THE MANAGEMENT OF VAGINAL DISCHARGE
Diagnosis in a community setting

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List of Abbreviations

BV	Bacterial vaginosis
CI	Confidence interval
COCP	Combined oral contraceptive pill
CT	*Chlamydia trachomatis*
DFA	Direct fluorescent antibody
DFFP	Diploma of the Faculty of Family Planning
EIA	Enzyme immunoassay
FFPRHC	Faculty of Family Planning and Reproductive Health Care
FP	Family Planning
FPA	Family Planning Association
GUM	Genitourinary medicine
GC	Gonoccocus
GP	General Practitioner
HIV	Human Immunodeficiency Virus
HSV	Herpes simplex virus
HVS	High vaginal swab
IMB	Inter-menstrual bleeding
IUD	Intrauterine (contraceptive) device
LCR	Ligase Chain reaction
NAAT	Nucleic acid amplification technique
NHS	National Health Service
PCB	Post-coital bleeding

PCR	Polymerase chain reaction
SD	Standard deviation
SDA	Strand displacement assay
STD	Sexually transmitted disease
STI	Sexually transmitted infection
STIF	Sexually Transmitted Infection Foundation
TOP	Termination of Pregnancy
TV	*Trichomonas vaginalis*
UK	United Kingdom
VD	Venereal disease
MLSO	Medical Laboratory Scientific Officer
NS	Not significant

DECLARATION

I declare that the contents of this thesis have not been submitted elsewhere for any other degree, diploma or professional qualification. This thesis has been composed by myself, and I have been responsible for recruitment of participants and clinical management unless otherwise acknowledged.

The work in this thesis has resulted in the following publications:

Melville, C., Bigrigg, A., & Nandwani, R. (2003) Impact of the Sexually Transmitted Infections Foundation course on the knowledge of family planning nurses and doctors. *Sexually Transmitted Infections*, **79**, p. 346.

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Melville, C., Bigrigg, A., & Nandwani, R. (2004) Client perspectives on sexual health service provision. *International Journal of STD & AIDS*, 15, pp. 380-383.

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SUMMARY

Women with abnormal vaginal discharge may seek treatment at a Family Planning (FP) or Genitourinary Medicine (GUM) clinic. This common problem may also be managed in Primary Care or at a gynaecology clinic. There is no accepted standard strategy in the United Kingdom (UK) for management of this condition. Protocols for care have evolved mainly by custom and practice rather than from a firm evidence base.

Although in the UK the specialities of GUM and FP have traditionally been organised separately, recently these services have become more integrated in order to provide an efficient, patient-orientated approach. In some centres, such as the Sandyford Initiative in Glasgow, FP and GUM services are now housed under the one roof. This has highlighted the difference in approaches to the management of vaginal discharge. The GUM strategy utilises near-patient microscopy of the genital specimens and offers an immediate microscopy-based diagnosis. Specimens from the FP strategy however, are transferred to the local laboratory for analysis. Using this strategy, the clinician will make a presumptive initial diagnosis based on the clinical signs and symptoms.

Integration of services at the Sandyford Initiative allowed us the opportunity to perform a study comparing the FP and GUM strategies for the management of vaginal discharge in terms of diagnostic accuracy. 200 women (100 each from FP and GUM) were recruited to, and completed this randomised controlled cross-over study. The FP and GUM strategies were performed on all participants. The sequence

in which the strategies were performed was randomised to avoid sampling bias. The initial FP diagnosis based on clinical symptoms and signs and the GUM microscopy diagnosis were compared with the reference standard of both strategies combined. In addition, the final results from both strategies were compared with the reference standard. Strategy accuracy was assessed by the difference of two paired proportions, together with 95% confidence intervals. Statistical significance was assessed by McNemar's test.

All participants completed the study. The mean age of participant was 28 years (range 16 - 51 years). There were 185 Caucasian participants and 15 participants from other ethnic origins. No significant difference was found in age and ethnicity when the participants from each clinic and each randomised sequence group were compared using the χ^2 test. 132 participants had one sexual partner in the previous year. GUM participants had significantly more sexual partners than FP participants in the last year ($p = 0.005$). The number of FP and GUM participants with a previous STI was statistically similar (23 and 31 respectively).

There were 140 diagnoses of non-sexually transmitted infections made in the study participants. These consisted of 63 cases of Bacterial vaginosis, 60 of *Candida albicans*, and 17 streptococcal infections. Nineteen sexually transmitted infections were diagnosed in 19 participants. There were 16 cases of *Chlamydia trachomatis*, two cases of *Trichomonas vaginalis* and one case of *Neisseria gonorrhoea*.

This study found that the strategy of near-patient microscopy (GUM) was more accurate than best clinical diagnosis (FP), in terms of immediate diagnostic accuracy

($p < 0.001$). The FP strategy however, was found to be significantly more accurate than the GUM strategy in terms of final diagnosis ($p = 0.019$). This is because the GUM strategy did not include a vaginal specimen for culture and therefore missed many of the diagnoses of *Candida albicans* and streptococci. The day 1 GUM strategy had a greater sensitivity and specificity than the day 1 FP strategy (72% and 98% vs. 68% and 59% respectively). The day 7 FP strategy had a greater sensitivity and specificity than the day 7 GUM strategy (86% and 100% vs. 75% and 99% respectively).

Prior to the introduction of new practices at the Sandyford Initiative it was considered essential to determine the views and needs of our clients. We therefore undertook a questionnaire-based study to assess user views of our service. 200 participants were questioned regarding various aspects of the GUM and FP clinics including access to the service, waiting times and views on the use of near-patient testing. When questioned about choice of service, most participants said they would prefer to attend an FP or GUM service for their sexual health needs rather than their General Practitioner (GP) or a hospital clinic. Although near-patient testing results in a longer time spent in clinic, 99% of participants expressed a preference for immediate microscopy results and treatment.

As sexual health services modernise and change in the UK, the traditional roles and duties of staff are adapting and expanding. It is vital that staff are equipped with the knowledge and skills necessary to competently extend their roles. In recognition of their educational needs, FP staff at the Sandyford Initiative were given the opportunity to attend the Sexually Transmitted Infections Foundation (STIF) course,

which was developed by the Medical Society for the Study of Venereal Diseases (MSSVD).

A study was undertaken to evaluate the educational impact of the STIF course. 16 FP doctors and 4 FP nurses were invited to participate in the study, which was designed to assess their knowledge of cervical and vaginal infections. The researcher administered four clinical case scenarios. Each participant had to make a diagnosis based on the patient history and clinical photographs, which were provided. Following attendance at the STIF course, the participants were re-tested with the initial scenarios. The pre- and post-course scores were compared. Statistical analysis was performed using one and two sample t-tests and confidence intervals for the difference of two means. There was a mean increase of 2.5 points in all participants' scores. Comparison of pre- and post-course scores revealed a statistically significant improvement ($p = 0.001$).

In summary the studies presented in this thesis were performed in response to the changing remit of sexual health services in the UK. The findings of these studies have been used to modify and influence practice at the Sandyford Initiative, and could be used to implement change in departments offering a similar service.

