiated at Harbourview Medical Centre and 'mid-level' clinicians (PAs and ARNPs) were employed to staff this service. Seven years later, Harbourview became the major STI service for Seattle-King County Department of Public Health (SKCDPH). Since then, mid-level clinicians have been the primary providers of STI care.

The Harbourview STI Clinic continues to be the chief public STI clinic in Seattle-King County. It has around 13,000 attendances per year. Staff are employed by University of Washington and the clinic is affiliated with the Seattle STI/HIV Prevention and Training Centre which is one of ten national training centres funded by the Centres for Disease Control and Prevention (CDC) to train health care providers in STI management.
The clinic provides a mixture of walk-in and booked appointments. All treatments including wart treatment are provided onsite. All results, apart from HIV, are given over the phone, although (perceived) ‘low risk’ clients can phone in for their HIV results. Clinical services are provided on a sliding scale of payment so that no one is refused care. Young persons and ‘high risk’ persons automatically receive free care and vaccinations.

Process of care
Seattle-King County Department of Public Health has developed STI Clinical Practice Guidelines for their staff (Marrazzo et al., 1998). These were developed after several months of careful deliberation, literature review, and consultation and reflect the 1998 STI Treatment Guidelines published by the CDC (Division of STD Prevention, 1998). Whenever a patient is evaluated or treated for a STI in a manner not explicitly defined in these guidelines, the reason needs to be clearly documented in the patient’s medical record.

PAs and ARNPs manage all patients unless they identify a problem beyond the scope of their practice. Only then is a doctor called to assess the patient. The PAs’ and ARNPs’ role is extremely autonomous and both are able to diagnose and prescribe within the confines of their respective professional licences. However, in Washington State, PAs are required to have any treatment order countersigned by a doctor. Unlike PAs, ARNPs are able to work as independent practitioners and do not require medical supervision. Apart from these professional licensing differences, ARNPs and PAs at Harbourview STI clinic work in exactly the same manner.

Each clinician sees up to twelve patients per day. They each work from an office equipped with an examination couch and the relevant examination and specimen collection tools. The patient can therefore be managed comprehensively in one room.
Appointment time slots are allocated according to the gender and sexuality of the patient. Women and homosexual men are given sixty minutes and heterosexual men thirty to forty five minutes.

Each clinician works autonomously to provide comprehensive care for each patient. They are not chaperoned, although patients can request the gender of their practitioner. A standardised proforma is used to document the sexual history, physical examination, specimens taken and treatment provided. This data is later entered into a database that can be used for audit and costing purposes.

Health promotion plays an important part of the clinician-patient consultation although clinicians have direct access to Disease Intervention Specialists (DIS). The role of the DIS includes partner notification, post-HIV test counselling and patient education.

Role of doctor

A doctor is available throughout the day for consultation of ‘complex’ cases and cases outside the clinic guidelines. The other main role of the doctor is to review and countersign the clinical records.

Role preparation & continuing professional development

There are four different levels of nursing in Washington State:

1) **Nurse Assistant** – 3-6 month training

2) **Licensed Practical Nurse** – one year training

3) **Registered Nurse** – 2-4 year training with a standardised state board exam.

4) **Advanced Registered Nurse Practitioner** – Registered Nurse with Masters level or training in specific area. The ARNP course is usually a programme of at least one year didactic teaching followed by one year of supervised practice.
before they can obtain a state licence as an ARNP. Once licensed as an ARNP, clinicians are required to complete an extra pharmacology course to prescribe and a further narcotic course if they wish to be licensed to prescribe narcotics.

For ARNPs and PAs to become mid-level STI clinicians, prior STI experience is not necessarily required. New staff commencing employment at Harbourview clinic undertake training at the Seattle STI/HIV Prevention and Training Centre in conjunction with on the-job practical tuition.

To maintain registration, ARNPs need 30 category one continuing medical education (CME) points, 15 pharmacology and 50 points for their specific area every two years. This can consist of in-house training sessions, meetings and presentations in addition to external courses and conferences. Every month there is a STI research programme in which the staff can attend.

**Monitoring and evaluation**

Individual performance is monitored in two ways. As mentioned, PAs are required to have their clinical records counter-signed by a doctor. For equity, the ARNPs also have their clinical records reviewed. This provides a twofold purpose of ensuring that (1) medicolegally, clinicians, and ultimately the clinic, are covered and (2) any poor performance is identified and discussed with the clinician involved.

A yearly performance appraisal is also conducted so that clinicians are able to see where they rank relative to their colleagues within a staff performance table. The performance tables highlight a number of factors, such as the number of patients seen, the number of patient complaints, the number of false negative/positive microscopy diagnoses, the number of swabs taken, whether they have been neglecting to take rectal and throat swabs from gay men etc. This information is captured from the data that has
been electronically entered from the clinical records that includes a unique clinician identifier code for each patient seen.

No known evaluations of mid-level clinicians (ARNPs and PAs) compared with doctors have been completed at Harbourview clinic. However, the quality assurance audits indicate the success of ARNP and PA care.

Perception of nurse-led clinics at Harbourview Clinic
Anecdotes from Harbourview Clinic staff regarding the perceived pros and cons of ‘mid-levels’ (ARNPs and PAs) when compared with doctors were reported as follows:
1. Because mid-levels are required to work within guidelines, they tend to provide a consistent standardised level of care. A disadvantage is that there is a higher risk of patients ‘falling through the net’, as mid-levels do not have the extensive medical training required to recognise some abnormalities.
2. Because mid-levels see the patient from start to finish, they are able to provide continuity of care. Doctors are more likely to resent performing tasks, such as swab taking, and end up delegating these jobs, therefore breaking the continuity of care.
3. Cost – it is cheaper to employ mid-levels although some mid-levels on their highest increment have comparable wages to junior doctors.
4. Reduced staff turnover – doctors are less likely to remain purely as STI care providers. The disadvantage of reduced staff turnover is that without a turnover of staff, ‘new blood’ does not enter the service.

3.1.3 Sydney
Background to service
The Sydney Sexual Health Centre (SSHC) was established in 1933 and was until 1971, only open to male patients. SSHC currently sees around 15,000 patients/year.
Twelve years ago the role of the nurse was limited to that of 'doctors' assistant' until a proactive nursing team and a supportive consultant physician gradually developed the nursing role. In 1989, SSHC piloted nurse-led clinics for follow-up patients, vaccinations and results. Between 1992 and 1993 these clinics progressed to enable the nurses to consult asymptomatic male and female patients requiring STI screening. The formulation of policies and guidelines for practice followed.

All staff (medical and nursing) work from the same clinic guidelines. All procedures have been standardised with an extensive list of policy and procedural guidelines related to the performance of each specific task. These tasks range from taking an anal swab to the diagnosis and management of each specific STI. No separate practice guidelines have been developed for the nurse-led clinics although there are sections of the guidelines that are specific to nurses and sections specific to doctors.

Process of care

Unlike Amsterdam and Seattle, nurses at SSHC take on different roles throughout the week. Each nurse rotates through these roles for half-day sessions:

1) One nurse triages patients that present without an appointment. The triage nurse explains his/her role to the patient and the need for a brief assessment that enables the patient to be streamlined to an appropriate service provider. The reason for presentation and the clinic guideline for ‘delegation of clinical practice’ guide the nurse triage so that appropriate referral to a nurse, doctor or counsellor can be made.

2) One nurse works on the telephone information line. The nurse answers all telephone queries in addition to providing telephone results for patients.

3) One nurse works in the specialised clinics that are run throughout the week. These include Thai and Chinese clinics, HIV eye clinics, colposcopy clinics and gynaecology clinics. In the Thai and Chinese clinics the nurse works with a doctor,
interpreter and multi-cultural health education officer. In the colposcopy clinic the nurse plays more of a co-ordinator and assistant role to the colposcopist.

4) Two nurses each have their own list of booked nurse-led clinic appointments. Urgent cases are seen in between the booked appointment slots. The role of the nurse in the nurse-led clinics is discussed below in detail.

In the nurse-led clinic, the nurse works in a ‘Nurse Practitioner’ capacity to co-ordinate the comprehensive management of patient care. However, the formalising of Nurse Practitioners within the nursing hierarchy has only recently undergone legislation in New South Wales. This followed on from the New South Wales nurse practitioner pilot project reported in December 1995 (NSW Department of Health, 1996).

Each nurse provides care from one room containing an examination couch and all relevant specimen collection equipment. The nurses manage the care of asymptomatic patients. The boundaries of nursing care are set out in a general policy statement for the ‘Delegation of Clinical Practices’. This is a document that acts as a general guideline for the roles that nurses are able to perform. It defines the limitations of clinical practice for nurses by stating those patients who must have either involvement from, or be seen by, a medical officer.

Role of doctor

The doctors work in a similar fashion to the nurses. They also have a mix of booked appointments and non-appointments. The main difference is that the doctors see the walk-in patients who are symptomatic. The doctors also provide prescriptions and support for nurses when problems are encountered beyond the nurse’s clinical expertise. The doctors are not chaperoned by nursing staff. They work independently to provide
comprehensive care for the patients that they see. This includes the doctors performing their own venepuncture, HIV pre-test discussions and specimen collection.

Role preparation & continuing professional development

Although preferred, there are no specific education or experience pre-requisites for employing new nursing staff at SSHC. Once employed, new nursing staff will have a minimum of two weeks orientation. During this time the nurse observes clinical sessions and commences a competency accreditation process. A nurse cannot perform patient consultations unobserved until they have been accredited. The accreditation process is based on the individual’s needs and previous experience.

New staff must complete the Family Planning Nurse Practitioner course. This course consists of three weeks of theory and fifty hours of clinical practice. New staff may also attend the six month Post Registration Nursing Course in Sexual Health and Venereology at the Sydney Hospital. The theoretical content of the course is presented in a series of four, two week study blocks integrated with three periods of clinical practice totalling eighteen weeks. Other relevant courses include HIV infection and disease course, family planning nurse practitioner course in sexual and reproductive health, family planning women’s health nurse course and a graduate certificate in health studies.

SSHC provides a number of continuing professional development opportunities for the nursing staff. Each Wednesday morning the clinic closes to allow for meetings, guest speakers and in-service training. Each nurse is also allocated a minimum of two hours per week project/research time in addition to one hour per week non-clinical time. This is a self-directed learning period. Staff are encouraged to read relevant journals and text books from the department library. Some of the nurses are involved in professional organisations so they can use this time for administration duties associated with such
organisations. External education/training opportunities are negotiated with the Clinical Nurse Consultant and Nurse Unit Manager and to maintain Clinical Nurse Specialist status, each CNS is required to conduct an annual project/audit. The nurses also participate in a fortnightly Balint group. The aim of this is to provide clinical and professional supervision and support. Each session is facilitated by a psychologist from outside the department and involves two nurses presenting a clinical case to the group. The nurses also conduct a journal club where a nurse presents a critique of a current journal article or case presentation.

Monitoring and evaluation

The SSHC team has developed procedural guidelines and policies on quality assurance (QA) of medical records. All new staff are placed in the continual medical record audit system until they have been accredited to ‘QA’ their own files and become part of the random audit system (this requires attainment of <5% error rate on patient record audit). Each week the departmental data manager retrieves a random 10% of files seen by each doctor and nurse for the one week period, four weeks previously. Each week the doctor/nurse assigned to QA will review these files.

The QA process involves assessing medical history taking, physical examination, appropriate investigations, the rationale for the management approach taken, adherence to clinic policy and procedures and completeness of the medical record e.g. public health unit notification, reply to referral letter. The QA doctor/nurse will complete a form detailing the outcome of the QA process that is then returned to the individual staff member for feedback and further discussion if required.

No formal evaluation has been conducted regarding the development of nursing roles at SSHC although the nurse-led clinics are regarded as an effective model of care (Anderson and Corkhill, 1994).
Perception of nurse-led clinics at SSHC

An informal group discussion with the SSHC nurses revealed the following:

- The current model of comprehensive care provides a structured and standardised approach to care
- The level of medical support provides a ‘safe’ process. The only problem is when needing to access a doctor when s/he is seeing their own patients
- Efficient quality assurance procedures continually challenge individuals and are generally felt to be of help
- The current model of care enables nurses to provide a holistic approach to care
- Nursing staff are well supported by policies and procedures
- The nurses feel that they have good working relationships with each other for support
- The Balint Group facilitated by an external person is felt to be a good support mechanism
- Future developments anticipated include more outreach work and more involvement in teaching

Perception of nurse-led clinics from medical staff:

- Nurses more conscientious and better at documentation
- One problem is that because there is increased job satisfaction, the nurses stay longer and therefore training opportunities for new nurses is reduced. The introduction of a 12-month training post aims to increase the pool of trained STI nurses in Sydney/NSW.
- The dynamics of the doctor-nurse professional relationship is very different to that of doctor-nurse relationships in other areas of health care provision. The nurses at SSHC are more assertive and autonomous in their roles and new medical staff can
find this a problem, particularly when a nurse approaches a doctor for a prescription when the doctor has not seen or examined the patient.

- The doctors do not see patients re-attending for results which leads to decreased continuity in care from the doctors’ perspective

### 3.1.4 Summary

Table 1 summarises the key similarities and differences between the three services visited. The differences in role preparation, ongoing professional development and limitations of practice are likely to be a result of the country and state specific legal and professional frameworks for nursing practice. For instance, in the USA the title ‘nurse practitioner’ is protected through professional regulation, in Australia, nurse practitioners are currently undergoing professional regulation and in Holland, recognition and regulation of advanced practice roles are at a level similar to the UK. Of the three clinics, the nurse practitioners in Seattle were able to perform the most extended roles. For example, they were able to diagnose and manage pelvic inflammatory disease without the intervention of a doctor, whereas nurses in the other two clinics could not. This again may be a reflection of the professional regulation, training and recognition that is in place in Washington State.

The study tour enabled the experiences of three different services in three different countries to be explored. The mere existence of nurse-led GUM care in Amsterdam and Seattle for over twenty-five years and Sydney for over ten years makes a positive statement about the concept of nurse-led sexual health care. The extensive experiences of nurses as first-line, comprehensive care providers in the three different settings should not be ignored even though none have ever conducted any formal studies, or have known of any studies, to support the introduction and continuation of nurse-led clinics. Although it is important for UK services to learn from international
colleagues, it is still, nonetheless, important to demonstrate that nurse-led GUM care in the UK is safe, acceptable and cost-effective.
<table>
<thead>
<tr>
<th>Role pre-requisites</th>
<th>Role preparation and ongoing professional development</th>
<th>Limitations of nursing practice</th>
<th>Role of doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amsterdam</strong></td>
<td>Registered Nurse. Degree level or Social Nurse training preferred STI experience not essential</td>
<td>On the job training/tuition for new staff Twice weekly clinical teaching sessions STI Foundation course available. Flexible CPD arrangements negotiable with clinic co-ordinator.</td>
<td>Local clinic guidelines state when referral to doctor necessary. Doctor required to perform pelvic exam and see any warts/HSV and other conditions needing clinical confirmation. Doctor prescribes all medication using the electronic records system once they have viewed the microscopy results on the computer. Limitations of ARNP practice defined by state licensing. Comprehensive patient care within the local clinic guidelines allows ARNP to perform all aspects of care including bi-manual pelvic examination, diagnosis and prescriptions. ARNPs are licensed in Washington State as independent prescribers but all prescriptions are co-signed, as are the Physician Assistants for equity and quality assurance reasons. ‘Delegation of Clinical Practice’ guideline state those patients who should be seen or managed by a doctor. Nurses cannot prescribe in NSW but can administer selected treatments using a Standing Order that requires a medical co-signature within 24 hours.</td>
</tr>
<tr>
<td><strong>Seattle</strong></td>
<td>Advanced Registered Nurse Practitioner licensed (ARNP) (2yr post RGN training) STI experience not essential</td>
<td>On the job training/tuition in addition to a training course at the Seattle STI/HIV Prevention and Training Centre is available for new staff. Specific education credits are required every 2 years to maintain ARNP licence. Access to monthly STI research meetings in addition to in-house meetings, seminars &amp; training and external conferences &amp; training</td>
<td>Available if clinical confirmation of unusual cases is requested by ARNP. Do not co-ordinate their own list of patients</td>
</tr>
</tbody>
</table>
3.2 Nurse-Led Care in England: A national survey

3.2.1 Introduction

In 1998, the Genito-Urinary Nurse Association (GUNA) conducted a postal survey devised to elicit data on staffing levels, grading and work roles of nurses in GUM clinics across the UK (Sutton et al., 1999). They found that 70% (107/152) of responding clinics conducted ‘nurse-led clinics’. Unfortunately this survey did not define nurse-led clinics. The results therefore captured a broad range of nurse-led clinics including specific task orientated practices and procedures co-ordinated and performed by GUM nurses, such as nurse-led genital wart treatments and nurse-led vaccination clinics.

This thesis concentrates on nurse-led clinics, in which the nurse co-ordinates the first-line, comprehensive care of patients presenting with sexual health conditions and issues. As discussed in chapter one, this type of nurse-led clinic can be termed ‘comprehensive care’ or ‘total patient management’ nurse-led sexual health clinics. In these clinics the nurse autonomously manages a caseload of patients with input from medical staff, only when the nurse reaches his or her limitations of nursing practice. The nurse takes on roles, such as eliciting the sexual history, performing the examination, making a diagnosis and supplying selected treatments, roles that in the past were mostly performed by doctors.

The number of GUM services conducting comprehensive care nurse-led clinics was not known. A postal survey was therefore conducted to elicit information regarding the growth of comprehensive care nurse-led clinics, the impetus for initiating such services, nursing roles undertaken, protocol/guideline development, medical support, monitoring and evaluation, educational pre-requisites and continuing professional development (CPD) opportunities. It was anticipated that the results would provide background data to support this thesis.
3.2.2 Methods

The survey sample consisted of all of the 209 Genitourinary Medicine clinics across England identified from a Communicable Disease Surveillance Centre (CDSC) database. This database represented GUM services that complete routine STI case surveillance data (KC60) for the CDSC (i.e. all GUM clinics located in England).

The postal questionnaire (Appendix 1) consisted of seventeen closed response questions presented within three sections. The first section identified the different types of nurse-led clinics being conducted in the respondent’s service. Respondents were then asked to continue the questionnaire only if their service conducted comprehensive care nurse-led clinics. A definition and example was provided. Those not conducting these clinics were asked to return the questionnaire at this point.

The second section of the questionnaire focused on comprehensive care nurse-led clinics only. A final section offered respondents the opportunity to make comments about any aspect of the questionnaire.

The questionnaire was piloted for content and layout with thirteen members of the Forum for Advanced Nursing Practice in GUM, a London based network of nurses affiliated with GUNA. Following alterations, the questionnaire was sent to the charge nurse at each of the 209 GUM clinics with a cover letter explaining the purpose of the study. Although not all clinics have a charge nurse, it was assumed that someone of equivalent status would eventually receive and complete the questionnaire. To maintain anonymity and offer respondents an opportunity to freely describe clinic practice patterns, we assured respondents that individual clinic details would not be linked to responses presented here. As an incentive to return the questionnaire, a tick-box was included at the end of the questionnaire offering all respondents the opportunity to receive a copy of the survey results. A pre-addressed envelope was enclosed for the return of the completed questionnaire.
Of the 209 questionnaires sent, there was an initial response of 66% (140/209). To improve the response rate, a second questionnaire and cover letter was sent to the non-responders. A further fifty questionnaires were returned giving an overall 91% (190/209) response rate. One questionnaire was returned stating that the clinic provided HIV outpatient services only and that no GUM services were provided onsite. This questionnaire was removed from the analysis. Incomplete and ambiguous questionnaire responses were clarified following a telephone call with the respondent.

The completed questionnaires were single entered onto a database and analysed using SPSS version 10.

Ethics committee approval was not necessary for this questionnaire. However, the project was registered with the North Central London Community Research Consortium.

3.2.3 Results

Of the 190 respondents, 150 (78.9%) conducted some form of nurse-led clinic. One hundred and forty one (74.2%) provided nurse-led wart treatment clinics, 99 (52.1%) test-of-cure clinics, 85 (44.7%) results clinics, 66 (34.7%) vaccination clinics, 65 (34.2%) cervical cytology clinics and 21 (11.1%) provided some other type of nurse-led service. These included nurse-led clinics for HIV testing, contraception and erectile dysfunction assessment.

Forty-four (23.2%) of the responding GUM clinics reported to provide comprehensive care nurse-led clinics. These responses were divided into three categories. Thirty one (16.3%) comprehensive care nurse-led clinics were part of the routine GUM services. Four (2.1%) services conducted comprehensive care nurse-led clinics in specific settings: one in a termination of pregnancy service, two in off-site young person clinics and one in the context of a recurrent candida study. Nine (4.7%)
GUM clinics provided comprehensive care nurse-led clinics on an ‘informal’, when required, basis. This meant that a senior nurse was able to provide comprehensive care nurse-led care when, for example, there was no doctor present in the clinic, when the clinic was busy, or when there were not enough female doctors available. Of the nine respondents providing ‘informal’ nurse-led services, four did not complete the remaining questions of the questionnaire.

Of those who did complete the second component of the questionnaire (n=40), thirty six (90%) comprehensive care nurse-led clinics have been initiated since 1995. Figure 1 displays the growth of comprehensive care nurse-led clinics. The two comprehensive care nurse-led clinics existing for over 40 years were military based GUM services.

**Figure 1 - Establishment of comprehensive care nurse-led clinics to end of July 2000**
Respondents were asked the reason(s) why their GUM service initiated comprehensive care nurse-led clinics. Most respondents provided more than one reason. Fifteen (37.5%) clinics were started as a response to government initiatives (e.g. junior doctors’ hours reduction, waiting time initiatives), 26 (65%) as a response to professional nursing developments (e.g. UKCC “Scope of Practice”), six (15%) as a response to purchaser encouragement, 14 (35%) as a means of retaining staff or attracting new staff, 11 (27.5%) for perceived cost savings, 31 (77.5%) for staff development, four (10%) to keep up with trends and 25 (62.5%) respondents provided other reasons, including not enough doctor appointments; to cope with workload; to provide holistic patient care; to cover absence of doctor or lack of female doctors; to formalise (nursing) practice that was already occurring; and, inability to recruit clinical assistants.

There was little consistency in the titles of the practitioners providing comprehensive care nurse-led clinics. Fifteen (37.5%) respondents used the title Nurse Practitioner, seven (17.5%) used Clinical Nurse Specialist, four (10%) used Specialist Nurse and there were 14 (35%) who used generic nursing titles such as Staff Nurse, Sister and Senior Staff Nurse. Sixteen (40%) respondents had only one nurse providing comprehensive care nurse-led clinics. Nine (22.5%) had two nurses, six (15%) had three nurses and nine (22.5%) had four or more. There was a mixture of grades that nurses conducting comprehensive care nurse-led clinics were employed at. Eight (20%) clinics employed nurses at F-grade only, eight (20%) at G-grade only, six (15%) at H-grade only and one (2.5%) at I-grade. Seventeen (42.5%) services had nurses working at different grades ranging from D to I grade. One clinic paid the nurses on an E-grade when a doctor was present and an F-grade when no doctor was present.

When asked what the minimum clinical experience required for nurses working in comprehensive care nurse-led clinics was, 22 (55%) required 2 years or more GUM experience, six (15%) stated one to two years of GUM experience, two (5%) stated less
than one year GUM experience, three (7.5%) didn’t know and seven (17.5%) stated other levels of experience were required. Examples of other levels of experience included five years G-grade minimum, five years GUM experience with at least two years at F-grade or above, relevant sexual health experience and as seen competent by supervisor.

Thirty four (85%) services also requested minimum educational requirements. Twenty eight (70%) required an ENB GUM course, 19 (47.5%) an ENB family planning course, 19 (47.5%) an ENB HIV/AIDS course and 13 (32.5%) requested that the applicant have, or be working towards, a degree or higher. Three (7.5%) stated other educational requirements including the ENB teaching course and DMS (military) GUM course and exam.

Clinics were asked about the processes involved in their respective comprehensive care nurse-led clinics. Five (12.5%) clinics provided comprehensive care nurse-led clinics for men only, four (10%) for women only and 31 (77.5%) for both men and women. The aspects of care provided by nurses conducting comprehensive care nurse-led clinics are detailed below in Table 2.
<table>
<thead>
<tr>
<th>Aspect of care</th>
<th>Number of services (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking a sexual history</td>
<td>40 (100)</td>
</tr>
<tr>
<td>External genital examination</td>
<td>39 (97.5)</td>
</tr>
<tr>
<td>Vaginal examination (female only)</td>
<td>32 (91.4)</td>
</tr>
<tr>
<td>Pelvic examination (female only)</td>
<td>4 (11.4)</td>
</tr>
<tr>
<td>Proctoscopy (male/female)</td>
<td>21 (52.5)</td>
</tr>
<tr>
<td>Specimen taking</td>
<td>39 (97.5)</td>
</tr>
<tr>
<td>Blood tests</td>
<td>39 (97.5)</td>
</tr>
<tr>
<td>Microscopy</td>
<td>34 (85)</td>
</tr>
<tr>
<td>Provision of results</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Health promotion discussion</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Partner notification</td>
<td>31 (77.5)</td>
</tr>
<tr>
<td>Provision of oral contraceptives (female only)</td>
<td>20 (57.1)</td>
</tr>
<tr>
<td>Supply of medication</td>
<td>37 (92.5)</td>
</tr>
</tbody>
</table>
In eleven (27.5%) of the clinics, nurses worked from specific nurse-led protocols, another 11 (27.5%) used the same protocols as the doctors, 17 (42.5%) used a combination of nurse and doctor protocols and one (2.5%) service reported to have no specific protocols at all.

With regard to the supply of medication, three (7.5%) services required all patients to see a doctor for prescribing, in 16 (40%) services the nurse requested a doctor to prescribe before supplying the medication, nine (22.5%) used group protocols (now known as patient group directions), ten (25%) used a combination of doctor prescribing and group protocols and in two (5%) services the nurse supplied the medication and then asked the doctor to sign the prescription at a later date.

In 24 (60%) services there was always a doctor available onsite when comprehensive care nurse-led clinics were being conducted, in six (15%) services there were times when there were no medical staff onsite (i.e. no medical cover at all) and in ten (25%) services there were times when there were no medical staff onsite but a medical officer was available to provide advice by telephone.

Only 11 (27.5%) services had conducted any form of audit/research to monitor or evaluate comprehensive care nurse-led clinics. Such projects included audit of documentation, patient satisfaction questionnaires, comment cards and ongoing collation of nurse-led activity.

When asked about continuing professional development (CPD) opportunities for nurses working in comprehensive care nurse-led clinics, 30 (75%) respondents had access to regular in-house training, 26 (65%) had access to a range of ENB courses, 15 (37.5%) had access to a range of degree courses and 10 (25%) had access to other opportunities, such as specific study days and conferences. Four (10%) of the services stated that there were no specific educational/professional development opportunities offered to the nurses working in their comprehensive care nurse-led clinics. When the
respondents were asked if they thought there was a need for an advanced GUM practice course focusing on nurses working in comprehensive care nurse-led clinics, 33 (84.6%) said yes, four (10.3%) said no, two (5.1%) did not know and one respondent did not answer the question.

3.2.4 Discussion

This survey attempted to distinguish between the various types of nurse-led clinics and focus on comprehensive care nurse-led clinics. The high response rate of 91% would suggest that the results are representative of GUM services across England. Such a response to a postal survey may also indicate the level of interest in this area of GUM nursing.

The survey showed a rapid growth of comprehensive care nurse-led clinics since 1995. This generally reflects the proliferation of new nursing roles seen across the UK in the last ten years (Read et al., 1999).

There was little consistency in the job titles and grading of nurses conducting comprehensive care nurse-led clinics. This again reflects the national nursing situation (Briggs, 1997; Read et al., 1999; Ibbotson, 1999). Nursing regulatory bodies have yet to define what constitutes advanced nursing practice and attach titles and pay awards that reflect the level of nursing practice. Following a UKCC consultation on its proposals for regulating nurses who are working at 'higher levels of practice', they concluded that further detailed work is required on definitions, and the standard/descriptor of higher level practice (United Kingdom Central Council for Nursing, 1999). Once defined, the job title of GUM nurses working in advanced roles may change to a more consistent and recognised one. In the interim, the GU Nurses Association have convened a working party to recommend standards for GUM nurse practitioner, clinical nurse specialist and nurse consultant job profiles (Genito Urinary Nurses Association, 2001).
It was encouraging to find that almost two thirds of the survey respondents requested that nurses providing comprehensive care nurse-led clinics have two years or more GUM experience and nearly 85% had some form of minimum educational requirement. However, this was not the case for all services. One case was described whereby nurses providing comprehensive nurse-led care had less than one year GUM experience with no specific educational preparation. Although senior nurses were always available to provide clinical advice for the lower grade nurses, it is still nonetheless, a concern that nurses with limited GUM experience were able to perform advanced practice roles. In addition, the majority of courses listed by respondents do not truly prepare nurses for advanced GUM practice. The courses offered by the ENB and associated institutions have been slow to change their curricula to reflect recent changes in GUM nursing practice and nurse practitioner degree pathways tend to have a generalist rather than specific focus. Unless nurse practitioner programmes are able to offer the flexibility of teaching, mentoring and assessment in the GUM setting, they risk failing to provide appropriate experience in applying the core skills and processes of patient care management and decision making to the complex problems encountered in the specialist GUM environment.

There was general consistency between clinics with regard to the core aspects of care provided, such as taking a sexual history, performing the examination and taking specimens and providing the results and health promotion. Who performed tasks, such as microscopy and partner notification, varied from clinic to clinic. This was most likely to be a result of varying staff resources and access to other health care workers, such as health advisers and laboratory technicians. Tasks such as pelvic examination and proctoscopy also varied between services. This was most likely to be dependent on individual nursing skill and expertise and consultant or hospital dictated policy, both reasons identified in a 1993 Department of Health study (Allen and Hogg, 1993). From
a professional nursing stance there is no reason within current UKCC nursing regulation why nurses with appropriate training cannot perform tasks, such as pelvic examination. The essence of the UKCC Scope of Professional Practice (UKCC, 1992) is that nursing practice should be limited only by the individual accountable practitioner's own knowledge and competence (Jowett et al., 2000).

Seventy percent of respondents worked to some form of specific nurse-led protocol/guideline. Whilst acknowledging the need to standardise clinical practice between doctor and nurse-led clinics, guidance specific to nursing practice can clarify the limitations of practice in line with local, national and legal frameworks for professional nursing practice. For example, guidelines agreed within the multidisciplinary team can list patients appropriate for routine assessment and management by nurses and those patients who must be seen by or involve a doctor.

Practice related to the supply of medication varied between clinics. For instance, there were two services in which supply of medication by nurses took place in the absence of any form of medical prescription or direction. Issues of accountability may also be raised when doctors prescribe for patients who they have not seen. To overcome this, patient group directions (PGDs) (NHS Executive, 2000) drawn up by multidisciplinary teams, approved by local advisory bodies and monitored accordingly can provide a safe and legal means for nurses to supply medication. With forty percent of respondent services conducting comprehensive care nurse-led clinics during times when no doctor was present, the need for practice guidelines and PGDs becomes implicit.

Finally, the poor level of monitoring and evaluation of comprehensive care nurse-led clinics indicates the need to develop core audit/evaluation tools that can be used to assess and measure process and outcomes appropriate to local GUM service provision. This supports the existing call for the development of general GUM outcome measures that could include service acceptability, compliance with clinical standards and
effectiveness of prevention work (de Ruiter and Bingham, 1994; Welch, 1997; Johnson, 1998).

3.3 Conclusion

The beginning of this chapter explored the experiences of nurse-led GUM care in three different countries. There was general consistency in the approaches to nurse-led care although all had slightly different training requirements and degrees of nurse autonomy in practice. Where professional recognition and regulation existed for advanced nursing practice roles, the boundaries of practice were extended accordingly.

The second part of this chapter reported on the survey of advanced practice roles for GUM nurses in England. The results indicated that a significant growth of advanced practice roles for nurses has occurred since 1995 and that there are a number of issues that require attention, such as role preparation, monitoring standards of care and ongoing educational opportunities. None of the survey respondents have conducted comprehensive evaluations of their nurse-led clinics.

This chapter has shown that although nurses in other countries have been providing comprehensive first-line STI care for some time and nurses in this country are increasing their capacity to undertake similar roles, studies to support nurse-led GUM care appear to be non-existent, both nationally and internationally. Support for a comprehensive evaluation of nurse-led GUM care is therefore warranted. The following chapter will provide further evidence, from the general body of nurse-led care research, to support the study of nurse-led GUM care presented in this thesis.
Chapter 4

Literature Review: The Evidence for Nurse-Led Care

This chapter begins by providing a brief overview of the context for change in nursing roles over the past decade, followed by a discussion of the debate that has occurred as a result of these changes. The research evidence for general and GUM specific nurse-led care is then presented within the themes of effectiveness, acceptability and cost. The chapter concludes by discussing the strengths and weaknesses of the existing research in order to identify the implications for evaluating nurse-led care within the GUM setting.

4.1 Nurse-Led Care: The Development of New Roles in Nursing Practice

The development of new roles for nurses, incorporating ‘nurse-led care’, derives from a number of professional, management and policy changes over the past decade (Shewan and Read, 1999). In 1992, the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) released the *Scope of Professional Practice* (Scope) (United Kingdom Central Council for Nursing, 1992). The aim of this document was to provide the nursing, midwifery and health visiting professions with the means to develop responsive and flexible health care services. Although it has very rarely been seen as an explicit driver of change, Scope has been seen as a working tool that has had
a key part to play in the development of health care (Jowett et al., 2000). Changing philosophies of clinical management, such as 'patient focused care' and 'case management' (NHS Executive Value for Money Team, 1994), greater freedom for Trusts to determine staffing patterns and responsibilities (Department of Health, 1989), the continued reduction in length of stay in hospital and the growth of day surgery, and specially funded initiatives, such as waiting list targets, have all been the key management forces contributing to nursing role developments (Shewan and Read, 1999). The key policy forces affecting nursing role development have included, amongst others, the move to reduce junior doctors’ hours and improve their training (NHS Management Executive, 1991; Calman, 1993).

As a consequence of change, there has been considerable discussion and debate regarding the new roles that nurses have been able to take on. The semantics of 'extended', 'expanded', 'specialist' or 'advanced' nursing practice (Davis, 1992; Hunt and Wainwright, 1994; Wright, 1995; Woods, 1997), accountability and legal issues (Dimond, 1994; Dowling et al., 1996) and criticism regarding nurses taking on new roles (Hay and Bowles, 1994; Short, 1995; Nolan, 1995) have all featured. Many of the criticisms from medical colleagues have provoked strong responses from the nursing community (Barton, 1995; Lunn, 2000; Cheater, 2000).

Criticism has also been directed towards the UKCC which initially attempted to set standards for 'advanced' and 'specialist' practice, but later decided not to until a further consultation was completed, although they did retain the definition of specialist practice (United Kingdom Central Council for Nursing, 1994; United Kingdom Central Council for Nursing, 1998; United Kingdom Central Council for Nursing, 1999). To date, there is still no regulatory framework in place for nurses who undertake roles previously performed by doctors. This not only leaves practitioners from the nursing profession confused, but also those from allied professions (Allen, 2000).
The inability of the UKCC to provide role definitions and standards of preparation and practice has left individual institutions and organisations to define their own (Woods, 1997; Hicks and Hennessy, 1998; Hicks and Hennessy, 1999; Atkins and Ersser, 2000; Robb, 2001; Roberts-Davis and Read, 2001). Some authors have remarked that roles such as the nurse practitioner may remain ambiguous for some time, since different players have different views and the role is still evolving (Barton et al., 1999). Others have been less complacent, suggesting, with associated research findings, that the lack of consensus for advanced nursing roles stems from the top of the nursing profession (Walsh, 1999a; Walsh, 1999b).

The debate has continued into the new millennium with questions being posed, such as, “Who will do nurses’ current tasks if advanced nursing roles continue to emerge?” (Anderson, 2000). Some still see these developments as a threat to the medical profession (Alcolado, 2000), but this has often been offset by doctors wanting nurses to carry out duties they dislike (White, 2000). Concern has also been raised that the presence of clinical nurse specialists is de-skilling junior doctors (Newland, 2001), although this notion is largely unfounded (Burns, 2001).

Despite the ongoing polemic surrounding the nature of advanced nursing practice, new nursing roles continue to emerge. Support and justification for nurse-led care has been highlighted in a number of Department of Health documents (Department of Health, 1999; Department of Health, 2000a) with more emphasis being placed on team working across professional boundaries to make the best use of the skills that all staff have (Department of Health, 2000b).

4.1.1 Summary

The concept of nurse-led care in the UK is relatively new. The complexities, semantics and rhetoric surrounding nurse-led care have dominated the literature. However, many
of the claims throughout the nurse-led movement have been poorly substantiated by empirical evidence. It is only in recent years that the effectiveness and cost of nurse-led care have been appropriately raised (Hobbs and Murray, 1999; Leman and Terris, 2000; Munro et al., 2000; Editorial, 2001).

The following section will now present the existing evidence relating to nurse-led care in the UK.

4.2 The Evidence for Nurse-Led Care

4.2.1 Introduction

The increase of nurse practitioners throughout North America led to a proliferation of research studies throughout the 1970's and 1980's. This was because of the apparent need to compare nurse practitioner practice to physician practice to determine its safety, efficiency and cost-effectiveness (Fenton and Bryczynski, 1993). One of the earliest of these studies was the Burlington randomised trial of the nurse practitioner (Spitzer and et al, 1974). This study demonstrated that a nurse practitioner could provide first-contact primary care as safely and effectively, with as much satisfaction to patients, as a family physician. Later in the 1980's, a systematic review revealed fifty-six North American studies relevant to nurse practitioner effectiveness (Feldman et al., 1987). These studies addressed the issues of nurse practitioner consumer acceptance/satisfaction, prescribing practices, quality of care, measurement of nurse practitioner performance against physician, successful treatment and health outcomes, safety and cost-effectiveness. A more recent review from North America concluded that nurse practitioner evaluation has primarily focused on efficacy in managing primary caseloads and cost-effectiveness during the care trajectory (Boyle, 1995).

The nurse-led movement in the UK, and subsequent research, has followed twenty to thirty years behind the experiences of colleagues in North America. To
explore the emergence of new nursing roles across the UK, a large Department of Health funded study mapped new roles in practice in five Trusts in each of the eight NHS regions in England (Read et al., 1999; Read et al., 2001). The study identified 603 new nursing roles. Approximately 75% of these had been initiated since 1992. The authors extrapolated the number of new roles identified in the sample across the country and concluded that there were at least 3000 new nursing roles in existence at the time of initial reporting (1999).

Although the UK saw a significant increase of nurse-led roles throughout the 1990’s, the existence of a body of evidence to support such roles has taken longer to generate. The UK literature currently provides many descriptive accounts of nurse-led services that have been successfully implemented in acute, outpatient and community settings. The majority of these publications have been restricted to describing processes involved in initiating and running nurse-led services. Examples include: the initiation of a nurse practitioner led rheumatology clinic (Hill, 1992); setting up a nurse-led wound healing clinic (Miller, 1994); an outpatient nurse-led care unit for people with motor neurone disease (Grice et al., 1995); setting up a nurse-led glaucoma clinic (Hume and Abbott, 1995); development of aural care clinics (Zeitoun, 1997); the development of a nurse-led paediatric day care unit (Callaghan et al., 1997); prostate assessment clinics (Billington, 1997); the establishment of minor injuries units within Accident & Emergency departments (Tye, 1997; Beales, 1997; Heaney and Paxton, 1997; Dolan et al., 1997; Macduff et al., 1999; Walsh, 2000); nurse-led family history (genetics) clinic (Gray et al., 2000); a nurse-led general practice (Baraniak, 2001); and nurse-led clinics in cancer care (Loftus and Weston, 2001).

However, despite the many descriptive accounts of new roles reported in the literature, the proportion of studies evaluating new nursing roles remains low. The following sections of this chapter will explore these studies by concentrating on the
methodological issues associated with evaluating nurse-led care. The different approaches to evaluation will be discussed, followed by the key outcome measures that have been utilised. But first, a summary of published evaluations is reported chronologically in Table 3. Publications reporting the findings of audit have been included amongst the more structured research studies, as many of these have contributed to the body of ‘evidence’ that has sustained existing nurse-led interventions and aided the establishment of new ones. In addition, many have used outcome measures that are relevant to future studies and therefore subject to discussion in the sections that follow.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Subjects/Setting</th>
<th>Design/Intervention</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td>(Kinley <em>et al.</em>, 2001)</td>
<td>1907 patients attending pre-operative assessment in four NHS hospitals were randomised. 1874 were evaluable.</td>
<td>Multicentre prospective randomised equivalence trial plus qualitative assessment of patient staff perceptions and economic analysis of pre-operative assessment by appropriately trained nurse (ATN) or pre-registration house officer (PRHO).</td>
<td>Effectiveness of assessment (history taking, examination &amp; ordering of tests).</td>
<td>Pre-operative assessment by ATN were equivalent to those performed by PRHOs in terms of under-assessment that might possibly affect peri-operative management. PRHOs ordered significantly more unnecessary tests than ATNs. The substitution of ATNs was calculated to be cost neutral. Qualitative assessment showed patient acceptability.</td>
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| (Steiner *et al.*, 2001) | 238 patients accepted for admission to nurse-led inpatient unit. | RCT of care in nurse-led inpatient unit or usual post-acute care with six month follow-up. | 1) Length of hospital stay  
2) Functional status (Barthel index)  
3) Subsequent move to more independent living arrangement | Length of stay significantly longer in nurse-led arm (14.3 days longer, 95% confidence interval (CI): 7.8 to 20.7). No differences in mortality, functional status, or living arrangements at any time. Patients in nurse-led unit received significantly fewer minor medical investigations and after controlling for length of stay, significantly fewer major reviews, tests or drug changes. |
| (Griffiths *et al.*, 2000) | 177 patients referred to a nursing-led inpatient unit (NLIU) in central London. | RCT of NLIU intervention compared with 'usual care' (medically managed inpatient care). | 1) Functional independence at discharge from hospital (Barthel index)  
2) Discharge destination (death; institutional care; independent)  
3) Length of stay | No difference between groups in functional independence at discharge. Patients in NLIU (n=97) stayed in hospital 18 days longer (95%CI: 4 to 31.9 days). No significant difference in overall discharge destination. |
(Kinnersley et al., 2000) 1368 patients requesting same day consultations in ten general practices in south Wales and south west England. RCT of nurse practitioner versus general practitioner for same day consultation in primary care. 1) Patient satisfaction 2) Resolution of symptoms & concerns 3) Care provided (prescriptions, investigations, referrals, recall, length of consultation) 4) Information provided to patients 5) Patients intentions for seeking care in future

Patients seeing nurse practitioners significantly more satisfied with their care. Resolution of symptoms did not differ between arms. Prescriptions issued, investigations ordered, referrals to secondary care and reattendances were similar between the two groups. Patients seeing nurse practitioners reported receiving significantly more information about their illness and in all but one practice, their consultations were longer than the general practitioners.

(Lattimer et al., 2000) All patients contacting the telephone service in a Wiltshire general practice cooperative over one year. Cost analysis from an NHS perspective using stochastic data from a RCT of nurse telephone consultation. 1) Costs and savings to the NHS

Total cost of service was £81,327 per annum but offset by a £94,422 reduction of other costs arising from reduced admissions.

(Reynolds et al., 2000) 108 patients with Parkinson’s disease at three centres. RCT of Parkinson’s disease nurse specialist (PDNS) care compared with consultant neurologist care with one-year follow-up. 1) Health outcomes (Hospital & Anxiety & Depression Scale; SF-36; Parkinson’s Disease questionnaire; Functional Disability Scale; patient satisfaction) 2) Cost of care provided by PDNS compared with consultant neurologist

Of 22 health outcome dimensions, physical functioning and general health significantly improved in the consultant control group. SF-36 scores favoured the consultant only group in two dimensions. Satisfaction for patients randomised to consultant but then referred to PDNS increased in dimensions of waiting time and information given about medications. Cost per month was significantly higher in PDNS group.
1815 patients requesting and offered same day appointments in five general practices in south east London and Kent.

Data analysed for 1292 patients in 20 general practices in England and Wales.

Multi-centre RCT of patients assigned to treatment for minor illness by trained nurse or general practitioner.

Multi-centre RCT for nurse practitioner versus general practitioner for patients requesting same day consultations in primary care.

1) Patient satisfaction
2) Length of consultation
3) Number of prescriptions
4) Referrals rates
5) Patient reported health status
6) Intention to seek future care
7) Number patients returned to service, visits to accident & emergency (A&E), out of hours calls

1) Consultation process (length of consultation, examinations, prescriptions, referrals)
2) Patient satisfaction
3) Health status
4) Return visits over 2 weeks
5) Service costs

Increased satisfaction in nurse group compared with doctors (78.6 vs 76.4; 95%CI: -4.07 to -0.38). Nurses had longer consultations (10 min) compared with doctors (8min) (p<0.001). 73% of patients managed by nurses without any input from doctors. Similar prescribing patterns. No difference in other clinical outcomes between groups.

Nurse practitioner consultations were significantly longer than those of the general practitioners (adjusted difference: 4.20 min, 95%CI: 2.98 to 5.41). Nurses carried out more tests (8.7% vs 5.6%; odds ratio (OR) 1.66, 95%CI: 1.36 to 2.73) and asked more patients to return (37.2% vs 24.8%; OR 1.93, 95%CI: 1.36 to 2.73). No significant difference for prescribing patterns or health status outcomes for two groups. Patients more satisfied with nurse practitioner consultation. No significant service costs (nurse practitioner £18.11 vs £20.70; adjusted difference £2.33, 95%CI: -£1.62 to £6.28).
(Williams et al., 2000) Eligible patients (n=274) identified from a postal questionnaire sent to a random selection of people (n=8437) from a Leicester Health Authority register. Quasi-experimental pre-post evaluation of patients attending a nurse-led continence service. 1) Change of urinary symptoms (frequency, nocturia, mean voided volume, urine loss) 2) Self-reported improvement

(Shaw et al., 2000) 23 patients who had completed nurse-led continence programme. Selection process not reported. In-depth qualitative interviews. 1) Patient views of service

(Campbell et al., 1999) 141 patients chosen from consultant’s radiotherapy patient caseload. Pre-post nurse-led audit and semi-structured interviews. 1) Patient perceptions 2) Consultants perceptions

Decrease in nocturia (p<0.0001) and frequency (p<0.0001). Rise in mean voided volume (p<0.0001). No difference in pad loss (p=0.59). Self-reported use of pads fell from 33.5% to 22% (p<0.0001). Significant improvements in all variables subjectively measuring impact of symptoms on life (p<0.05). 99% reported satisfaction of nurse-led service.

Informal friendly approach by nurses with good communication skills relieved patients’ embarrassment and anxiety, giving confidence in nurses, thus facilitating information exchange and effectiveness of care.

Increase in provision of information resulted in increased consultation times. Increased referrals to support services (nurse 62.4% vs doctor 5.6%). Decreased waiting times (15% of nurse-led patients waited over 15 minutes compared with 32% for doctors). No problems perceived by patients. Benefits for nurses conducting the nurse-led clinics included increased work satisfaction.
<table>
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<tr>
<th>Reference</th>
<th>Description</th>
<th>Methodology</th>
<th>Findings</th>
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| Macduff et al., 1999 | Nurses, general practitioners (GP) and service users involved in nurse-led minor injury unit in Scotland. | Descriptive survey (process), clinical audit and cost analysis for nurse-led minor injury unit. | 1) Impact on clinical practice (nurse, GP and service user questionnaires)  
2) Quality of documentation (note audit)  
3) Cost (routine financial data)  
Nurses were positive about intervention although difficulties identified. Support from GPs. No problems identified by patients. Areas of poor documentation highlighted for improvement. Marginal cost over one year was £165,798 although full economic evaluation not done, therefore unable to draw firm conclusions in relation to cost-effectiveness. |
| Sakr et al., 1999   | 1453 eligible patients with minor injuries in Sheffield Accident and Emergency department. | RCT of nurse practitioner versus junior doctor care. | 1) Adequacy of care (history taking, examination of patient, interpretation of radiographs, treatment decision, advice and follow-up)  
2) Patient satisfaction questionnaire  
3) Work rates and cost  
Nurse practitioners and junior doctors made clinically important errors in 65/704 (9.2%) and 80/749 (10.7%) respectively (p=0.2). Nurse practitioners better at documenting medical history and fewer patients seeing nurse practitioner had to seek unplanned follow-up advice. Non-significant differences in accuracy of examination, adequacy of treatment, planned follow-up, requests for radiography and interpretation of radiographs in nurse practitioner and junior doctor groups. Nurse practitioners took 10.89 min to assess patient compared with junior doctor 9.02 (p=0.04). Salary costs for nurse practitioners were more expensive than junior doctors. No difference found in overall satisfaction between groups. |
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
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| (Thompson et al., 1999) | All patients contacting overnight service (2315-0800) for a general practice cooperative in Wiltshire. | RCT of nurse-led night telephone consultation.                               | 1) Deaths within 7 days contact with the out of hours service  
2) Emergency admission within 24 hours and within 3 days of contact  
3) Attendance at A&E within 3 days contact  
4) Number and management of calls in each arm of the trial  
5) Number of patients attending daytime surgery within 3 days of contact  
59% of calls managed by nurses alone (95%CI: 48.7 to 68.7). Reduced number of calls requiring general practitioner advice or home visit. No significant differences found in other variables. |
| (Campbell et al., 1998) | 1173 patients under 80 years with coronary heart disease from random sample of 19 general practices in north east Scotland. | RCT of secondary prevention clinics run by nurses compared with no intervention. | 1) Health status (SF-36)  
2) Chest pain  
3) Anxiety and depression (HAD scale)  
4) Use of health services before and during study  
Significant improvements in six of eight health status domains. Fewer patients reported worsening of chest pain (OR 0.59, 95%CI: 0.37 to 0.94). Fewer intervention group patients required hospital admission (OR 0.64, 95%CI: 0.48 to 0.86). No effect on anxiety or depression. |
| (Garvican et al., 1998) | 150 consecutive new breast care referrals.               | Postal survey to patients and GPs and audit of fine needle aspirates.         | 1) Patient satisfaction  
2) GP awareness  
3) Technical expertise  
Patients significantly more satisfied with the nurses than other aspects of hospital care (p<0.0001). 64/91(70%) of GPs were aware of nurses role although only 8/91 (9%) had informed their patients that the clinic was run by nurses. A lower percentage of inadequate samples aspirated by the specialist nurses when compared with other team members apart from the pathologists. |
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<tr>
<th>Study</th>
<th>Patients/Scope</th>
<th>Study Design</th>
<th>Outcomes</th>
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| Lattimer et al., 1998         | All patients contacting out of hours service (evenings and weekend days/evenings) for a general practice cooperative in Wiltshire. | RCT of nurse-led out of hours telephone consultation. 156 matched pairs of days and weekends in 26 blocks – one of each pair was randomised to receive intervention. | 1) Deaths within 7 days contact with the out of hours service  
2) Emergency admission within 24 hours and within 3 days of contact  
3) Attendance at A&E within 3 days contact  
4) Number and management of calls in each arm of the trial |
| McHugh et al., 1998           | 98 patients awaiting coronary artery bypass graft (CABG) surgery in Scotland. | RCT of nurse-led shared care or routine care for patients awaiting CABG surgery. | 1) Uptake of programme  
2) Patient & GP satisfaction  
3) Lifestyle & risk factor change (smoking, alcohol, cholesterol, blood pressure, body mass index & exercise levels).  
4) Anxiety & depression (HAD scale)  
5) Quality of life (SF-36)  
6) Angina symptoms |

14,492 calls received in trial period. Nurses managed 49.8% of calls during intervention periods without referral to a general practitioner. A 69% reduction in telephone advice from a general practitioner, together with a 38% reduction in patient attendance in primary care centres and a 23% reduction in home visits. Equivalence was observed in number of deaths, number of emergency admissions and number of attendances at A&E.

Significant CHD risk factor and angina symptom reduction (all variables p<0.01). Less anxiety (p=0.000); less depression (p=0.000); improved quality of life (p=0.000). 85% programme uptake. 74% of GP practices participated although this level increased to 87% who would be happy to provide the service as a part of shared care for future patients if training was incorporated.

62% of patients seen a nurse practitioner alone.
(Fall et al., 1997) 634 patients from two general practices in Trent. Prospective observational cohort of patients receiving ear care at general practice with trained ear care nurses versus standard practice.

1) Changes in discomfort and pain
2) Effect on normal life
3) Health status
4) Patient satisfaction
5) Resources used

(Heaney and Paxton, 1997; Paxton and Heaney, 1997) Patients attending minor injury unit in Edinburgh. 810 patient notes reviewed. Audit of nurse-led minor injury unit care.

1) Effectiveness of care (audit of notes)
2) Impact of service on existing A&E services (attendance rates, referrals, questionnaire to local GPs)
3) Patient satisfaction


1) Pre-operative information
2) Self-reported pain levels
3) Analgesics prescribed

No significant changes in ear pain, discomfort or health status. Increased patient satisfaction, reduced GP consultations, reduced cost and reduced use of systemic antibiotics were found in the nurse-led ear care cohort.

88% referrals considered appropriate. Decreases in local A&E attendances. 93% of nurse practitioner management considered appropriate. 87% of patients said the nurse was able to do what they expected. 94% of patients happy to be seen by a nurse.

In 1995, 92.4% of patients recalled pre-op information being given compared with 81% (p=0.03) in 1992. Self-reported levels of pain had dropped significantly with 4.7% of patients reporting pain worse than discomfort in 1995 compared with 15% in 1992 (p<0.01). Use of patient controlled analgesia increased from 50% to 78.3% (p<0.001), intra-muscular analgesia reduced from 50% to 21.7% (p<0.001). Changes in type of analgesia had also occurred between 1992 and 1995.
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<tr>
<th>Study (ref.)</th>
<th>Sample Description</th>
<th>Methodology</th>
<th>Outcome Measures</th>
<th>Results</th>
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<td>(McGhee <em>et al.</em>, 1997)</td>
<td>149 patients from the community, residential or hospital care settings referred by primary care team.</td>
<td>Prospective cohort pre-post nurse-led intervention.</td>
<td>1) Patient diaries 2) Effect on lifestyle (patient questionnaire)</td>
<td>Levels of incontinence improved highest in the community group (69% improvement) followed by the residents' wing (30%) and hospital wing (13%). Cost of incontinence products decreased in nursing home.</td>
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<td>(Murray, 1997)</td>
<td>Convenience sample of 41 patients attending nurse-led claudicant (vascular disease) clinic.</td>
<td>Descriptive survey of patients attending nurse-led service.</td>
<td>1) Patient satisfaction</td>
<td>High levels of satisfaction reported.</td>
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<td>(Oldam, 1997)</td>
<td>Random sample of 40 patients attending nurse-led asthma clinic.</td>
<td>Clinical audit.</td>
<td>Peak expiratory flow rates</td>
<td>70% of patients had an increased improved peak expiratory flow rates from their first to last visit.</td>
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<td>(Ridsdale <em>et al.</em>, 1997)</td>
<td>251 patients taking anti-epileptic drugs or had an attack in the past 2 years in six general practices in South Thames region.</td>
<td>RCT of nurse-run epilepsy clinics versus 'usual care' in primary care.</td>
<td>Information and advice given to patient (data from clinical notes)</td>
<td>Increased checking of blood concentrations (nurse 66% vs doctor 17% p&lt;0.01). Percentage of notes with advice documented was significantly different in favour of the nurse-led arm (p&lt;0.0001)</td>
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<td>(Mackie, 1996)</td>
<td>Undefined sample size.</td>
<td>Retrospective audit of care in a nurse-led anti-coagulant clinic.</td>
<td>1) Appointment waiting times 3) Treatments outcomes (INR rates)</td>
<td>Reduced waiting times from six weeks to 2-3 days. Average INR rates remained the same for nurse specialists compared with clinical assistants.</td>
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<td>(Neasham, 1996)</td>
<td>Patients attending pre-admission assessment for day surgery. Sample not defined.</td>
<td>Audit – not clearly defined.</td>
<td>Not clearly defined.</td>
<td>Reduced non-attendance rate from (undefined) to 1%. Reduced involvement of junior doctors for pre-surgery assessment from 100% to 3%. Patients more satisfied.</td>
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(Wonderling et al., 1996) 4185 aged 40-59 and their 2827 partners from thirteen general practices across Britain. Cost-effectiveness analysis of RCT intervention of nurse-led heart disease risk reduction programme with follow-up according to degree of risk. 1) Cost of programme itself 2) Overall short term cost to NHS 3) Cost per 1% reduction in coronary risk per year

(Guerrero, 1994) Patients undergoing cranial radiation. Undefined sample size. Retrospective audit following introduction of nurse-led radiation follow-up service. 1) Patient caseload for doctors 2) Hospital attendance rates

(Hill et al., 1994) 70 patients at a rheumatology outpatient clinic. Single blind RCT comparing care by rheumatology nurse practitioner (RNP) or consultant rheumatologist with 48-week follow-up. 1) Effectiveness - Clinical outcomes (plasma viscosity, C-Reactive Protein), clinical assessments (Ritchie Articular index, pain scores, morning stiffness), physical function & psychological status (Arthritis Impact Measurement Scales) 2) Acceptability – Leeds satisfaction questionnaire 3) Safety – blood tests

Cost of programme for one year was £63 per person (95% CI: £60 to 65). Short term cost to NHS was £77 per man (£29 to 124) and £13 per woman (-£48 to 74). Cost per 1% reduction in risk was £5.08 per man and £5.78 per woman. The direct costs of the programme to a four partner practice of 7500 patients would be approximately £58 000 annually. This is unlikely to be reimbursed under the current health promotion banding scheme. 30% of the medical patient caseload had shifted to the clinical nurse specialist. Reduced amount of patients needing to attend service in person.

By week 48, no significant differences between groups for plasma viscosity, CRP and articular index. In patients managed by the RNP, pain, morning stiffness, psychological status, patient knowledge, and satisfaction had all improved significantly, improvements not mirrored by the consultant cohort. Between group comparisons showed the RNP patients had lower levels of pain (p<0.05), higher levels of knowledge (p<0.0001) and were more satisfied (p<0.0001).
RCT of nurse-led cardiovascular screening and lifestyle intervention in general practice.

1) Total coronary (Dundee) risk score
2) Cigarette smoking, weight, blood pressure, and random blood cholesterol and glucose concentrations

In men the overall reduction in coronary risk score was 16% (95% CI: 11% to 21%) in the intervention practices at one year. The reduction for women was similar. For both sexes reported cigarette smoking at one year was lower by about 4%, systolic pressure by 7 mm Hg, diastolic pressure by 3 mm Hg, weight by 1 kg, and cholesterol concentration by 0.1 mmol/l, but there was no shift in glucose concentration.
4.2.2 Study Designs

Thirty-two ‘evaluations’ are cited in Table 3. However, it must be noted that fourteen of these have been published since the commencement of the study reported in this thesis. Although the methodological issues published from early 1999 onwards did not contribute to the original thesis study design, it is nonetheless useful to reflect on recent developments in order to justify the methods used and learn lessons for future studies.

Intervention Types

The majority of nurse-led interventions detailed above in Table 3 were described as nurses completing roles or tasks normally performed by doctors. However, there were seven nurse-led interventions that were described as new initiatives to improve the quality of care and/or promote health. These were described as adjuncts to existing health care services rather than initiatives to substitute roles performed by doctors. These interventions focused on three areas of health care including interventions to improve continence (McGhee et al., 1997; Williams et al., 2000; Shaw et al., 2000), improve pain control (Mackintosh and Bowles, 1997), and promote lifestyle changes for the primary prevention (Wood et al., 1994) and secondary prevention (Wonderling et al., 1996; McHugh et al., 1998; Campbell et al., 1998) of coronary heart disease.

Design and Sampling

Randomised controlled studies

Ten evaluations reported the use of randomised controlled trial designs to directly compare nurse-led care with doctor-led care.

Eight of these studies determined sample size on the basis that a benefit in patient care outcomes would be detected as a result of nurse-led intervention (Wood et al., 1994; Campbell et al., 1998; Sakr et al., 1999; Kinnersley et al., 2000; Venning et al.,
Anticipated differences for sample calculation were mostly estimated from pilot studies.

The other two evaluations utilised randomised equivalence designs. One of these based the sample size on the nurses not exceeding the 15% underassessment observed amongst pre-registration house officers by more than 25% of this figure (3.75%) (Kinley et al., 2001). The sample size for the evaluation nurse-led telephone consultation (reported as three separate adjuncts) was based on detecting equivalence in a rare event (death within seven days of a call) with the usual service run by general practitioners (Lattimer et al., 1998; Thompson et al., 1999; Lattimer et al., 2000).

Although the majority of randomised studies reported the methodology in detail, generally to a standard of the CONSORT statement (Begg et al., 1996), three did not (Hill et al., 1994; Ridsdale et al., 1997; Reynolds et al., 2000). Issues such as sample size calculation, description of assignment to intervention/control groups and description of masking issues were not reported in these two studies. Therefore, it was difficult to determine whether there was poor study design or just inadequate reporting in the publication.

**Quasi-experimental studies**

Two studies used quasi-experimental designs (Mackintosh and Bowles, 1997; Williams et al., 2000). Both used pre-nurse-led and post-nurse-led intervention outcome assessment procedures rather than direct comparison with existing doctor-led care as in a randomised study.

**Non-experimental studies**

Four of the evaluations reported in Table 3 were classified as observational (cohort) studies (Fall et al., 1997; McGhee et al., 1997) or descriptive (cross-sectional surveys)
studies (Murray, 1997; Garvican et al., 1998). Seven were classified as clinical audit (Guerrero, 1994; Neasham, 1996; Mackie, 1996; Vowden et al., 1997; Earnshaw and Stephenson, 1997; Oldam, 1997; Heaney and Paxton, 1997). One evaluation used a combination of audit, cross-sectional surveys and cost analysis (Macduff et al., 1999). Two studies used qualitative interview methods to determine patients' views of service delivery (Campbell et al., 1999; Shaw et al., 2000).

Summary

Not all of the reported nurse-led interventions concern developments in which nurses perform roles that were previously performed by doctors. Of those interventions and evaluations that did compare nurse and doctor roles, the methodology chosen for these studies varied according to setting. Some used randomised controlled trials to detect a difference between groups, whilst others used randomised equivalence studies to demonstrate that nurses could perform equally to doctors. Sampling was generally based on the results of previous or pilot studies, or an expectation of junior doctor equivalence. The majority of studies reporting the methodology for randomised studies were of high quality. However, methodological weaknesses of two studies included no description of sample size calculations, group assignment or masking procedures.

Although providing varying 'strengths of evidence', other studies using quasi-experimental, descriptive, observational and audit designs have resulted in findings that have reportedly had significant influence on the future direction of nurse-led interventions. Elements of these evaluations, such as outcome measures used, are also useful to learn from and incorporate within future studies. However, the methods and outcomes for a number of these studies were poorly defined in the respective publications. Conclusions for many of these studies should therefore be treated with caution.
4.2.3 Outcome Measures

Clinical effectiveness

One of the main contributions to the research of nurse-led care has been the outcome measure of effectiveness. Effectiveness has primarily been measured in two ways. Firstly, patient health outcomes resulting from nurse-led intervention have been measured (e.g. resolution of symptoms, mortality, functional status, health status). Such outcomes were generally more objective, thus easier to measure, and less likely to be subject to bias. The use of validated questionnaires and scales to measure health and functional status reduced measurement bias also. Physical functioning was measured using Barthel index in two studies (Griffiths et al., 2000; Steiner et al., 2001). In four studies, health status was measured using the SF-36 scale (McHugh et al., 1998; Campbell et al., 1998; Venning et al., 2000; Reynolds et al., 2000). One study used scales and biological blood measurements relevant to the chronic arthritis setting being evaluated (Hill et al., 1994).

The second measure of effectiveness used in the reported studies involved measuring attributes of the process of care resulting from nurse-led decision making (e.g. ordering of tests and investigations, history taking, interpretation of radiographs, advice given to patient, prescriptions issued). However, some of these outcome measures are subject to measurement or observation bias as result of the subjective nature involved in measuring these outcomes. Some studies have attempted to account for these, but the majority have not. For example, to determine the adequacy of care provided by a nurse practitioner or junior doctor in an emergency department, all clinical notes were transcribed so that the consultant assessing the adequacy of care was blinded as to whether the patient was seen by a nurse practitioner or junior doctor (Sakr et al., 1999). In another study, the authors identified that blinding observers would have been ideal, but for pragmatic reasons this was not possible (Kinley et al., 2001).
Acceptability

Acceptability of nurse-led care has largely been measured quantitatively through the use of patient satisfaction surveys. Of thirteen studies reporting patient satisfaction, none found nurse-led care to be less acceptable than doctor-led care. The majority found significantly increased levels of patient satisfaction. However, the quality of the methodology used to make these claims varied between publications.

Seven randomised controlled studies measured patient satisfaction with patient self-administered surveys (Hill et al., 1994; McHugh et al., 1998; Sakr et al., 1999; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000; Reynolds et al., 2000). All of these studies used previously validated satisfaction questionnaires with the exception of Reynolds et al. (2000) and McHugh et al. (1998) who devised their own without performing any reliability and validity testing.

Other publications reported attempts to measure patient satisfaction in descriptive cross-sectional surveys (Murray, 1997; Garvican et al., 1998; Macduff et al., 1999), an observational cohort (Fall et al., 1997), and through clinical audit (Heaney and Paxton, 1997; Paxton and Heaney, 1997). Murray (1997) modified a previously validated satisfaction survey to suit her study setting and population. However, the modifications were not stated and no evidence of further validation was reported. Garvican et al. (1998) and Paxton & Heaney (1997) designed their own surveys, although the development and validation process was not reported. Macduff et al. (1999) used a local survey although the validity of this survey was not stated. Fall et al. (1997) used questions from a survey developed by the Medical Research Council. Again, no validation was reported.

Only two studies used qualitative methods to elicit the views of services users (Campbell et al., 1999; Shaw et al., 2000). Shaw et al. (2000) used an in-depth interview technique to explore the process of care that resulted in high levels of information
exchange and effective care, whereas Campbell et al (1999) used semi-structured interviews to explore patients’ perceptions of a nurse-led radiotherapy review clinic.

Cost

Eight studies paid attention to cost as an outcome of nurse-led care. The viewpoint from all analyses was from the perspective of the NHS, although three studies also took patient costs into consideration (Wonderling et al, 1996; Fall et al, 1997; McGhee et al, 1997).

The different approaches to economic analysis included: cost analysis (McGhee et al, 1997; Sakr et al, 1999; Macduff et al, 1999; Lattimer et al, 2000; Reynolds et al, 2000); cost-effectiveness analysis (Wonderling et al, 1996; Fall et al, 1997; Venning et al, 2000); and cost-minimisation analysis (Kinley et al, 2001).

The costs measured varied according to setting and type of economic analysis used. Salary costs were common to all studies. Training costs were estimated in interventions where extra training was conducted. Other costs included diagnostic test, prescription and referral costs.

Clear rationale for the type of analysis used and the costs measured (or not measured) were generally well described in all publications apart from Reynolds et al (2000). Where assumptions were made, sensitivity analysis was performed accordingly (Wonderling et al, 1996; Lattimer et al, 2000; Kinley et al, 2001).

Discounting of costs was not applied in any of the studies. All studies were performed over short periods of time. None looked at the long-term benefits or consequences of patient care that would require discounting.

Cost analysis outcomes were presented as direct comparisons between doctor and nurse-led interventions (Sakr et al, 1999), marginal and incremental costs of nurse-led intervention (Macduff et al, 1999), and direct costs and relevant savings of nurse-
led intervention (McGhee et al., 1997; Lattimer et al., 2000). Cost-effectiveness and cost-minimisation analysis outcomes were presented as cost per patient episode of care (Fall et al., 1997; Venning et al., 2000; Kinley et al., 2001) and cost per reduction in risk in a nurse-led cardiovascular screening programme (Wonderling et al., 1996).

Summary

There were two types of outcomes measuring effectiveness - patient health care outcomes and care process outcomes. The later outcomes were more subject to bias. One study dealt with this by blinding observers and another provided a rationale for not blinding. Acceptability was principally measured using satisfaction scales. Many studies used previously validated surveys. A number of studies developed their own without any validation procedures. Only eight studies considered cost as an outcome of nurse-led care. Cost was mostly measured using cost analysis, although cost-effectiveness and cost-minimisation analysis also featured. All economic evaluations measured cost from the perspective of the NHS, although three studies also considered patient costs. Staff salary was the main cost accounted for when comparing nurse-led and doctor-led interventions, although prescription practices, referrals and training were also considered in some studies. No studies discounted costs and sensitivity analysis was performed in studies only where assumptions were explicitly stated.

### 4.2.4 Evaluation Findings

Table 4 summarises the findings of the thirty-two nurse-led care evaluations. Of the randomised studies carried out, equivalence in clinical outcomes between nurses and doctors was achieved in many studies (Lattimer et al., 1998; Sakr et al., 1999; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000; Kinley et al., 2001). Other randomised studies have shown increased benefits to patients for clinical outcomes (Hill
et al., 1994; Wood et al., 1994; McHugh et al., 1998) and patient satisfaction (Hill et al., 1994; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000). However, not all nurse-led interventions have shown benefit to patient health care outcomes (Griffiths, 1996; Griffiths and Wilson-Barnett, 1998; Griffiths et al., 2000; Reynolds et al., 2000; Steiner et al., 2001).

Where patient benefits have been demonstrated, other factors such as cost have often not been accounted for. Where cost has been accounted, increased costs have sometimes been associated with nurse-led care (Sakr et al., 1999; Reynolds et al., 2000). Even after an economic analysis, cost impact can still remain unclear (Wonderling et al., 1996).

With the exception of a small number of studies, the majority of randomised controlled studies have neglected to evaluate the process of nurse-led care alongside outcomes. As a result, such studies fall short of providing empirical evidence as to why the outcomes of nurse-led care were better, worse or the same as care undertaken by doctors. Instead, many authors have drawn conclusions regarding the process-outcome relationship with tentative anecdote. Where process has been investigated, the most significant result found was that nurses documented care better than doctors (Sakr et al., 1999), but nurse consultations were often longer than doctors (Sakr et al., 1999; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000). However, the clinical significance of these findings is unclear given that one study demonstrated cost-effectiveness (despite longer nurse consultation times) (Venning et al., 2000) and another showed increased work costs (associated with longer nurse consultation times) (Sakr et al., 1999). Other aspects of process have been demonstrated in the qualitative studies that were more likely to focus on the process of care by looking at patient and staff perceptions of nurse-led care (Campbell et al., 1999; Shaw et al., 2000).
Table 4 - Summary of findings from nurse-led care evaluations

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Key:
- RCT = randomised controlled trial
- Quasi = Quasi-experimental study
- NE = Non-experimental study/observation/audit
- 0 = no significant difference
- + = favourable to NLC
- - = negative effect of NLC
- +/- = mixed effects
- © = inadequate methodology to determine significant result
- blank = not studied
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4.3 Conclusion

The development of new roles for nurses working in the speciality of genitourinary medicine is part of a wider process of change in nursing and the NHS over the past decade. A number of authors have reviewed the policy context for change, many have commented, criticised and applauded such changes with reference to both nursing care and nursing as a profession. However, many of the claims made throughout the discussion of nurse-led care in the UK have not been substantiated with adequate evidence for the clinical effectiveness, cost-effectiveness and acceptability of nurse-led care. Although on the increase, the number of high quality studies relating to new roles for nurses remain relatively low despite the exponential growth of nurse-led care over the past decade.

Of the studies comparing nurse-led care with ‘usual’ or doctor-led care, numerous methodological limitations have been reported and should be considered for future studies. Studies should be well planned and appropriately powered to demonstrate equivalence or to detect differences in patient care outcomes. The choice of sampling will depend on the setting and expected outcome of nurse-led care. Techniques to ensure study rigour such as blinding or masking observers should be applied, or justification should be provided where such techniques are not feasible. Outcome measures should be validated to ensure that they are measuring what is intended. A process component of the evaluation can help to draw conclusions as to the findings of the outcome evaluation. An economic component is justified to ensure that nurse-led care provides a better service at the same or higher cost, or the same outcomes at a lower cost.

Finally, the findings of nurse-led care evaluations are not always conclusive or generalisable. Therefore, it should not be assumed that nurse-led care always provides benefits to patients and improves the effectiveness and efficiency of healthcare services.
Nurse-led care should not be automatically associated with cost savings to the NHS. Even when nurse-led initiatives have proved to be effective and efficient under research conditions, the cost implications of wider generalisability and applicability often require further demonstration.