CHAPTER 1: INTRODUCTION AND AIMS

"Seeing much, suffering much, and studying much, are the three pillars of learning."
Benjamin Disraeli, Prime Minister of Great Britain, 1874-1880

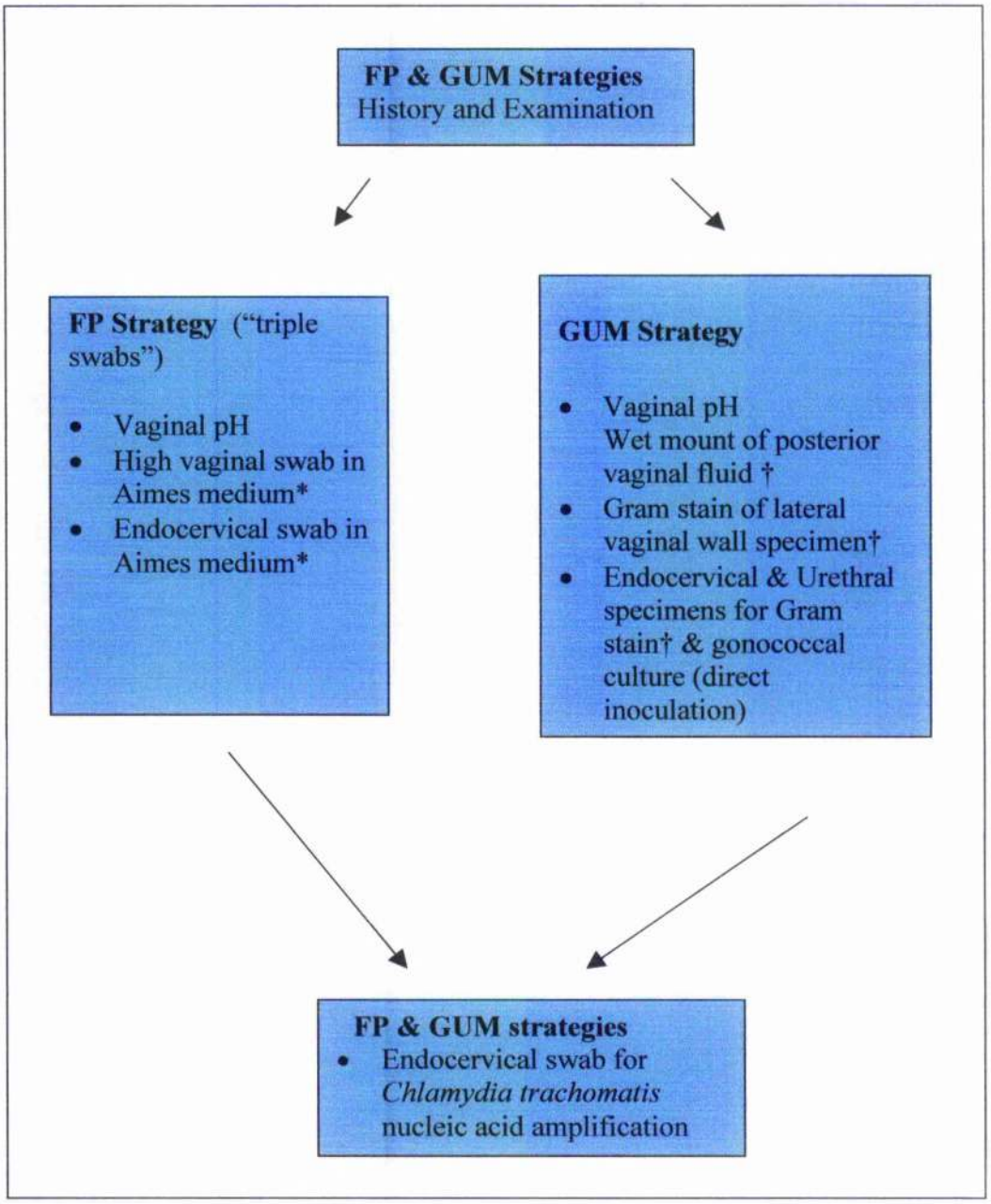
1.1 General introduction

Many women experience abnormal vaginal discharge at some time in their lives. (Hay 1999b). At least 25% of women attending Genitourinary Medicine (GUM) clinics receive treatment for one of the three common causes of abnormal vaginal discharge: bacterial vaginosis, candidiasis and trichomoniasis. As an alternative to GUM services, women with vaginal discharge may choose to attend their General Practitioner (GP), or a Family Planning (FP) or gynaecology clinic.

The management of women presenting with vaginal discharge varies according to the service. There are two main strategies of management in current use in the UK. The strategy traditionally utilised in community settings such as Primary Care and FP as well as in hospital settings such as gynaecology, is that of 'triple swabs' (Figure 1.1.1). This consists of swabs taken from the endocervix and vagina for microbiology culture and an endocervical sample for *Chlamydia trachomatis* testing. These specimens are sent to the local laboratories for analysis. Using this strategy, the clinician will make a presumptive initial diagnosis based on the clinical signs and symptoms and will manage the patient accordingly, whilst awaiting the laboratory results. In contrast, GUM services utilise on-site laboratory facilities for near-patient microscopy of the genital specimens (Fig 1.1.1). This results in an immediate microscopy-based diagnosis.

These strategies have been developed historically and although there is a large evidence base for the use of specific diagnostic tests, there is a lack of evidence supporting the use of either strategy. Although the role of near-patient microscopy has been evaluated within the GUM setting in asymptomatic women, (Andrews et al. 1994) there are no studies to date that directly compare the accuracy of these different strategies in either asymptomatic or symptomatic individuals. No evidence base currently exists to confirm that on-site microscopy should be enlisted in the management of all women presenting with vaginal discharge.

Figure 1.1.1 Current strategies for the diagnosis of vaginal discharge



FP = Family Planning. GUM = Genitourinary Medicine

*These specimens are transported to the local laboratory for: culture on selective and non-selective gonococcal agar (incubation for 48 hours at 37°C in 5% CO_2), and chloramphenical containing Sabarouds medium; incubation in Feinbergs medium for 48 hours at 37°C and inverted light microscopy; and Gram film and microscopy.

†These specimens are examined with on-site microscopy. The inoculated gonococcal plates are then transported to the local laboratory for incubation and examination.

1.2 Background to Service provision

FP and GUM services were developed separately and on the whole continue to evolve independently (Kane & Wellings 1999; Stedman & Elstein 1995). Although both services undertake similar work and aim to deliver patient-centred care, they still function, as a whole in parallel (Stedman & Elstein 1995; Wilkinson, Hampton, & Bradbeer 2000).

GUM services were developed along a medical model in hospital settings. They were initially created to meet the needs of army personnel returning from the First World War with venereal diseases (VD), (Adler 1980; Adler 1982; Wyke 1973). At the beginning of the 20th century, the Royal Commission on Venereal Diseases produced a document, which led to the Public Health (Venereal Diseases) Regulations in 1916 (Royal Commission on Venereal Diseases 1916). This allowed for the establishment of specialist clinics for the diagnosis and treatment of STI's. The emphasis of these clinics was to provide confidential services, which were free of charge. In 1948 at the inception of the National Health Services (NHS), these services were brought into hospitals.

In the post World War II era, penicillin dramatically changed the face of VD. The incidence of syphilis and gonorrhoea fell to an all time low in the 1950s (Moore J.E. 1956), allowing those physicians working in VD clinics to concentrate on other 'STD's'. Most venereologists changed their name to genitourinary physicians around this time to reflect the change in workload (Birley et al. 2002). The majority of GUM departments are today housed in hospital settings and staffed by physicians.

FP services in the UK were initiated with the opening of the first birth control clinic in London founded by Marie Stopes in 1921. The first clinics were met with much resistance from the medical profession, the church and society in general (Belfield 2000). Demand for such family planning services however, continued, particularly in the light of rising maternal mortality rates. In 1930, the National Birth Control Council was formed from the union of separate birth control societies. This was to become the Family Planning Association (FPA) in 1939.

It was not until the mid 1970s that family planning services became freely available to all by the passing of the NHS reorganisation Act (Belfield 1999; Wilkinson, Hampton, & Bradbeer 2000). As a result of this, the FPA clinics were handed over to Area Health Authorities and Boards. The structure of the services remained substantially different from other primary care services and from secondary care within the NHS, as they provided direct access for women, and were run on a less hierarchical basis than was usual in the NHS. To date the majority of FP services are based in community settings.

For most of the 20th century, the specialities of GUM and FP continued to evolve in parallel. In the early 1990s, there was increased interest in combining and integrating the two services. Providers of the services and commissioners realised that the traditional separate services offered by GUM and FP were in many ways imperfect. Neither speciality offered the entire spectrum of sexual health services in a holistic manner, but at the same time there was considerable overlap in service provision. The obvious strengths of the GUM service were human immunodeficiency virus infection (HIV) and sexually transmitted infection (STI) expertise, with its weakness

being the provision of contraception. FP primarily offered a contraceptive service and was predominantly attended by women. Its main weakness was the area of STI management (Dawson & Greenhouse 1996).

In 1995, a Consensus Workshop on Sexually Transmitted Diseases and Contraception, Sexual Health Promotion and Service Delivery was jointly sponsored by the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Medical Society for the Study of Venereal Diseases (MSSVD) and the Faculty of Public Health Medicine, and endorsed by the Association for Genitourinary Medicine (Kubba & Randall 1998). This national consensus workshop recommended that the services should converge to provide more holistic sexual healthcare (Dawson & Greenhouse 1996). This change in service provision would offer greater acceptability, convenience and cost effectiveness, whilst avoiding service duplication and errors due to clinical ignorance. It was recognised that practical constraints might be a barrier to full integration of FP and GUM, and therefore as a minimum, it was advocated that collaboration and coordination between the two services should occur (Searle 1995).

The first ever National Strategy for Sexual Health and HIV in England was published at the end of July 2001 (Department of Health 2001). The strategy has recognised the current problems, and wide variations in access to sexual health services throughout the UK. One of the key proposals is to 'evaluate the benefits of more integrated sexual health services, including pilots of one-stop clinics'. The strategy also defines three levels of service activity with different elements of care

provided by primary care teams, GUM, gynaecology and FP (Adler et al. 2002; Robinson & Rogstad 2003).

Convergence of FP and GUM services is becoming more widespread, and the number of centres in which they are now housed under one roof has increased over recent years (Bloxham, Capstick, & Greenwood 1999; Dawson & Greenhouse 1996; Jones 2000; Laughlin et al. 2001). Although it has been recognised that the integration process has many challenges (Stedman & Elstein 1995; Wilkinson, Hampton, & Bradbeer 2000), much progress has been made across the UK.

1.3 The Sandyford Initiative

The Sandyford Initiative in Glasgow, established in June 2000 is an example of a centre offering GUM and FP services under one roof (Laughlin et al. 2001). In addition, it houses 'The Centre for Women's Health'. This organisation established in 1995 aims to promote women's health in a social model context. Since its inception, the Sandyford Initiative has aimed to deliver a 'joined up' service, which provides client centred care whilst optimising available skills and resources. It was recognised that initially the FP and GUM departments at the Sandyford Initiative, were functioning in parallel, and were essentially separate organisations in the same building. Since it opened, the departments have undergone a gradual process of integration.

As part of the integration process, attention was given to the development of unified clinical systems and protocols. It was noted that clients could attend the Sandyford

Initiative with a specific problem and experience quite different strategies of management depending on which department they attended. An area in which this was highlighted was the management of women presenting with vaginal discharge. At the time of our study, a woman could present to either GUM or FP for management of this condition, and different protocols would be followed (Figure 1.1.1).

The FP strategy is widely used throughout General Practice and hospital gynaecology departments. A history is taken from the patient followed by clinical examination. Our FP protocol includes taking a vaginal sample for pH, although this is not always performed in other health care settings. Three specimens from the genital tract are then collected. These are sometimes known as 'triple swabs'. A lateral vaginal wall/posterior vaginal fornix specimen (high vaginal swab) and an endocervical specimen are taken and transported in Amies Transport Medium with charcoal (Amies 1967) to the local bacteriology laboratory. These specimens are plated onto selective and non-selective gonococcal agar (incubation for 48 hours at 37°C in 5% CO_2) for culture. They are also plated onto chloramphenical containing Sabarouds medium; incubated in Feinbergs medium for 48 hours at 37°C with subsequent inverted light microscopy; and subject to gram film and microscopy. The third genital tract specimen is an endocervical swab taken for *Chlamydia trachomatis* detection by a nucleic acid amplification technique (NAAT). This sample is transported to the local virology laboratory.

The GUM strategy is similar to that utilised in other GUM departments in the United Kingdom. The initial parts of the strategy – history, examination, and vaginal pH –

are identical to those performed in the FP strategy. The sample taken for detection of *Chlamydia trachomatis* is also processed in an identical manner. The key difference in the strategies is the use by GUM of near-patient laboratory facilities. A wet mount of vaginal fluid and samples from the lateral vaginal wall, endocervix and urethra are gram stained and examined with microscopy on-site. An additional difference is the direct plating of endocervical and urethral samples onto selective and non-selective gonococcal agar prior to transport for culture.

We recognised the need to develop an evidence based strategy, which could be implemented in both departments in the Sandyford Initiative, and adopted by other services managing this condition such as primary care and gynaecology settings. We therefore undertook a study to directly compare these strategies in terms of diagnostic accuracy.

1.4 Aetiology of Vaginal Discharge

The vagina is lined at birth with stratified squamous epithelium, produced in response to maternal oestrogen. It is a dynamic ecosystem which is sterile at birth, becoming colonised within a few days with a predominantly Gram-positive flora. Within a few days of birth the vagina is lined with cuboidal epithelium which persists until puberty. The vaginal pH in premenarchal females is approximately neutral (pH 7.0). At puberty, the epithelium once more becomes stratified squamous, the predominant flora changes to lactobacilli, and the pH decreases to less than 4.5 (Hay 1999b).

Normal or physiological vaginal discharge consists of desquamated epithelial cells from the vagina and cervix, mucus from the cervical glands, bacteria, and transudate from the vaginal wall. It is white in colour and non-offensive (Table 1.4.1). Abnormal vaginal discharge is a non-specific and subjective symptom (Wilson 2003). If a woman has underlying concerns regarding an STI, she may perceive a physiological discharge as abnormal.