The following chapters will now move on to the empirical evaluation of nurse-led GUM care conducted for this thesis.
Chapter 5

Methodology for Evaluation of
Nurse-led GUM Clinics

The primary aim of this study was to demonstrate the effectiveness, acceptability and cost of nurse-led clinics for women attending a central London GUM service. Specific questions to be answered included:

- Can GUM specialist nurses competently provide routine comprehensive care for female service users to a level of quality at least equivalent to that of a senior house officer (SHO)?
- How does patient satisfaction compare between doctor-led and nurse-led clinics?
- Does a nurse-led clinic affect patient waiting times?
- What is the economic impact of introducing nurse-led clinics?

The secondary aim of the study was to explore the processes involved in the implementation of nurse-led clinics. Specific issues to be explored included:

- Training and induction of specialist nurses;
- Role transition from staff nurse to specialist nurse;
- Effect of nurse-led clinics on other team members;
- Process and approach to nurse-led care.

This chapter describes and justifies the methodology used in the study to achieve these aims. The framework chosen for evaluating nurse-led GUM care, the evaluation approaches and methods and the study management and ethical issues are discussed.
5.1 Framework for Evaluation

5.1.1 Introduction

In developing a research proposal, some authors recommend that the conceptual model be explicitly identified with the theoretical and empirical components of the study (Fawcett and Downs, 1992). However, others subscribe to the notion of methodological pluralism and pragmatism, indicating what is important is the credibility of research and the amount of confidence one has in the findings, and not the particular methodological tradition or paradigmatic perspective (e.g. interpretivist, post-positivist, feminist, social theorist) that underpins it (Schumacher and Gortner, 1992; Bond, 1993; Thompson, 2000). In addition, the design of any research should be influenced not just by theoretical, but also by pragmatic considerations (McDonnell et al., 2000).

These issues bear relation to the choice of an evaluation framework for the study of nurse-led GUM clinics, as in general, frameworks with underpinning paradigms for evaluating nurse-led care in the UK had not been published at the time of designing this study. Therefore, methods for evaluating the nurse-led GUM intervention were drawn from the literature review presented in chapter four, in addition to their relevance and ability to meet the stated aims of the study. Pragmatic considerations also featured strongly in the choice of methods. Thus, the conceptual framework for this study can be best described as one of methodological pluralism and pragmatism that evolved from previous research and a sound understanding of what would feasibly and realistically work in the clinical setting to achieve the study aims.

Working from this premise, the following sections discuss the methodological framework for evaluating nurse-led GUM care that was developed for the study.
5.1.2 Quality of Care

Underpinning the evaluation of nurse and doctor-led care is the concept ‘quality of care’. Donabedian (1988) proposed that quality of care embraces four key elements: performance of practitioner; amenities of care; contributions of care by patients; and care received by the community as a whole. The performance of the practitioner can be divided into technical care and interpersonal process. Technical care is defined by the knowledge and judgement of the practitioner and interpersonal process is the vehicle by which technical care is implemented. Maxwell (1984) proposed six dimensions of health care quality: access to service; relevance to need (for the whole community); effectiveness (for individual patients); equity; social acceptability; and efficiency and economy. In addition to Donabedian (1988) and Maxwell’s (1984) dimensions, Higginson (1994) suggested that those measuring quality of care should also consider including the concept of patient empowerment, in order that patients may increase their control over the services received. Finally, with direct reference to the National Health Service (NHS) in the UK, a document for assessing (general) service performance outlined six areas of quality of care: health improvement; fair access; effective delivery of appropriate health-care; efficiency; patient/carer experience; and health outcomes of NHS care (NHS Executive, 1998).

Not all of these dimensions of quality of care were relevant for evaluation in this study. For instance, amenities of care, access to service, care received by the whole community and relevance to need were wider service issues not related to the aims, nor within the scope, of this study. Further to this, the weaknesses of previous research identified in the literature review (chapter four) also required attention. For example, the literature review highlighted the paucity of studies incorporating an economic component. Therefore, an economic analysis was justified to demonstrate whether nurse-led GUM care provided a better service at the same or higher cost, or the same
outcomes at a lower cost. As a result of the above considerations, the effectiveness of care, service user acceptability, and efficiency and economy of care were regarded as the most important aspects of care to be evaluated.

5.1.3 Evaluating Quality of Care

Quality of care needs to be evaluated within a framework appropriate to service delivery. As no framework for evaluating nurse-led care in the UK was identified in the literature, reference was made to the general health service evaluation framework developed by Donabedian (1980). He proposed that the evaluation of health services be based on the collection of data about the structure, inputs, process, outputs and outcomes of the service. Structure and inputs of an organisation refer to the buildings, equipment, staff and so on to meet defined standards. Process refers to how the service is organised, delivered and used. Output refers to the impact or effectiveness of the activities that occur through the use of the resources in the system. Outcomes can be defined as the changes in patients' health as a result of antecedent health care.

Donabedian (1988) stated that the choice of measuring structure, process, output or outcome should be determined by the question being addressed, as well as pragmatic constraints, such as availability of information, accuracy of measurement and cost. In this study, it was felt that assessing the structure of the organisation would offer little to the aims of the study and assessing longer-term health outcomes of patient care and health promotion, such as sustained sexual behaviour change and reduced STI transmission rates, would have been complex, costly and requiring long follow-up periods. Therefore, only the process and immediate patient and service related outcomes of care were evaluated.
5.1.4 Summary

The various dimensions of quality of care and Donabedian’s (1980) framework for evaluation served as important references for developing a realistic, feasible and achievable solution to evaluating nurse-led care in the GUM setting. As a result, the study pragmatically evaluated the process and outcomes of care by measuring the quality of care provided by specialist nurses and doctors. The quality of care assessment included three main components: (i) effectiveness of care (the performance of practitioners); (ii) acceptability (patient satisfaction); and (iii) cost (efficiency and economy). The methods and justification for assessing these aspects of quality are described below within the respective process and outcome evaluation sections.

Figure 2 provides an overview of the process and outcome evaluation within the timescale for the nurse-led clinic pilot.
Figure 2 - Overview and timescale of nurse-led clinic evaluation

**Process Evaluation**
- 10 semi-structured interviews with two specialist nurses
- 6 semi-structured interviews with two SHOs
- 3 focus groups with female clinic nursing team
- 6 semi-structured interviews with four senior doctors
- 2 semi-structured interviews with a senior health adviser
- Quantitative clinical activity recording
- Field diary

**Outcome Evaluation**
- RCT – documentation audit
- Patient satisfaction survey
- Patient exit interviews
- Patient waiting time survey
- Cost analysis

**Analysis**

**Provisional reporting**

| January 1999 | February | March | April | May | June | July | August | September |
5.2 Process Evaluation

Process (or implementation) evaluations study the ways in which services or interventions are delivered (Donabedian, 1980). They are designed to assess or monitor the stated goals of the intervention and to describe how an intervention works, with whom and why (Tones and Tilford, 1994; Scott and Weston, 1998). When a program is new, a process evaluation provides invaluable feedback to administrators and other stakeholders about the progress that has been made (Rossi et al., 1999). Process evaluation can also help confirm whether the favourable or unfavourable findings from an outcome evaluation are a result of the intervention (Bloch, 1975).

For this study, a focused ethnographic approach (Savage, 2000) was adopted for the process evaluation. In this approach, research questions were identified prior to entering the field in order to understand the impact of nurse-led clinics on both clinicians and patients. Methodological triangulation, the use of multiple methods to study a single problem (Denzin, 1978), was used to gain a broad ranging view of the implementation and process of nurse-led clinics. The five key data collection methods were: (i) semi-structured interviews; (ii) focus group discussions; (iii) non-participant observation; (iv) quantitative clinical data recording; and (v) a field diary. Each method had its own advantages and disadvantages in contributing to the process evaluation. These are discussed below.

5.2.1 Semi-Structured Interviews with Specialist Nurses & SHOs

Semi-structured interviewing, also known as semi-standardised interviewing (Berg, 1998) or non-schedule standardised interviewing (Denzin, 1970), is conducted using a loose structure of open ended questions that define the area to be explored, at least initially, and from which the interviewer may diverge in order to pursue an idea in more detail (Britten, 1995). The semi-structured interview is based on a written list of
questions and topics and has much of the relaxed quality of unstructured interviewing, such as probing the interviewee for more information. Semi-structured technique also demonstrates that you are in control of what you want from an interview whilst allowing you and your respondent to follow new leads (Russell Bernard, 2000). Unlike structured interviewing, the particular phrasing and ordering of questions is adapted to suit individual respondents (Denzin, 1970).

Ten semi-structured interviews were used in this aspect of the study to elicit the viewpoints of the two specialist nurses (five interviews each) with regard to their induction and role preparation period, clinical supervision and clinical practice within the first few weeks of commencing nurse-led clinics. Similarly, six semi-structured interviews (three each) were also conducted with two new SHOs to compare their experiences of role transition with those of the specialist nurses. The two SHOs who were interviewed were self-selected volunteers. Although the interviews involved only small numbers of staff, hence generalisability was not an objective, it was anticipated that this data would contribute to the objectives the process evaluation offered.

5.2.2 Interviews & Focus Group Discussions with Women's Clinic Team

Focus groups are group discussions that gather people from similar backgrounds or experiences to discuss a specific topic of interest to the researcher (Dawson et al., 1993). The benefits of focus groups are well recognised, in particular the opportunity they afford to the researcher to observe group participants interacting and recounting specific views, opinions, attitudes and experiences (Berg, 1998). They also encourage participation from people reluctant to be interviewed on their own or who feel they have nothing to say (Kitzinger, 1995).

Three focus group discussions were conducted with the nursing team of the women's clinic to explore the impact of the nurse-led clinics on them and the service as
a whole. The nursing team in this instance was defined as all of the nursing staff of the women’s clinic apart from the two specialist nurses. A focus group discussion was conducted prior to the start of the nurse-led clinics, at one month and at three months after the nurse-led clinics had started.

Two semi-structured interviews were also conducted with a senior health adviser and five semi-structured interviews with four senior medical staff. These interviews were conducted prior to the start of the nurse-led clinics and at four months after the nurse-led clinics had commenced. Individual interviews were conducted in preference to focus group discussions as they were easier to organise for the individuals concerned.

The focus group discussions and semi-structured interviews aimed to explore the problems that existed prior to commencing nurse-led clinics and compare these perceptions with the changes to service that followed the commencement of nurse-led clinics.

5.2.3 Non-Participant Observation

Direct non-participant observation involves watching people in their natural settings and recording their behaviour on the spot (Russell Bernard, 2000). An important advantage of observation is that it can help overcome the discrepancy between what people say and what they actually do (Mays and Pope, 1995). This approach was used to observe patient consultations and document the process of nurse-led and doctor-led care.

Unlike the other methods of the process evaluation, this method required a random sample of patient consultations to observe. This was to ensure that selection bias was reduced, and allowed ‘routine’ consultations to be observed in both the nurse-led and doctor-led study groups.

A stratified random sample of eight women from the doctor-led group and ten from the nurse-led group were invited to take part in the consultation observation. These
women were selected from the sample of women who were randomised for the outcome evaluation. The stratification aimed to reflect a mixture of new and old attendees from across the working day. Written consent was obtained from individual patients invited to take part (Appendix 2). Patients declining to take part were recorded as non-responders, their basic demographic data recorded, and the following patient invited to participate. There were no exclusion criteria apart from women not willing to provide consent and women requiring language translators. The consultation was observed particularly for the interpersonal process of sexual history taking, adherence to clinic protocol and provision of health promotion information.

In the original study proposal it was anticipated that consultations would be video recorded and reviewed by independent observers. Video evidence is being increasingly used for the training and assessment of doctors (Beckmann et al., 1995; Kurtz et al., 1998; Allen et al., 1998), the evaluation of training interventions (Roter et al., 1990) and more recently, to assess the performance of trainee nurse practitioners in general practice (Bond et al., 1999). However, during piloting, the low levels of patient acceptability resulted in this methodological approach being excluded. An alternative to video recording would have been to introduce simulated patients who could provide constructive feedback to the researchers. This method has been used within the developing country context where syndromic management of STIs does not require clinical examination (Franco et al., 1997). However, simulated patients do not appear to have been used within the UK GUM setting. This is likely to be a result of the simulated patient not having clinical signs, so the handling of such cases would be atypical (Saidel et al., 1998).

The data from the observations resulted in two outcomes. Firstly, thematic analysis of the observation data allowed the approach to care, by both doctors and specialist nurses, to be compared and later triangulated with other process and outcome
measures. Secondly, process flow maps, based on process modelling, were developed to illustrate the main stages involved in the nurse-led and doctor-led patient consultations. Process modelling offers a way of increasing the understanding of how the current situation (i.e. doctor-led care) works and provides a clear articulation of how the new one (i.e. nurse-led care) differs (Illes and Sutherland, 2001).

5.2.4 *Clinical Activity Reports*

The specialist nurses used a proforma to record their clinical activity during their first fifteen weeks of clinical practice. The quantitative data included the name of the specialist nurse, date, patient identification, patient reason for attendance, whether or not a doctor was required to examine the patient, whether or not a doctor was required to prescribe medication and the length of time taken for the consultation. The time recorded was restricted to the history and examination time and did not include the time that patients waited for their results, or the time for giving results.

The patient’s reason for attendance was coded within nine categories:

- **A** - asymptomatic blood tests only
- **B** - asymptomatic/contact check-up
- **C** - results/follow-up
- **D** - symptomatic vaginal discharge/irritation/dysuria/warts
- **E** - genital ulcer/atypical warts/bartholins cyst
- **F** - dermatological
- **G** - pelvic pain
- **H** - sexual dysfunction/urological/complicated dermatological
- **I** - other (specify)
These categories were proposed to reflect the degree of ‘case difficulty’ for the patients presenting at the clinic. They were agreed with the lead consultant and clinical service manager. Categories A-D were cases that were likely to be managed independently by the specialist nurses, categories E-F were cases that could be managed by specialist nurses but may also require input and/or diagnosis confirmation by a doctor, and G-I were regarded as the cases that were beyond the remit of the specialist nurse role requiring referral to a doctor.

5.2.5 Field Diary of Events

A field diary was maintained throughout the study period. This detailed the stages of planning and implementation, as well as the problems and issues as they occurred. These issues were identified formally through regular meetings with the nurse-led clinic steering group and informally through observation and interaction with the staff of the women’s clinic.

5.3 Outcome Evaluation

In addition to Donabedian’s (1980) definition of outcome, a diversity of interpretations and applications of the term ‘outcome’ have been used in the literature (Bond and Thomas, 1991; Douglas and Lindsay, 2000). Shanks and Frater (1993) defined four key themes associated with the use of the term: outcomes refer to the results of care; reflect the change in one or more dimensions of health; are attributed to interventions; and are predetermined, expected and/or anticipated. Nursing quality of care outcomes can include patient functional status, knowledge of disease and its treatment and satisfaction with care (Irvine et al., 1998). Cost outcomes of nursing care can be divided into cost for the patient, the institution and/or the health care system (Sidani and Irvine, 1999).
A substantial amount of work has been conducted in the development of outcome measures for STI services in developing countries. The World Health Organization uses two composite prevention indicators to measure the proportion of patients presenting with symptoms who are diagnosed and treated appropriately and to measure the proportion who receive basic counselling about condoms and partner notification (World Health Organization/Global Programme on AIDS, 1994). Dallabetta & Hassig (1995) list thirty one output and outcome indicators that are also specific to assessing services for the treatment of STIs in developing countries. Various data collection techniques have been described for the assessment and measurement of STI service outcomes in developing countries. These include, observing and interviewing care providers, patient encounter forms/record reviews, patient exit interviews and simulated patients (Franco et al., 1997; Hassig et al., 1998; Saidel et al., 1998).

In contrast, outcome measures of STI services in developed countries have mostly focused on monitoring the trends in the number of infections diagnosed from year to year (Horn et al., 1999). Although an important marker for the national and regional incidence of STIs, they do not measure the quality of care delivered by service providers. As a result, other outcome measures specific to service provision have been suggested by a number of authors (Welch, 1997; Johnson, 1998; Horn et al., 1999). These include symptom control, cure rates of infections, uptake of hepatitis vaccinations, lack of complications, incidence of infections, patients’ knowledge, patients’ satisfaction, contact tracing and compliance with clinical standards. Some of these service specific outcome measures were appropriate for measurement within the broader themes of effectiveness and acceptability of care that will now be discussed within the context of their use in this study.
5.3.1 Randomised Controlled Trial

To compare the effectiveness of care between specialist nurses and senior house officers (SHOs), an open randomised controlled trial (RCT) was performed. Patients were randomised to receive care from a specialist nurse or a senior house officer and those who attended their appointment had their clinical records audited using the audit form described below.

Measuring effectiveness of care

Diagnosing and treating sexually transmitted infections at the Mortimer Market Centre is standardised through the use of an in-house ‘Clinic Guide’. For example, a woman presenting with a vaginal discharge should have a defined set of investigations performed to reach a diagnosis. Once a diagnosis has been determined, treatment and instructions should be given according to the Clinic Guide. The clinic also has a casenote proforma for documenting care processes. This proforma prompts a series of questions to ensure a consistent and standard level of reporting within the patient casenotes.

In this study, effectiveness of care was defined as managing care according to the Clinic Guide. To assess and measure effectiveness of care, an audit form (Appendix 3) was developed and piloted to audit the completion of the casenote proforma and adherence to the Clinic Guide. The audit form listed thirty key variables in addition to a section to record the patient’s date of birth, ethnic origin and presenting condition. From the audit form, a scoring system was devised to provide an overall unitary index score, out of a total of 100 points, for each set of clinical casenotes. Objective criteria were established on how to judge each variable before allocating a score between zero and one. For example, a score of zero was given if details of the sexual history were not recorded, 0.5 if there was incomplete data and a score of one if a complete sexual
history was recorded according to the clinic proforma. In instances when no information was required, for example when the patient did not require an examination, a non-applicable option was available. The unitary index score was calculated for each set of patient casenotes and then converted to a percentage for analysis. The main variables associated with the outcome of specialist nurse and SHO decision making (diagnostic test request, preliminary diagnosis and treatment provided) were then analysed independently.

Since two different models of care were essentially being compared, documentation by staff nurses supporting the SHOs and documentation from doctors supporting the specialist nurses was also counted. Casenotes in which appropriate management was difficult to determine were discussed with the lead consultant physician.

Score reliability
The reviewer was not blinded to the identity of the practitioners. However, fifty percent (112/224) of clinical records were randomly selected and reviewed for score reliability by a second person (lead consultant physician). Pearson’s correlation coefficient was used to measure the strength of the association between the final unitary index scores of the reviewers. For each of the thirty items used to create the unitary index score, the proportion of cases where the two reviewers agreed as to whether the item was recorded or not was then computed to determine those items where discrepancy between reviewers was greatest.

RCT sample size determination
Dimond (1994) states that nurses need to consider the legal aspects of role expansion when adopting roles that are normally performed by doctors. Patients are ‘entitled to the
standard of care which would be expected of the skilled practitioner exercising and professing to have that special skill’ (p.65). Therefore, nurses undertaking activities normally performed by doctors are expected to meet the standards of care that would be required from a doctor were the doctor to perform the tasks. These principles were key to determining the sample size and outcome measure comparisons used in this study.

The objective of many trials is to show that one treatment is significantly better than another, or that two treatments are equally effective (equivalence). The principal objective of this study, and that used in determining its power, was to establish that care provided by specialist nurses was not inferior to care provided by SHOs. Senior house officers (SHOs) were chosen as controls as this was the minimum level of care expected of the specialist nurses.

The sample size for the clinical record audit was based on a sample of (November 1998) case notes (n=23) that were reviewed utilising the audit form. The notes reviewed had a mean score of 85.5 (s.d. 7.5). Based on this we accepted specialist nurses functioning at a level at least as good as SHOs, if we were 95% certain that their true mean score was no more than five points less than the SHOs. The necessary sample size depended on how specialist nurses were expected to perform relative to SHOs. Therefore, a sample of 130 in each arm was calculated with 90% power to detect whether nurses were in truth three points less than SHOs on average, using two tailed tests.

**RCT sampling strategy**

Patients were randomised to see a specialist nurse or a doctor when they telephoned for an appointment. SHO cases were selected from the doctor group at a later date, as reception staff were unable to determine between SHOs and other medical staff grades at the time of randomisation.
A computer program was used to generate three simple random sequences in order to allocate patients to specialist nurse:doctor in ratios of 1:3, 1:4 and 1:5 with block sizes of eight, ten and twelve. The different ratios were generated to account for the daily changes in appointment availability. For example, if there were not enough specialist nurse appointments available, the ratio could be changed to account for this. The telephone reception staff were provided with a simple table listing the randomisation allocations, with a space next to each allocation to enter the patient clinic reference number as the appointment was booked. Although concealing treatment allocations in randomised trials seeks to eliminate selection bias (Altman and Schulz, 2001), the reception staff were not blinded to the randomisation allocations for pragmatic reasons. The practicalities of managing and motivating the reception staff to use a masked system (e.g. a sealed envelope approach) may have led to poor enrolment in addition to service disruption. However, to reduce any selection bias, the time of appointment booking was recorded next to each allocation and regular supervision of the reception staff performing the randomisation ensured that no favouring of group allocation occurred. Reception staff do not perform any triage of patients and therefore it was not in their interests to influence the order of enrolment.

Not all patients seeing specialist nurses and SHOs during the study time were randomised. Some patients attended the service without an appointment and there were times when the telephone reception staff were too busy to carry out the randomisation. However, all staff at clinic level (i.e. doctors and specialist nurses) were blinded to those patients who had been randomised.

Patients were not consented at the time of randomisation. All patients were informed of the study when they presented at the clinic and were given an opportunity to opt out of the randomisation if unhappy with their allocated practitioner. Post-randomisation pre-intervention consent served as a solution to the issues of consenting
patients over the telephone. For further discussion relating to the randomisation process, see Section 5.4.3 regarding ethical issues. A summary of the randomisation process is presented below in Figure 3.

**Figure 3 - Randomisation procedure**

Patient telephones for appointment

↓

Randomised by receptionist from a fixed randomisation schedule

🪱🪱

A specialist nurse (SpN)  B senior house officer (SHO)

↓  ↓

Name of practitioner given to patient

↓

Patient arrives at clinic and given study information sheet – able to opt out and see a different practitioner at this stage

↓  ↓

<table>
<thead>
<tr>
<th>A1 see SpN</th>
<th>A2 objects &amp; see SHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1 see SHO</td>
<td>B2 objects &amp; see SpN</td>
</tr>
</tbody>
</table>

Intent to treat analysis

i.e. A1A2 compared to B1B2
RCT Analysis

Following the randomisation period, patients who were randomised to specialist nurse and SHO groups were checked for attendance. Those who attended their appointment had their casenotes reviewed. Data were extracted and entered onto the audit form as described above. Following this, data from the audit forms were single-entered and analysed using SPSS. An intention to treat analysis was used. For instance, if a patient was randomised to see a specialist nurse but was referred to a doctor in the course of the appointment, the data were analysed within the specialist nurse arm. The $\chi^2$ test, and Fisher’s Exact test where appropriate, were used to compare the specialist nurse and SHO groups with respect to rates of attendance and the individual variables. Non-parametric Mann-Whitney $U$ tests were used to compare the unitary index scores between specialist nurse and SHO groups.

5.3.2 Patient Satisfaction Survey

During an extensive literature review, a patient satisfaction questionnaire suitable for the study population and setting was not identified. Therefore, a patient satisfaction questionnaire was developed specifically for the study. This was piloted and tested for reliability, validity and stability. The development of this questionnaire is presented below, followed by the sampling and analysis strategies. The final questionnaire can be seen in Appendix 4.

Development of the satisfaction questionnaire

Phase 1 – literature review

The first phase of developing the patient satisfaction questionnaire involved a comprehensive literature review to identify previously validated questionnaires suitable for adaptation. Although the views of GUM service users have been elicited through
questionnaires (Monday, 1990; Rogstad, 1991; Monteiro, 1995), none have been appropriately validated. There was also a paucity of questionnaires that have been developed and adequately validated for the general outpatient setting. The nearest alternative was the Leeds Satisfaction Questionnaire (LSQ). The LSQ was developed to compare nurse-led and consultant-led care within a chronic rheumatology outpatient setting in Leeds (Hill et al., 1992; Hill, 1997). The LSQ was chosen as a questionnaire suitable for adaptation to the GUM setting, primarily for its ability to measure patient satisfaction for both doctor and nurse-led care, and the rigorous development and validation process that was performed during its development.

Phase 2 – identifying patient expectations

The second phase of the questionnaire development involved brief structured interviews with female clinic attendees (n=19). These service users were asked about their general expectations of the service, and more specifically, their expectations of the consultation with the lead doctor or specialist nurse providing their care. Thematic analysis of the data identified four key aspects, or sub-scales, of care. These were (i) specific attributes of interpersonal relationship, (ii) quality and competence of technical care, (iii) provision of information and (iv) service attributes. These aspects of care reflected some of the dimensions identified by Risser (1975) and Ware et al. (1983). They were also similar to the six sub-scales used by Hill (1992): giving of information; empathy with the patient; technical quality and competence; attitude towards patient; access to the service and continuity of care. The latter category suggested by Hill was more relevant to a chronic outpatient setting, whereas the majority of visits to sexual health clinics are one-off. Consequently, continuity of care between appointments was not seen to be an issue with the study population. In addition, access to the clinic was not used within the
questionnaire, as this was a wider service issue not incorporated within the study objectives.

Phase 3 – preliminary design of questionnaire

The LSQ was therefore modified with irrelevant statements being excluded and more specific statements formulated to reflect the issues highlighted in the phase two patient interviews. The first draft of the satisfaction questionnaire consisted of a pool of fifty seven items that included a mixture of positive and negative statements reflecting the four sub-scales. A fifth sub-scale, labelled ‘overall satisfaction’, contained three specific statements to act as an internal consistency check. Ambiguous statements were avoided, as were statements that included more than one issue at a time. Statements were kept short and language simple. Participants were asked to respond to individual items by circling a number from one to five on a five point Likert scale that corresponded with the labels ‘strongly agree’, ‘agree’, ‘unsure’, ‘disagree’ and ‘strongly disagree’. A panel of clinic ‘experts’, including a Clinical Service Manager, Consultant Physician, Charge Nurse and a Clinical Psychologist, assessed the content and face validity of individual statements.

Although inconsistent reports exist, there is nonetheless, evidence to suggest that ethnicity, age, social status and educational attainment have a bearing on the satisfaction of individuals (Fitzpatrick, 1991; Sitzia and Wood, 1997). Therefore, a panel of questions to collect these background variables was included at the beginning of the questionnaire. A series of questions were phrased to determine the Standard Occupational Classification Groups (Office of Population Censuses and Surveys, 1995) that were later re-coded to provide the category ‘Social Class based on Occupation’ (Office of Population Censuses and Surveys, 1991). Two further questions, sexual orientation and previous visits to the service were also included. Questionnaires
remained anonymous to reduce 'social desirability response bias' and 'ingratiating response bias' (LeVois et al., 1981). Assuring anonymity also allowed patients to lodge informal complaints without fear of future unfavourable treatment.

Phase 4 – face validity
The second draft of the questionnaire was reviewed for face validity with nine patients of various ethnic origin and age. Difficult statements were then reworded and ambiguous questions excluded. A number of statements were not relevant to some of the women. This led to two filter questions being included.

Phase 5 – reliability testing
A third draft consisted of forty eight statements that were reordered to maintain a balance of the five sub-scales throughout the questionnaire. Forty three patients completed the questionnaire once they had completed their appointment with their respective practitioner. All data were entered, re-coded and analysed using SPSS. The forty eight statements were also coded into the five sub-scales. The analysis produced scores, out of a total of five, for each individual questionnaire. The range of scores was 3.09-4.53.

Internal consistency, the consistency of items within the same test (Kaplan and Saccuzzo, 1993), was checked using Coefficient alpha (Cronbach, 1990), calculated when each statement was deleted to discard those in which alpha significantly increased above the total alpha of 0.88. Eight statements were eliminated giving a resulting alpha value of 0.93.

It was thought that too many paired statements (positive/negative) remained and that the questionnaire was still too long. Although a study reviewing 210 satisfaction studies found a weak correlation between number of items and response rate (Sitzia and
Wood, 1998), it was decided that the shorter the questionnaire, the more compliant patients would be in completing all items in the questionnaire. Previous experiences of administering patient questionnaires within the study setting suggested that most patients want to leave the clinic as quickly as possible once their appointment was complete.

To reduce the questionnaire length, sub-scale homogeneity was calculated by correlating each statement with their respective sub-scale (Pearson’s correlation). Statements that correlated significantly higher in scales other than the one it belonged to were discarded, taking care to maintain the balance of statements by choosing to discard only one of a paired item.

**Phase 6 – test-retest stability**

The final questionnaire consisted of thirty four statements. The questionnaire was repeated (n=28) in the clinic, and thirteen women agreed to receive a second postal questionnaire. The second questionnaire was used to confirm stability with a test-retest analysis. Eight questionnaires were returned (62% response rate) with a mean of 13.75 days between the first and second questionnaires (range 8-20). A Pearson correlation score between the original and retest scores was 0.95 (p<0.001) demonstrating stability of the questionnaire. The retest scores were slightly higher than the original questionnaire scores as shown in Table 5.

**Table 5 – Satisfaction survey stability: test-retest scores**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>First questionnaire</td>
<td>4.17</td>
<td>3.00</td>
<td>4.82</td>
</tr>
<tr>
<td>Retest questionnaire</td>
<td>4.18</td>
<td>3.26</td>
<td>4.93</td>
</tr>
</tbody>
</table>
Phase 7 – construct validity

The demonstration of validity requires more than just peer judgements. Empirical evidence must be produced to show that the tool measures what is intended (Streiner and Norman, 1989). Concurrent validity could involve the developed questionnaire being administered alongside an existing measure to determine whether there is a strong correlation between the two. Since no measure of satisfaction relevant to GUM was identified, a comparative measure against another scale was not possible. In the absence of a concurrent test, the next best approach to measuring validity is labelled ‘construct validity’. Construct validity involves setting a hypothesis to explore the difference between two populations that have different levels of the property being assessed (i.e. satisfaction). If the expected relationship is found, then the hypothesis and measure are sound (Streiner and Norman, 1989). The problem was how to identify people at each end of the satisfaction continuum. Ideally, these people were to be identified from the local quarterly complaints reporting. However, this notion was opposed. Since the satisfaction questionnaire included a final section for patient comments, questionnaires with comments describing extremes of satisfaction were used for construct validity testing. However, there were not enough of these comments completed in the pilot phases. Therefore, the construct validity testing could not be performed until after the questionnaire was used in the main study. The results of the construct validity tests are presented here.

From the 282 completed questionnaires, nine questionnaires were identified with negative comments. In order to demonstrate construct validity, it is important to show ‘not only that a test correlates highly with other variables with which it should theoretically correlate, but also that it does not correlate with variables from which it should differ’ (Anastasi and Urbina, 1997; p. 129). Therefore, ten questionnaires were randomly selected from the large number of questionnaires with positive comments.
The questionnaires with negative comments correlated positively with low scores, as did the positive comments with high scores. There was no evidence of positive comments corresponding with low scores and vice versa. Although the numbers used in this example are small, the construct validity testing indicates the survey’s ability to identify ‘satisfied’ and ‘dissatisfied’ respondents.

Comment
There were a number of issues relating to the development of the satisfaction measurement tool that warrant discussion before proceeding. The satisfaction survey was developed utilising a previously validated survey (Hill et al., 1992) and the findings of qualitative interviews exploring patient expectations within this service. Staniszewska and Ahmed (1999) suggest that in the development of satisfaction surveys, the target group’s expectations should be considered. This of course assumes that a relationship exists between expectations and satisfaction. The role of expectations in the evaluation of care, most often expressed in terms of satisfaction, has been debated with some studies suggesting expectations influence satisfaction, while others have not found a relationship. Nonetheless, it was felt that the involvement of patients in the development process was valuable in targeting the actual needs and issues of service users within this setting.

Bond and Thomas (1992), Carr-Hill (1992), Fitzpatrick (1997) and Sitzia and Wood (1997) are among the many reviewers who have discussed the concept and scope of measuring patient satisfaction. Although this study did not attempt to define the concept of patient satisfaction within the GUM setting, it was acknowledged that patient satisfaction was perceived as a desired outcome of care. Donabedian (1988) states that an expression of satisfaction or dissatisfaction is the patient’s judgement on the quality of care in all its aspects, but particularly concerning the interpersonal process between
the practitioner and patient. The interpersonal process is of particular importance in any health care setting, but specific attention is required within the sexual health setting considering the sensitive and personal nature of patient/practitioner consultations.

In a review of measuring patient satisfaction with nursing care, Bond and Thomas (1992) concluded that in the majority of studies, instruments were developed specifically for the study, often without paying due attention to the methodological issues of reliability and validity. A further review by the same authors four years later, found the situation largely the same (Thomas and Bond, 1996). The development of the satisfaction survey for this study included reliability and validity testing that influenced the final content of the questionnaire. The internal consistency and sub-scale homogeneity analysis helped to exclude questions that were irrelevant and inconsistent for measuring satisfaction within the survey population. The ultimate reliability analysis of the 282 analysed questionnaires indicated high internal reliability with a Cronbach’s alpha coefficient of 0.94. Pearson’s correlation coefficients between the five sub-scales and the mean overall score ranged between 0.74 and 0.88 (p<0.01) indicating sub-scale homogeneity. However, the results of the stability testing (test-retest Pearson’s correlation = 0.95 (p<0.001)) should be interpreted with caution, as respondent numbers in this development phase were low (n=13).

Satisfaction within this study was treated as a unitary concept to provide a ‘total score’ of satisfaction. Carr Hill (1992) and Williams (1994) have discussed the difficulties of defining a unitary satisfaction index. Carr Hill (1992) suggested that the statistical reduction to a single index or simple expression of satisfaction presumes that there is an underlying unity to ‘satisfaction’, for which there is very little evidence. In addition, he proposes that in order to produce a total score, the scores of the different dimensions should ideally be weighted; something that was not done in this study. High levels of dissatisfaction on one aspect, for instance the provision of information, could
be masked by high levels of satisfaction on other aspects. However, the objective of this satisfaction survey in this study was to quantitatively compare two different models of care. This was where a unitary index of satisfaction proved to be useful.

Sitzia and Wood (1997) also suggest that health care providers should be circumspect in their interpretation of positive responses to satisfaction surveys and that a satisfaction measure must form part of a more wide-ranging review of service quality. They propose that a positive response in a satisfaction survey should not be interpreted as indicating that care was ‘good’, but simply that nothing ‘extremely bad’ occurred. Therefore, exit interviews (discussed below in Section 5.3.3) were employed to support the reliability of the satisfaction survey findings.

Finally, another limitation of the satisfaction questionnaire was that, from an economic perspective, it incorporated no concept of opportunity cost. This is a general point about the limitations of satisfaction questionnaires and the need for them to be seen in a broader context. Asking people to simply state their level of satisfaction ignores scarcity of resources (Ryan, 1996). The results of satisfaction surveys do not address the real decision-making issues that policy makers face. For example, the survey could highlight dissatisfaction with waiting times, but it could not tell by how much waiting time should be reduced to bring about satisfaction.

Satisfaction survey sampling strategy

Although preferable, incorporating the satisfaction survey into the randomised controlled aspect of the outcome evaluation was not possible for a number of reasons. Randomisation took place in a non-clinical area of the building prior to patients attending their appointment and therefore cross-referencing patient attendance with the randomisation list was not feasible at the time of the visit. In addition, not all of the women attending the women’s clinic had been randomised. For instance, some would
have attended without an appointment, therefore bypassing the randomisation process. The satisfaction survey was anonymous, therefore retrospective matching of surveys with a randomisation list was not possible either. Even if this were done, a much larger number of women would have had to complete the survey to achieve the required number of survey responders.

Therefore, the survey was given to a non-random, convenience sample of patients at the end of their appointment. Consecutive patients were approached and invited to complete the survey until 150 questionnaires had been completed for each arm of the study. All non-responders were recorded and attempts were made to obtain basic demographic details from these patients. To further encourage honest responses from participants, anonymity was assured with completed surveys being placed in a central deposit box prior to leaving the clinic. There were no exclusion criteria for completing the satisfaction questionnaire apart from women who had completed a questionnaire on a previous visit and women not able to read or write English.