Table 1.4.1 Characteristics of vaginal discharge

	Colour	Consistency	Odour	Associated symptoms	Vaginal pH
Physiological	Clear White	Varies (with cycle)	None	None	3.5 - 4.5
Bacterial Vaginosis*	Grey Milky White	Watery Thin Profuse	Fishy	None	> 5.0
Candida albicans*	White	Thick Curd-like	None	Itch Soreness Swelling	3.5 - 4.5
Chlamydia trachomatis*	Mucopurulent Blood stained	Thick	None	PCB IMB Abdominal pain	3.5 - 4.5
Neisseria gonorrhoeae*	Mucopurulent Blood stained	Thick	None	Abdominal pain Dysuria	3.5 - 4.5
Trichomonas vaginalis*	Yellow	Thin Frothy	Fishy	Itch Irritation Dysuria Vaginitis	>> 5.0

PCB = postcoital bleeding; IMB = intermenstrual bleeding
*These infections can be completely asymptomatic.

An abnormal discharge can arise from anywhere in the genital tract, and may be due to infective or non-infective causes. Infections may be vaginal or cervical and may be sexually or non-sexually transmitted (Table 1.4.2).

Table 1.4.2 Causes of vaginal discharge

Non-infective
- Physiological
- Cervical ectopy
- Foreign bodies
- Contraception related

*Infective, non-STI
- Bacterial vaginosis
- Candida infections

*Infective, STI
- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Trichomonas vaginalis*

*The infective causes are in order of frequency of occurrence.

Bacterial vaginosis

Bacterial vaginosis (BV) is the most common cause of vaginal discharge in women of reproductive age (Hay 1999a). The reported prevalence varies from 5% in a group of asymptomatic individuals, to as high as 50% of women in Uganda (Wawer, Sewankambo, & Serwadda 1999). It was found in approximately 10%-15% of women attending a UK gynaecology clinic (Hay & Taylor-Robinson 1992). In the UK, the rates are about 9% in general practice, 15% in pregnant women, 20%-25%

in women undergoing termination of pregnancy (TOP), and 30% in women attending STI clinics (Wilson 2003).

BV is not an STI, although it may be associated with an increased number of sexual partners. In a study in the United States, microscopy consistent with BV was found in 12% of virgin girls (Bump & Buesching 1988). It is caused by an overgrowth of anaerobic bacteria, *Gardnerella vaginalis* (*G. vaginalis*) and genital mycoplasmas, with reduced or absent lactobacilli (Holst et al. 1987). Known risk factors for BV include smoking, vaginal douching and use of an intrauterine device (IUD). The prevalence is high among lesbian women. In some women the vaginal flora is in a very dynamic state and BV may develop and remit spontaneously within a few days. It develops most often around the time of menstruation and resolves mid-cycle, suggesting that hormonal influences are important in the control of the vaginal flora (Keane, Ison, & Taylor-Robinson 1997).

Approximately 50% of women with BV are asymptomatic. When present, the symptom most commonly complained of is copious, malodorous (fishy) discharge. The odour is caused by the production of volatile amines by anaerobic bacteria and is often worse during menstruation or after intercourse. There is no associated itch or soreness of the vulva. On examination, the discharge has a typical milky appearance and may be frothy. There is no vulvovaginitis, and the vaginal pH is elevated to as high as 7.0. Diagnosis of BV can be made using the Amsel criteria (Amsel et al. 1983). Three of four composite criteria must be present (Table 1.4.3). Alternatively, a Gram-stained vaginal smear can be examined using the Hay/Ison criteria or the Nugent criteria (Hay 1999b; Nugent, Krohn, & Hillier 1991).

Table 1.4.3 Criteria for the diagnosis of BV

Amsel Criteria (At least 3 of 4 must be present)	Criteria used in Sandyford GUM (At least 2 of 3 must be present)
• Thin, white, homogeneous discharge • pH of vaginal fluid >4.5 • Clue cells on microscopy • Release of fishy odour on adding 10% potassium hydroxide to vaginal fluid*	• Offensive (fishy) vaginal discharge • pH of vaginal fluid >5.0 • "Intermediate" or "Abnormal" pattern of vaginal flora on gram stain (Hay's criteria)

*Whiff or amine test

Recent studies have shown that a Gram-stained vaginal smear is sensitive and specific for the diagnosis of BV, and may be easier to use than Amsel's criteria (Wilson 2003). The Hay/Ison criteria are defined as: grade 1 (normal flora); grade 2 (intermediate flora) and grade 3 (abnormal flora), (Appendix II). The Nugent score is derived from estimating the relative proportions of bacterial morphotypes to give a score between 0 and 10. A score of less than four is normal, four to six is intermediate, and greater than six is BV (Hay 1999a). The GUM department at the Sandyford Initiative employs a combination of Amsel's and Hay's criteria (Table 1.4.3). The high vaginal swab (HVS) and the endocervical swabs are sent from the FP department at the Sandyford Initiative to the local laboratory in Aimes transport medium and then Gram-stained and examined with Hay's criteria (Table 1.4.4). Culture of vaginal secretions is not a useful diagnostic test for BV as 30% - 50% of women are colonised with *G. vaginalis* and anaerobes as part of their normal vaginal flora (Wilson 2003).

Table 1.4.4 Diagnosis of specific infections at the Sandyford Initiative

	GUM Protocol	FP protocol*
Bacterial Vaginosis		
Sample	• Lateral vaginal wall	• Lateral vaginal wall
Laboratory	• On-site	• Local bacteriology
Technique	• Hay's criteria on Gram-stain	• Endocervical swab and HVS in Aimes. Gram-stained for microscopy. Hay's criteria
Candida albicans		
Sample	• Lateral vaginal wall	• Lateral vaginal wall
Laboratory	• On-site	• Local bacteriology
Technique	• Gram-stain	• Endocervical swab and HVS in Aimes. Gram-stained for microscopy & plated onto Sabouraud's medium for culture
Chlamydia trachomatis		
Sample	• Endocervical swab	• Endocervical swab
Laboratory	• Local virology	• Local virology
Technique	• LCR*	• LCR*
Neisseria gonorrhoeae		
Sample	• Endocervical, urethral	• Endocervical
Laboratory	• On-site and local	• Local bacteriology
Technique	• Microscopy of Gram-stain & direct inoculation onto GC selective and non-selective agar. Transported to local laboratory. 48 hour incubation.	• Endocervical swab and HVS in Aimes. Delayed inoculation onto selective & non-selective GC agar. 48 hour incubation.
Trichomonas vaginalis		
Sample	• Posterior vaginal fornix	• Posterior vaginal fornix
Laboratory	• On-site	• Local bacteriology
Technique	• Wet mount microscopy (0.9% saline)	• Endocervical swab and HVS in Aimes. Cultured in Feinbergs medium (48hrs at 37°c), and inspected by inverted light microscopy

LCR= ligase chain reaction; HVS= high vaginal swab; GC = gonococcus
* LCR has now been withdrawn because of the risk of false positive results. The current test in use at the Sandyford Initiative is strand displacement assay (SDA).

Treatment of BV is recommended for all symptomatic women, those undergoing gynaecological surgery (including TOP), and pregnant women with a previous preterm birth (Hay 1999a). Treatment is usually in the form of metronidazole tablets (400mg twice daily for 5 - 7 days), but alternatively, metronidazole suspension (2g stat), or intravaginal clindamycin cream (2%) can be prescribed. All these treatments have been shown to achieve cure rates of 70% - 80% after four weeks in controlled trials (Hay 1998; Hillier et al. 1993; Larsson 1992; Lugo-Miro, Green, & Mazur 1992) . Treatment of sexual partners has not been shown to decrease the recurrence rates and therefore is not required (Colli, Landoni, & Parazzini 1997).

Candidiasis

It is estimated that 75% of women will experience at least one episode of symptomatic vaginal candidiasis in their lifetime. Fortunately for most women it responds to simple treatments, however, 40% - 50% will have a further episode. There is a 15% - 20% point prevalence of asymptomatic candida carriage in young, non-pregnant, premenopausal women (Bingham 1999). In 80% - 92% of cases the causative agent is *Candida albicans*. The remainder are caused by *Candida glabrata* and other species (Daniels & Forster 1999). There are a number of recognised predisposing host factors for genital candidiasis, which affect either local or systemic immunity, and encourage candida to become symptomatic. These factors are pregnancy, diabetes, immunosuppression, antimicrobial therapy and vulval irritation/trauma (Hay 1999b). The cyclical nature of symptoms in those women with recurrent infections, and the rarity of candida infections premenarche and postmenopausally, suggest a sex hormone dependance (Wilson 2003). Although use of the older 'high oestrogen dose' combined oral contraceptive pills may have been

associated with candidiasis, no association has been shown with use of current low dose oestrogen preparations (Davidson & Oates 1985). Men can be colonised with candida however, it is not recognised as an STI. There is no evidence to support treatment of asymptomatic male sexual partners, and this has not been shown to reduce recurrent infections (Bisschop et al. 1986).

Women with candida infections most commonly complain of vulval or vaginal itch. This is accompanied by the typical curdy white discharge in about 50% of women. The discharge is non-offensive. Other symptoms include soreness of the vulva, external dysuria and superficial dyspareunia. On examination, there may be vulval oedema, erythema, and fissuring. The typical white plaques of discharge adhering to the vaginal walls may be seen (Daniels & Forster 1999). The vaginal pH is within normal limits (4.0 - 4.5). A Gram-stain of vaginal discharge collected from the lateral vaginal wall looking for spores or pseudohyphae may detect 65% of symptomatic cases (Sonnex & Lefort 1999) (Appendix II). The sensitivity of a wet mount slide (saline microscopy) of vaginal discharge is 40% - 60% (Sobel 1997). Direct inoculation onto Sabouraud's medium is the most sensitive diagnostic method, and if culture plates are not available for direct plating, the vaginal swab can be placed in Aimes or Stuart's medium for transport and delayed inoculation. Sabouraud's medium supports the growth of all clinically important yeasts. Culture has a sensitivity of 70% - 80% and a specificity of greater than 99% (Sobel 1997; Wilson 2003). The current method for the diagnosis of candida infections in the Sandyford Initiative GUM department is a gram stained vaginal wall slide. In the FP department, culture by means of delayed inoculation of the HVS and endocervical

swab onto Sabouraud's medium is routinely employed (Figure 1.1.1 and Table 1.4.4).

Management of vulvovaginal candidiasis should begin with general advice regarding the avoidance of wearing tight fitting synthetic clothing and use of local irritants such as perfumed soaps and bubble baths (Daniels & Forster 1999). Many antifungal preparations are available for the treatment of candida, all with efficacies of 80% - 90%. A Clotrimazole 500mg pessary is the treatment of choice at the Sandyford Initiative, with an alternative being a single oral dose of fluconazole 150mg. A UK study showed that approximately 50% of women preferred oral treatment (Tooley 1985), however these therapies are contraindicated in pregnancy. Sexual partners do not need treatment unless they also have typical symptoms of candida.

Chlamydia trachomatis

Chlamydia trachomatis infection is common, affecting 3% - 5% of sexually active women attending UK general practice (Department of Health 1998; Stokes 1997). The second National Survey of Sexual Attitudes and Lifestyles (Natsal 2000) found a chlamydia prevalence of 2.2% in men and women aged 16 – 44 years and a prevalence of 3.0% in women aged 18 – 24 years (Fenton et al 2001). Community chlamydia screening pilot studies involving women less than 25 years in Portsmouth and the Wirral have found higher rates of infection (approximately 10%) (Tobin, Harindra, & Tucker 2000; Wilson 2003). In 2003 there were 2006 diagnoses of female genital chlamydia infection in Greater Glasgow (440.31/100,000 female population) and 9199 female cases in Scotland (350.71/100,000 female population).

Complications cost at least £50 million annually in the UK and therefore this infection is considered to be a serious public health issue (Taylor-Robinson 1994).

Chlamydia is a sexually transmitted disease in adults with approximately 60% - 70% of sexual partners being infected. The primary site of infection in women is the cervix, with the urethra also being infected in about 50% of cases. The rectum and the pharynx may less commonly be infected. Risk factors for infection include; age less than 25 years, new sexual partner or more than one sexual partner in the recent years, lack of barrier contraception, and use of the oral contraceptive pill (Horner & Caul 1999). Women undergoing termination of pregnancy also appear to be at increased risk. Knowledge of these risk factors has aided the introduction of chlamydia screening programmes and pilot schemes throughout the UK.

Approximately 80% of women with *Chlamydia trachomatis* infection are asymptomatic. The remainder may complain of purulent vaginal discharge, postcoital or intermenstrual bleeding, lower abdominal pain or dysuria. On examination the cervix may look normal, but there may be a mucopurulent cervicitis and contact bleeding (Horner & Caul 1999). Chlamydial diagnostics continue to be a rapidly developing field. As *Chlamydia trachomatis* is an intracellular bacterium, it can only be grown in cell culture. Although culture is highly specific (100%), it has a comparatively low sensitivity of 40% - 85% and therefore is not used in routine practice except for medico-legal cases. Other methods including enzyme immunoassay (EIA) and direct fluorescent antibody (DFA) detection are being replaced by NAAT's. Levels of detection can be increased to over 90% by use of a NAAT, which is more sensitive than culture, EIA, or DFA. An additional advantage

of a NAAT is that a first void urine sample can be used instead of an endocervical swab (SIGN 2000). At the time of our study, both the GUM and FP departments at the Sandyford Initiative were testing for *Chlamydia trachomatis* in women with vaginal discharge by means of an endocervical swab sent to the local virus laboratory for ligase chain reaction (LCR), (Figure 1.1.1, Table 1.4.4).