Satisfaction survey analysis

Non-parametric Mann-Whitney \( U \) tests were used to compare satisfaction scores between the doctor and specialist nurse groups. Non-parametric Spearman’s Rank Correlation test was used to test the linear association between satisfaction score and the following variables: age, further education, and previous visit. Non-parametric Kruskal-Wallis one-way analysis of variance test was used to compare the association between satisfaction scores and variables with multiple values i.e. sexual orientation, social class and ethnicity.
5.3.3 Patient Exit Interviews

A stratified random sample of ten women from the doctor-led arm and ten from the nurse-led arm were invited to take part in the exit interviews. As with the non-participation observations, these women were selected from the sample of women who had been randomised for the outcome evaluation. The stratification aimed to reflect a mixture of new and old attendees from across the working day. Practitioners were blinded to those patients selected for interview. Written consent was obtained from individual patients invited to take part (Appendix 2). Patients declining interview were recorded as non-responders, their basic demographic data recorded, and the following patient invited for interview. There were no exclusion criteria apart from women not willing to provide consent for the taped interview and women requiring language translators.

The exit interview topic guide (Appendix 5) followed the following themes:

- expectations being met
- relevance to individual need
- efficiency
- effectiveness
- acceptability

5.3.4 Patient Waiting Time Survey

A patient waiting time survey (Appendix 6) was attached to every set of female clinic notes over a six week period from June 1999. The time data were entered onto the waiting time surveys by reception, medical and nursing staff. The completed waiting time surveys were entered and analysed using SPSS. Independent sample t-tests were used to compare mean waiting times between the doctor and specialist nurse groups. No
sample size was calculated. The aim was to collect as many waiting time surveys as possible during the six week period.

### 5.3.5 Formal Complaints Reporting

Permission was requested from the Camden & Islington Community Health Services NHS Trust Corporate Affairs Department for access to a summative description of all complaints relating to the women’s clinic of the Mortimer Market Centre between January and October 1999. This information was seen as another aspect of patient acceptability, one that would complement the satisfaction questionnaires and exit interviews.

### 5.3.6 Cost Analysis

The economic component of the study set out to address the question: ‘What is the expected cost per completed patient appointment for patients who receive their care in the nurse-led clinics and those in the doctor-led clinics?’

An assumption was made that the clinical outcomes of care, for both doctor and nurse-led clinics, would be the same, and would therefore not need measuring as would be done in a full cost-effectiveness evaluation (Drummond *et al.*, 1997). Thus the economic evaluation can best be described as a cost analysis in which resource use for the conduct of nurse-led clinics was compared with resource use for the doctor-led clinics.

The three key outcomes of the cost analysis were: (1) incremental cost of the nurse-led intervention; (2) average cost per patient pre and post-nurse-led intervention; and (3) marginal cost per patient seen in the nurse-led clinics. Although a societal perspective would have brought wider benefits to the study (Byford and Raftery, 1998), the viewpoint for the analysis was primarily from the NHS service provider perspective.
Range of costs considered and their measurement

Costs were converted to monetary value by first measuring the quantities of resource use followed by the assignment of unit costs. The costs considered included:

(i) **Health Service Costs** - Practitioner salaries were the main fixed cost measured. The other fixed cost that differed between doctor and nurse-led approaches was office space. Fixed costs such as heating and lighting were not measured as they were estimated to be the same or of minimal difference. Variable costs, such as examination equipment, diagnostic tests used, medication dispensed and the referrals made were also either estimated to be the same for both doctor and nurse-led approaches or of minimal cost that would not affect the overall cost outcome. The training cost of SHOs and specialist nurses was considered but not assessed due to the difficulty in measuring the on-the-job training approach used. The indirect cost of supervision was not assessed, again due to the difficulty of measuring the true informal supervisory time that accounted for the majority of supervision beyond the regular formal supervision of both SHOs and specialist nurses.

(ii) **Costs Borne by Patients** – Health economists disagree about the most appropriate technique for measuring the opportunity cost of time (Palmer and Raftery, 1999). Ideally, the best valuation of the cost of time for working age adults, is the wage they are, or could be making in paid work (Gold et al., 1996), varying according to whether the time lost involves lost work or leisure time (Posnett and Jan, 1996) and the likelihood of being unemployed (Koopmanschapp and Rutten, 1996). With these difficulties in mind, the true opportunity costs of patient time were not pursued within this study. The viewpoint of the analysis was therefore restricted to that of the NHS.
(iii) **External Costs or Cost to Other Sectors** – These were not measured as the effects of increased costs to those not directly involved in the intervention were regarded as too small or diffuse to merit inclusion in the analysis.

**Adjusting for timing of costs**

The costs relevant to the economic analysis occurred in the present. That is, the analysis was conducted at one point in time. Thus, by convention, discounting was not required (Drummond *et al.*, 1997).

**Opportunity costs**

The opportunity costs of investing in a health care intervention are best measured by the health benefits that could have been spent on the next best alternative intervention (Russell, 1992). Opportunity cost is best assessed directly with cost-effectiveness or cost utility analysis using comprehensive, disaggregated data at the individual patient level (Palmer and Raftery, 1999). In this economic analysis, only resource use, and not the consequences of service provision by the specialist nurse and doctor groups, were directly compared using basic accountancy data and crude patient numbers and assumptions. Therefore, the true opportunity costs of the nurse-led clinic intervention could not be measured.

**Dealing with uncertainty**

To allow for uncertainty in the assumptions made, one-way sensitivity analysis was performed (Drummond *et al.*, 1997). In this approach, estimates for individual parameters were varied one at a time in order to study the impact on study results. In the base-case scenario, it was conservatively estimated that 50% of the nurses’ time was attributed to supporting the doctor-led clinics and that a total of two hours per week of
doctors' time was attributed to supporting the two specialist nurses. In the sensitivity analysis, these two parameters were increased, as they were considered the most significant estimates that could affect the outcomes of the cost analysis. This is because they were the most subjective, non-evidence-based assumptions estimated for the analysis. All of the other assumptions were based on realistic figures. For example, the numbers of patients seen in the doctor-led clinics were based on actual statistical returns.

5.4 Study Management

5.4.1 Data Collection

All interviews and focus group discussions were tape-recorded and transcribed verbatim. Field notes were taken during the non-participation observations of consultations and later transcribed. Satisfaction surveys were entered onto a SPSS database. Data extracted from clinical records were entered onto the audit form and later entered onto a SPSS database. Cost analysis data was collected with the assistance of a Camden & Islington Community Health Services NHS Trust (C&ICHST) accountant. Cost calculations and sensitivity analysis were performed using an Excel spreadsheet.

5.4.2 Data Entry & Analysis

As a result of resource limitations, data were single entered only. All quantitative data collected were analysed using SPSS. All qualitative interview data were analysed using the basic principles of 'Grounded Theory' (Strauss and Corbin, 1990). In this approach, conceptual labels were placed on discrete happenings, events and phenomena before grouping these concepts to form categories or 'themes' (open coding). Sub-categories were then constructed by establishing the connections between the categories with regard to the context in which the category was embedded within the outcomes or
results of action or interaction (axial coding). This type of analysis can be regarded as theme analysis or concept development. NUDIST*QSR software was utilised to facilitate the analysis. Observation notes were transcribed, entered onto NUDIST, and analysed in the same manner as the interviews. As a result of resource limitations, a second 'coder' was not used to check the reliability of the qualitative analysis. This was regarded as one of the main weaknesses of the qualitative analysis.

5.4.3 Ethical Issues

With regard to randomised controlled trials, it is conventional practice to seek patient consent immediately before randomisation takes place (Pocock, 1983). In this study, randomisation occurred at the time of booking an appointment over the telephone. Obtaining consent at this point was considered neither feasible nor ethical. As an alternative, randomising and consenting patients at a later date (i.e. when they attended) would have led to significant service disruption. Therefore, in order to overcome these problems, patients were randomised without their written consent. All patients were informed of the study when they presented at the clinic and were given an opportunity to opt out of the randomisation if unhappy with their allocated practitioner. It was considered that consent for entry into this study by not objecting was quite sufficient, as long as the patients were aware that research was taking place. This was justified by the fact that nurse-led clinics had been a routine part of the service for over six months at the time of the randomisation. During this time, patients were 'haphazardly' allocated to doctor or specialist nurse. Randomisation only sought to control the process of patient allocation.

Patients attending the clinic were therefore informed of the study by posters in the clinic waiting area in addition to leaflets that were distributed on arrival (Appendix 7). The review of clinical records and completion of the satisfaction questionnaire were
regarded as research interventions not requiring individual consent. The only point at which written consent was required was for the patient exit interviews and the consultation observations.

Post-randomisation pre-intervention consent served as a solution to the issues of consenting patients over the telephone. This technique may be likened to the randomised consent design, or Zelen's method of trial design, in which study participants consent to take part in a study post-randomisation (Zelen, 1979; Pocock, 1983). In a true Zelen's method, participants who are randomised to the control arm of the study never provide consent. Only those randomised to the intervention provide consent. Zelen's method involves asking trial participants to consent to receive the treatment they have been randomised to rather than to randomisation itself. In this study, participants were asked to consent to the research interventions (interview and consultation observation) beyond randomisation, rather than the randomisation and intervention itself. Although slightly different, other evaluations of nurse-led care have utilised post-randomisation consent designs to reduce study attrition (Griffiths, 1996; Griffiths et al., 2000) and to overcome ethical, practical and scientific difficulties associated with conventional randomisation and consent (Steiner et al., 2001).

This study was peer reviewed, registered as a research project with the Camden & Islington Community Health Services NHS Trust (C&ICHST) Research Consortium, and then approved by the C&ICHST Local Research Ethics Committee.

C&ICHST data protection requirements were observed for all electronically stored patient data.
Chapter 6
Process Evaluation Results

This chapter provides an overview of the processes involved throughout the implementation of nurse-led clinics. It commences by reporting how staff perceived the services of the women’s clinic prior to the nurse-led clinic initiative. Besides setting the scene for the development of the new model of nurse-led care, this phase of the study provided a baseline from which changes to service provision could be tracked and compared to during the nurse-led clinic pilot period. The second section details the implementation phase of the nurse-led clinic pilot: the specialist nurse role preparation and transitional period; the ‘scope of practice’ issues; and the personal and professional outcomes. The third section describes the clinical activity of the specialist nurses and the level of support required from medical colleagues. The fourth section uses process flow maps to illustrate how the new model of nurse-led care differed from the existing model of doctor-led care. The chapter concludes by exploring the interpersonal approaches to nurse-led and doctor-led care.

The broader implications drawn from these findings in relation to the outcomes of care will be discussed in chapter eight once the results of the outcome evaluation have been presented in chapter seven.
6.1 Service Provision Prior to the Nurse-Led Clinic Initiative

Prior to the start of nurse-led clinics, medical, nursing and health advising staff were represented in semi-structured interviews and focus groups discussions (FGDs) to explore the functioning of the women’s clinic. Four main categories arose from the data analysis. These are presented as an overview in Table 6 and then discussed in depth. Comments from the specialist nurses in this section relate to their previous roles as staff nurses. Quotes from study participants are italicised followed by a unique personal identifier and the period of time relating to the commencement of nurse-led clinics.
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6.1.1 Women's Clinic Objectives

Primary

All of the staff interviewed were asked what they thought the overall objectives of the women's clinic were. A common theme ran through all of the suggestions made. Each staff group specified that the clinic purpose was primarily to offer a high quality and efficient service to identify and treat sexually transmitted infections:

*I think ideally that the female clinic should be identifying people with sexually transmitted infections and offering them prompt treatment. (Dr8, pre-nurse-led clinic (NLC))*

*To provide a good level of care around prevention and treatment of sexually transmitted infections. (SpN2, pre-NLC)*

Secondary

Participants identified a number of secondary functions of the women's clinic. Some staff felt that the clinic had an important role as a primary referral point, directing patients on to other relevant services:

*...and provide a sort of onward referral to other agencies say for teenage pregnancy and gynaecology, or going and seeing a GP. (Dr16, pre-NLC)*

Although it was clear that the main focus of the women's clinic was sexual health and that cases beyond the remit of the clinic should be referred elsewhere, one senior doctor felt that it was still important to have a broader understanding of other medical conditions in order to be able to reassure the patient:
I don't think that you should necessarily be managing it, [gynaecological problems] but it is useful when someone comes in with pelvic pain to have somebody around who can shed some light on the pathology that may not necessarily be sexual health, and to at least quickly talk to the patient about it. In a nutshell give some comfort by knowing a little bit about other medicine. (Dr14, pre-NLC)

Finally, although most objectives were focused on the individual, this statement made it clear that the clinic had a much broader public health purpose to be considered:

...but also to be a centre involved in the public health control of sexually transmitted infections in women which is important. (Dr15, pre-NLC)

6.1.2 Effectiveness of Clinic

Service delivery

The perceived effectiveness and efficiency of the women's clinic varied between individuals, with no particular staff group representing any particular view. Responses ranged from 'pathetic compared to other clinics' to 'could be better' to 'on the whole it is a good service'. The main concern related to the process of delivery rather than the actual care provided. The service was often seen as being fragmented and disjointed resulting in patients waiting long periods:

I think that it is really bitty. After the doctor takes the history the patient waits around before the nurses takes the notes, pops her into the room and has a chat. Then if it's a male doctor you have to wait around for them to go into the room and then if they have got caught up, it all takes some time. (SpN2, pre-NLC)
It seemed that the service became disjointed when the teamwork broke down - the result being an increased waiting time for patients:

*If there is lots of people coming in [as non-appointment attendees] and the nurse is doing all that [attending to these patients], then the male doctor is not getting chaperoned and the patients start to battle.* (Dr14, pre-NLC)

Care management

Although there were breakdowns in the process of care, on the whole it was felt that the care that was provided at an individual level was good:

*I think that the information and treatment that we give is really good... you get people coming back, so we can't be doing things too badly.* (Dr14, pre-NLC)

### 6.1.3 Problems Achieving Clinic Goals

**Service related issues**

A major problem recognised by most staff was waiting times for patients. The waiting times were tied in with other problems, such as waiting for a senior doctor to examine a patient, the patient waiting between a history being taken and examination and doctors waiting for chaperoning:

*I think that from a patient’s point of view there are problems with the length of time that a visit takes. If I were a patient here I would think that it was all drawn out and long winded.* (Dr14, pre-NLC)
When a patient is booked to see a doctor they are seen in various stages. First they have their history taken, then they wait for a room to be set up, a nurse then calls them in to the room and discusses the procedures before the patient again waits for the doctor to carry out the examination. It was felt that this fragmented service led to service inefficiency and extended patient waiting times. This problem had an effect not only on the patient, but also led to dissatisfaction for both doctors and nurses:

*I think that it can seem quite bitty and frustrating because you are constantly doing different things all the time rather than focusing on one patient, being able to give them all the information and give them the time rather than in blocks.* (SpN2, pre-NLC)

Mortimer Market Centre was recognised as a successful central London clinic that relied on self-referral as its main source of patients. A number of staff felt that the clinic had done so well in establishing its reputation that the service now faced the problem of working at full capacity on a constant basis:

*The difficulty that I see is that with it being an open access clinic and the reputation that we have here is that people without sexually transmitted infections actually access the service.* (Dr8, pre-NLC)

With this success came the problem of service user appropriateness. It was noted that the women’s clinic saw a large proportion of women who had no signs of infection. Unlike the men’s clinic with its large population of gay men, it was thought that the majority of women presenting at the women’s clinic were relatively ‘low risk’ clients.
Therefore, it was questioned whether the women’s clinic saw those who really needed the services the most:

*I think that there is an issue if we make more appointments available we are just going to see more of the same type of client and perhaps we could look at why we are seeing that client group and what we could do about that.* (Dr8, pre-NLC)

The problem of time allocated to see a patient was a problem, particularly for the doctors, although this problem was also recognised by other staff members. The doctors had fifteen minute appointment slots to take a history and pre-test counsel those wishing to test for HIV. This time did not allow for the time that it took to continue with the examination and give the results. One of the suggested aims of the clinic was to get as many people as possible screened for STIs. In following this objective, it was felt that the constraints in time impacted on the clinic’s ability to provide a good service:

*There are a lot of constraints of time and I think that they have a knock on effect on the way the services are delivered.* (Dr15, pre-NLC)

**Personnel issues**

Some of the doctors felt that there was a lack of clarity in the various role definitions that existed within the clinic. With reference to the nursing role, it was felt that the nurses’ skills were often under-utilised. This perception came from all disciplines. One doctor said:
Certainly the majority of the nurses on the female floor are very experienced and I feel perhaps that their skills are under-utilised. (Dr16, pre-NLC)

Blurring of roles also led to role crossover when the service was pressured. This quote came from a doctor who suggested that aspects of his role were performed by other staff to keep the ‘system’ going:

There are particular instances when a health adviser and a lot of the nurses do certain aspects of your [doctor] work which is not fair, but you have to because you are under pressure. (Dr15, pre-NLC)

Staff morale was a problem identified across all staff groups. One comment from a nurse suggested that many of the doctors did not like working in the women’s clinic too frequently:

And you’ve also got doctors complaining all the time about doing female clinics all the time. (SpN1, pre-NLC)

One doctor stated poor teamwork to be a reason for not enjoying the work of the women’s clinic:

It’s a nightmare getting through seven or eight patients ... sometimes there is an atmosphere of resistance and people just aren’t there to get on and help you. (Dr8, pre-NLC)
However, this view was not representative of all doctors. Another doctor reported that 'everyone on the female floor was friendly and approachable.' (Dr14, pre-NLC)

With the various problems and low morale that occurred on the women's clinic, one doctor explained a side-stepping solution that often happened:

*I think that a number of consultants, in fact most consultants in this organisation, the way they handle their problems with the female floor is just not to do clinics which I think is not appropriate.* (Dr8, pre-NLC)

Another staffing problem involved the SHO rotation periods. One of the nurses and a health advisor suggested that the six monthly rotations of new SHOs through the clinic often led to a lack of continuity of care:

*As a nurse you feel that you have no sooner got someone who knows how to do all the forms, knows how to talk to the patients and can put a speculum in well, and then they are gone and then it takes another good four months for someone to be really confident again.* (SpN1, pre-NLC)

In addition to the SHO turnover there was an issue of senior medical staff turnover. During the months leading up to the start of the nurse-led clinics there was a shortage of Specialist Registrars (SpR). This resulted in patients with more complicated problems having to wait longer periods than usual to see a senior doctor:

*Trying to get to see a senior doctor is a problem as there has been few senior doctors around, so patients have to wait quite a long time.* (SpN1, pre-NLC)
So I think that for continuity on the floors, medical expertise is absolutely vital and sometimes for our six month change over of SHOs there have been problems with more established doctors who have been busy and are not around as they are snowed down with other things. (Health Adviser, pre-NLC)

Two senior doctors questioned staff resource allocation suggesting that there were those ‘routine’ patients who could be managed by a nurse and those that really needed a doctor. It was felt that a filter system or triage system might be better in matching the level of patient case difficulty with appropriate skill and experience:

Some kind of filtering service would be more appropriate and [the senior doctors] seeing more patients that really require doctors intervention. (Dr15, pre-NLC)

Patients that were triaged to senior doctors faced the problem of time constraints mentioned above:

In fact many of my follow-up appointments are taken with cases that other people have had trouble with so they actually require a lot of time and yet they are stuck into five minute follow-up appointments. (Dr8, pre-NLC)

Although seen as a problem, no ideal solution was identified to put such a filter system into practice. Filtering the ‘difficult’ cases towards senior doctors was considered inappropriate with regards to training opportunities for junior doctors. If junior doctors never saw difficult cases, they would not learn how to manage such cases:
...but I'm at a bit of a loss to know how you would filter the work load appropriately unless you stop consultants doing straight forward clinics then you would probably want a problems clinic, but then you have the issues of teaching as well. (Dr8, pre-NLC)

Many of the problems that the women's clinic faced were interrelated and although the interview participants were not asked to suggest solutions, those that did realised that there were no easy answers. Some participants felt that the introduction of nurse-led clinics could provide some answers particularly for the nurses' morale and satisfaction, whereas others were more sceptical. One doctor concluded with the following statement:

*If there is an issue with this [function of the women's clinic] then it needs to be sorted out. There is no point side-stepping it or indeed depositing the responsibility on nurses rather than doctors. I mean I think that's not necessarily the best way forward either and it will solve a few problems but it won't necessarily look at all the issues that appertain to the female floor.* (Dr8, pre-NLC)

### 6.1.4 The Role of the Staff Nurse

With resources being channelled into creating a new career pathway for nurses on the women’s clinic, this category provided a better understanding of the (E grade) staff nurse role so that the role transition of the new (F grade) specialist nurses could be tracked.
Patient focus

All staff groups felt that an important aspect of the staff nurses’ role was to provide support and information to the patient:

*I think that they have more of a role in actually providing more of the health education aspects because they do potentially in fact have a little more time to spend with the patients.* (Dr8, pre-NLC)

One of the nurses had a very clear idea of how her role in supporting the patient was fulfilled. Her statement revealed not only the concept of providing support, but also an insight into her actual approach:

*...to make women as comfortable as possible, being in a non-judgmental area and being able to discuss problems that they might have. To make them feel comfortable enough to be able to bring things up or to be able to ask them questions in an environment that is safe for them to be able to divulge information.* (SpN1, pre-NLC)

Apart from the major health promotion role, the other role frequently discussed by all staff groups was that of the ‘hands on’ clinical or technical role:

*Nurses do a lot of examinations on their own - the patients that have been in within the last year and do not have abdomen pain and just need a check-up.*

(SpN1, pre-NLC)
Nurses frequently talked of being an advocate for the patient, especially when a male doctor was examining the woman. Their role as a chaperone was not regarded simply as handing instruments to the doctor, but to ensure that the welfare of the patient was being taken care of and that 'everything was OK and that there was an independent person there' (SpN1, pre-NLC).

In an advocating role, the staff nurse was also regarded as a ‘moderator’ of care. Nurses felt that they were able to gauge the mood of the patient and relate this information to the medical staff, therefore advocating for the patient:

\[\text{You do feel like a bit of a moderator, especially if there is a medical student there and the patient is not too sure what is going on. So I'll go outside and have a chat with them [the medical student] and then have a chat with the patient on their own to see what they really feel and if they do feel really uncomfortable then I would say no medical student. (Nurse, FGD1, pre-NLC)}\]

Doctors also saw the nurses’ advocacy role as an important function, even when this role was one of picking up on what the doctor was doing, or not doing, for the patient:

\[\text{...and to kind of be an advocate for patients. You do see them [the nurses] stopping and talking to you and saying do you think you should do this or that and what about this. (Dr15, pre-NLC)}\]

**Undefined roles**

In addition to the moderating role that occurred at the individual patient level, on a wider scale, one doctor saw the nurses as the key people involved in running the clinic:
I think that they are essential to the running of the fast and efficient service. I think that the nurses are the most essential people because they do the majority of the work on the female floor and keeping it all running smoothly and together. (Dr14, pre-NLC)

In general, the nurses did not like to be seen purely as doctors’ assistants, although they often felt that they were treated in this way. They often found the chaperone role frustrating when they were assisting procedures that they were competent in doing themselves:

...because it’s like being a trolley dolly really because you are handing over the swabs to the doctor and it’s quite clear that your aim is to be there for the patient... (SpN2, pre-NLC)

It was also thought that patients really did not understand the full role of the nurse, but this was acceptable and not considered a problem:

I think that patients also see us as doctors’ assistants... and I don’t mind if doctors and patients don’t understand, as I know that I’m there to ensure that everything is OK between doctor and patient. (SpN1, pre-NLC)

Although the nurses often felt that the doctors misunderstood their role, this statement countered this perception:

I mean certainly every female should be accompanied by a female member of staff, but it is the patient that benefits ... there have been quotes in the past of
people saying doctors' handmaiden. I'm not advocating that, but there are some scenarios where a lot of their work does end up being just in the room with the male doctor. (Dr16, pre-NLC)

Nurses were also seen as crucial for providing 'back-up' to the doctors. The nurse often identified and managed aspects of the doctors' consultation that were missed. The nurses saw it as being a frustrating role as little credit was accorded to them:

You have got a patient in the examination room and you are covering things that you feel should have been covered in the [doctor's] consultation. (SpN1, pre-NLC)

On the other hand, one doctor was grateful for this aspect of the nurses role and implied that doctors often relied on this back up to provide effective patient care:

...and they will often pick up another tier if you like of vigilance or surveillance for each individual patient. They are able to tease out individual questions which under pressure anyone can miss so it is good to have that. (Dr15, pre-NLC)

Although the nurses pointed out their frustration of having to back-up the doctor's work, one nurse was able to justify why this was necessary:

They [new SHOs] don't really think about these things and they may not have the time and they have a long list of patients that they haven't the time for, so I think that it is fair to back it up in the examination room. (SpN1, pre-NLC)
The teaching of medical students was a role expectation described in the nurses' job description. However, the nurses felt that their role in teaching medical students was given little credit. In addition to medical students, it was also felt that it was the nurses who were often left to train and 'supervise' the new SHO recruits:

\[
\text{It's not really expected but it just happens that way that you are the one in the room and often you have to teach or take over what the SHO is doing which often they don't mind. (Nurse, FGD1, pre-NLC)}\]

Finally, the nurses reported frustration and dissatisfaction with certain aspects of their role that resulted from the under-utilisation of their skills and knowledge:

\[
\text{I do like the type of work that I do but it is the under-utilisation that is frustrating at times. You've got the skills to be able to get in and do something but it's not been formalised or recognised. We've made some amends to that like the increase in the examinations that we do, but at times you've felt under-utilised. (SpN2, pre-NLC)}\]

This underuse of skills was also recognised by a health adviser and by a number of the doctors:

\[
\text{Certainly the majority of the nurses on the female floor are very experienced and I feel perhaps that their skills are under-utilised and perhaps the majority of the nurses have more experience than some of the junior SHOs when they first come into the clinic. (Health Adviser, pre-NLC)}\]
They [the nurses] could be doing the screening and I [Dr] could be doing something more. There is no sense in two people doing the job of one [referring to doctor and nurse chaperone] and I kind of get the feeling that the reason that we are doing it is some twisted legal defensive approach you've got to have the doctor in case you miss something but I think that our nurses are knowledgeable and trained enough to pick up the role. (Dr15, pre-NLC)

6.1.5 Summary

This section has focused on exploring the many issues that existed prior to the commencement of the nurse-led clinic pilot. Although the level of care was generally thought to be good, the actual process of care was considered fragmented with room for improvement. A number of reasons for the lack of cohesion in service delivery were highlighted. Prominent amongst these were the issues of role definition and use of staff. These were also interrelated with the perception of the staff nurse role. For example, it was established that the role of the staff nurse was wide and varied, often leading to the blurring of their role. Staff nurses felt they could, and often did, perform many of the tasks normally carried out by medical staff, albeit on an informal, when required basis. This has been an issue for the women’s clinic for some time. Whittaker (1993) also reported the underutilisation of nurses. In an ethnographic study of the nurses’ daily work in the women’s clinic, she described how many of their roles in the care of patients were ‘invisible’ and unrecognised by other staff groups. Following Whittaker’s report and recommendations in 1993, there was a commitment to change the nature of the staff nurse role. For example, staff nurses were able to perform more ‘routine’ vaginal examinations at the direction of medical staff. However, seven years on, this study discovered the ongoing dissatisfaction that staff nurses felt regarding the many aspects of their work that remained unrecognised.
In addition to performing clinical tasks, staff nurses also provided a degree of training and supervision of medical undergraduates and new SHOs. This left the staff nurses in a conflicting situation. Informally, they were left to provide a degree of training, yet they were unable to perform these tasks and roles themselves unless designated by a doctor to do so. This issue is not unique to GUM. Wright (1995) described the mutual interdependence between doctors and nurses, quoting Dowling and Barrett’s (1991) study that demonstrated how nurses often supervised the practical induction period for new pre-registration house officers.

This section of the process evaluation has therefore set the scene for implementing nurse-led clinics in the women’s clinic. There were many challenges to overcome. In particular, the under-utilisation of nursing skill and expertise, and the fragmented process of care delivery. Many of the issues raised here will be reflected upon later in the chapter in relation to the extent to which nurse-led clinics changed the delivery of services in the women’s clinic.

6.2 Nurse-Led Clinic Implementation

The nurse-led clinic pilot began in January 1999. A mix of interviews and focus group discussions with doctors, staff nurses, health advisers and specialist nurses aimed to capture the relevant issues relating to the role preparation, induction and implementation period that followed the commencement of the nurse-led clinic initiative. The categories, subcategories and concepts derived from the data are summarised in Table 7 and then discussed in depth.
Table 7 - Analysis of interview data relating to the theme of nurse-led clinic implementation process

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6.2.1 Role Preparation

Prior to commencing clinical practice, a two week induction and training programme was planned for the specialist nurses. It was anticipated that this would consist of a mixture of informal lectures, discussions and periods in which the nurses could observe consultations by experienced doctors and health advisers. The content of these sessions would cover aspects of care that had not been formally performed by the specialist nurses in the past. For example, history taking, examination techniques and supplying medication. Unfortunately, as a result of circumstance, the specialist nurse training period did not proceed as intended. Because of staff shortages, the two specialist nurses continued to work in their previous staff nurse roles during the planned two week induction period. As a result, only a small number of informal teaching sessions were conducted. The effects of this are highlighted below in the interviews with the specialist nurses.

Problems identified from the training period

Although a two week period had been set aside for role preparation, at the end of this period the specialist nurses felt unprepared for their new role in practice:

*By the end of the week we felt disgruntled because we really weren’t ready, really ready for taking on clients. I suppose that we felt that, I felt not pushed into it, but not set up properly.* (SpN1, week1)

One of the main reasons for the ‘inadequate’ training was that there were not enough nursing staff on the women’s clinic for the two new specialist nurses to be released to concentrate on the training. The specialist nurses felt a strong commitment to continue
working ‘on the floor’ to maintain staffing levels rather than prioritising their own needs:

\[
\text{But because we were rostered to work on the floor, it was very much try and arrange an hour here and an hour there [for training]. We weren’t actually able to take a step back from that and actually start our own role. (SpN2, week1)}
\]

Although the specialist nurses were encouraged to plan their own training agenda, they felt that the ad hoc approach did not meet their expectations. They felt that the training was not planned and organised enough in advance. They then found themselves approaching staff who were unable to take time off their usual work schedule at short notice to provide training. In addition, there were some staff who allocated time off, but had last minute responsibilities to fulfil:

\[
\text{We didn’t actually sit down with Kate [SHO]. We were supposed to, but it was cancelled because she had to cover the clinic. (SpN1, week1)}
\]

Useful aspects of the training period

Although inadequacies were identified, what training they did have was thought to be useful. The doctors and health advisers who provided their time were appreciated. Each individual was considered to be ‘competent in their own area and able to talk about their own experiences’. It was these personal experiences that the specialist nurses were able to identify with:

\[
\text{It was really helpful seeing Sarah and Mike [health advisers] especially how to break bad news that we discussed with Sarah. She went into it in a bit more}
\]
depth about what you say and what you don’t say - what she says really, how she deals with it. That was good. (SpN1, week1)

Successes to build on

The specialist nurses were asked to suggest ways in which their experiences could contribute to the future training of other specialist nurses. The main emphasis was the need for protected training and preparation time. It was seen as important ‘to remove the person from their previous role so that they don’t get caught up working instead of training’ (SpN1).

Although planned, the opportunities to observe doctor-led sessions did not occur. In addition to this, the specialist nurses also wanted more direct supervision of their own clinical practice. A doctor did observe some of the specialist nurse clinical sessions in the first week of clinical practice, but they felt that they would have liked more.

Advanced planning was also emphasised so that ‘people doing the training would know well in advance so that they could plan the session and they would know to have an hour or two clocked off’ (SpN2, week1). It was felt that the sessions could be more structured, rather than the ad hoc nature of some of the sessions.

Regarding the format of the teaching, the consensus was that a mixture of lectures, informal discussions and observing doctor-led consultations would be best. It was felt that there was ‘something to be said in having someone standing up and giving you a lecture... you might know things but it is still good to go over things from their point of view’ (SpN1, week1). In addition to observing the routine doctor-led clinics on the women’s clinic, arrangements to visit other relevant services could be useful, such as the ‘Vulval Clinic’ at a neighbouring hospital.
6.2.2 Specialist Nurse Role Transition

Individual competency

In the first few weeks the specialist nurses expressed numerous anxieties and insecurities about their new role:

*I think the major causes behind feeling nervous were I didn’t know whether it would be someone that I was going to be able to deal with... I was a bit worried about over testing... I was wondering whether I would actually be increasing their [patients] waiting time.* (SpN2, week 1)

By the fifth week one specialist nurse reported her increased confidence:

*When you first started you were thinking, what’s out there waiting for me. I don’t feel so much of that anxiety now because I have got into the swing of it and even when you think you’ve got something that’s quite tricky, you never actually think oh where do I go from here.* (SpN2, week 6)

The same specialist nurse also stated that over time she was taking a smaller number of cases to her clinical supervision session. This in itself demonstrated her confidence in managing cases more independently. However, she remained hesitant in feeling overly confident:

*Well I think we’ve definitely been taking less up for clinical supervision so I suppose if you were looking for evidence that would be it really. It just seems as if it’s gone a bit too smoothly at the time and I still think it’s early days yet.* (SpN2, week 6)
With this confidence came the desire to have a more in-depth knowledge to be able to offer more to patients:

_I could give better information about gynaecological things if I had more knowledge myself, so I could do that bit better._ (SpN1, week 14)

In addition to knowledge, the desire to take boundaries that bit further was evident, particularly relating to the supply of medication:

_I mean, as long I know what I am doing, if I am checking everything, then I should be able to [supply medication]._ (SpN1, week 8)

Supervision

The specialist nurses made it clear in the initial weeks that they were not used to formal supervision and did not really know what to get out of it. Although there was a lack of clarity of what was to be expected from supervision, they found it useful for identifying the clinical aspects of their practice that needed addressing:

_We have been going through the notes with her [consultant physician] and she might say well what if that had happened and I might say what would you have done in the situation. Do you think that I did the right thing?_ (SpN1, week 2)

As time progressed, the specialist nurses were concerned that they were not getting enough clinical supervision. Every set of patient notes from the first two weeks was reviewed but from then on, it was up to the individual specialist nurse to take a selection
of patient notes to their supervision session. The concern was that there was the possibility of mistakes being made and that nobody was picking them up:

*I don't feel as if I am being closely supervised and yet I feel that if something happens, the shit is going to hit the fan.* (SpN1, week 14)

*I think that it would be nice to have someone independently reviewing notes. We are taking the cases that we are having problems with to supervision, but are there some mistakes that are getting through that somebody could pick up on?* (SpN2, week 19)

Direct supervision during clinic time was, at times, felt to be more productive than the weekly formal supervision:

*I don’t really know what to get out of supervision really. It’s more interesting when I’ve had [the consultant] in, like this morning [to see a woman with pelvic pain] and afterwards the discussion I had with her about the different things that it could be.* (SpN1, week 8)

Apart from the supervision of clinical effectiveness, the specialist nurses felt that their emotional and personal needs were being met with the support of the health advisers and nurses in the clinic. This type of supervision or support was made easier as a result of the existing relationships that the specialist nurses had with the staff of the women’s clinic:
As far as supervision goes regarding how you feel, your changing role and what sort of personal support you get from that, there is nothing structurally that's in place, but I think you get it informally at this clinic anyway because you go to the nurses station and you talk about it straight away. I think that it's a very informal system of doing it, and that's the way that things have worked for a long time up here. (SpN2, week 6)

Operational issues

One problem that was recognised within the first few weeks of nurse-led clinic implementation was the insufficient length of the nurse-led clinic appointment times. The original thirty minute appointment times were an underestimate of the true time the 'one-stop' approach to care actually took. Extending the appointment times to forty minutes rectified this problem:

*I know that there is an argument about when you get used to doing the clinic then you will pick up the time but actually I don't feel that there was any area of those consultations and examinations that I could've cut back on.* (SpN2, week 2)

Another problem related to locating a doctor when the specialist nurses required assistance:

*I mean, you do get frustrated when you have someone with pelvic pain and you have to go out and get a doctor. The time that you do spend doing that means you have less to give to patients in other ways.* (SpN2, week 19)
In addition to locating a doctor, there were a number of times when the specialist nurses were faced with the problem of no medical cover at all:

\[\text{At the end of the day on Friday afternoon I was doing an examination at a quarter to four, and that was a pain, and then apart from a clinical assistant who was still around, all of the other doctors had gone and I had this PID woman. (SpN1, week 4)}\]

This problem of medical cover was also recognised by the other nursing staff:

\[\text{We had a bit of a panic when [the SpN] was off sick and it all went a bit bananas and no one was sure who was supposed to be on cover and the next thing there was an email to stop [the SpN] clinic indefinitely – completely mad. (FGD3, week 12)}\]

Prior to the commencement of nurse-led clinics, there were some concerns about the professional boundaries of specialist nurses. However, within the first few weeks of practice it was clear that the specialist nurses were able to recognise their limitations of practice. For instance, they were clear what type of patients should not be booked into their clinic. They knew that patients for follow-up of PID (pelvic inflammatory disease) should be booked in to see a doctor for a bi-manual pelvic examination. However, these patients were still inadvertently getting booked into the nurse-led clinics by other staff. Sometimes the reason for this was the shortage of female doctors as seen in the second quote:
Well it was better this week. At the end of last week we were getting foul-ups. We were getting PID referrals from casualty and things like that. (SpN1, week 4)

I think that the other thing that is happening is that some of the patients that are inappropriate to be seen by the specialist nurses have been booked in to see them because they are female...because with all male doctors, the receptionists shove patients in with the specialist nurses and it's inappropriate. (FGD3, week 12)

Conflict

Although the transition from staff nurse to specialist nurse was relatively smooth and positive, there were some aspects of the specialist nurses’ previous role they found hard to leave behind and some old roles that now conflicted with their new role. The specialist nurses also felt isolated from the rest of the nursing team:

As time goes on if you are fully booked then I do feel pretty isolated from the rest of the team and I didn’t think that would happen but because you are not out there involved in the general work, you feel that you are on your own. (SpN2, week 19)

Another issue of conflict related to how the role of the specialist nurse was viewed by other staff. Although there has been widespread support for the nurse-led clinics, there were times when the specialist nurses felt that some doctors took control from them, even when the specialist nurse concerned was clear about her observations. On such occasions the specialist nurse felt her judgement undermined:
There was this lichen sclerosis that happens in a lot of women. Previously I had taken one or two of them to a doctor just to write the referral to EGA [Elizabeth Garrett Anderson Hospital]. With the most recent one the doctor didn’t do that. She wanted to see them visually before she referred them to EGA and I felt a bit snubbed by that, but I thought fair enough she’s checking because she wants to see what’s being referred. But I wondered if she had referred another doctor’s patient, would she have seen their patients before referring them out? If I had to refer everything I would feel a bit snubbed by it because that’s why I am doing the job. You need all the experience to be able to do the job and with that experience I can diagnose, but if you are stopped at every post that doesn’t do a lot for your ego. (SpN1, week 14)

Conflict also surrounded clinical decision making. There was one incident reported when disagreement between a specialist nurse and a SHO led to the specialist nurse going to another doctor for a second opinion. In this instance, the specialist nurse was taking the patient’s choice into consideration and the SHO was sticking rigidly to the clinic guide. As it turned out the second doctor agreed with the specialist nurse’s decision to acknowledge the patients right to exercise her choice for treatment:

I went to one of the SHO’s and he wouldn’t write up doxycycline. I was like I’ve discussed this with the patient and he said there is a possibility of pregnancy - what if her boyfriend asks her to marry him and then they want to have the baby and I said that’s not up to you it’s the patient’s choice. I had to leave and get a registrar because I wasn’t happy with that... I had to discuss with a registrar and go through the whole story again to get them to write it up and they said have you discussed it with the patient and I was like yes I have discussed it all
and she doesn't want it so can I get doxycycline? I know it's their signature but it's the patient's decision if you have given them all the information. (SpN1, week 14)

Another issue for the specialist nurses was when they were getting conflicting advice between different doctors:

On a couple of occasions that I have approached a doctor there has been a difference of opinion between the doctor that I spoke to at the time and the doctor who took up the referral. (SpN2, week 19)

6.2.3 Scope of Practice Issues

This section addresses the professional issues of the specialist nurses and contrasts them with those of the new intake of SHOs during the first few months in their new roles on the women’s clinic.