Recommended treatments for uncomplicated chlamydial infection are oral doxycycline 100mg twice daily for one week, or azithromycin 1g as a single dose. The former is less expensive, however azithromycin is recommended if poor adherence is suspected (Horner & Caul 1999). In pregnancy, erythromycin or amoxycillin should be used as doxycycline is contraindicated, and the safety of azithromycin has not yet been fully assessed. Patients should be told to abstain from sex until they and their partners have completed treatment. It is recommended that partner notification (contact tracing) take place in order to prevent re-infection. A test of cure is not required after completed treatment with doxycycline or azithromycin as both are highly efficacious. A test of cure should be considered after treatment with erythromycin. This test should be postponed for 3 weeks after the end of treatment. If taken earlier it may detect non-viable organisms or miss late failures (Horner & Caul 1999).

Gonorrhoea

Gonorrhoea is a sexually transmitted infection caused by the Gram-negative diplococcus *Neisseria gonorrhoeae*. There has been a rise in infection rates in the UK over the past few years, particularly in women aged between 15-19 years. In England over the past 6 years, new cases of gonorrhoea have increased by 86%

(Alder 2003). There were 37 episodes of female gonorrhoea reported in Greater Glasgow in 2003 (8.12/100,000 female population). Overall in Scotland there were 156 episodes reported in women in 2003 (5.95/100,00 population). The Department of Health has set a target of a 25% reduction in gonorrhoea infections by 2007 (Department of Health 2001). Transmission of the infection is by direct inoculation of secretions from one mucous membrane to another. Between 60% - 80% of sexual partners will also be infected. The primary site of infection in women is the cervix, but the urethra is also infected in 70% - 90% of cases (Wilson 2003). Co-infection with *Chlamydia trachomatis* occurs in up to 40% of women (Bignell 1999). Women taking the combined oral contraceptive pill (COCP) may be more vulnerable to gonorrhoea as the amount of columnar epithelium on their ectocervix is increased. Barrier methods of contraception protect against acquisition.

In up to 50% of women infection is asymptomatic. The most common symptom is increased or altered vaginal discharge (up to 50%). In addition, women may complain of lower abdominal pain (up to 25%), dysuria, postcoital or intermenstrual bleeding (Bignell 1999). *Neisseria gonorrhoeae* may co-exist with other genital mucosal pathogens, such as *Trichomonas vaginalis*, *Candida albicans* and *Chlamydia trachomatis*. These pathogens may in fact be responsible for symptoms if present. On examination, there may be mucopurulent endocervical discharge which may be blood stained. Contact bleeding of the cervix may be easily induced. Pelvic or lower abdominal tenderness may be elicited (Barlow & Philips 1978). The 'gold standard' method of diagnosis of *Neisseria gonorrhoeae* is culture. This method offers a sensitivity of greater than 95%, and is readily available and inexpensive. It also allows antimicrobial sensitivity testing. In women it is recommended that

specimens be taken from both the urethra and endocervix. If an endocervical swab alone is taken then only 85% of cases of infection will be detected. Selective culture media containing antimicrobials are often used to reduce contamination (Jephcott 1997). If facilities for direct inoculation are not available, specimens may be transferred to the laboratory in a transport medium such as Aimes. Direct plating of media and use of transport media both give acceptable results (FitzGerald & Bedford 1996). The isolation rate after transport in medium at room temperature is approximately 100% within 12 hours, and more than 90% within 24 hours, although the number of colonies decreases markedly (WHO 1999). In addition to culture, microscopy of a Gram-stained smear of the urethral and cervical swabs can be performed. This allows direct visualisation of *Neisseria gonorrhoeae* as monomorphic Gram-negative diplococci within polymorphonuclear leukocytes (Appendix II). In women the sensitivity of microscopy of Gram-stained endocervical smears is 37% - 50% and urethral smears is 20% (Barlow & Philips 1978). In the Sandyford Initiative GUM department, specimens are routinely collected from the urethra and cervix. Microscopy is performed on-site and the specimens are directly inoculated onto selective and non-selective gonococcal culture plates for incubation. Rectal and pharyngeal specimens are taken if indicated (e.g. sexual assault). In the FP department, the HVS and endocervical swabs are transported in Aimes medium to the local laboratory for microscopy of the Gram-stained specimens and culture on selective and non-selective gonococcal agar (Figure 1.1.1, Table 1.4.4).

First line antimicrobial treatment for infection with *Neisseria gonorrhoeae* is under regular review in the light of evolving patterns of resistance. The chosen regimen should eliminate infection in at least 95% of those presenting in the local community

(FitzGerald & Bedford 1996). Treatments for uncomplicated genital infection are ciprofloxacin 500mg as a single oral dose or ofloxacin 400mg as a single oral dose or ampicillin 3g plus 1g of probenacid as a single oral dose (only where regional prevalence of penicillin resistant *N. gonorrhoeae* is <5%) (Bignell 1999). Pregnant women should not be treated with quinolone or tetracycline antimicrobials. Ceftriaxone 250mg or cefotaxime 500mg by intramuscular injection can be used in this situation. At the Sandyford initiative, all women diagnosed with *Neisseria gonorrhoeae* are simultaneously screened and treated for chlamydia infection due to the high rate of co-existence. Partner notification is carried out, and all patients are asked to abstain from sex until they and their partner(s) have been treated. Patients are reviewed 14 days after their initial treatment and repeat slides and cultures are performed at all previously positive sites.

Trichomonas vaginalis

Prevalence of the infection *Trichomonas vaginalis* has decreased in the UK over the past 15 years. However, in other parts of the world in particular Africa and Asia, the infection remains a major cause of vaginal discharge (Wilson 2003). There were 73 diagnoses of female trichomoniasis made in Scottish GUM clinics in the year up to 31 March 1999. *Trichomonas vaginalis* is a flagellated protozoon, 10 - 20 μm in diameter. In women the organism is found in the vagina, urethra and paraurethral glands. Although urethral infection is present in about 90% of episodes, it is the sole site of infection in less than 5% of cases. In adults transmission is almost exclusively sexual (Sherrard 1999). Due to site specificity, infection can only follow intravaginal or intraurethral inoculation of the organism. There is an increased cure rate in women when their sexual partners are treated. *Trichomonas vaginalis* is associated

with other STI's such as gonorrhoea and chlamydia. Women are the main carriers of the infection. Some men seem to be able to clear the organism without treatment. In one study, *Trichomonas vaginalis* could be found in 70% of men within 48 hours of intercourse with an infected woman and in only 33% after two weeks (Weston & Nicol 1963).