Recognising practice limitations

If a specialist nurse was unsure about her practice, she was clear that she would consult a doctor for advice:

Interviewer: So when you have been faced with a case that is outside your scope of practice, what have you done?

SpN: Got the doctor in to do a PV examination or even if you’re not sure about what’s the best way to follow-up. (SpN2, week 2)
In contrast, the SHOs were more likely to consult the clinic guide before going to a senior colleague:

If there was something that I was unsure about like hepatitis B vaccinations and stuff whether someone needed another booster dose or whatever there is always the guide to consult or something that I was unsure about yesterday I got one of the registrars to have a look at it. (Dr2, week1)

The point of time and the type of case that was referred to a senior doctor also differed between specialist nurse and SHO. The specialist nurses were clear that their practice boundaries lay with their previous knowledge and experience and that they ‘wouldn’t be happy to take on anything more without training.’ (SpN2, week 19)

But if it's something that you haven’t seen before, you wouldn’t just try and deal with it on your own. You’d always have to get a second opinion on it...I’m not going to deal with anything that I don’t feel capable of handling. (SpN2, week 6)

On the other hand, the SHOs, with limited or no previous GUM experience, had to rely on other markers to define their limitations of practice. One of the SHOs talked about consulting a senior colleague when there were legal implications or other complexities involved, such as pregnancy:

Interviewer: In terms of the limitations of cases that you can take on - how do you know your boundaries - are there any?
Respondent: I think that there are. I think that with legal cases. I think with pregnancies, I would probably with like herpes, I would want to take some advice from one of the registrars or consultants but most things I get by with without having to consult. (Dr2, week 12)

The specialist nurses reported that they recognised their boundaries within the scope of their own professional practice and experience. They realised that they had to recognise their boundaries, for not only their own professional protection, but also to meet the best needs of patients:

You wouldn’t put a patient at risk if there was something that I didn’t have the experience or knowledge to cope with. I would definitely get a doctor. It’s too scary to think that somebody, imagine if you went home with something that you weren’t too sure about and then you couldn’t get into contact with them. You know its too scary to contemplate so I would rather get someone to wait and see somebody. (SpN1, week 1)

If I am doing the examination and somebody is saying they are having deep pain when they are having sex and it is happening on a particular side and they are not constipated and there is no wind there or you know things like that, then I would rather for the patient’s sake have somebody do the internal just to put their mind at rest. (SpN1, week 4)

The SHOs’ reasons for recognising limitations of practice and referring on patients were not explicit from the interviews.
Recognising effective practice

Both SHOs and specialist nurses were asked how they knew whether or not they were providing the correct care and treatment for the patients they were seeing. Once again there were differences between the specialist nurses and the SHOs. The specialist nurses were clear about recognising effectiveness. Both specialist nurses suggested one main way was from patient feedback. The SHOs did not raise this concept:

You know the feedback that I am getting back at the moment is people who are coming back in and who say after the consultation yeah thanks very much I really appreciate it and that’s been great. (SpN1, week 2)

Obviously from the feedback that they’d give you, like, thanks you’ve been very helpful. (SpN2, week 6)

Other means by which the specialist nurses recognised effective practice was through experience, personal reflection and by laboratory result confirmation:

Well, when you give the treatment you usually get a result back so you know what you are doing. On experience I have a good idea about what works and what doesn’t work and what solves things and on patient experience and patients telling you what went on and what’s worked and what hasn’t and looking back in the notes to see what’s been happening, to see what they have been treated with and if it has been ongoing and if it’s been documented about information they have been given... (SpN1, week 4)
In contrast, the SHOs having little or no previous experience in GUM care found it difficult to recognise effective practice. The two SHOs were more likely to rely on supervision and the assumption that someone was reviewing their work:

- Well basically there is a kind of middle grade still going over the notes with us. A couple of times that has been really useful. (Dr2, week 2)

- [re: team meetings] You just present the patients basically and one of the consultants there would just talk it through. That is very useful, I mean that’s what you need, just so other people can talk about it as well, in a positive way... Otherwise you could just be going ahead and have no idea, have no feedback at all and just get things consistently wrong... (Dr2, week 2)

In addition to supervision and team meetings, the SHOs found other staff, particularly nurses, a reliable source for detecting effective or ineffective practice:

- I’ve missed things already. Mainly things like warts that haven’t looked like anything special to me and the patient has been arguing with me telling me that it is something and I have said I don’t think that it is and then I have said fine, perhaps see what the nurse says and the patient has come back and the warts have been treated and I’ve said look I’m sorry you’re right - the nurses have picked up on loads of things that I’ve missed. (Dr3, week 1)

During the first week of consulting patients, one of the SHOs was honest about his uncertainty as to whether he was managing patients correctly. He also made an assumption that there was a system to pick up any errors that he had made:
I look at the clinic guide if I'm not sure. Most of what I have picked up is what I have sat in on, which was with a junior SHO anyway, so whether that was the most appropriate teaching. Especially for the common things I didn't quite grasp the right things and I think that I have done a few things wrong just because I didn't know and at the start you try to concentrate on filling out the forms and not necessarily patient management. So you are more worried about filling in the proforma. So I do think that I did get the wrong end of the stick with a few things but whether that is because the person that I was learning off was doing it wrong or because I misinterpreted it. I'm not quite sure and I don't know really. I get the impression that someone looks through the notes, the consultants, and I get the impression that if I have done it wrong I'll soon hear about it. I've no idea if I'm doing it right or not is the honest answer. (Dr3, week 1)

Another SHO found it more difficult to judge effective practice with female patients because of the lack of objective clinical endpoints:

I think that its much less obvious on the female floor because obviously there seems to be less gonorrhoea and NSU where there's less endpoints so it is less obvious that you have done the right thing... (Dr2, week 12)

6.2.4 Personal and Professional Outcomes

Job satisfaction

One of the original objectives for initiating the nurse-led clinics was to offer a new career opportunity for nurses. This objective was fulfilled as both of the appointed
specialist nurses reported increased satisfaction with their jobs with a sense of
fulfilment, increased control and support for their new roles:

You know in your job at the end of the day when you go home and think bugger,
I wish that I had just sat down with that patient or just done that with a patient
rather than going for my tea-break - I haven't felt like that. (SpN1, week 5)

I think that the reaction from the doctors has been quite positive really and the
people or the doctors that we have spoken to have said you know it sounds like a
good idea. (SpN2, week 3)

On the other hand, there was some disappointment from the staff nurses. There were
some prior expectations that introducing nurse-led care would offer something for all
the nurses on the clinic. Although the staff nurses had been very supportive of the
specialist nurses, little changed for them:

I was excited that something might change, but nothing has. (FGD2, week 3)

Suggestions for the future direction of the staff nurses came from the focus groups:

We all know that we are capable of doing it and hopefully when this pilot is over
we will get a chance. It would be nice if we could all be involved in doing the
clinics at some stage. (FGD2, week 3)
Working relationships

Both the specialist nurses and the staff nurses felt there had been some change in the team dynamics. The staff nurses felt that the specialist nurses had moved on to become more a part of the doctor team. However, it was felt that this was to be expected. A rationale for this change was provided in this focus group exchange:

P1: *I think that it's changed the whole team dynamics of the nurses' station a bit as they have moved down the corridor kind of thing...*

P2: *...a lot of people have been working here for two years or more so there is quite an established group of people so of course you are going to feel it when people change...*

P3: *They do feel quite removed from us. They seem to be more part of the doctor group rather than an extension of the nurses...*

P1: *I think that is only because they have to go to the doctors for a bit more help in situations that crop up...* (FGD2, week 3)

However, the specialist nurses made efforts to maintain their rapport and contact with the nursing team:

*I do feel that when all the patients have turned up that it can feel very much that you're isolated in the room and you don't often have contact with a lot of the team so you do miss out on that in a way. But if you do have a DNA [non-attendance] then you occasionally get the chance to catch up and help out with them [the staff nurses].* (SpN2, week 6)
6.2.5 Summary

This section of the process evaluation explored the nurse-led clinic training, preparation and implementation period. The specialist nurses discussed how unprepared they felt for their new role and areas were highlighted in which improvement could be made for future training interventions. In particular, the specialist nurses suggested that there should be protected time for role preparation and that a mix of lectures, observation and mentoring would be useful.

Despite the training problems, the transition from staff nurse to specialist nurse was relatively smooth and positive. Although there were initial anxieties and insecurities about forgetting or missing something important in the patient consultation, an increasing confidence was evident after the first month, and with this a desire to extend practice boundaries. The major change for the specialist nurses was the isolation from the other nurses and the difficulty breaking away from their previous roles.

There were occasional periods of conflict in the decision-making between the specialist nurses and doctors and the occasional feeling of being undermined by medical staff. The transition period also was a time for the specialist nurses to become familiar with clinical supervision and how it could benefit their practice. Operational issues, such as appointment times and accessing a doctor, were identified. These were all issues that were addressed by the nurse-led implementation team. Overall, there were no problems that could not be overcome, or could have jeopardised the nurse-led clinic initiative.

The interviews also explored the professional conduct of the specialist nurses with regard to their scope of practice. Contrary to early concerns that the specialist nurses would have problems identifying their limitations of professional practice, the interview data demonstrated very clearly that the specialist nurses were not only clear about their limitations, but clear why they needed to be able to acknowledge such
limitations. They were also confident about how to recognise effective practice, something the new SHOs were not so sure about.

The ability to recognise patient feedback as a measure of effective practice was something that the specialist nurses seem to have learnt from their previous role as staff nurses. In an exploratory study of the role of the GUM staff nurse, Whittaker (1993) found that not only did patient feedback influence staff satisfaction, but it was also a way of making nurses’ work visible to themselves. With the lack of a defined and often unrecognised role, it could be said that staff nurses have often looked to patients for recognition of their role. From the interview data in this study, it appears that the specialist nurses have continued to rely on patient feedback as a measure of personal and professional success.

Finally, the personal and professional outcomes for the specialist nurses, as individuals, were very positive. However, the expectations of other staff were not met. Little had changed for the rest of the nursing team. In addition, the team dynamics between the staff nurses and the specialist nurses had changed – the specialist nurses becoming more distant from their origins as staff nurses. The interview data also indicated there was general support for the new specialist nurse role from the medical and health advising staff. This is encouraging at a time when there have been reports from other fields of healthcare opposing changes to the future direction nursing roles (Barton, 1995; Tye and Ross, 2000).

The remainder of the chapter will concentrate on the process of nurse-led care by describing the clinical activity of the nurse-led clinics and then exploring how this care was delivered.
6.3 Clinical Activity of Nurse-Led Clinics

This section reports quantitative data collected over the first fifteen weeks of nurse-led clinics focusing on:

- the patient caseload (reason for attendance) in the nurse-led clinics
- the time taken to complete a patient history and examination
- the number of patients requiring referral to a doctor
- the number of cases needing a doctor’s prescription.

This information was recorded by the specialist nurses at the completion of each appointment.

6.3.1 Nurse-Led Clinic Patient Workload

The two specialist nurses saw a total of 565 patients during their first fifteen weeks of clinical practice. During the first two weeks the nurse-led clinics had extended consultation times to allow the specialist nurses to adjust to their new role. By week three the specialist nurses were feeling confident enough to have fully booked clinics. During this week the number of patients peaked. With over-run clinics and long patient waiting times, it became clear that the thirty minute appointment slots and ten minute follow-up slots did not provide enough time for effective care to be carried out. From the beginning of week four the appointment times for new cases were changed to forty minutes and follow-up appointments were given fifteen minutes. The decline in patient numbers after week three corresponds with this change in appointment availability (see Figure 4).

Figure 5 presents the reason for attendance. The data indicated that the majority of patients attending nurse-led clinics fell into the categories that were specified as those likely to be independently managed by the specialist nurses. During the planning of the nurse-led clinics, pelvic pain raised considerable concerns with regard to its
management. As the specialist nurses were not trained to manage pelvic pain, some doctors worried that this would mean an increase in their own workload. Overall, only 41 cases (7.3%) of pelvic pain presented during the first fifteen weeks.

Figure 4 - Number of patients seen by specialist nurses during first 15 weeks of clinical practice (n=565)

Figure 5 - Reason for attendance for patients visiting nurse-led clinics
6.3.2 Specialist Nurse Consultation Time

The time of the consultation was recorded for each patient seen. This time was restricted to the history and examination time and did not account for the time that patients waited for their results and the time it took to give their results. A breakdown of the average time of consultation for each category is presented in Table 8. Note that this section is independent of the waiting time survey reported in chapter seven that compares specialist nurse and doctor consultation times.

Table 8 - Consultation times reported by specialist nurses during induction period

<table>
<thead>
<tr>
<th>Reason for Attending</th>
<th>Mean Time (minutes)</th>
<th>No. Cases (%) (n=565)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A - asymptomatic blood tests only</td>
<td>35</td>
<td>11 (1.9)</td>
</tr>
<tr>
<td>B - asymptomatic/contact check-up</td>
<td>38</td>
<td>131 (23.2)</td>
</tr>
<tr>
<td>C - results/follow-up</td>
<td>15</td>
<td>134 (23.9)</td>
</tr>
<tr>
<td>D - symptomatic vaginal discharge/irritation/dysuria/warts</td>
<td>41</td>
<td>205 (36.5)</td>
</tr>
<tr>
<td>E - genital ulcer/atypical warts/bartholins cyst</td>
<td>44</td>
<td>16 (3)</td>
</tr>
<tr>
<td>F - dermatological</td>
<td>41</td>
<td>8 (1.4)</td>
</tr>
<tr>
<td>G - pelvic pain</td>
<td>51</td>
<td>41 (7.3)</td>
</tr>
<tr>
<td>H - sexual dysfunction/urological/complicated dermatological</td>
<td>13</td>
<td>5 (0.9)</td>
</tr>
<tr>
<td>I - other</td>
<td>43</td>
<td>10 (1.9)</td>
</tr>
</tbody>
</table>
6.3.3 Proportion of Referrals to Doctors

Of the 565 patients seen by the specialist nurses, sixty seven (12%) required a doctor for examination purposes. Figure 6 presents the proportion of patients per category who required examination by a doctor. The specialist nurses managed the remaining 497 (88%) patients independently without needing to access a doctor.

It was anticipated that a doctor would examine all women presenting with pelvic pain. However, seven women (17%) with pelvic pain did not get referred. The specialist nurses also managed some of the other patient categories that were expected to be examined by a doctor. Some of these instances were justified. For example, the specialist nurse would refer a woman with sexual dysfunction directly to a health adviser if she thought that the problem was of psychological origin, therefore negating the need for a doctor’s examination.

Figure 6 – Patients from nurse-led clinics requiring examination by a doctor
6.3.4 Proportion of Patients Requiring Medication Prescriptions

Of the total patients seen, two hundred (35.4%) required medication to be prescribed by a doctor. The level of prescribing remained fairly consistent apart from week six when the number of prescriptions required dropped to 8.7%. This was likely to be a reflection of the patient caseload: there were only five symptomatic cases of vaginal discharge/irritation/dysuria during this week compared with the usual ten to twenty.

6.3.5 Summary

By monitoring and documenting the clinical activity of nurse-led clinics, sufficient evidence was available for the nurse-led implementation team to review and make changes to practice almost immediately. The times allocated for appointments were initially too short so were subsequently extended to forty minutes for new appointments and fifteen minutes for follow-up appointments. The other main finding was that only 12% of all 565 cases required a doctor’s examination - the other 88% were managed independently by the specialist nurses. However, 35% of all cases still required a doctor’s prescription. With this evidence in hand, the development of patient group directions was pursued to enable the specialist nurses to supply selected medications without the need to locate a doctor for a written prescription.

6.4 Mapping the Process of Care

The ‘process flow maps’ (Figure 7 and Figure 8) illustrate the key stages and timing of care that were observed from the doctor and specialist nurse consultations. The consultation time was recorded from when the patient consultation commenced (and not when the patient entered the clinic), to when the patient completed their consultation with the health care worker. The average times of the doctor and specialist nurse consultations can be compared in the process flow maps. Although the sample was
small, the results do provide some indication of what were considered to be ‘typical’ consultations.

It should be clarified at this point that the structure of a nurse-led clinic was considerably different to that of a doctor-led clinic. The specialist nurses had forty minute appointment slots to see a patient from start to finish. They generally worked from one room and did not have the assistance of a chaperone. The doctor-led appointment slots were for fifteen minutes. The history was taken in one room and the examination in another. The doctors always worked with a staff nurse who was often delegated to complete the examination and take the required specimens. Male doctors were always chaperoned by a female staff nurse. The differences in approaches to care will become clearer as the consultations are explored below.

6.4.1 Patients Who Did Not Have to Wait for Preliminary Results

Figure 7 outlines the process of a ‘typical’ appointment for patients who did not have to wait for preliminary microscopy results. For the specialist nurse working from one room, there were no waiting periods observed apart from one occasion. This was when the specialist nurse went to locate a doctor to complete an examination. However, this only took a few minutes. The preparation and labelling of specimens occurred when the patient was behind the curtain getting undressed for her examination. Dialogue between the specialist nurse and the patient generally continued throughout this period. The average total consultation time was 35 minutes with 97% of this time being direct contact time with the practitioner.

In contrast, the doctor appointments incurred more waiting periods accounting for an average waiting time of approximately ten minutes. This time was broken into two separate waiting periods. First, when the assisting staff nurse was preparing the examination room and labelling the specimens and second, when waiting for the doctor
to come and complete the examination. In one case a woman was left waiting for nearly twenty minutes in the examination room while the doctor was seeing another patient.

Although the total appointment time from the start to the finish of the consultation (31 minutes) was slightly less than that of the specialist nurses (35 minutes), the actual contact time with a practitioner in relation to the total time in the clinic was also less. Only 68% of the appointment time was spent in direct contact with the doctor compared with 97% with a specialist nurse. As a result, the specialist nurses spent thirteen minutes longer with the patient than the doctors did.

Figure 7 – Process flow map: Patients who were not required to wait for preliminary results

<table>
<thead>
<tr>
<th>Specialist Nurse (n=6)</th>
<th>Doctor (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
<td><strong>History</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Examination / Specimen Collection</td>
<td>Pt waits while nurse prepares room</td>
</tr>
<tr>
<td></td>
<td>Pt has blood test by Nurse</td>
</tr>
<tr>
<td></td>
<td>Pt prepares for examination +/- wait</td>
</tr>
<tr>
<td></td>
<td>Examination / Specimen Collection by Dr or Nurse</td>
</tr>
<tr>
<td>Home</td>
<td>Home</td>
</tr>
</tbody>
</table>

*Patient contact time = 34 min (97%)*

*Patient waiting time = 1 min (3%)*

*Patient contact time = 21 min (68%)*

*Patient waiting time = 10 min (32%)*
6.4.2 Patients Who Were Required to Wait for Microscopy Results

Figure 8 outlines the process of a ‘typical’ appointment for patients who were required to wait for microscopy results. Patients who saw a specialist nurse had an average total appointment time (from start to finish of consultation) of seventy five minutes compared with eighty minutes for those seeing a doctor. The waiting period for specialist nurses and doctors was twenty eight and forty eight minutes respectively. This meant that not only were the doctors’ patients in the clinic for longer, but their total contact time (41%) in relation to the time spent in the clinic was much less than those seeing a specialist nurse (62%). Again, the specialist nurses spent on average thirteen minutes longer with the patient.

**Figure 8 – Process flow map: Patients who were required to wait for microscopy results**

<table>
<thead>
<tr>
<th>Specialist Nurse (n=4)</th>
<th>Doctor (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>History</td>
</tr>
<tr>
<td>Examination / Specimen Collection</td>
<td>Pt wait</td>
</tr>
<tr>
<td>Pt wait</td>
<td>Pt has blood test by nurse</td>
</tr>
<tr>
<td>Results / Treatment</td>
<td>Pt prepares for examination +/- wait</td>
</tr>
<tr>
<td>Home</td>
<td>Examination / Specimen Collection by Dr or Nurse</td>
</tr>
</tbody>
</table>

*Patient contact time = 46 min (62%)*  
*Patient wait time = 28 min (38%)*  

*Patient contact time = 33 min (41%)*  
*Patient wait time = 48 Min (59%)*
6.4.3 Summary

The process flow maps made it clear that the nurse-led and doctor-led consultations were in fact two different approaches to care, or models of care. The nurse-led model can be regarded as a ‘one-stop’ approach, whereas the doctor-led model was fragmented with longer waiting times for patients. This fragmented approach to care was highlighted as a problem in the pre-nurse-led clinic interviews. The process flow maps have therefore shown how the model of nurse-led care can benefit patients in terms of consistency throughout an appointment. Patients were not getting passed from one room to another and had most of their care provided by one person.

Although the total appointment times were approximately the same for both models of care, the specialist nurses spent an average of thirteen extra minutes in direct contact with the patient. Some of this time was accounted for during the period when the specialist nurse was preparing the specimens and the patient was preparing for examination (i.e. patient and specialist nurse were in the same room and still able to maintain communication). In contrast, the same process occurred at different periods during the doctor-led model (i.e. the staff nurse was setting up the room whilst the patient was waiting in the corridor).

The following sections will provide further detail of how the ‘extra’ time was used by the specialist nurses in addition to exploring the interpersonal processes of ‘typical’ nurse-led and doctor-led consultations.

6.5 Approach to Care

Section 6.3 of this chapter presented the clinical activity of the nurse-led clinics and section 6.4 illustrated how the delivery process differed between the nurse-led and doctor-led models of care. Using data from the non-participant observations, this section continues to explore the clinical activity and delivery process with respect to the
interpersonal approaches to nurse-led and doctor-led care. Extracts from the patient exit interviews and staff interviews are also presented to support the observational data.

In general, each practitioner (doctor and specialist nurse) had his or her own style that was repeated for each consultation. Therefore, the patterns of care by individual practitioners were established relatively quickly and are discussed within six categories. Table 9 provides an overview of these categories and their respective subcategories and concepts that were a result of the data analysis.
<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategories</th>
<th>Concepts arising from data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishing the presenting problem</td>
<td>Style of introduction</td>
<td>Formal, informal</td>
</tr>
<tr>
<td></td>
<td>Factors influencing interview technique</td>
<td>Level of experience, time, focus</td>
</tr>
<tr>
<td>Eliciting a sexual history</td>
<td>Questioning style</td>
<td>Direct, preparing patient</td>
</tr>
<tr>
<td></td>
<td>Patient experience</td>
<td>Comfort zone, importance of questions, preference</td>
</tr>
<tr>
<td>Establishing HIV/STI risk factors</td>
<td>Patterns of questioning</td>
<td>Individual styles, consistency</td>
</tr>
<tr>
<td>The examination process</td>
<td>Explanation</td>
<td>Clear vs poor, simplicity</td>
</tr>
<tr>
<td></td>
<td>Co-worker support</td>
<td>Information back-up</td>
</tr>
<tr>
<td>Providing results and treatment</td>
<td>Explanation</td>
<td>Inconsistencies</td>
</tr>
<tr>
<td></td>
<td>Reinforcing understanding</td>
<td>Use of literature, demonstrations</td>
</tr>
<tr>
<td>Health promotion</td>
<td>Factors affecting health promotion activity</td>
<td>Time, experience</td>
</tr>
<tr>
<td></td>
<td>Delivery style</td>
<td>Holistic, proactive vs reactive, use of supportive literature, condoms, question time</td>
</tr>
</tbody>
</table>
6.5.1 Establishing the Presenting Problem

Style of Introduction

All doctors and specialist nurses introduced themselves once the patient had entered the room. Most practitioners were informal, using their first names, although some of the doctors preferred a more formal “I’m Dr...”. Following the brief introduction both specialist nurses and doctors established the presenting problem quickly and directly:

“I’m Dr... - What brings you here today?” - patient says that she had an HIV test last week and has come back for a check-up today. The Dr asks “any symptoms that you are concerned about?” (observation, CL31, Dr11)

Factors Influencing Interview Technique

Each person had their individual style of taking notes. Some people preferred to take notes as the patient spoke, whilst others would wait for the patient to complete their statement. However, all consultations appeared friendly with the practitioner using open and friendly body language with good eye contact. The main difference between the doctor and specialist nurse consultations was the time factor. Some of the doctor consultations felt rushed, barely giving the patient time to answer the questions. However, this was not the case for all the doctors. It appeared that more experienced doctors were skilled in getting a lot of information in short periods of time:

She has a calm, direct and sensitive manner and answers the patient questions comprehensively with clear explanations. Her experience seems to show. She has the ability to get through many questions in a short space of time without the feeling of rushing the patient. (Observation, GM28, Dr12)
One problem observed in a less experienced doctor was side-tracking and discussing issues that were not really related to the consultation. The key skill in keeping to time appeared to be the ability to remain focused:

*Patient gives history of a non-STI related problem and the doctor asks more details of this problem than he does of the presenting STI problem.* (observation, AN34, Dr6)

The specialist nurses appeared to have more time to explore the presenting problem and get the intricate details of the symptoms:

*She then goes back over to fill in other parts of presenting symptoms, checking other symptoms that patient has not mentioned such as dysuria, itch. It was good that she did this as patient was also having deep dyspareunia that the patient didn't mention at the outset. The specialist nurse then explores the type of sex that caused deep dyspareunia - a quite open discussion including intricacies of sex i.e. deep penetration, change of position etc.* (observation, TL6, SpN1)

This does not mean that the doctors did not go into depth regarding the patient symptoms when required.

### 6.5.2 Eliciting a Sexual History

**Questioning style**

There were individual styles and approaches to obtaining a sexual history. Some practitioners prepared the patient for the personal questions, whereas others asked more directly. There appeared no particular pattern or difference between specialist nurses
and doctors, nurse-led or doctor-led models of care. Instead, the patterns seemed to be set by individual practitioner experiences:

*Prepares patient for questions to follow by normalising them* - “these are questions that I ask everyone - are you in a regular relationship...” (observation, JO27, Dr3)

*The specialist nurse moves on to take the sexual history and asks directly when she last had sex. She then asks whether she had oral and anal sex. She does this while maintaining good eye contact, addressing the patient directly in a lowered reassuring voice.* (observation, SB18, SpN2)

There was only one case when a sexual history was not established. This was when a patient was returning for a doctor-led follow-up appointment:

*No sexual history taken and it has not been established whether there has been any risk of re-infection apart from the fact that her boyfriend is abroad – Is he possibly assuming that she hasn’t had sex or any new or other partners?* (observation, AN34, Dr6)

Patient experience
The various approaches to establishing sexual histories were supported by the patients in the exit interviews. Most patients generally felt comfortable answering the personal sexual behaviour questions no matter how they were phrased:
Umm, she just asked them straight out. She asked what she needed to know and I just answered it. I didn’t feel embarrassed answering them but that doesn’t really bother me that sort of thing. (exit interview, JW21, SpN1)

I'm not concerned about talking about sex because they have to know these things and I'm not fussy. (exit interview, SZ19, Dr2)

Many of the patients realised the importance of the sexual behaviour questions and the need to give honest answers:

Yeah, I mean I would much rather say as much information as I can because I'd rather know about myself if you know what I mean. I would much rather give as much information so I can get information back. (exit interview, CC25, Dr4)

I know that if you don’t answer them they can’t get an accurate idea of what your problems are so you just have to remove yourself from the embarrassment side of it and just say it as it is. (exit interview, JM7, SpN2)

Although most people were happy to be asked directly about their sexual behaviour and expected this, some were a little shocked. One patient suggested that a preparation for what she was about to be asked would have helped:

Some of the questions I suppose I recoiled a little bit. Really slightly, although I recognised why I had to be asked all those questions... she did it as part and parcel of all the other questions - it felt OK and any discomfort wasn’t about how she was asking it but more about the question really... but thinking about it
maybe some sort of preliminary thing about “I’m going to ask you about these questions” might help you prepare for those type of questions. (exit interview, LC1, SpN1)

6.5.3 Establishing HIV/STI Risk Factors

Patterns of questioning

Again, there was no major difference between the way doctors and specialist nurses asked patients about their HIV and STI risk factors. Some practitioners routinely asked the questions about sex work and recreational drug use to all women, asking them in the same tone as all the other questions, whilst those who did not ask these questions, appeared to neglect them on a regular basis. The observation process did not explain why these patterns existed with the individual practitioners:

She asks the patient about whether she takes recreational drugs. The patient says no so she moves straight onto the next question about sex work. She uses very frank questions and doesn’t beat about the bush or make an issue of it. She doesn’t make a point of the questions being any different from the other questions. (observation, TL6, SpN1)

Asks directly have you used any recreational drugs in last three months, ever injected drugs, ever sold sex, ever had an HIV test. (observation, GM28, Dr12)

When asking about HIV testing, most practitioners were more direct in establishing the risk factors by running through the known risk factors i.e. injecting drug use/bisexual partners. One of the specialist nurses routinely used a more patient orientated approach
to establishing these factors by asking the open question: "What do you consider your risks to be since your last HIV test?"

6.5.4 The Examination Process

Explaining the process

Throughout the consultation observations it became clear that both doctors and specialist nurses were, in general, good at providing explanations about the examination process:

*The doctor returns and warms the speculum. She gets the patient comfortable and then explains what she is doing - “I'm just examining your skin so you will feel me touching you...just inserting the speculum...opening up...”* (observation, CL31, Dr11)

*She gets patient comfortable and again explains the process - “I'm just going to feel your groin and check the skin around the outside...inserting and opening...” and she says when she is doing each swab and smear - “you might feel a little pushing”.* (observation, CO38, SpN2)

There were a small number of instances from both doctors and specialist nurses when all the tests were not fully explained:

*She says she is taking the tests but doesn't explain what in specific they are.* (observation, RS3, SpN1)
The patient asks what tests he will do and he says syphilis and then discusses hepatitis B but never goes back to tell her about the other tests he is performing, such as chlamydia, gonorrhoea, bacterial vaginosis etc... (observation, LK14, Dr6)

There was one case when the doctor (SHO) gave no explanation at all:

The patient gets undressed and the doctor starts the examination with no explanations of what he was doing. He doesn't speak to the patient. The nurse chaperone asks if patient is OK and has general chit-chat while the doctor is taking the swabs. (observation, AN34, Dr6)

In addition to the observations, a small number of patients also commented that the explanations that they received from the specialist nurses were clear and simple and 'not too medical':

Very simply, in the simplest possible terms which means it's user friendly for everyone... (exit interview, CH16, SpN2)

One specialist nurse took the process of explaining the tests a step further by showing the patient the instruments that she was about to use, whilst giving her a chance to opt out:

Yeah, every time she used something different she would actually show it to me and say that "I'm going to use this and this is what I am going to do now" and she gave me the option as to which tests I could have and if I didn’t want to do
any type of test, and I wanted to come back and make another appointment, that was fine. You know I was under no pressure to do everything straight away.

(exit interview, JM7, SpN2)

Support from co-workers

The assistant role of the staff nurse was identified in the pre-nurse-led clinic staff interviews (section 6.1.4). This role was observed in practice when some of the doctors gave brief explanations to the patient that were then backed up with further explanations by the assisting/chaperoning nurse. The following observation took place when the staff nurse was preparing the patient for examination. This was after the doctor had conducted the initial interview:

*The nurse explains the swabs and tests – the patient says that she doesn’t know what she is talking about so the nurse asks if she wants her to explain the tests more specifically and the patient says ‘go for it’. (observation, CL31, Dr11)*

*Yeah, he explained what he was going to do and then the nurse went through very briefly what he was going to do. (exit interview, BH5, Dr6)*

*The nurse explained a little more about the sexual diseases and what they are and what they could do. So she offered just a little bit more than the doctor did. (exit interview, SS23, Dr10)*
6.5.5 Providing Results and Treatment

Explanation

During most of the observations, both the specialist nurses and doctors gave good explanations of the results:

The specialist nurse explains that the results showed mixed flora, but likely to be bacterial vaginosis and explains the cream for treatment. (observation, CD15, SpN1)

It was very clear that I should take this prescription and why he was giving it to me and even though I may not have pelvic inflammation I should cover my arse so to speak. (exit interview, LP20, Dr9)

There were no incidents observed during the specialist nurse observations in which poor explanations of results were given. However, there was one doctor case that lacked a full explanation:

The doctor tells the patient that she has trichomonas but doesn’t really say what this is, how it is caused etc. The patient is shocked and asks why this was not found on her previous visit. The doctor suggests that there may not have been sufficient specimen to cause a positive result on the last visit. He doesn’t ask the patient if she has had any new sexual partners. He gives her some metronidazole tablets and explained that she shouldn’t drink alcohol for two days after taking them. He asks for her to see a health adviser and gives her a contact slip. He doesn’t give her a chance to ask any questions and tells her to book a test of
cure appointment in one week. This was the end of the consultation.
(Observation, AN34, Dr6)

When it came to supplying treatment, there was generally some form of explanation by
the doctor or specialist nurse. However, there was some medication supplied with
incomplete explanations by both specialist nurses and doctors.