Infection in women is asymptomatic in 10% - 50% of cases. If symptoms are present, a yellow vaginal discharge is the most commonly experienced. About 50% also complain of offensive odour due to amine production by anaerobic bacteria. Vulval pruritus occurs in 25% - 50% of women and can sometimes be severe. External dysuria and superficial dyspareunia may also be present. Occasionally the presenting complaint is of lower abdominal discomfort (Wolner-Hanssen, Kreiger, & Stevens 1989). Examination findings reflect the acute inflammatory response that trichomoniasis produces. Vulvitis with vulval oedema and excoriation are seen in 10% - 30% of women. Vaginal discharge will be seen in up to 70% of women. The commonly described yellow-green, thin, frothy discharge is evident in less than 50% of women. More frequently, the discharge has a grey colour. Approximately 2% of women will have the 'strawberry cervix' appearance to the naked eye. This is due to punctate haemorrhages. This appearance is more commonly seen at colposcopic examination. Up to 15% of women will have no abnormalities seen on examination (Sherrard 1999). The vaginal pH is usually raised to between 4.5 - 7.0. Microscopy of a wet-mount smear or acridine orange slide from the posterior vaginal fornix will diagnose 40% - 80% of cases. Experienced observers can recognise non-motile organisms, but it is usually the movement of the flagellae which leads to the identification of the trichomonads. An increased number of polymorphonuclear

leukocytes is usually also observed. Culture media such as Fineberg-Whittington or Bushby allow optimal growth of the organism. This method is more sensitive than microscopy and will diagnose up to 95% of cases in women (Bickley et al. 1989). If culture medium is not available for direct inoculation, a vaginal swab can be placed in Aimes or a similar transport medium. Studies have shown no significant difference in sensitivity between delayed and immediate inoculation methods (Beverly et al. 1999; Schwebke, Venglarik, & Morgan 1999). Polymerase chain reaction (PCR) based diagnostic tests have recently been developed and sensitivities and specificities approaching 100% have been reported (Madico et al. 1998). This technique is still not widely available. Trichomonads are sometimes reported on cervical cytology, but there is a false positive rate of about 30% therefore the diagnosis should be confirmed by culture. The GUM department at the Sandyford Initiative employs on-site wet-mount microscopy for routine diagnosis of *Trichomonas vaginalis* (Appendix II). Culture is available at the local laboratory, but this is not a routine test in GUM. In the FP department, the HVS and endocervical swabs are transported in Aimes medium to the local laboratory where they are incubated in Feinbergs medium for 48 hours at 37°c, and inspected by inverted light microscopy (Figure 1.1.1, Table 1.4.4).

Most strains of *Trichomonas vaginalis* are sensitive to metronidazole and other imidazole antibiotics. A single 2g dose of oral metronidazole suspension can be given. This results in an 80% - 85% cure rate which increases to 95% with simultaneous treatment of sexual partners. Alternatively, oral metronidazole 400mg twice daily can be given for five to seven days. Partner notification is recommended and abstinence from sex should be advised until treatment is completed in both

partners. As 30% of women with *Trichomonas vaginalis* will also have either gonorrhoea or chlamydia a full STI screen should be performed (Sherrard 1999).

Other causes of vaginal discharge

Abnormal discharge may be associated with the presence of a foreign body, such as a retained tampon or fragments of condoms. Women using the IUD for contraception may complain of watery or mucoid discharge. Infection should be excluded (especially BV), and the woman can then be reassured. The low dose COCP does not usually affect vaginal discharge, however cervical ectopy is more likely to occur in women using this method of contraception, and this may account for increased vaginal discharge. Cervical ectopy is the term applied to a red area on the ectocervix which surrounds the external os: this abnormality is often erroneously called an 'erosion'. An ectopy is a physiological change consequent upon an increase in cervical bulk, as occurs at puberty or in pregnancy; this causes an unfolding of the cervix with eversion of the distal endocervix out into what is anatomically the ectocervix. The thin endocervical columnar epithelium is relatively transparent and hence the subepithelial vessels impart to an ectopy its characteristic redness. The exposure of the delicate endocervical epithelium to the acidity of the vagina results in squamous metaplasia, a protective mechanism (Fox & Elston 1992). Some women with cervical ectopy produce an excessive amount of mucus and will often describe their discharge as 'thick and stringy'. Infection should always be excluded in these women. The patient can then be reassured or offered treatment with cryotherapy or diathermy provided there is a normal cervical smear history. Lancefield group A and B streptococci are uncommon causes of vaginitis. Approximately 50% of women with group B infection report symptoms of vaginal irritation and soreness. Group A

infection is less common, but more likely to produce symptoms. There is often a marked vaginitis and a serosanguineous discharge (Sonnex 1996b).

1.5 Aims

The provision of sexual health services in the UK is evolving. Integration of service providers such as FP and GUM is occurring and greater links with primary care teams are being encouraged. To ensure that resources are effectively utilised and that evidence based, patient-centred care is delivered, common guidelines for patient management should be introduced. In addition to developing an evidence base for new common strategies of care, it is vital that users of the service are consulted prior to implementation of change, and that their views are taken into account. As sexual health services change, the role of staff working in these departments will also change. It is important that staff working in the field of sexual and reproductive health care are equipped with the practical skills and knowledge required to implement their new roles with confidence.

The studies presented in this thesis were carried out to meet the above challenges. The first study compares the current strategies in use at the Sandyford Initiative for the management of women with vaginal discharge in FP and GUM. This study was undertaken in order to develop a common evidence based strategy that could be used in our centre and in other departments providing this service. The second study evaluates user views of the sexual health services provided at the Sandyford Initiative. The final study was undertaken to assess the knowledge of FP staff prior to, and following attendance at the Sexually Transmitted Infections Foundation

(STIF) Course. FP staff were given the opportunity to attend this course with the aim of equipping them with knowledge for the effective management of STI's.

In summary, this thesis aims to address the following questions:

- Which strategy for the management of vaginal discharge is more accurate in terms of diagnosis - FP or GUM?

- What are the Sandyford Initiative users views of the GUM and FP services?

- Does attendance at the STIF course improve the knowledge of FP nurses and doctors?

CHAPTER 2: A RANDOMISED CONTROLLED CROSS-OVER STUDY OF THE STATEGIES FOR THE MANAGEMENT OF WOMEN WITH VAGINAL DISCHARGE IN FAMILY PLANNING AND GENITOURINARY MEDICINE.

2.1 Introduction

Women suffering from abnormal vaginal discharge may present to a FP, GUM or gynaecology clinic or to their General Practitioner (GP). Abnormal vaginal discharge is a common problem and may be due to infective or non-infective causes (Hay 1999b), (Chapter 1, Table 1.4.2). Currently, there is no accepted standard strategy employed for the management of women with vaginal discharge in different health care settings. The main strategies in use in the UK can be broadly categorised into two groups (Chapter 1, Figure 1.1.1). Women attending their GP, FP or gynaecology clinic will have genital samples taken ('triple swabs'), which are transported to the local laboratories (microbiology and virology) for analysis. The clinician will often make a presumptive diagnosis based on the available clinical information, and may treat the patient accordingly. The laboratory diagnosis will be available in approximately seven days. In contrast, the strategy employed in most GUM settings in the UK is that of near-patient microscopy of the genital specimens. The patient attending this health care setting will receive initial results and treatment based on the microscopy findings. The culture plates for *Neisseria gonorrhoeae* are subsequently transferred to the local microbiology laboratory for incubation, and the chlamydia swab is transferred to the virology laboratory. These results are available in approximately seven days.