Partner notification dealt with using a contact slip and although she explains
the medication side effects of metronidazole and alcohol there is no mention of
any of the doxycycline side effects. (observation, SS35, Dr2)

Talks of thrush and antibiotics and then moves onto discussing the treatment
with cytosporin and trimethroprim. She tells the patient about the dosage of
each, but no other information. She tells the patient how to apply the
hydrocortisone, but doesn’t mention which treatment is for what problem.
(observation, TL6, SpN1)

Reinforcing understanding
Overall, the specialist nurses took the time to provide more comprehensive
explanations. This was demonstrated in the following observation in which the
specialist nurse read through the instructions on the medication packaging with the
patient:

The specialist nurse explains the interactions with doxycycline and the pill and
advises the use of condoms during this period. She then explains, while reading
with patient from the bottle, the antibiotic name, dose and how to take it and
then the side effects of sunbathing and checks that she is not on iron tablets and antacids. She then finishes with "are you clear about what I said about the pill..." (observation, RS3, SpN1)

6.5.6 Health Promotion

Factors affecting health promotion activity

As with other aspects of health care delivery, time and experience appeared to be key factors affecting the level, content and style of health promotion. For this new SHO, time was a factor that limited what he could discuss with the patient, in addition to his inexperience of working in the field of sexual health:

\[
\text{Well again in that situation you're definitely going to present the medical approach, the medical model, beyond that probably we don't do terribly much of finding out maybe why they are doing what they are doing. There just isn't the scope or the time for that ... I don't have any personal experience at all. Maybe I try and tell people as much as possible but then what I know I read in books and maybe I don't have enough experience yet to be able to answer every single question. (Dr2, interview week 2)}
\]

Therefore, the time limitation resulting from the model of doctor-led care could be seen as an important factor in relation to the type and amount of health promotion delivered. However, the health promotion approach of an experienced doctor was demonstrated in the following observation where a woman had a positive pregnancy test. The doctor used effective listening skills, reflected well on the patient's reaction, spent time calming the patient and gave pregnancy advice whilst being forthright about the risks of miscarriage:
The pregnancy test was positive and she tells the patient while showing her the dipstick result at the same time. The patient starts to cry and the doctor gives her some tissues. The doctor goes on to say that spotting may be a symptom of early miscarriage and that there is at this stage a 50/50 chance of miscarriage and advises the patient to repeat the test in one week. The doctor responds to the patient’s shocked response very well by giving her time... she goes onto say that if she is to keep the baby she needs to start folic acid supplement and stop smoking... the doctor goes to get leaflets and can’t find folic acid one so advises the patient to ask at a pharmacy for advice on correct dose of folic acid. She then offers the patient a chance to ask any further questions. (Observation, AC33, Dr13)

Delivery style

Both of the specialist nurses talked about their health promotion approach revolving around the patient’s lifestyle. They encouraged patients to look at what was going on in their lives, their menstrual cycle, sexual behaviour, diet, bowel habits, and how these related to the types of problems that they were facing, such as recurrent thrush and bacterial vaginosis. This was one aspect of care that was not observed in the doctor-led consultations in such a consistent fashion.

In particular, the specialist nurses reported how their experience of talking to women as a nurse, and as a woman, had equipped them with rational and practical answers to the basic questions that were often asked by patients:

I’m trying to get more information that is not perhaps medically orientated, but about lifestyle and how that affects what they are doing at the moment and that’s playing a bigger part than something medical you know. It’s usually like if you
look at thrush and bacterial vaginosis and the cycles, it's more about them as a person rather than medical and perhaps when the doctor approaches the patient it's all medical in doing the tests... I suppose it's from personal experience and discussing with other women you know and other women telling me about their experiences about how things have changed for them and how much better it was for them when things changed. (SpN1 interview week 2)

This 'holistic' approach was observed in many of the specialist nurse consultations:

Advises patient about washing hair in bath, washing knickers in mild soaps etc. and practical information about not wiping from back to front and drinking lots of cranberry juice. (observation, TL6, SpN1)

In general, both doctors and specialist nurses were good at offering condoms. During the exit interviews, all patients were asked if they were offered condoms and most said that they were. There were some patients who weren't offered condoms, but they felt that it was inappropriate in any case:

I didn't get so much advice as such and if I did I would have found it quite extremely condescending because I do practice safer sex and I did talk to the nurse about it...(exit interview, SL26, Dr3)

From this information it is difficult to judge whether the opportunity to offer condoms was neglected or whether the practitioner made an independent judgement not to offer the patient condoms that actually suited the patient. However, there was one woman who saw a doctor and was not offered condoms but actually wanted some:
Interviewer: Was there any talk about safer sex and condom use if appropriate?

Patient: No there wasn't. I did actually want some condoms but I forgot to ask.

(exit interview, MW37, Dr5)

Doctors and specialist nurses offered contraception services, particularly when the patients raised the issue themselves. The specialist nurses appeared more proactive and systematic in their approach towards ensuring the contraceptive needs of patients were being met:

Asks about contraception - patient says withdrawal – the specialist nurse picks up on this and goes on to ask: “Do you know about emergency contraception?”

The nurse explains and then asks the patient whether she knows of a family planning centre where she could go. (observation, AR24, SpN2)

Patients reported receiving leaflets from both doctors and specialist nurses. This was also recorded during the consultation observations. Once again, it was apparent that the specialist nurses were more proactive, rather than reactive, in giving out leaflets, not only for STIs, but more general leaflets, such as the women’s service of the homeopathic hospital and leaflets about the menstrual cycle. Two patients were given leaflets during the specialist nurse consultation, given time to read them while they were waiting, and then offered time to ask questions:

The specialist nurse gives the patient a leaflet about herpes while she sets up the trolley and then offers her the chance to ask more questions. (observation, LS36, SpN2)
During the doctor and specialist nurse consultation observations the questions that patients asked were generally answered adequately. In addition, the specialist nurses routinely gave patients the time to ask if they had any more questions. In contrast, there were three separate occasions recorded when there was no opportunity provided by the doctor for the patient to ask questions. However, as with many of the accounts provided here, no inference can be made about doctors in general, as these three occasions were restricted to two individuals who were also poor at offering condoms and explaining the examination process.

6.5.7 Summary

This section showed how the approaches to care differed between individual practitioners. The level of GUM experience and the time available appeared to be the driving factors affecting the approach to care, rather than whether the practitioner was a doctor or specialist nurse. The specialist nurses and senior doctors were more skilled in the delivery of care than the new SHOs. It could be said that the specialist nurses had more time to explore issues. However, experienced doctors were skilled in utilising the time they had to the maximum benefit of the patient.

The time factor may also relate to the model of care that practitioners worked within. Although the doctor-led model of care did have time restrictions, this was in part due to the fragmented approach to care. There were periods when a patient was waiting in the corridor, or time being used transferring from room to room. In contrast, the specialist nurses did not need to spend time moving from room to room. When they were preparing the specimens and examination equipment, the patient was in the same room getting undressed behind the curtain. During this time dialogue continued between the specialist nurse and patient - the specialist nurse probing for more information or just chatting and building rapport with the patient. It should also be remembered that
although the specialist nurses had more time with the patient, they were mostly working alone, whereas the doctors worked with staff nurses who were an important source of information and support.

The only consistent difference seen between doctors and specialist nurses was the style of health promotion activity. The specialist nurses were very patient focused and more proactive in providing leaflets to support their explanations and more consistent in offering condoms. This may relate to their previous staff nurse role in which information and support played a key part. Each specialist nurse had accumulated over three year’s experience in delivering health education and promotion. This experience was now being applied within their new specialist nurse role. The specialist nurses themselves viewed their care as being more holistic than medicine and more patient focused. These elements of care could be seen as the ‘nursing’ component of the specialist nurse role, therefore negating any belief that the specialist nurses worked merely as doctor substitutes. The nursing component of new roles previously performed by doctors is something that has been stressed by nurses in other areas of advanced nursing practice (Tye and Ross, 2000).

### 6.6 Conclusion

The process evaluation was important in demonstrating how some of the key problems of the women’s clinic were addressed through the better utilisation of nurses. The process evaluation clarified why it was necessary to develop a new model of care, followed the process of implementation and attempted to understand how the model of nurse-led care worked and how the model differed to that of doctor-led care. It also showed how the process of patient care was affected by the structure of the two models, rather than whether a doctor or a specialist nurse led the process.
The process evaluation showed how the nurse-led clinic intervention was delivered, or not delivered in the case of training and preparation, as planned. In the ethos of action research, it also enabled operational issues to be identified and addressed almost immediately. It allowed a process of constant review and learning to be built into the project management and process of achievement. Where gaps were identified, steps were taken to close these gaps. For instance, the monitoring of clinical activity identified how 35% of patients required a prescription from a doctor. This meant that the specialist nurse had to locate a doctor for one in every three patients they saw. The response of the project management team was to develop patient group directions (PGDs). A subsequent audit showed how the introduction of three PGDs reduced the amount of prescriptions required from a doctor from 35% to 16.9% of the specialist nurse caseload (Miles et al., 2001).

The final elements of the process evaluation provided an understanding of the specialist nurses’ ability to recognise effective practice and acknowledge their limitations of practice. It also demonstrated how the specialist nurses integrated the essential health education and promotion skills learnt from their previous staff nurse roles. This chapter has therefore begun to understand the ‘nursing’ element of the nurse-led model of care.

The next chapter will concentrate on comparing the outcomes of nurse-led care with those of doctor-led care.
Chapter 7
Outcome Evaluation Results

The findings of the outcome evaluation are presented within six main headings that relate to the methodologies employed: (1) Randomised Controlled Trial; (2) Patient Satisfaction Survey; (3) Exit Interviews; (4) Waiting Time Survey; (5) Formal Complaints Reporting; and (6) Cost Analysis. As with the process evaluation, a discussion of the outcome evaluation findings will be presented in chapter eight.

7.1 Randomised Controlled Trial

7.1.1 Study Population

The randomised controlled trial (RCT) element of the study involved an audit of clinical documentation to determine the effectiveness of care between the specialist nurses and senior house officers (SHOs).

Figure 9 shows the flow of patients through the randomisation; 1172 patients telephoned for an appointment; 880 of these were randomised to provide 169 patients in the specialist nurse arm and 178 in the SHO arm of whom 103 and 121 respectively kept their appointment. There was no statistically significant difference in non-attendance rates between specialist nurse and SHO groups (specialist nurse 66/169 (39%) v SHO 57/178 (32%) p=0.2). The remaining 533 patients allocated to doctors other than SHOs (n=491) or incorrectly randomised by reception staff (n=42), were not
included in the analysis as the comparison was with SHOs only. Two hundred and ninety two patients (25%) were not randomised. The main reasons for non-randomisation are presented in Table 10. Apart from non-attenders, no patient opted out following randomisation.

As a result of the randomisation, the clinical records from 103 specialist nurse and 121 SHO consultations were eligible for review. The anticipated sample size of 130 patients for each arm was not achieved for three main reasons. Firstly, the non-attendance rate was high during the randomisation period. This led to higher than expected attrition from the randomised sample. The initial sample size calculation was based on January 1997 to September 1998 non-attendance rates for new (17.1%) and follow-up (21.5%) patients. The unusually high non-attendance rate seen in the randomised sample reflected the June 1999 non-attendance figures for the women’s clinic that peaked at 33.3% for all new patient appointments. Secondly, the telephone receptionists conducting the randomisation had difficulties in randomising consistently throughout the day. During busy periods with low staffing levels, randomisation procedures were not carried out in order to prevent further service disruption. Finally, as a result of the slow uptake in randomisation and high attrition from the randomised sample, the six-month period of SHO rotation came to an end before the estimated sample size was reached. At this point the SHOs were required to take on new clinical placements. It would have been inappropriate to randomise patients to, and review clinical casenotes from, the following intake of new SHOs, as they would have been new to GUM medicine. The anticipated five to six week randomisation period had extended to nine weeks before ending at the completion of the SHO’s clinical placement period.
Figure 9 - Randomisation flowchart

Telephoned for appointment (n=1172)

→ Not randomised (n=292)

Randomised (n=880)

→ Managed by Drs other than SHOs (n=491)
  Incorrectly randomised (n=42)

Specialist nurse (n=169)

→ Did not attend (n=66)
  Clinical records reviewed (n=103)

SHO (n=178)

→ Did not attend (n=57)
  Clinical records reviewed (n=121)
<table>
<thead>
<tr>
<th>Reason</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specialist nurse appointment available</td>
<td>137 (46.9)</td>
</tr>
<tr>
<td>No doctor appointment available</td>
<td>60 (20.5)</td>
</tr>
<tr>
<td>Patient requested specific time</td>
<td>40 (13.7)</td>
</tr>
<tr>
<td>Specific female practitioner request</td>
<td>37 (12.7)</td>
</tr>
<tr>
<td>Specific request for doctor</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td>Specific request for specialist nurse</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Requested herpes (HSV) clinic appointment</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Unaccounted</td>
<td>10 (3.4)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>292</strong></td>
</tr>
</tbody>
</table>
Table 11 shows the characteristics and presenting conditions of the women who were randomised to the specialist nurse and SHO groups. The two groups were comparable in terms of age, ethnic origin and presenting condition.

Table 11 Randomised sample characteristics of patients and their presenting conditions

<table>
<thead>
<tr>
<th></th>
<th>Specialist Nurse group</th>
<th>SHO group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median (range) age in years</strong></td>
<td>28.6 (18-53)</td>
<td>28.7 (17-52)</td>
</tr>
<tr>
<td><strong>Ethnic Origin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>72 (70)</td>
<td>85 (70)</td>
</tr>
<tr>
<td>Black African</td>
<td>6 (6)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Black Caribbean</td>
<td>3 (3)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Black Other</td>
<td>1 (1)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Indian</td>
<td>1 (1)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Chinese</td>
<td>4 (4)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Asian Other</td>
<td>3 (3)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Other Ethnic Group</td>
<td>3 (3)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Missing Data</td>
<td>10 (10)</td>
<td>19 (16)</td>
</tr>
<tr>
<td><strong>Presenting Condition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>asymptomatic blood test and/or check-up</td>
<td>26 (25)</td>
<td>33 (27)</td>
</tr>
<tr>
<td>symptomatic vaginal discharge/dysuria/irritation</td>
<td>42 (41)</td>
<td>39 (32)</td>
</tr>
<tr>
<td>genital ulcer/warts</td>
<td>7 (7)</td>
<td>10 (8)</td>
</tr>
<tr>
<td>pelvic pain</td>
<td>4 (4)</td>
<td>8 (7)</td>
</tr>
<tr>
<td>results</td>
<td>9 (9)</td>
<td>16 (13)</td>
</tr>
<tr>
<td>other</td>
<td>15 (15)</td>
<td>15 (12)</td>
</tr>
</tbody>
</table>

Data are number (%) unless indicated otherwise
7.1.2 Findings of the Documentation Audit

A unitary index score (%) was calculated for each set of patient casenotes to determine the adequacy of care according to local guidelines. The median unitary index scores for the specialist nurse group and SHO group were 92% (range: 32-100) and 85.2% (range: 20-100) respectively (p<0.0001). The thirty variables were reviewed independently and are presented in Figure 10 as relative risk estimates for the specialist nurse and SHO documentation score differences. There was no significant difference between specialist nurse and SHO documentation for 25 of the 30 variables assessed. The five variables in which the specialist nurses’ documentation was significantly (p<0.05) more complete than the SHOs’ were: details of menstrual cycle, physical examination, medication instructions given to patients, health promotion discussion and provision of condoms.

When interpreting multiple significance tests, there is a danger of attaching too much importance to individual variables showing significance among a mass of non-significant ones (Bland, 2000). This is because of the risk of obtaining at least one result in twenty occurring by chance alone at the 0.05 significance level. However, since significance was demonstrated on the overall score, there should be no cause for concern that five of the thirty variables showed significant differences. Consequently, Bonferroni calculation was not applied to account for any spurious significant differences that may have occurred as a result of multiple significance testing.

Of the 224 casenotes audited, 15 (6.7%) were regarded as ‘difficult’ to judge whether the practitioner had provided care according to the clinic guide. These casenotes were discussed with a consultant physician and a consensus reached on the scoring outcomes.
Figure 10 – Relative risk estimates with 95% confidence intervals (CI) for specialist nurse versus SHO documentation scores for the variables that could be calculated

<table>
<thead>
<tr>
<th>Variable</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presenting problem</td>
<td>(RR=0.99; 95% CI 0.98-1.05)</td>
</tr>
<tr>
<td>Sexual history</td>
<td>(1.07: 0.97-1.19)</td>
</tr>
<tr>
<td>Partners in 3 months</td>
<td>(1.07: 0.96-1.20)</td>
</tr>
<tr>
<td>Past STI history</td>
<td>(0.97: 0.88-1.06)</td>
</tr>
<tr>
<td>Past medical history</td>
<td>(1.03: 0.93-1.13)</td>
</tr>
<tr>
<td>Medication history</td>
<td>(0.99: 0.91-1.07)</td>
</tr>
<tr>
<td>Allergies</td>
<td>(1.02: 0.93-1.12)</td>
</tr>
<tr>
<td>Recreational drug use</td>
<td>(0.98: 0.85-1.15)</td>
</tr>
<tr>
<td>Sex work</td>
<td>(0.89: 0.70-1.15)</td>
</tr>
<tr>
<td>HIV test</td>
<td>(1.01: 0.91-1.12)</td>
</tr>
<tr>
<td>Last unprotected sex</td>
<td>(1.10: 0.97-1.23)</td>
</tr>
<tr>
<td>Cytology history</td>
<td>(1.03: 0.93-1.13)</td>
</tr>
<tr>
<td>Contraceptive history</td>
<td>(1.07: 1.00-1.11)</td>
</tr>
<tr>
<td>Last menstrual period</td>
<td>(1.04: 0.97-1.11)</td>
</tr>
<tr>
<td>Menstrual cycle</td>
<td>(1.17: 1.03-1.32)</td>
</tr>
<tr>
<td>Pregnancies</td>
<td>(1.01: 0.91-1.13)</td>
</tr>
<tr>
<td>Examination</td>
<td>(1.38: 1.21-1.59)</td>
</tr>
<tr>
<td>Test request</td>
<td>(1.06: 0.99-1.15)</td>
</tr>
<tr>
<td>Cytology request</td>
<td>(0.99: 0.97-1.01)</td>
</tr>
<tr>
<td>Correct diagnosis</td>
<td>(1.03: 0.95-1.12)</td>
</tr>
<tr>
<td>Appropriate treatment</td>
<td>(0.99: 0.91-1.08)</td>
</tr>
<tr>
<td>Medication instruction</td>
<td>(4.12: 1.95-8.76)</td>
</tr>
<tr>
<td>Partner notification</td>
<td>(1.55: 0.73-3.31)</td>
</tr>
<tr>
<td>Health promotion</td>
<td>(2.26: 1.76-2.88)</td>
</tr>
<tr>
<td>Offered condoms</td>
<td>(2.04: 1.42-2.94)</td>
</tr>
<tr>
<td>Outcome recorded</td>
<td>(0.98: 0.91-1.06)</td>
</tr>
<tr>
<td>Notes signed</td>
<td>(0.96: 0.90-1.01)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>(1.11: 0.96-1.29)</td>
</tr>
</tbody>
</table>
From the thirty variables assessed, there were three key variables that are considered clinically important for establishing clinical effectiveness. These three variables were analysed independently and are discussed below.

**Requesting the correct diagnostic test**

Table 12 shows that according to the clinic guidelines and algorithms, the specialist nurses and SHOs requested the correct amount of diagnostic tests in 97% and 91% of cases respectively ($\chi^2=2.813; \text{df}=1; p=0.093$). The SHOs were more likely to request fewer tests (e.g. no microscopy) than the specialist nurses.

**Table 12 - Diagnostic test requests* by specialist nurses and SHOs**

<table>
<thead>
<tr>
<th></th>
<th>Specialist Nurse (n=92)</th>
<th>SHO (n=99)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct</td>
<td>89 (96.7)</td>
<td>89 (90.8)</td>
</tr>
<tr>
<td>Too few tests requested</td>
<td>3 (3.3)</td>
<td>9 (9.2)</td>
</tr>
</tbody>
</table>

*p=0.09 Data are number (%)

*not all patients required diagnostic tests to be performed

**Provision of the correct diagnosis**

Table 13 shows the diagnoses that were recorded as either correct, incorrect according to clinic guide or where no diagnosis was recorded. The specialist nurses performed equally to the SHOs in making correct diagnoses according to the clinic guide ($\chi^2=0.874; \text{df}=2; p=0.646$). The term ‘incorrect’ was arbitrary in that it did not imply the diagnoses were poor or unsafe clinical decisions. It only indicated that the diagnostic decisions were not strictly made according to clinic guideline criteria. The majority of the ‘incorrect’ diagnoses involved cases of bacterial vaginosis where only one or two of the preferred three diagnostic criteria were met. For example, clinical signs and symptoms were present but a positive microscopy result was not obtained.
Table 13 - Preliminary diagnosis* recorded by specialist nurses and SHOs

<table>
<thead>
<tr>
<th></th>
<th>Specialist Nurse (n=92)</th>
<th>SHO (n=103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct</td>
<td>76 (82.6)</td>
<td>80 (77.7)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>12 (13.0)</td>
<td>16 (15.5)</td>
</tr>
<tr>
<td>Correct but does not fit with clinic guidelines</td>
<td>4 (4.3)</td>
<td>7 (6.8)</td>
</tr>
</tbody>
</table>

p=0.6 Data are number (%)  
*not all patients required a preliminary diagnosis to be made

Provision of the correct treatment

The documentation of treatment can provide a clear unambiguous account of clinical decision making. This assumes that what is documented is what was supplied to the patient. Table 14 presents the accuracy of the treatments supplied to patients according to the clinic guidelines. The results showed there was no significant difference between specialist nurses and SHOs in the proportion of treatment decisions considered ‘incorrect’ according to clinic guide ($\chi^2=0.874; df=2; p=0.646$). The ‘incorrect’ treatments provided were reviewed by a consultant physician and were not regarded as clinically incorrect or ineffective. Nonetheless, the treatments were provided outside what was clearly stated in the clinic guidelines (see Table 15). It is important to note that at the time of the clinical record review, the specialist nurses were not using patient group directions (PGDs). Subsequently, the treatment decisions reported in Table 14 and Table 15 were all authorised by a doctor. Where treatment was recorded, there were seventeen instances in which the treatment was documented incompletely in the casenotes (specialist nurse 8/49 (16.3%) v SHO 9/57 (15.2%) p=0.9). For example, the drug name was recorded but no dose documented.

Table 14 - Treatment* recorded by specialist nurses and SHOs

<table>
<thead>
<tr>
<th></th>
<th>Specialist Nurse (n=49)</th>
<th>SHO (n=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct</td>
<td>47 (95.9)</td>
<td>57 (96.6)</td>
</tr>
<tr>
<td>Incorrect according to clinic guide</td>
<td>2 (4.1)</td>
<td>2 (3.4)</td>
</tr>
</tbody>
</table>

p=0.6 Data are number (%)  
*not all patients required treatment
Table 15 - Treatments provided outside clinic guidelines by specialist nurses (SpN) and SHOs

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpN93</td>
<td>Clotrimazole pessaries given for trichomoniasis. Patient breast-feeding.</td>
</tr>
<tr>
<td>SpN78</td>
<td>Clindamycin gel given for vaginal discharge of unknown origin.</td>
</tr>
<tr>
<td>SHO127</td>
<td>Eight clotrimazole pessaries given on patients request without any</td>
</tr>
<tr>
<td></td>
<td>confirmed candidiasis diagnoses in over two years.</td>
</tr>
<tr>
<td>SHO135</td>
<td>Metronidazole stat followed by another stat dose in 72 hours for</td>
</tr>
<tr>
<td></td>
<td>bacterial vaginosis.</td>
</tr>
</tbody>
</table>

7.1.3 Score Reliability

The review of fifty percent of the clinical records by a second person (a GUM consultant physician) found the scoring system to be reliable. Pearson’s correlation coefficient of 0.886 (p<0.001) indicated a strong association between the final unitary index scores of the two reviewers. There was a high proportion of cases in which score agreement was reached for each of the thirty individual items (median score agreement 98%; range 78-100%). The areas in which there was a difference in scores were those that required more subjective measurement. For example, there was only 88% scoring agreement in the item documenting the physical examination. Although criteria were set on how to measure each item, there was still a difference in what each reviewer perceived to be complete documentation. However, it is important to note that the unitary index scores of both reviewers consistently showed specialist nurses’ documentation to be more complete than SHOs’ (Table 16).

Table 16 - Unitary index score totals of both reviewers

<table>
<thead>
<tr>
<th></th>
<th>Specialist Nurse (n=60)</th>
<th>SHO (n=52)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewer 1</td>
<td>90.3</td>
<td>83.9</td>
<td>0.008</td>
</tr>
<tr>
<td>Reviewer 2</td>
<td>92.6</td>
<td>85.7</td>
<td>0.002</td>
</tr>
</tbody>
</table>
7.1.4 Summary

The randomisation of 880 patients resulted in the audit of 103 specialist nurse and 121 SHO clinical casenotes. The median unitary index scores for the specialist nurses and SHOs were 92% and 85.2% respectively (p<0.0001). There were five variables in which the specialist nurses’ documentation was significantly (p<0.05) more complete than the SHOs: menstrual cycle; examination; medication instruction; health promotion and condoms offered. The specialist nurses performed equally to the SHOs in respect to the correct diagnostic test request, diagnosis made and the provision of correct treatment.

7.2 Patient Satisfaction Survey

7.2.1 Sample Characteristics

The demographic characteristics of the women who completed the satisfaction survey are displayed in Table 17. A total of 282 patient satisfaction surveys were completed. One hundred and fifty of the respondents saw a doctor and 132 saw a specialist nurse. Of the women invited to complete the questionnaire there was a recorded response rate of 90%. Patients in the two practitioner groups were well matched for age, first time visit to clinics, sexual orientation and social class based on occupation and continued education. Of those declining to complete the satisfaction questionnaire (n=28), only 15 (54%) completed the shorter non-responder questionnaire.

The characteristics of the non-responders are included in Table 17. There was a significant difference for further education (p<0.005) and sexual orientation (p<0.05) between the responder and non-responders.
Table 17 - Characteristics of satisfaction survey respondents by practitioner group

<table>
<thead>
<tr>
<th></th>
<th>Specialist group (n=132)</th>
<th>Nurse group (n=150)</th>
<th>Doctor group (n=150)</th>
<th>Non-responders (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (range) in years</td>
<td>28 (17-53)</td>
<td>27 (16-50)</td>
<td>25 (19-60)</td>
<td></td>
</tr>
<tr>
<td>First time visit to clinic</td>
<td>64 (49.6)</td>
<td>65 (49.2)</td>
<td>13 (59.1)</td>
<td></td>
</tr>
<tr>
<td>Ethnic Origin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>100 (76.9)</td>
<td>105 (72.4)</td>
<td>18 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>12 (9.2)</td>
<td>22 (15.2)</td>
<td>8 (29.6)</td>
<td></td>
</tr>
<tr>
<td>(African/Caribbean/other)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South East Asian</td>
<td>6 (4.6)</td>
<td>2 (1.4)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>5 (3.8)</td>
<td>4 (2.8)</td>
<td>1 (3.7)</td>
<td></td>
</tr>
<tr>
<td>(Indian/Pakistani/Bengali)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>7 (5.4)</td>
<td>12 (8.3)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexual</td>
<td>121 (96.0)</td>
<td>140 (95.9)</td>
<td>12 (80)</td>
<td></td>
</tr>
<tr>
<td>Homosexual</td>
<td>2 (1.6)</td>
<td>1 (0.7)</td>
<td>1 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Bisexual</td>
<td>3 (2.4)</td>
<td>5 (3.4)</td>
<td>2 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Social Class based on Occupation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I - professional</td>
<td>14 (10.6)</td>
<td>13 (8.6)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>II - managerial &amp; technical</td>
<td>47 (35.6)</td>
<td>54 (36.0)</td>
<td>5 (31.3)</td>
<td></td>
</tr>
<tr>
<td>IIIN - skilled non-manual</td>
<td>26 (19.7)</td>
<td>28 (18.6)</td>
<td>4 (25)</td>
<td></td>
</tr>
<tr>
<td>IIIM - skilled manual</td>
<td>3 (2.3)</td>
<td>3 (2.0)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>IV - partly skilled</td>
<td>6 (4.5)</td>
<td>3 (2.0)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>V - unskilled</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>010 inadequately described</td>
<td>11 (8.3)</td>
<td>13 (8.6)</td>
<td>1 (6.3)</td>
<td></td>
</tr>
<tr>
<td>occupation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>020 retired, seeking work,</td>
<td>5 (3.8)</td>
<td>15 (10.0)</td>
<td>1 (6.3)</td>
<td></td>
</tr>
<tr>
<td>unemployed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>030 student</td>
<td>16 (12.1)</td>
<td>18 (12.0)</td>
<td>3 (18.8)</td>
<td></td>
</tr>
<tr>
<td>040 independent means</td>
<td>1 (0.8)</td>
<td>2 (1.3)</td>
<td>1 (6.3)</td>
<td></td>
</tr>
<tr>
<td>050 permanently sick,</td>
<td>1 (0.8)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>disabled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>060 housewife</td>
<td>1 (0.8)</td>
<td>1 (0.7)</td>
<td>1 (6.3)</td>
<td></td>
</tr>
<tr>
<td>070 no previous job, school</td>
<td>1 (0.8)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>leaver with no previous job</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continued Education</td>
<td>110 (84.6)</td>
<td>116 (78.9)</td>
<td>8 (53.3)</td>
<td>n=15</td>
</tr>
</tbody>
</table>

Data are number (%) unless indicated.
7.2.2 Questionnaire Findings

Each questionnaire was scored out of a total of five. The overall score for the 282 completed questionnaires was 4.33 (95% confidence interval: 4.28 to 4.38) indicating that patients were generally satisfied with the care they received. There was no significant linear correlation between the overall satisfaction scores and age (Spearman correlation coefficient: 0.07, p=0.3), previous visits to the clinic (0.03, p=0.6) or further education (0.01, p=0.9). There was no significant correlation between the overall satisfaction scores and sexual orientation (Kruskal-Wallis one-way analysis of variance: $\chi^2$ (df=2) 0.048, p=0.9), social class according to occupation ($\chi^2$ (df=4) 14.73, p=0.2) or ethnicity ($\chi^2$ (df=4) 5.88, p=0.2).

The median satisfaction scores for the specialist nurse and doctor groups were 4.47 (range 3-5) and 4.30 (range 3-5) respectively, giving a significant difference of 0.17 (p=0.05) in favour of the specialist nurses. The five sub-scales were then analysed separately and are reported in Table 18. Specialist nurses scored significantly (p<0.05) more highly in three of the five sub-scales: quality and competence of technical care, provision of information and overall satisfaction.

Table 19 presents the responses to the individual questionnaire statements.

Table 18 - Summary of satisfaction survey sub-scale scores

<table>
<thead>
<tr>
<th>Sub-scale</th>
<th>nurse-led clinic (range)</th>
<th>doctor-led clinic (range)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific attributes of interpersonal relationship</td>
<td>4.37 (3-5)</td>
<td>4.24 (3-5)</td>
<td>0.11</td>
</tr>
<tr>
<td>Quality and competence of technical care</td>
<td>4.67 (2-5)</td>
<td>4.44 (2.75-5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Provision of information</td>
<td>4.50 (3.12-5)</td>
<td>4.29 (2.12-5)</td>
<td>0.015</td>
</tr>
<tr>
<td>Service attributes</td>
<td>4.20 (3-5)</td>
<td>4.32 (3-5)</td>
<td>0.26</td>
</tr>
<tr>
<td>Overall satisfaction</td>
<td>4.33 (3-5)</td>
<td>4.33 (1-5)</td>
<td>0.012</td>
</tr>
</tbody>
</table>
Table 19 - Satisfaction survey responses

<table>
<thead>
<tr>
<th>Specific attributes of interpersonal relationship</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was given as much time as I needed for my appointment</td>
<td>SpN 94(71.8)</td>
<td>36(27.5)</td>
<td>1(0.8)</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Dr 97(66)</td>
<td>43(29.3)</td>
<td>7(4.8)</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>I felt that my personal circumstances were being judged</td>
<td>SpN 6(4.6)</td>
<td>2(1.5)</td>
<td>4(3.1)</td>
<td>24(18.3)</td>
<td>95(72.5)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Dr 5(3.4)</td>
<td>4(2.7)</td>
<td>9(6.2)</td>
<td>48(32.9)</td>
<td>80(54.8)</td>
<td>4</td>
</tr>
<tr>
<td>The person I saw doesn’t understand what it is like having to come to the clinic</td>
<td>SpN 1(0.8)</td>
<td>-</td>
<td>4(3.1)</td>
<td>32(24.6)</td>
<td>93(71.5)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Dr 1(0.7)</td>
<td>1(0.7)</td>
<td>4(2.7)</td>
<td>56(38.4)</td>
<td>84(57.5)</td>
<td>4</td>
</tr>
<tr>
<td>I felt that I was treated as a person rather than a disease</td>
<td>SpN 64(50)</td>
<td>52(40.6)</td>
<td>3(2.3)</td>
<td>4(3.1)</td>
<td>5(3.9)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dr 72(49.7)</td>
<td>60(41.4)</td>
<td>2(1.4)</td>
<td>4(2.8)</td>
<td>7(4.8)</td>
<td>5</td>
</tr>
<tr>
<td>The person that I saw did not make personal judgements about my situation</td>
<td>SpN 80(63)</td>
<td>39(30.7)</td>
<td>3(2.4)</td>
<td>-</td>
<td>5(3.9)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Dr 79(54.9)</td>
<td>50(34.7)</td>
<td>6(4.2)</td>
<td>3(2.1)</td>
<td>6(4.2)</td>
<td>6</td>
</tr>
<tr>
<td>Visiting the clinic is not a stressful occasion</td>
<td>SpN 28(22)</td>
<td>40(31.5)</td>
<td>20(15.7)</td>
<td>32(25.2)</td>
<td>7(5.5)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Dr 28(19)</td>
<td>63(42.9)</td>
<td>28(19)</td>
<td>24(16.3)</td>
<td>4(2.7)</td>
<td>3</td>
</tr>
<tr>
<td>I was made to feel comfortable answering personal questions</td>
<td>SpN 69(54.3)</td>
<td>47(37)</td>
<td>4(3.1)</td>
<td>2(1.6)</td>
<td>5(3.9)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Dr 67(46.2)</td>
<td>62(42.8)</td>
<td>12(8.3)</td>
<td>3(2.1)</td>
<td>1(0.7)</td>
<td>5</td>
</tr>
</tbody>
</table>

Data are number (%)
<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>The person who I saw seems to know how I feel about being here in the clinic</td>
<td>SpN 59(46.1)</td>
<td>56(43.8)</td>
<td>12(9.4)</td>
<td>1(0.8)</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dr 50(35.2)</td>
<td>61(43)</td>
<td>27(19)</td>
<td>2(1.4)</td>
<td>2(1.4)</td>
<td>8</td>
</tr>
<tr>
<td>My feelings about my treatments were taken into consideration*</td>
<td>SpN 19(33.9)</td>
<td>31(55.4)</td>
<td>2(3.6)</td>
<td>3(5.4)</td>
<td>1(1.8)</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>Dr 20(29.4)</td>
<td>33(48.5)</td>
<td>12(17.6)</td>
<td>3(4.4)</td>
<td>-</td>
<td>82</td>
</tr>
<tr>
<td><strong>Quality and competence of technical care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The person that I saw in the clinic did not always talk sense</td>
<td>SpN 1(0.8)</td>
<td>1(0.8)</td>
<td>-</td>
<td>23(17.7)</td>
<td>105(80.8)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Dr -</td>
<td>2(1.4)</td>
<td>-</td>
<td>52(35.9)</td>
<td>91(62.8)</td>
<td>5</td>
</tr>
<tr>
<td>I've no confidence in the person who was treating me</td>
<td>SpN 2(1.5)</td>
<td>3(2.3)</td>
<td>2(1.5)</td>
<td>21(16)</td>
<td>103(78.6)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Dr 2(1.4)</td>
<td>3(2.1)</td>
<td>4(2.8)</td>
<td>36(24.8)</td>
<td>100(69)</td>
<td>5</td>
</tr>
<tr>
<td>I felt that the problem that I came with was sorted out properly</td>
<td>SpN 63(48.8)</td>
<td>50(38.8)</td>
<td>12(9.3)</td>
<td>1(0.8)</td>
<td>3(2.3)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Dr 65(46.1)</td>
<td>53(37.6)</td>
<td>19(13.5)</td>
<td>-</td>
<td>4(2.8)</td>
<td>9</td>
</tr>
<tr>
<td>The person I saw in the clinic appeared uncertain about what they were doing</td>
<td>SpN 1(0.8)</td>
<td>-</td>
<td>-</td>
<td>27(21.4)</td>
<td>98(77.8)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Dr 3(2.1)</td>
<td>1(0.7)</td>
<td>3(2.1)</td>
<td>51(35.2)</td>
<td>87(60)</td>
<td>5</td>
</tr>
<tr>
<td>I felt that I was in good hands</td>
<td>SpN 74(58.7)</td>
<td>52(41.3)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Dr 73(49.7)</td>
<td>69(46.9)</td>
<td>5(3.4)</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>The person that I saw in clinic was not as thorough as she/he should have been</td>
<td>SpN 1(0.8)</td>
<td>-</td>
<td>1(0.8)</td>
<td>34(27.9)</td>
<td>86(70.5)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Dr 3(2.1)</td>
<td>3(2.1)</td>
<td>11(7.6)</td>
<td>58(40)</td>
<td>70(48.3)</td>
<td>5</td>
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</table>

Data are number (%)
<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>It took a long time to get my results today§</strong></td>
<td>SpN</td>
<td>2(4)</td>
<td>4(8)</td>
<td>8(16)</td>
<td>24(48)</td>
<td>12(24)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>4(5.4)</td>
<td>7(9.5)</td>
<td>7(9.5)</td>
<td>40(54.1)</td>
<td>16(21.6)</td>
</tr>
<tr>
<td><strong>The person that I saw made sure I was physically comfortable during my examination†</strong></td>
<td>SpN</td>
<td>73(62.9)</td>
<td>42(36.2)</td>
<td>-</td>
<td>-</td>
<td>1(0.9)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>72(56.7)</td>
<td>49(38.6)</td>
<td>1(0.8)</td>
<td>3(2.4)</td>
<td>2(1.6)</td>
</tr>
<tr>
<td><strong>I felt that some of the tests were not the ones that I needed‡</strong></td>
<td>SpN</td>
<td>1(0.9)</td>
<td>3(2.6)</td>
<td>4(3.4)</td>
<td>41(35.3)</td>
<td>67(57.8)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>3(2.4)</td>
<td>2(1.6)</td>
<td>11(8.7)</td>
<td>50(39.4)</td>
<td>61(48)</td>
</tr>
<tr>
<td><strong>Provision of information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My questions were answered in words that I found hard to understand</td>
<td>SpN</td>
<td>3(2.3)</td>
<td>3(2.3)</td>
<td>1(0.8)</td>
<td>30(23.1)</td>
<td>93(71.5)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>1(0.7)</td>
<td>5(3.4)</td>
<td>4(2.7)</td>
<td>49(33.3)</td>
<td>88(59.9)</td>
</tr>
<tr>
<td>I feel that I could not rely on the information that I was given</td>
<td>SpN</td>
<td>4(3.1)</td>
<td>5(3.8)</td>
<td>2(1.5)</td>
<td>36(27.5)</td>
<td>84(64.1)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>4(2.8)</td>
<td>3(2.1)</td>
<td>6(4.2)</td>
<td>46(31.9)</td>
<td>85(59)</td>
</tr>
<tr>
<td>I was told everything that I want to know about my condition</td>
<td>SpN</td>
<td>70(53.4)</td>
<td>50(38.2)</td>
<td>6(4.6)</td>
<td>1(0.8)</td>
<td>4(3.1)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>59(41.8)</td>
<td>60(42.6)</td>
<td>16(11.3)</td>
<td>5(3.5)</td>
<td>1(0.7)</td>
</tr>
<tr>
<td>I was not told why I needed tests such as swabs and bloods‡</td>
<td>SpN</td>
<td>4(3.5)</td>
<td>2(1.7)</td>
<td>3(2.6)</td>
<td>30(26.1)</td>
<td>76(66.1)</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>6(4.7)</td>
<td>7(5.5)</td>
<td>2(1.6)</td>
<td>39(30.5)</td>
<td>74(57.8)</td>
</tr>
<tr>
<td>I was given good advice on how to cope with my condition*</td>
<td>SpN</td>
<td>31(53.4)</td>
<td>26(44.8)</td>
<td>1(1.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Dr</td>
<td>28(40.6)</td>
<td>35(50.7)</td>
<td>5(7.2)</td>
<td>-</td>
<td>1(1.4)</td>
</tr>
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</table>

Data are number (%)
<table>
<thead>
<tr>
<th>Statement</th>
<th>SpN</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects of treatments were barely discussed during my appointment*</td>
<td>4(7.1)</td>
<td>4(7.1)</td>
<td>9(16.1)</td>
<td>27(48.2)</td>
<td>12(21.4)</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>3(4.4)</td>
<td>11(16.2)</td>
<td>16(23.5)</td>
<td>25(36.8)</td>
<td>13(19.1)</td>
<td>82</td>
</tr>
<tr>
<td>I was told everything about the medication given to me*</td>
<td>22(39.3)</td>
<td>27(48.2)</td>
<td>5(8.9)</td>
<td>2(3.6)</td>
<td>-</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>18(26.5)</td>
<td>39(57.4)</td>
<td>6(8.8)</td>
<td>3(4.4)</td>
<td>2(2.9)</td>
<td>82</td>
</tr>
<tr>
<td>During my consultation I was given little or no explanation about my condition*</td>
<td>1(1.7)</td>
<td>-</td>
<td>-</td>
<td>27(46.6)</td>
<td>30(51.7)</td>
<td>74</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>5(7.2)</td>
<td>3(4.3)</td>
<td>30(43.5)</td>
<td>31(44.9)</td>
<td>81</td>
</tr>
</tbody>
</table>

**Service attributes**

<table>
<thead>
<tr>
<th>Statement</th>
<th>SpN</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>The clinic staff were very friendly</td>
<td>65(50)</td>
<td>59(45.4)</td>
<td>2(1.5)</td>
<td>3(2.3)</td>
<td>1(0.8)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>92(63)</td>
<td>48(32.9)</td>
<td>3(2.1)</td>
<td>3(2.1)</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>I feel reassured that the clinic will keep my personal information confidential</td>
<td>65(50.4)</td>
<td>43(33.3)</td>
<td>8(6.2)</td>
<td>2(1.6)</td>
<td>11(8.5)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>88(59.9)</td>
<td>40(27.2)</td>
<td>11(7.5)</td>
<td>4(2.7)</td>
<td>4(2.7)</td>
<td>3</td>
</tr>
<tr>
<td>I felt that the clinic needed a good cleaning</td>
<td>3(2.1)</td>
<td>3(2.4)</td>
<td>10(7.9)</td>
<td>45(35.4)</td>
<td>67(52.8)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>3(2.1)</td>
<td>5(3.5)</td>
<td>11(7.7)</td>
<td>52(36.4)</td>
<td>72(50.3)</td>
<td>7</td>
</tr>
<tr>
<td>I’m worried that my personal information will be given out to other people</td>
<td>-</td>
<td>2(1.6)</td>
<td>12(9.4)</td>
<td>44(34.6)</td>
<td>69(54.3)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2(1.4)</td>
<td>-</td>
<td>18(12.2)</td>
<td>44(29.9)</td>
<td>83(56.5)</td>
<td>3</td>
</tr>
<tr>
<td>No matter how long you have to wait it’s worth it</td>
<td>32(25.8)</td>
<td>54(43.5)</td>
<td>16(12.9)</td>
<td>19(15.3)</td>
<td>3(2.4)</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>41(28.3)</td>
<td>59(40.7)</td>
<td>26(17.9)</td>
<td>15(10.3)</td>
<td>4(2.8)</td>
<td>5</td>
</tr>
</tbody>
</table>

Data are number (%)
<table>
<thead>
<tr>
<th>Overall satisfaction</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>The care in the clinic was just about perfect</td>
<td>SpN 72(56.3)</td>
<td>49(38.3)</td>
<td>4(3.1)</td>
<td>1(0.8)</td>
<td>2(1.6)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dr 71(48)</td>
<td>57(38.5)</td>
<td>14(9.5)</td>
<td>2(1.4)</td>
<td>4(2.7)</td>
<td>2</td>
</tr>
<tr>
<td>There were some things about my care in the clinic that could be improved</td>
<td>SpN 2(1.6)</td>
<td>10(7.9)</td>
<td>12(9.4)</td>
<td>58(45.7)</td>
<td>45(35.4)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Dr 3(2.1)</td>
<td>24(16.8)</td>
<td>20(14)</td>
<td>57(39.9)</td>
<td>39(27.3)</td>
<td>7</td>
</tr>
<tr>
<td>I was satisfied with the care that I received in the clinic today</td>
<td>SpN 81(63.3)</td>
<td>47(36.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dr 81(55.9)</td>
<td>54(37.2)</td>
<td>6(4.1)</td>
<td>2(1.4)</td>
<td>2(1.4)</td>
<td>5</td>
</tr>
</tbody>
</table>

Data are number (%)

SpN = patient saw specialist nurse
Dr = patient saw doctor
§ Only answered if patient waited for microscopy results
† Only answered if patient had a vaginal/internal examination and/or blood tests taken
* Only answered if treatment was supplied to patient
7.3 Exit Interviews

This section presents the findings of the semi-structured interviews conducted with patients following the specialist nurse (n=10) and doctor (n=10) consultations. Four main categories arose from the data analysis. These are presented as an overview in Table 20 before discussing in depth. Quotes from study participants are italicised followed by a unique personal identifier, their age, country of birth and the practitioner whom they saw.

Table 20 – Overview of exit interview data analysis

<table>
<thead>
<tr>
<th>Categories</th>
<th>Concepts arising from data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care process</td>
<td>Efficiency, waiting times, resolving issues</td>
</tr>
<tr>
<td>Information/advice</td>
<td>Advice, question time</td>
</tr>
<tr>
<td>Interpersonal</td>
<td>Friendly, non-judgemental, informal atmosphere, felt listened to, able to relax</td>
</tr>
<tr>
<td>Model of care</td>
<td>Just one person, time factors, working from one room, confidence in specialist nurse, medical back-up</td>
</tr>
</tbody>
</table>

7.3.1 Care Process

The majority of patients from both doctor and specialist nurse clinics felt that the waiting times throughout their appointment were satisfactory:

*I was amazed it was so quick. I sort of expected to be here for quite a while longer.* (LA13, 24yo Danish, Dr2)

Even when a patient had to wait a little longer, the key to keeping them satisfied was keeping them informed. Once informed, patients did not seem to mind:
"I waited a little bit longer because the receptionist told me I have to wait... but it was OK, about 20 or 30 minutes." (FA11, 19yo Somalian, SpN2)

There were only two patient accounts of having to wait a long time. Both were with doctor appointments. One woman was kept waiting about 35-40 minutes before her appointment but ‘then it was very fast once I was in the system’ (LP20, 24yo UK, Dr9).

Another problem unique to the doctor-led clinics, also observed during the participant observation process, occurred when a patient was placed in the examination room by the nurse chaperone, and then had to wait for the doctor to come in and complete the examination:

Yeah, I thought it might have been a few minutes, but it was probably about fifteen. (SS23, 38yo UK, Dr10)

7.3.2 Information and Advice

Good advice was reported between both doctor and specialist nurse consultations, but one woman indicated that the specialist nurse was able to give that bit more:

"It was good, I mean she has also given me tips, which like for example the fact that I am planning for pregnancy. She explained that if I am taking folic acid...

(AD9, 31yo Italian, SpN2)

All patients visiting a specialist nurse and most of the patients visiting a doctor reported a relaxed atmosphere, particularly when clear explanations were provided:
She put me at ease straight away because coming to a clinic, especially when you are in the waiting room for a long time, you start getting apprehensive and anxious and all those kind of things. So she was very good and comforting and she explained everything that she was doing and asked me lots of questions.

(JM7, 27yo Australian, SpN2)

Although most of the doctor consultations were reported to be good, this woman felt that the doctor she saw was ‘nice you know, nothing amazing’, but thought that her use of terminology was inappropriate:

*The other thing is that she referred to my vagina as ‘down there’...I suppose that in a place like this I would imagine that there would be a relaxed atmosphere about talking about these things. The doctor seemed a bit uncomfortable about this.* (MW37, 27yo Australian, Dr5)

All patients from both doctor and specialist nurse consultations felt that their issues were resolved on leaving the clinic and were generally satisfied with the overall service that was provided:

*Yeah, I wanted to know the answer to one particular question and I got that answer and have personally very little to worry about.* (BH5, 38yo French, Dr6)

*I suppose it’s ten out of ten because I’ve got everything I wanted.* (JW21, 23yo UK, SpN1)
7.3.3 Interpersonal Skills

All patients felt that the service provided by both specialist nurses and doctors was relaxed, informal and non-judgmental:

*She was really friendly and like I said before it was just really relaxed... I think that it’s important, especially in sexually transmitted disease clinics, that people aren’t judging you. You should be able to tell the truth.* (CH16, 23yo UK, SpN2)

*Even though there were a lot of people passing through the clinic, I didn’t feel like I was on a conveyor belt. I felt that the information was very clear and I thought that the relation between the staff was very laid back, appropriately, and it was a nice atmosphere.* (LP20, 24yo UK, Dr9)

Both specialist nurses and doctors were reported to be ‘friendly but professional’. When patients were asked to explain this concept they clarified that the right balance was made between being friendly enough to relax them, whilst at the same time still being able to get on with the consultation. It appeared that this was what patients wanted:

*She was nice and kind of asked questions and bits and pieces, but not sitting there and chatting too much. There’s being chatty and nice, but not kind of too much so that you forget what you’re actually there for.* (HW4, 22yo UK, SpN1)

*He was just beginning to be like really calm and like really, not too over friendly, but he was friendly, very good... he was friendly, but he was very professional.* (MP8, 22yo Spanish, Dr1)
Good listening skills were reported in both doctor and specialist nurse consultations:

> Well she just genuinely seemed to care about the problem you know. She just seemed really sincere about what she was doing. Sometimes you can come into a doctor's clinic or whatever and you can really sense that the person that you're seeing sees people come in and out every day and sometimes they are just not tuning into the reason that you've come in with. They just want to get you in and out. I didn't sense that for one moment. (JD12, 32yo UK, SpN1)

However, there was one patient who reported that the doctor she saw appeared uninterested:

> Yeah, her approach was methodical and not as if she was particularly interested in what I was saying. (PB32, 32yo UK, Dr5)

### 7.3.4 Model of Care

As seen above, both doctor and nurse-led clinics were generally seen to be efficient. However, there were some differences noted when the data were analysed according to the previous experiences of patients. First time attenders had no previous experience to compare with, and were, therefore, happy with whichever service they received. However, those who had been seen by a doctor in the past, therefore having something to compare with, felt that the specialist nurses were able to offer 'something different'. The concept of one person dealing with all aspects of the appointment was felt to be more relaxing and more efficient:
Well you feel more at ease because you don't have two people standing there, just the one person, so I don't know, it is a bit more relaxing, as I say, you feel a bit more at ease because it's just one person dealing with you. (AD9, 31yo Italian, SpN2)

In addition, the process of working from one room was popular:

Yeah, it was more focused because there was just the two of you in the room so yeah, that's better and you're not going from one room to the next. (JD12, 32yo UK, SpN1)

Time was a big factor. A number of women felt that they were less rushed and given more time than in previous doctor consultations. The time was used to ensure that their understanding was clear before they left the clinic:

I felt that there was more time given too, um, because there was a couple of particular problems that I came with and she just, she didn't stop until I felt okay that all the information was received. (JD12, 32 UK, SpN1)

It's like you know I came here before but today is a little bit different. You know the person that I see is a little bit like, I don't know how to say it, some people just ask you questions and then you go, but some people ask you many questions and make you feel comfortable. (FA11, 19 Somalian, SpN2)
I felt that I was given the time to explain my concerns and the confusion that I was feeling about my symptoms and she just really responded really clearly. (LC1, 41yo other ethnic group, SpN1)

Three different women expressed the reassuring nature of their consultations with the specialist nurses and how the problems they were facing were seriously acknowledged:

...because what I came back for was very similar to what I had three years ago and last time the symptoms were very confused and it was quite difficult to separate out all the symptoms, but with her I felt that she was acknowledging that the symptoms were confused... she actually said that it was probably a mixture of all those things, so it was reassuring for me to hear that really. (LC1, 41yo other ethnic group, SpN1)

There were, however, three women who felt that their consultations were no different to that of previous consultations with doctors:

I have only seen gynaecologists before and doctors and there wasn't that much of a difference. (PW29, 28yo French, SpN2)

The specialist nurses, as individuals, were perceived to be competent in their work and there were no problems identified by patients. When patients were asked how they felt about seeing a nurse, there was general support. It appeared that the majority of patients did not really seem to mind that they saw. Some were not even aware that they were seeing a specialist nurse rather than a doctor:
One reason for this was provided in one of the early focus groups with the nursing staff. The nurses suggested that patients were becoming more familiar with seeing a nurse in the place of a doctor when they visited their general practice, or in minor injury units. The following statement supported this concept:

No I don't mind. Last time I had my smear done it was done by a nurse [at general practitioner service] so I don't have a problem with that. (HW4, 22yo UK, SpN1)

However, there was one woman who had initial reservations about seeing a nurse, but was soon convinced otherwise:

Well, at first I thought that, well oh gosh a nurse! Maybe if I ask something maybe she hasn’t got the answer; maybe she has to get a doctor. Instead I was very surprised because anything that I wanted to know she gave me the right answer. (AD9, 31yo Italian, SpN2)

It was clear that patients accepted the new specialist nurse role and that they felt safe knowing there was medical back up when needed:

Well there was a doctor who actually did examine me as well, so I’m pretty confident that I’m OK.... (PW29, 28yo French, SpN2)
7.3.5 Summary

In general, all patients were satisfied with the care they received. The services in nurse-led and doctor-led clinics were reported to be relaxed, informal, friendly and non-judgmental. Good advice was reported from most consultations, although patients seeing a specialist nurse indicated that the specialist nurse was able to provide more time to do this. There was one incident when a patient felt that the doctor was not listening to her and one incident when a doctor used inappropriate terminology. The majority of patients from both doctor and specialist nurse groups felt that waiting times were satisfactory, although there were two accounts of longer waiting times in the doctor group. Specialist nurses were perceived to be competent in their work and patients did not report any specific problems. Women visiting a specialist nurse who had seen a doctor in the past (therefore having something to compare with) felt that the specialist nurses were able to offer ‘something different’. However, the increased satisfaction appeared to be more about the model of care than the type of practitioner. For instance, the concept of one person offering all care from one room was felt by some to be more relaxing and more efficient. This ‘one-stop’ process of care led some patients to feeling less rushed than they had in previous doctor-led consultations.

7.4 Waiting Time Survey

Five hundred and forty six waiting time surveys were completed for consecutive specialist nurse (n=239) and doctor (n=307) consultations carried out over a six-week period. The results are presented in two phases detailing the initial ‘waiting to be seen’ period, followed by the actual time patients spent in consultation with the specialist nurse or doctor. These times provide a patient focused outcome of the processes of doctor and nurse led care. The findings of the waiting time survey complement aspects
of the process evaluation results in chapter six. Triangulation of these process and outcome evaluation elements will be discussed in chapter eight.

**7.4.1 Initial Waiting Period**

The mean waiting period from arriving at the clinic to being seen by the appointed practitioner was 14.1 minutes (range 0-70) for specialist nurses and 15.8 minutes (range 0-90) for doctors. The small difference of 1.7 minutes was not statistically significant (95% CI: -1.1 to 4.5).

**7.4.2 Practitioner-Patient Contact Time**

In the women’s clinic, patients were generally offered one of four main appointment types: new, results, urgent and walk-in. ‘New’ appointments were allocated to patients who would usually require a sexual history, examination and specimen collection followed by preliminary results and treatment. ‘Result’ appointments were reserved for patients attending for test results and partner notification follow-up. The specialist nurses did not have urgent or walk-in appointment types. Table 21 presents the consultation time for each of these appointment types. Recording of the consultation time began from when the patient entered the consultation room to have their sexual history taken, to when the consultation was completed with the patient leaving the consultation or examination room with their provisional diagnosis and/or treatment.

For ‘new’ appointments, the specialist nurses had slightly longer consultation times than the doctors, although the mean difference of 2.1 minutes was not statistically significant (95% CI: -7.2 to 2.9). For ‘result’ appointments, the specialist nurses also had longer appointment times. However, the mean difference of 3.3 minutes was also non-significant (95% CI: -10.8 to 4.2).
Table 21 – Waiting time survey: Total consultation time (minutes) per practitioner

<table>
<thead>
<tr>
<th>Appointment type</th>
<th>Specialist Nurse</th>
<th>Doctor</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time</td>
<td>n</td>
<td>range</td>
</tr>
<tr>
<td>New</td>
<td>49.5</td>
<td>191</td>
<td>4-125</td>
</tr>
<tr>
<td>Results</td>
<td>17.5</td>
<td>48</td>
<td>5-75</td>
</tr>
<tr>
<td>Urgent</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Walk-in</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
7.4.3 Summary

A total of 546 waiting time surveys were completed: 239 were specialist nurse and 307 doctor consultations. There were no significant differences in the time patients waited to be seen by a specialist nurse or doctor, or the time it took from the start to the finish of the appointment consultation.

7.5 Formal Complaints Reporting

There were two formal complaints received from patients attending the women’s clinic at Mortimer Market Centre between 31/01/99 and 30/09/99. Neither of the two formal complaints involved a specialist nurse, nor any aspect of the nurse-led service.

7.6 Cost Analysis

The cost analysis aimed to address the question: ‘What is the expected cost per completed patient appointment for patients who receive their care in the nurse-led clinics and those in the doctor-led clinics?’ The results to this question are presented in six stages. First, the costs of care pre-nurse-led intervention are presented. Second, the actual costs of the nurse-led intervention. The third section models the costs of an alternative approach to care using clinical assistants. The fourth provides an incremental analysis in which the various models of care are compared. Fifth, the sensitivity analysis findings are reported. The sixth section completes the cost analysis by presenting the fixed cost of room space.

7.6.1 Salary Costs Pre Nurse-Led Clinic Intervention

Table 22 and Table 23 provide the baseline salary costs (including on-costs, such as superannuation and National Insurance) for doctors and staff nurses providing doctor-led clinics prior to the introduction of nurse-led clinics. The salaries of the doctors were
calculated on a sessional basis (an average working week involves approximately twelve clinical sessions), whereas the nursing staff were valued on a weekly basis. The nursing staff estimated that they contributed approximately fifty-percent of their working week to assisting the doctors by chaperoning, venepuncture, and completing examinations and specimen collection as delegated (the other fifty percent of nursing time involved triage, telephone advice, wart treatment and general nursing and administration duties not directly associated with doctor-led clinics). Therefore, the salary cost to conduct the doctor-led clinics included the total sessional cost of medical staff, plus fifty percent of the weekly nursing salary cost. This totalled £3696.23 per week. An average of 420 patients per week were seen in the women’s clinic\(^1\). As a result, an average cost of £8.80 was calculated for every patient seen in a doctor-led appointment.

### Table 22 - Salary costs for doctors at baseline pre nurse-led intervention

<table>
<thead>
<tr>
<th>Sessions/week</th>
<th>Cost(£)/doctor/week(^2)</th>
<th>Cost(£)/session(^3)</th>
<th>Total cost(£)/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHO</td>
<td>10</td>
<td>529.33(^4)</td>
<td>44.11</td>
</tr>
<tr>
<td>Specialist Registrar</td>
<td>3</td>
<td>602.40(^5)</td>
<td>50.20</td>
</tr>
<tr>
<td>Consultant</td>
<td>2</td>
<td>1265.96(^6)</td>
<td>105.50</td>
</tr>
<tr>
<td>Professor</td>
<td>1</td>
<td>1837.12</td>
<td>153.09</td>
</tr>
<tr>
<td>Clinical Assistant</td>
<td>12</td>
<td>-</td>
<td>78.96</td>
</tr>
<tr>
<td><strong>Sub-total</strong></td>
<td><strong>1903.31</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) based on attendance figures Jan97-Dec98  
\(^2\) based on a 37.5 hour week  
\(^3\) assuming one session = 1/12 of week  
\(^4\) average SHO scale 1&2  
\(^5\) average SpR scale 2&3  
\(^6\) average consultant scale 2&3
Table 23 - Salary costs of staff nurses pre-nurse-led intervention

<table>
<thead>
<tr>
<th>Grade</th>
<th>Staff/week</th>
<th>Cost (£)/nurse/week</th>
<th>Total cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G</td>
<td>1</td>
<td>564.04</td>
<td>564.04</td>
</tr>
<tr>
<td>F</td>
<td>1</td>
<td>444.81</td>
<td>444.81</td>
</tr>
<tr>
<td>E</td>
<td>6</td>
<td>429.49</td>
<td>2576.94</td>
</tr>
</tbody>
</table>

50% of nursing time attributed to assisting doctors 3585.79

Sub-total 1792.90

7.6.2 Salary Costs Post Nurse-Led Clinic Intervention

Table 24 presents the additional nursing budget outlay to create the specialist nurse positions. These salary costs were based on one newly created F-grade post and one E to F upgrade (i.e. the incremental cost to implement the nurse-led clinics was approximately 1.5 full-time equivalent F-grade nurse). The senior doctor played an integral part in co-assessing 12% of the specialist nurse caseload in addition to the 35% requiring a pharmacological prescription. The amount of doctor time taken to provide support for the two specialist nurses was therefore estimated to be a total of two hours per week. As a conservative measure, a consultant grade doctor was used as a basis to cost this time. The details of these costs are also provided in Table 24.

As a result, the incremental salary cost to implement the nurse-led clinics was £565.73 per week. Therefore, at an average of 60 patients per week the average cost per patient seen in the nurse-led clinics was estimated at £9.43.

---

7 nursing team estimate
8 this figure was based on 25 nurse-led sessions between Jun-Jul 99
### Table 24 - Salary costs incurred in implementing nurse-led clinics

<table>
<thead>
<tr>
<th></th>
<th>Cost (£)/year</th>
<th>Cost (£)/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist Nurse</td>
<td>26440</td>
<td>508.46</td>
</tr>
<tr>
<td>Consultant</td>
<td>55840</td>
<td>57.27^9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>565.73</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 7.6.3 Cost of a Hypothetical Alternative to Nurse-Led Care

The marginal cost per patient seen in the nurse-led clinics was £9.43, sixty-three pence higher than that of the doctor-led clinics. Therefore, it could be considered that the introduction of nurse-led clinics was done at an extra cost to the service. Specifically, in economic terms, the cost function of the women’s clinic began to show diminishing returns to scale as the nurse-led clinics were introduced. However, without the introduction of nurse-led clinics, more medical staff would be needed if the additional sixty patients were to be seen. Therefore, the cost function was remodelled using a hypothetical model of employing a clinical assistant to see the same sixty patients as the specialist nurses.

A clinical assistant sees an average of 7.27 patients per clinical session^10. Therefore, for a clinical assistant to see 60 patients, it would take 8.25 sessions. The cost of a clinical assistant is £78.96 per session. Therefore, it would cost £651.42 to see the extra sixty patients, or £10.86 per patient.

Because this would place extra demand on the staff nurses, their time should also be considered. Assuming that one clinical assistant session would require 1/24 of a nurse’s time in one week, the average nursing cost to assist a clinical assistant would be

---

9 assuming total time utilised by SpNs = 2 hours/week

10 based on 25 sessions Jun-Jul 99
£18.68 per session\textsuperscript{11}. Therefore, the nursing costs for 8.25 clinical assistant sessions would be £154.11. As a result, the total cost of a clinical assistant with appropriate nursing support would equal £805.53 per week or £13.43 per patient.

Therefore, it would cost £239.79 per week more than the current option of nurse-led clinics if a clinical assistant were employed to see the same amount of patients as the specialist nurses. This can be seen more clearly in Table 25.

As a result, economies of scale would be exhausted earlier if more clinical assistant sessions were deployed, than they would with the implementation of nurse-led clinics. Thus, in the present setting and particular instance, introducing nurse-led clinics could be said to be more economically efficient (least cost option) than purchasing further clinical assistant sessions.

\textbf{7.6.4 Incremental Analysis}

For meaningful comparison, Table 25 examines the additional costs of providing either the nurse-led clinics or additional clinical assistant sessions, imposed over the existing doctor-led service, compared with the additional benefits (i.e. the additional number of patients seen).

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|c|}
\hline
\textbf{Salary Costs (£)} & \textbf{Number patient/week} & \textbf{Total cost/week} & \textbf{Total average cost/patient} & \textbf{Incremental cost/week} & \textbf{Marginal cost/patient} \\
\hline
Baseline doctor-led care (pre-Jan 99) & 420 & 3696.23 & 8.80 & - & - \\
Baseline plus nurse-led clinics & 480 & 4261.96 & 8.88 & 565.73 & 9.43 \\
Baseline plus hypothetical clinical assistant scenario & 480 & 4501.76 & 9.38 & 805.53 & 13.43 \\
\hline
\end{tabular}
\caption{Incremental analysis}
\end{table}

\textsuperscript{11} based on average nursing team salary
7.6.5 Sensitivity Analysis

One-way sensitivity analysis was conducted to account for two of the assumptions made: (i) proportion of nursing time to support the doctor-led clinic and (ii) proportion of doctor time to support the nurse-led clinics. The findings of this analysis showed how the average, incremental and marginal costs, changed relative to the assumptions made. This is demonstrated in Table 26, although for simplicity, the marginal and incremental costs are not presented. Despite cost changes, the nurse-led clinics always remained a least cost option than the hypothetical clinical assistant scenario.

Table 26 – One way sensitivity analysis showing how average costs change relative to assumptions

<table>
<thead>
<tr>
<th>Total average cost per patient (£)</th>
<th>Base-case parameters†</th>
<th>Parameter 1*</th>
<th>Parameter 2‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline doctor-led care (DLC) alone</td>
<td>8.80</td>
<td>9.65</td>
<td>8.80</td>
</tr>
<tr>
<td>DLC plus Nurse-led clinics</td>
<td>8.88</td>
<td>9.63</td>
<td>9.00</td>
</tr>
<tr>
<td>DLC plus hypothetical clinical assistant alternative</td>
<td>9.38</td>
<td>10.13</td>
<td>9.38</td>
</tr>
</tbody>
</table>

† nursing support time = 0.5; doctor support time = 2 hours per week
* nursing support time = 0.6; doctor support time = 2 hours per week
‡ nursing support time = 0.5; doctor support time = 4 hours per week

7.6.6 Office Space Costs

In addition to the salary costs, office space was estimated, as a difference was likely to exist between the doctor-led and nurse-led models of care. The average size of a consultation and examination room in the women’s clinic was 7.02m² and 9.27m² respectively, giving a total floor space use of 16.29 m² for the doctor-led clinics. One of the specialist nurses worked from a single consultation/examination room of size 9.49 m². Floor space costs £186 m²/year\(^{12}\) giving an average cost for room space of

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\(^{12}\) Camden & Islington Trust Accounts Department estimate
£3029.94/year for a doctor-led clinic and £1765.14/year for one of the nurse-led clinics. The result is an annual saving of £1264.80 for nurse-led clinics operating from a single consultation/examination room.

7.6.7 Summary

The average cost per patient seen in the women’s clinic before the nurse-led clinics started was £8.80. With the additional 60 patients seen in the nurse-led services the average cost per patient rose to £8.88. The incremental cost of providing nurse-led clinics was £565.74 per week giving a marginal cost of £9.43 per patient. If the same 60 patients were to be seen by a clinical assistant, the average cost per patient would increase to £9.38, but more importantly, the marginal cost would be significantly higher at £13.43 per patient with an incremental cost of £805.53/week. There is an annual saving of £1264.80 as a result of one of the specialist nurses working from a single room. In conclusion, the introduction of two specialist nurses did not place any significant additional financial burden on the service.
Chapter 8
Discussion

This thesis set out to provide evidence to support the development of nurse-led clinics in the speciality of GUM. It did this by conducting a process and outcome evaluation to demonstrate the effectiveness, acceptability and cost of nurse-led GUM clinics for women, and to explore the processes involved in the implementation and conduct of nurse-led GUM clinics.

This chapter discusses the findings of the process and outcome evaluation. It begins by reviewing the main findings, discussing the study limitations and providing possible explanations. This is followed by a discussion of the implications for practice and future research.

8.1 Main Findings and Explanations

GUM nurses have been performing extended roles for some time, although comprehensive care nurse-led GUM clinics are still a relatively new concept in the United Kingdom. Previous reports have described the recent changes to GUM nursing (Allen, 1998; Sutton et al., 1999) and one prospective audit showed that GUM nurses could undertake assessment, take specimens for diagnostic tests and diagnose and treat patients with uncomplicated STIs (Harindra et al., 2001). However, no studies have
rigorously evaluated the quality of care (effectiveness, acceptability, cost) provided in nurse-led GUM clinics using controlled trials.

The results of the randomised controlled trial showed that specialist nurses, supported within the multidisciplinary team, were at least as effective in the assessment and management of female patients as SHOs. There were no serious clinical errors made by the specialist nurses, and the documentation of the process of care was as good, and in some respects more complete, than that of the SHOs. The specialist nurses scored significantly more highly in the documentation of the physical examination, medication instructions given to patients, health promotion and provision of condoms. This result is consistent with the findings of the audit of nurse-led GUM by Harindra et al (2001). The results are also consistent with studies from other fields of practice that have shown nurses to be capable of carrying out procedures and roles usually the domain of doctors (Hill et al., 1994; Wood et al., 1994; Campbell et al., 1998; Sakr et al., 1999; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000; Griffiths et al., 2000; Steiner et al., 2001; Kinley et al., 2001).

Several methodological weaknesses of the randomised controlled trial are apparent. Firstly, reception staff were not blind to the randomisation allocations. The practicalities of managing and motivating staff to use a masked system (e.g. a sealed envelope approach) may have led to poor enrolment in addition to service disruption. It was possible that those responsible for booking appointments channelled participants with more severe symptoms to the doctors and those without symptoms to the specialist nurses, or vice versa. Although inadequate allocation concealment has been shown to be associated with bias (Schulz et al., 1995), the randomisation procedures in this study led to the two groups of patients being comparable in terms of age, ethnic origin and presenting problem. This suggests that allocation was not biased towards either arm of the study. Secondly, resources were not available to transcribe all 224 patient clinical
records to create masked conditions. With a nurse researcher conducting the audit of clinical records under non-masked conditions, measurement bias may have been introduced to the study. However, steps were taken at the outset to reduce any such effects. Clear, objective criteria were created for the audit and the review of fifty percent of all clinical records by a GUM consultant physician showed inter-reviewer score reliability.

Despite the methodological limitations of the randomised controlled element of the study, methodological triangulation enabled the findings of the RCT to be confirmed and explained. The level of clinical competency demonstrated by the specialist nurses was likely to be a result of the extensive experience gained whilst working as staff nurses in the women’s clinic. The pre-nurse-led clinic interviews demonstrated how staff nurses already performed many of the roles of doctors. Indeed, they were often relied upon to train new SHOs in many of their tasks, such as clinical examination. It therefore came as no surprise that the specialist nurses could take an accurate history from the patient, perform the clinical examination and make a provisional diagnosis. On the other hand, the SHOs had limited experience of working in a GUM environment, but this situation is true of all SHOs who rotate through the service on a six-monthly basis. Although relatively inexperienced, these SHOs were generally supported by a team of experienced staff nurses who contributed to the documentation of care, whereas the specialist nurses were mostly working alone, accessing advice only for cases beyond their clinical expertise and for medication prescription. Therefore, in practice, neither the SHOs nor specialist nurses worked totally independently. The specialist nurses needed to access a doctor for a prescription in 48% (49/103) of cases. From the clinical records it was difficult to determine how many of the treatment decisions made by the SHOs also required input from senior doctors and other colleagues within the multidisciplinary team. As a result, the differences in the clinical outcomes cannot be
attributed to the profession of the practitioner alone, but as a possible result of the different models of care within which the practitioners worked.

There are a number of plausible explanations for the better documentation by specialist nurses. One could suggest that nurses in general, are better at documenting patient care, as shown in other studies (Sakr et al., 1999), or that the specialist nurses documented more conscientiously whilst their new role was under scrutiny. The latter explanation is likely to be true when documenting the physical examination. With regard for the increased documentation of patient information, health promotion and condoms provision, this is more likely to be an actual reflection of the specialist nurses’ practice. This explanation can be supported with findings from other elements of the study. For example, the observational data found that the specialist nurses gave clear explanations of patients’ medication and results, and provided systematic and proactive health promotion including offering condoms: both supporting the findings of the clinical record audit. Although issues of observer bias can be highlighted, in that a nurse researcher conducted the consultation observations and data analysis, the observational data did provide a clearer picture as to what practitioners actually did for the patient in relation to what was documented, or not documented, in the patient casenotes. The observational data analysis may also be criticised as only a relatively small number of consultations were observed. This left practitioners little time to get used to the researcher observing their work and therefore, each individual was susceptible to Hawthorne effect (Roethlisberger and Dickenson, 1939). The effect of having a researcher present may have changed the individual practice behaviours leading to false representation of clinical practice, although this effect was likely to be equal for doctors and specialist nurses.

Despite the limitations of the consultation observations, the resulting analysis was considered to be valid. The activities observed were supported by the interviews
with the specialist nurses and other staff, therefore confirming the level of competence specialist nurses had in providing health promotion and patient information. Elements of the staff interviews were able to demonstrate how the specialist nurses approached the issue of health promotion and communication with patients: in particular, the 'holistic' approach to health promotion discussions. On the other hand, poorer documentation of certain aspects of care provided by SHOs also reflected their level of practice. The interviews with the new SHOs indicated their lack of knowledge and experience in GUM. They often relied on the staff nurses to back up their explanations and provide further information for the patient. It is therefore no surprise that specialist nurses could deliver and document aspects of patient information and health promotion more completely than SHOs.

There is, however, an argument that the specialist nurses had more time to explore the issues of health promotion. The observation phase of the process evaluation confirmed that the specialist nurses did have more direct patient contact time than the doctors, although on the whole, patients seeing a specialist nurse spent no longer in the clinic than those seeing a doctor.

A number of other studies have shown that nurses spend more time than doctors to achieve similar clinical outcomes (Sakr et al., 1999; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000). However, it is not clear why nurse consultations often take longer. Kinnersley et al (2000) speculates that nurse consultations may be longer because they provide more information or because of different time constraints. This was shown to be the case for this study. The specialist nurses did spend more time providing patient information and they did have different time constraints, but this was likely to be a result of the way in which the nurse-led model of care was structured. It may be that the nurse-led model of care enabled the specialist nurses to utilise the time they had in a different way. This was clearly seen with the use of the process flow maps
in chapter six. For instance, the specialist nurse was in direct contact with the patient whilst preparing for the physical examination. This was a time used to build rapport with the patient, ask further questions and discuss health promotion issues. Conversely, in the doctor-led model of care, the patient was left waiting in the corridor whilst the examination room was being prepared. The various waiting periods seen in the doctor-led model of care can be regarded as 'dead' time from the individual patients' perspective (although doctors saw other patients in this time), or time that was not used as constructively as it was in the nurse-led model of care.

The second main finding of the study was that female patients were more satisfied with the care provided within a nurse-led clinic, than care provided within a doctor-led clinic. The main limitation of this finding was that patients answering the satisfaction survey were not randomised to their respective practitioner. However, anecdotally, patients generally do not choose their practitioner and are mostly allocated to a practitioner by a receptionist, without any form of triage.

Despite this limitation, the finding of increased satisfaction concurs with studies from other fields of clinical practice that have shown increased patient satisfaction associated with nurse-led care (Hill et al., 1994; Kinnersley et al., 2000; Venning et al., 2000; Shum et al., 2000). It may be that the specialist nurses had better interpersonal skills resulting in increased patient satisfaction, or that the high level of satisfaction was an effect of the model of care the specialist nurses worked within. The latter explanation was supported by qualitative data obtained from the exit interviews. Patients stated general satisfaction seeing either a doctor or a nurse. However, the main difference was observed in those patients who had experience of both the doctor and nurse-led models of care. These patients preferred the 'one-stop' approach to care being provided by one person, in one room. The observational data also confirmed that the efficiency of the nurse-led model was slightly better than the existing model of doctor-led care. For
example, the reduced number of waiting periods. It is therefore possible that the model of care, rather then the practitioner, was the key determinant that led to higher satisfaction scores in the nurse-led clinic group.

The economic analysis formed the third main element of the study. It showed that implementing a model of nurse-led care did not hold any significant cost implications for this service when compared with the existing doctor-led clinics. Maintaining the average and marginal cost of nurse-led clinics may have resulted from the salary grade of the specialist nurses (F-grade). However, higher salaries could possibly be offset with the savings involved with prolonged retention of these nurses resulting from their increased job satisfaction.

Cost neutrality has been seen in other studies evaluating nurse-led care (Venning et al., 2000), although increased costs have been demonstrated in others (Sakr et al., 1999; Reynolds et al., 2000). Therefore, it is difficult to speculate on the generalisability of the findings of this study to the broader GUM service environment. Firstly, the basic demography of attending populations will differ between services. For instance, caseload variations (e.g. higher incidence of pelvic pain) would determine how many patients could be seen by specialist nurses and what level of support they would need from medical colleagues. Secondly, variations may also occur in how the model of nurse-led care is delivered. For example, not all clinics will have the option of a nurse providing all care from one room whilst others will work in the same fragmented model of care traditionally used by doctors. The availability of staff resources will differ between settings, such as access to a microscopist and access to medical expertise. The level of remuneration for specialist nurses will also differ, as demonstrated by the national survey in chapter three. All of these factors are likely to affect the relative cost of nurse-led care.
The limitations of conducting a partial economic analysis based on salary cost alone must also be acknowledged. For instance, the cost of training specialist nurses was not included, although, similar to the cost analysis conducted by Sakr et al. (1999), this cost could be considered as a one-off cost, because the specialist nurses are permanent members of staff, whereas the SHOs change every six months. The ability for the cost analysis to measure the true opportunity costs of the nurse-led intervention also remains an issue, although this was identified as a study limitation at the outset. The results did, nonetheless, fulfil the objective of providing a basis for which a decision on the future of nurse-led clinics could be made in this particular setting.

The secondary aim of the study was to explore the processes involved in the implementation of nurse-led clinics. In the short space of a few months the transformation from staff nurse to specialist nurse was seen. Role preparation, role uncertainty, anxiety and insecurity, previous role conflict and conflict with other staff were issues observed throughout the specialist nurse role socialisation process. These issues are not unique to this study. Training and role preparation is an issue that has been highlighted in the general context of advanced nursing practice (Woods, 1997; Hicks and Hennessy, 1998; Read et al., 1999; Atkins and Ersser, 2000; Wiles et al., 2001) and anxiety and insecurity is regarded as part of the natural role development and socialisation process, as is the stage when the nurse is vulnerable to role challenges from other staff (Hixon, 1999). Isolation and previous role conflict during the role socialisation process has also been observed in other areas of nurse-led care (Dowling S. et al., 1995).

The progression of the specialist nurse could be explained within Benner’s (1984) model that describes the progression of skills and competency of the staff nurse from novice to expert. The process evaluation observed the staff nurse, as patient advocate and technical and information assistant, move through the role socialisation
and development process to become the specialist nurse, an autonomous, capable, responsible and accountable decision maker, diagnostician and sexual health promotion expert.

Throughout the process of role socialisation, interviews with the specialist nurses highlighted the change in their job satisfaction. They particularly enjoyed the autonomy and ability to manage the patient from start to finish. At a time when staff recruitment and retention is becoming an increasing problem for GUM employers (London Standing Conference for Nurses, 2001), this is an important aspect for retaining staff and ultimately improving the care outcomes for patients. This has been seen in the ‘magnet’ hospitals in America where aspects of the practice environment, such as the nurses' autonomy to make clinical decisions within their areas of competence, have shown positive effect on nurse retention and patient outcomes (McClure et al., 1983; Aitken et al., 1994). Other studies have also shown that job satisfaction is a useful predictor of quality of care (Leveck and Jones, 1996). It could therefore be postulated that the job satisfaction of the specialist nurses may have been another of the contributing factors that led to the positive clinical outcomes and high satisfaction of service users.

Finally, at the beginning of the study, interviews with the clinic staff identified a number of problems that existed in the women’s clinic. The issues of a ‘fragmented service’ and ‘time constraints’ have been addressed through the implementation of nurse-led clinics, but only for those patients attending these clinics. The majority of patient care still occurs in the doctor-led service, and the care of these patients remains unchanged. From the above discussion, it is likely that the actual model of care had more of an influence on the positive outcomes of care for patients, than the profession of the practitioner. There is, therefore, scope to consider whether the traditional, fragmented model of doctor-led care is now outdated and requires changing to reflect
the new needs of patients. However, if all practitioners were to work within a one-stop model of care, it could be argued that this would significantly increase service costs. It would, particularly if senior doctors continued to see those patients who could be seen by specialist nurses. For instance, working to a one-stop model of care, a senior doctor performing a routine check-up on an asymptomatic woman would be more expensive than if a specialist nurse were to see the same patient. However, if the presenting case-mix of patients was appropriately matched with clinical expertise, the cost of service provision could potentially be maintained. This approach to service was seen at the Sydney Sexual Health Clinic, as described in chapter three: asymptomatic patients saw the nurses and symptomatic patients saw the doctors. It could also be suggested that continuing to employ clinical assistants is expensive and patients seeing these doctors could be seen by specialist nurses. Clinical assistants do take GUM expertise back into the community and bring primary care expertise into GUM clinics. However, after a period of training and practice, there is limited justification to continue supporting the employment of individual clinical assistants for prolonged periods of time.

In conclusion, this study has had a two-fold effect. It has not only shown that GUM nurses can provide safe and effective care, but also that a comprehensive package of care delivered in a one-stop clinic model is efficient and leads to the increased satisfaction of service users.

8.2 Implications for Practice

This study has important implications for policy and practice. The recently released National Strategy for Sexual Health and HIV proposes that nurses will have an expanding role as specialists and consultants for the future management and control of STIs (Department of Health, 2001). The results of this study are therefore timely. In response to the Government’s drive for evidence-based health care (Department of
Health, 1996) and proposals to promote team-working across professional boundaries and better utilisation of the skills and expertise of all staff (Department of Health, 2000a; Department of Health, 2000b), evidence from this study can be used to support nursing role development in other GUM settings. The study also contributes to the growing number of nurse-led care evaluations that have incorporated a randomised controlled trial element. The study is also the first to explore comprehensively the many issues associated with implementing nurse-led interventions in the GUM setting. The well documented processes and lessons learnt can contribute constructively to the future planning and development of other nurse-led interventions.

It is important to acknowledge the benefits of this study, as the advantages of nurses providing first-line sexual health care are many. The skills of experienced nurses can be fully realised and these nurses therefore retained in the speciality, and doctors relocated from routine services can concentrate on more medically complex aspects of service provision. Understanding the important contribution that nurses can make to STI control also promotes the professional capacity and capability of GUM nurses. Until now the main way for GUM nurses to progress their career has been to move into management. Nurse-led clinics provide one way for nurses to develop and retain their clinical skills and increase their autonomy whilst being appropriately rewarded. Nurse-led care is one area that is also likely to be supported by nurse consultant posts in GUM/sexual health. There is also potential for trained and experienced nurses to deliver sexual health care outside the GUM setting, in outreach and other primary care settings. Finally, there is scope for nurses working in these roles to pursue international development opportunities as practitioners and trainers of other health care staff involved in the management of STIs.

However, if GUM nurses are to take on more advanced clinical roles, a number of issues require consideration. Lessons from studying the nurse-led intervention are
important and are generally in line with those identified by Levenson & Vaughan (1999). For those who intend to develop nurse-led services it is first important to assess local need, rationale and resource for advanced GUM nursing roles. The obstacles for implementation need to be identified and the benefits of implementation need to be worth the cost and effort involved.

Local protocols and guidelines need to be developed to ensure and enhance professional practice and accountability. Practice guidelines, negotiated with all key stakeholders, can define the boundaries or limitations of nursing practice. For example, some services will be able to provide the appropriate training and support for nurses to perform pelvic examination, whereas others will not. Patient group directions (PGDs) drawn up by multi-disciplinary teams, approved by local advisory bodies and monitored accordingly, can also provide a safe and legal means for GUM nurses to enhance professional practice and streamline the provision of care.

It is important that adequate preparation and continuing education and training are addressed at local level, although this is also a broader issue involving those responsible for providing education for GUM nurses at a national level. Education agendas need reviewing in light of the advanced skills required by such nurses. Educationalists need to respond to the new skills and knowledge that GUM nurses need in not only providing direct patient care, but in the development of practice protocols, PGDs and clinical governance initiatives to monitor and maintain standards of patient care. Course planners should also reflect on the elements of ‘nursing care’ that can be incorporated into these new nursing roles. GUM nurses should not lose the core fundamental aspects of caring that have always reflected nursing as a profession.

It is important that an infrastructure for adequate support and clinical supervision is in place. Although clinical supervision may be a new concept for nurses, the specialist nurses in this study found it useful for identifying the clinical aspects of
their practice that needed addressing. In addition to clinical support, management support should include regular reviews of new nursing roles to ensure they remain useful and in line with patient and service needs and advances in clinical practice.

Finally, it is important to recognise and reward the contribution of nurses working in advanced GUM practice roles, but this should be done in the context of supporting the important contribution that other nurses, not involved in advanced practice, also make to patient care. Their roles should not be marginalised alongside those working in nurse-led clinics.

### 8.3 Implications for Future Research

This is the first substantive evaluation of nurses as first line care providers for women with sexually transmitted infections. Further randomised controlled studies are needed in other GUM settings to demonstrate that the effects of nurse-led clinics are not restricted to this setting and these nurses. The study presented here was based on two specialist nurses in one clinic, so at present, the outcomes of nurse-led GUM care cannot be generalised to reflect other services. Nurse-led models of sexual health care will differ across the country according to the level of need, resource, patient caseload and service infrastructure. However, there is no reason to believe that experienced GUM nurses, provided with the appropriate training and support, would not achieve similar outcomes of care.

Further economic analyses are also needed. Cost is something that is likely to be significantly different between settings. The setting for this study was unique in that it has a large proportion of training doctors on lower grades. Where services are staffed entirely by consultant grade physicians, nurse-led models of care are likely to be comparatively cheaper. Such a hypothesis could be tested using economic modelling techniques utilising data from this study as a baseline.
This study contributed to the understanding of the complexities involved in nurse-led GUM care. It raised the concept of decision making, but again this was based on only two specialist nurses. Therefore, once more nurses are working in this role, a better understanding of their decision making processes could contribute to future education and training initiatives, as well as enhancing the professional understanding and status of nurses in the speciality. Research of this kind could follow the format used by Offredy (1998). She explained four strategies of decision making within the context of nurse practitioners in general practice: hypothetico-deductive method, decision analysis, pattern recognition, and intuition. This was done through retrospective verbalisation and observation of nurse practitioners in practice.

Decision making is just one aspect of the nurse-led role. Further research is required to fully understand the fundamental aspects of nursing, such as the notion of ‘caring’, that are, and can be, incorporated into nurse-led sexual health services. Unless the domain of advanced GUM nursing practice is thoroughly understood there is a risk of GUM nurses working in advanced practice roles being seen merely as doctor substitutes. This has already been seen in the case of a nurse-led intermediate care unit (NLU) (Wiles et al., 2001). Although nurses working in the NLU derived increased satisfaction, junior and middle grade nurses and other professional groups regarded the NLU role as having a low status that was not equated with the continuing professionalisation of nursing.

On a methodological note, the audit form used in the randomised controlled aspect of the study to determine the effectiveness of care needs to be refined to ensure its transferability into other GUM settings. At present the audit proforma relates directly to the documentation proforma that is used in the study clinic. The key elements of the nurse-led consultation identified in the process evaluation (establishing the presenting problem, eliciting a sexual history, establishing HIV/STI risk factors, examination
process, providing results, treatment and health promotion) could form the basis for establishing a generic evaluation or monitoring tool for use in other GUM settings.

With regard to the satisfaction survey, the transferability of this measure into other sexual health settings needs addressing. In particular, it should be adapted and revalidated for use with male service users. Further work is also required to construct satisfaction measures that incorporate an economic component. The use of conjoint analysis (Ryan, 1996; Ryan, 2000) may be one economic technique to complement the satisfaction measurement tool to provide evidence of the strength of preference for the key attributes associated with nurse-led GUM clinics.

Evaluating process alongside the outcomes of care have benefited this study in providing social meaning and context to the concept of nurse-led care. In addition to identifying the operational issues of implementing this model of care, process evaluation has helped to explain why and how the model of nurse-led care has succeeded. The eclectic use of quantitative and qualitative methods within this process-outcome research strategy has also contributed to a better understanding of the results of the study. Experimental quantitative methods alone would have led to many more assumptions as to what the findings meant. Equally, qualitative methods used alone would have greatly reduced the possibility of measuring the efficacy of the nurse-led intervention. Combining process and outcome methodologies to evaluate nurse-led interventions have not been widely used in the UK although Sidani and Irvine (1999) have developed and tested such a framework with nurse practitioners in Canada. Studies that have evaluated process and outcome in sexual health are also relatively rare and have generally been restricted to behavioural and health promotion interventions (Kamb et al., 1996; Elford et al., 2001), rather than health service interventions. Therefore, this is an area in the general discourse of research and development that requires attention. Evaluations of nurse-led care need to capitalise on the benefits of combining
methodological strategies. This study has shown how sterile the results of outcome alone could have been without the complete understanding, through the use of process evaluation, of how these outcomes were achieved.

Finally, it is important that nurses themselves are involved in any research activities exploring areas of GUM nursing practice. If nurses do not involve themselves, it is possible that other professional groups will lead on the evaluation of nursing, resulting in nurses losing, rather than gaining, autonomy and authority (Bonell, 1999).

8.4 Conclusions

The burden of sexually transmitted infections in the UK is substantial and shows no sign of waning. Therefore, the demand for GUM nurses to develop their skills and take on new roles cannot be ignored, regardless of the motivation for doing so. Whether the changes to GUM nursing practice are pragmatic (to see more patients), economic (to cut costs) or professional (to develop the nurse), redefining the occupational and professional boundaries of GUM nurses needs to be seen in a positive light. If GUM nurses are to progress their care into the 21st century and effectively contribute to the reduction of STIs in this country, opportunities need to be identified and acted upon. GUM nurses can make a difference and should now be seen as key partners in shaping and delivering sexual health services for the future.
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Appendices

Appendix 1 - National Postal Survey of Nurse-led Clinics

Appendix 2 - Sample Patient Information Sheet & Consent Form for Consultation
  Observation and Exit Interviews

Appendix 3 - Documentation Audit Proforma

Appendix 4 - Patient Satisfaction Survey

Appendix 5 - Interview Schedule for Patient Exit Interviews

Appendix 6 - Waiting Time Survey

Appendix 7 - Clinic Research Study Information
National GUM Nurse-led Clinic Survey

For this study I have deliberately adopted a loose definition of nurse-led care which encompasses roles at the interface between nursing and medicine. By this I mean roles undertaken by nurses that may have been previously, or still are, undertaken by medical staff. The various levels of nurse-led care will become evident when you answer the questions.

Please follow the instructions carefully throughout the questionnaire.

To answer please tick ✓ the boxes □

If you have any questions please telephone Kevin Miles on 020-7387 9300 ext. 8191

Please give your honest answers. The details of individual responses will remain confidential. Any publications resulting from this study will not identify individual clinics.

Thank you for assisting with this study
APPENDIX 1

Section 1 – Types of Nurse-led Clinics

1. What type(s) of Nurse-led clinic does your GUM service provide?
   ✓ all that apply
   □ none
   □ nurse-led wart clinics
   □ nurse-led test-of-cure clinics
   □ nurse-led results clinics
   □ nurse-led vaccination clinics
   □ nurse-led smear clinics
   □ total patient management nurse-led clinics where the nurse sees patients requiring higher levels of clinical decision making e.g. a man attending with a urethral discharge - the nurse independently takes a history, examination, swabs, diagnosis, results etc...
   □ any other type of nurse-led clinic (please describe)

Please continue with Section 2 ONLY if you have ticked total patient management nurse-led clinics – otherwise Go To Section 4 page 6.

Section 2 – Total Patient Management Nurse-led Clinics

2. What year did your GUM clinic start total patient management nurse-led clinics?.........................

3. Why did your GUM clinic decide to start total patient management nurse-led clinics?
   ✓ all that apply
   □ government policy initiatives (e.g. junior doctors' hours reduction, waiting time initiatives)
   □ professional developments (e.g. UKCC “Scope of Practice”)
   □ purchaser encouragement
   □ staff retention or attracting new staff
   □ perceived cost savings for service
   □ staff development opportunity
   □ keeping up with trends
   □ don't know
   □ other (please describe) .............................................................
APPENDIX 1

4. What Job Title do you use for the nurse(s) providing total patient management nurse-led clinics?
   ✓ one only
   □ Nurse Practitioner □ Specialist Nurse
   □ Clinical Nurse Specialist □ Other (specify) ..................

5. How many nurses currently work in your total patient management nurse-led clinics?
   ✓ one only
   □ 1 □ 2 □ 3 □ 4 □ 5 or more

6. What is the current Grade of the nurses working in your total patient management nurse-led clinics?
   ✓ all that apply
   □ D □ E □ F □ G □ H □ I
   □ don’t know □ other (specify) ..................

7. Do you provide total patient management nurse-led clinics for: -
   Male patients □ Yes □ No
   Female patients □ Yes □ No

8. What aspects of care do the nurse(s) provide in your total patient management nurse-led clinics?
   ✓ all that apply for either or both male and female nurse-led clinics
   
   Male    Female
   □ □ taking a sexual history
   □ □ external genital examination (labia, penis, scrotum, etc)
   □ □ vaginal examination (speculum)
   □ □ pelvic examination (bi-manual)
   □ □ proctoscopy
   □ □ specimen taking (throat, urethral, cervical, rectal)
   □ □ blood tests
   □ □ microscopy
   □ □ gives patient results
   □ □ provides health promotion discussion/information
   □ □ partner notification
   □ □ provision of oral contraceptives (e.g. PC4, OCP)
   □ □ dispensing medication
APPENDIX 1

9. The nurse(s) providing total patient management nurse-led clinics work to:
   ✓ one only
   □ specific nurse-led clinic protocols/guidelines
   □ the same clinic protocols/guidelines used by the doctors
   □ a combination of both specific nurse-led and general clinic
     protocols/guidelines
   □ no protocols/guidelines are used at all

10. How is medication dispensed to patients in your total patient
    management nurse-led clinics?
    ✓ one only
    □ all patients see a doctor for medication prescribing/dispensing issues
    □ the nurse gets a doctor to prescribe all medication before dispensing
      the medication to the patient
    □ the nurse dispenses all medication directly to the patient using group
      protocols*
    □ using a combination of doctor prescribing and group protocols
    □ other (please describe) .................................................................

11. What level of medical support is available for the nurses conducting
    total patient management nurse-led clinics?
    ✓ one only
    □ medical staff are ALWAYS available onsite when total patient
      management nurse-led clinics are being conducted
    □ there are times when there are NO medical staff available onsite
      when total patient management nurse-led clinics are being
      conducted
    □ there are times when there are NO medical staff onsite but a
      medical officer can provide ADVICE BY TELEPHONE
    □ other (please describe) .................................................................

12. Has your service conducted any audit or research to monitor/evaluate
    total patient management nurse-led clinics? (e.g. documentation audit,
    patient satisfaction survey)
    □ No
    □ don’t know
    □ Yes (please describe all attempts) ..................................................

* A Group Protocol allows named nurses to supply medication in identified clinical situations
APPENDIX 1

Section 3 – Education/Continuing Professional Development

13. What is the minimum clinical experience required for the nurse(s) working in your total patient management nurse-led clinics as stated in their job description?
   ✓ one only
     □ less than one year GU experience
     □ one to two years GU experience
     □ 2 years or more GU experience
     □ other (specify) .................................
     □ don’t know

14. What are the minimum educational requirements for the nurse(s) working in your total patient management nurse-led clinics as stated in their job description?
   ✓ all that apply
     □ no specific education/course requirements
     □ ENB GUM course (N07/275/276)
     □ ENB Family Planning (901/8103)
     □ ENB HIV/AIDS (934/280)
     □ degree level or higher
     □ other (specify) .................................
     □ don’t know

15. What educational/professional development opportunities are offered specifically for the nurses working in your total patient management nurse-led clinics?
   ✓ all that apply
     □ no specific training/development opportunities
     □ regular in-house training
     □ ENB courses (specify) .................................
     □ degree courses (specify) .................................
     □ other (specify) .................................
     □ don’t know
APPENDIX 1

16. Do you think there is a need for an Advanced GUM Practice course focusing on nurses working in total patient management nurse-led clinics?
   □ Yes
   □ No – I think that there are adequate educational opportunities already
   □ Don’t know

17. Would you or your colleagues attend such a course?
   □ Yes
   □ No
   □ Don’t know

Section 4 – Final Comments

Please feel free to comment on any aspect of this questionnaire.
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
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........................................................................................................................................

☐ I would be interested in receiving the results of this survey
   ☐ Please give your name and clinic so that we can send the report directly to you.
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

Thank you for taking the time to complete this questionnaire.
Patient Information Sheet 2 - Observation

A process & outcome evaluation of nurse-led clinics for women attending a Central London sexual health service.

You are invited to take part in a research study that is evaluating the doctor and nurse-led care in this clinic. You may have some questions and we hope that the information in this leaflet helps answer them.

What is the purpose of this study?
Nurse-led clinics have been successfully conducted at other sexual health clinics in London and started here at Mortimer Market Centre in January of this year. This new type of clinic is being piloted for 12 months and it is this evaluation study that will aid the decision as to whether the nurse-led clinics will continue past the 12 month pilot period.

What does the study involve?
The study has many different aspects but for today you are being asked if a clinic researcher can sit in during your appointment with the doctor or specialist nurse. The researcher will observe what happens during your appointment, specifically seeing how the doctor/specialist nurse performs according to clinic guidelines and standards. The researcher will not ask you any questions and will leave the room when you are being examined.

How long will the study last?
The new nurse-led clinics started in January of this year and this study will be carried out for approximately 3 months from May 1999. You will be only be asked to take part for today only and will not be required to return to the clinic apart from your usual care and treatment.

What are the risks in taking part?
There are no risks in taking part in this study. We ask only for your time. You will not be asked to produce any extra blood samples or tests.

If you decide not to participate, or agree and then change your mind
You do not have to take part in this study if you do not want to. If you decide to take part you may withdraw at any time without having to give a reason. Your decision whether to take part or not will not affect your care and management in any way.

Confidentiality
The information gathered during your appointment will remain strictly confidential and no one apart from the clinic researchers and staff will have access to this information. The results gathered from the study may be presented at meetings and published so that this information will be helpful to others. This information will not contain your name or any other details that will identify you.

All proposals for research using human subjects are reviewed by an ethics committee before they can proceed. This proposal was reviewed by the Camden & Islington Community Health Services NHS Trust ethics committee.

If you would like more information before taking part please speak to Kevin Miles 0171-380 9878
APPENDIX 2

Consent Form - Direct Observation

Title of Study: A process & outcome evaluation of nurse-led clinics for women attending a Central London sexual health service.

Investigators Name: Kevin Miles

To be completed by the participant

1. I have read the information sheet about this study YES/NO
2. I have had an opportunity to ask questions and discuss this study YES/NO
3. I have received satisfactory answers to all my questions YES/NO
4. I have received sufficient information about this study YES/NO
5. I understand that I am free to withdraw from this study:-
   * at any time
   * without giving a reason for withdrawing
   * without affecting my future medical care YES/NO
6. I agree to take part in this study YES/NO

Signed X ........................................... Date ........................

Print Name X ........................................................................

Health professional ........................................... Date ........................
APPENDIX 3

**Documentation Audit Proforma**

<table>
<thead>
<tr>
<th>DLC</th>
<th>NLC</th>
<th>[ ] [ ] [ ]</th>
</tr>
</thead>
</table>

### Date of visit: / / 99  
Pt Ref. No. ______________  
DOB ______ / ______

### Ethnic Group:

<table>
<thead>
<tr>
<th>White □</th>
<th>Black Caribbean □</th>
<th>Black African □</th>
<th>Other ethnic group □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian □</td>
<td>Bangladeshi □</td>
<td>Pakistani □</td>
<td>Missing □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. Presenting complaint</th>
<th>recorded □</th>
<th>incomplete □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2. Case load</th>
<th>A₁</th>
<th>B₂</th>
<th>C₃</th>
<th>D₄</th>
<th>E₅</th>
<th>F₆</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Sexual history</th>
<th>recorded □</th>
<th>incomplete □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4. No. of partners in last 3/12</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5. Past STI history</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>6. Past medical history</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>7. Drug history</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>8. Allergies</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>9. Recreational drugs</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>10. Sex work</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>11. HIV test &amp; PTC</th>
<th>recorded □</th>
<th>incomplete □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>12. Last UPSI</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>13. Cytology</th>
<th>recorded □</th>
<th>incomplete □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>14. Contraception</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>15. LMP</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>16. Cycle</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>17. Pregnancies</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>18. Examination</th>
<th>recorded □</th>
<th>incomplete □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>19. STI test request</th>
<th>correct □</th>
<th>too many □</th>
<th>too little □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>20. Cytology correct per policy □</th>
<th>should’ve been requested □</th>
<th>inappropriate request □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>21. Diagnosis</th>
<th>correct □</th>
<th>incorrect □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>22. Appropriate treatment</th>
<th>correct □</th>
<th>wrong Rx □</th>
<th>wrong dose □</th>
<th>other incorrect □</th>
<th>incomplete □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>23. Medication instructions</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>24. Partner notification</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>25. Health promotion discussion</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>26. Offered HBV vax</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>27. Offered contraception services</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>28. Offered condoms</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>29. Outcome: f/u appt/referral/discharge</th>
<th>recorded □</th>
<th>not recorded □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>30. Notes signed</th>
<th>recorded □</th>
<th>not recorded □</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>31. Evidence of f/u</th>
<th>attended □</th>
<th>DNA □</th>
<th>N/A □</th>
</tr>
</thead>
</table>

308
This questionnaire has been designed to tell us about your overall opinion of the care that you received from the doctor or specialist nurse who you saw today. It is not a test and there are no right or wrong answers. We are interested in your opinions and impressions.

Please follow the instructions carefully and if you have any questions please ask to speak to Kevin Miles, the study co-ordinator.

The first section asks for basic information about you. Remember that this questionnaire is anonymous so we cannot identify you.

Please tick or fill in the blank, as appropriate, in each item.

Q1 Have you ever had an appointment here in the female clinic before?
   No □ 1
   Yes □ 2

Q2 Who was your appointment with today?
   Specialist Nurse □ 1
   Doctor □ 2

Q3 What was your age at your last birthday? (Write your age here) __________

Q4 At any time in the last week were you:
   In a full-time job □ 1 Go To Question 5
   In a part-time job □ 2

   Waiting to start a job already accepted □ 3
   Seeking work □ 4
   Prevented by temporary illness from seeking work □ 5 Go To Question 8
   Permanently disabled □ 6
   Wholly retired from employment □ 7
   At school or full-time student □ 8
   Other (please specify) ____________________________ □ 9

   TURN TO NEXT PAGE
APPENDIX 4

Q5 Are you: 

- An apprentice or articled trainee □ 1
- An employee not supervising other employees □ 2
- An employee supervising other employees □ 3
- Self-employed, not employing others □ 4
- Self-employed, employing others □ 5
- Other specify □ 9

Q6 Please give details of your occupation *(Write your job title here)*

___________________________________________________________________________

Q7 Please describe the actual work you do: __________________________________________________________________________

Q8 Since leaving school, have you continued your education at a university, polytechnic, technical college or college of further education? *(Tick one only)*

- Yes □ 1
- No □ 2
- Not Applicable □ 3
  (student still at school)

Q9 Which of the following ethnic groups best describes you? *(Tick one only)*

- White □ 1
- Black (African/Caribbean/Other) □ 2
- South East Asian □ 3
- Asian (Indian/Pakistani/Bengali) □ 4
- Other *(Please specify)* □ 5

Q10 How would you describe your sexual orientation? *(Tick one only)*

- Heterosexual □ 1
- Homosexual/Lesbian □ 2
- Bisexual □ 3
APPENDIX 4

The following questions are intended to see how you personally feel about the care you have received today. The person that you saw refers to the Doctor or Specialist Nurse who asked the questions about your medical history and sexual behaviour. Read each item carefully, and then decide whether you agree or disagree with the statement. Please circle the number which most closely represents your feelings and answer all questions unless instructed otherwise.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was given as much time as I needed for my appointment</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person that I saw in the clinic did not always talk sense</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt that my personal circumstances were being judged</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The care in the clinic was just about perfect</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person I saw doesn't understand what it is like having to come to the clinic</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The clinic staff were very friendly</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I've no confidence in the person who was treating me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>My questions were answered in words that I found hard to understand</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I feel reassured that the clinic will keep my personal information confidential</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I feel that I could not rely on the information that I was given</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt that the clinic needed a good cleaning</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I was told everything that I want to know about my condition</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt that the problem that I came with was sorted out properly</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**please check you have answered all the above**
## APPENDIX 4

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>There were some things about my care in the clinic that could be improved</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt that I was treated as a person rather than a disease</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I’m worried that my personal information will be given out to other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person that I saw did not make personal judgements about my situation</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person I saw in the clinic appeared uncertain about what they were doing</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>No matter how long you have to wait it’s worth it</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Visiting the clinic is not a stressful occasion</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I felt that I was in good hands</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person that I saw in clinic was not as thorough as she/he should have been</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I was made to feel comfortable answering personal questions</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>The person who I saw seems to know how I feel about being here in the clinic</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>I was satisfied with the care that I received in the clinic today</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(answer only if you waited for results today)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It took a long time to get my results today</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Please check you have answered all the above

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**TURN TO NEXT PAGE**

---
APPENDIX 4

Did you have a vaginal/internal examination and/or tests taken?

- No  □1  If No - GO TO NEXT PAGE
- Yes □2  If Yes - please answer ALL following questions

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was not told why I needed tests such as swabs and bloods</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>The person that I saw made sure I was physically comfortable during my examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I felt that some of the tests were not the ones that I needed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

TURN TO NEXT PAGE
APPENDIX 4

Did you receive any medication or treatments today (e.g. creams, tablets, pessaries, cryac spray)?

No  □ 1  If No - You are FINISHED (No more questions)

Yes  □ 2  If Yes - Answer ALL final questions below

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was given good advice on how to cope with my condition</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Side effects of treatments were barely discussed during my appointment</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I was told everything about the medication given to me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My feelings about my treatments were taken into consideration</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>During my consultation I was given little or no explanation about my condition</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

We value any further comments about the care you have received today ______________________

______________________________

______________________________

______________________________

______________________________

PLEASE PLACE YOUR COMPLETED QUESTIONNAIRE IN THE BOX AT RECESSION
OR GIVE TO A MEMBER OF STAFF BEFORE YOU LEAVE

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE
APPENDIX 5

Interview Schedule for Patient Exit Interviews

Tell me about the consultation that you just had

What did you think about the approach of the person that you saw - what was their manner like

How did you feel the person that you saw related to you

How did you feel you related to the person that you saw

How comfortable did you feel answering the questions

How did they explain the things that they were doing - the tests, examination etc

Tell me the things that didn’t make sense

How was the examination?

Tell me what was good and what was not so good about the examination

What about the advice that they gave you

How did you feel about waiting

How do you feel now your visit is over

How did you feel about the gender of the person that you saw

Finally any other comments that you would like to make about you visit today
APPENDIX 6

Waiting Time Survey

Date: ______/_____/99      New/Old    Dr/SpN (circle)

Booked time of appointment: ___________________

Time patient actually arrived in clinic: _______________

Time patient first seen by Dr/SpN: _______________

Time patient completed appointment (i.e. after all tests and results): __________
Clinic Research Study Information

In January of this year we started an alternative approach for the care and treatment of women attending the female clinic. This involves trained Specialist Nurses providing the same routine quality service that doctors have traditionally done. Instead of all patients seeing a doctor, some of you will see a Specialist Nurse. If for any reason you still need to see a doctor, the Specialist Nurse will arrange this.

We are now assessing the Specialist Nurse clinics to ensure that your needs are being met. In order to compare nurse-led care with doctor-led care we have randomly booked you to see either a Doctor or Specialist Nurse. Today you have been booked to see Specialist Nurse _____________ who has experience and specialist training in sexual health.

- If you are happy with this you do not have to do anything, and the level and quality of care provided will not be affected by your participation.
- If for any reason you do not want to see the Specialist Nurse or Doctor that your appointment has been booked with, please speak to the receptionist and other arrangements will be made.

At some time during your visit you may be approached by a clinic researcher who may ask you to complete a questionnaire, interview you or ask to observe your appointment with the Doctor or Specialist Nurse. The researcher will give you more information about this and of course your participation is voluntary. If you decide not to take part or wish to withdraw at any time during the study, your care will continue unaffected.

If you have any further comments or questions please ask to speak to Kevin Miles or Dr Danielle Mercery on 0171-380 9878.

This study has the approval of the Camden & Islington Community Health Services NHS Trust Ethics Committee.