Recently in the UK concerns have been expressed regarding inadequate provision of sexual health care. The House of Commons Health Select Committee has highlighted this major public health problem in the published enquiry on sexual health (House of Commons Health Select Committee 2003). GUM departments are under increasing pressure, and attendance at these clinics in England has doubled over the past 10 years (Adler 2003). Development of 'managed service networks' as recommended by the English National HIV and Sexual Health Strategy (Department of Health 2001) will help meet some of this increased demand by increasing service provision by primary care teams. In addition, expansion of consultant posts in GUM and an increase in resources have been recommended (House of Commons Health Select Committee 2003). These changes alone will not fulfil all requirements, and therefore many GUM departments in the UK are assessing means in which current practices can be modified in order to optimise resources. One such area where change is being considered is routine near-patient microscopy (Robinson & Rogstad 2003). Conventionally this is offered to all GUM attendees, and is deemed superior to delayed diagnosis using swabs. There have been no studies however to validate this assumption. The role of near-patient microscopy has been evaluated within the GUM setting in asymptomatic women (Andrews et al. 1994). This study by Andrews et al performed in a GUM department in Birmingham concluded that a policy of selective microscopy did not lead to any significant delay in the diagnosis and treatment of patients with STIs, and was beneficial in terms of more efficient utilisation of manpower and resources. There are however no studies to date that directly compare the accuracy of the FP and GUM strategies in either asymptomatic or symptomatic individuals. No evidence base currently exists to confirm that on-site microscopy

should be enlisted in the management of all women presenting with vaginal discharge.

The Sandyford Initiative in Glasgow is an example of a centre offering both GUM and FP services. It is part of the local primary care trust. The centre was established in June 2000 and a main objective since its inception has been to improve integration of the FP and GUM services. At the time of the study, there was no common strategy for the management of women with vaginal discharge. Women with this problem could present to either clinic and be managed by different approaches. This study was therefore performed to provide an evidence base for the development of a strategy that could be implemented in both the FP and GUM clinics in our centre, and employed by other similar services.

The study was designed to assess which strategy performed better in terms of diagnostic accuracy. Firstly, the strategy of initial diagnosis based on clinical symptoms and signs (day 1 FP diagnosis) and the strategy of near-patient microscopy (day 1 GUM diagnosis) were compared with the reference standard of both strategies combined. Secondly the final laboratory results from the two strategies (day 7 diagnoses) were compared with the reference standard.

2.2 Materials and methods

200 women attending the Sandyford Initiative GUM and FP clinics with the primary complaint of vaginal discharge were invited to participate in this study. 100 participants were recruited from each clinic between December 2001 and June 2002.

Suitable participants were identified at the clinic reception desk using a tick sheet. A tick sheet was already in use at the FP reception desk, in order to guide clients to the service they required such as contraception or pregnancy counselling. For this study, the tick sheet was modified to include 'vaginal discharge' as an option. A similar sheet was introduced at the GUM reception desk. Participants underwent the study protocol in the clinic they had presented to.

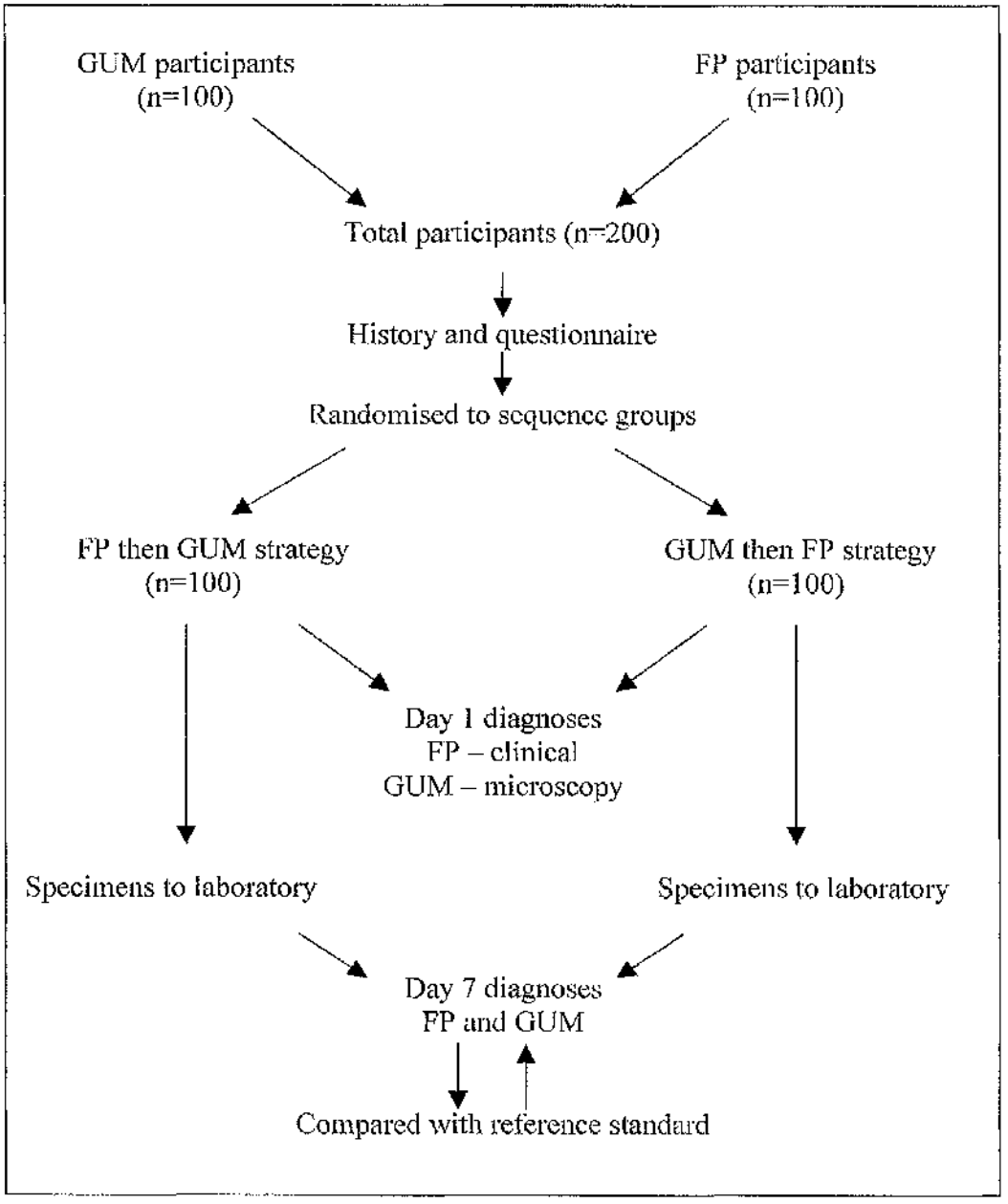
Patients were deemed suitable for inclusion in the study if they were aged greater than 16 years, with a primary symptom of vaginal discharge and were willing to participate. Exclusion criteria comprised: current participation in other research projects, inability to give informed consent, antibiotic therapy within preceding four weeks, pregnancy, systemic illness, genital ulceration, known contacts of sexually transmitted infections and clients attending due to sexual assault.

A randomised controlled cross-over design was used (Figure 2.2.1). Each participant was consented for the study and then a clinical history was taken followed by a questionnaire. Demographic data was collected using a standard proforma. A single researcher (CM) performed all consultations and examinations. Each participant then underwent both the FP and GUM strategies in a randomised order. The sequence in which the strategies were performed was determined using randomly allocated numbers within independently sealed envelopes. Participants were randomised to either GUM strategy first or FP strategy first. Equal numbers of participants were randomly allocated to each sequence group (Figure 2.2.1). Subsequent to the examination, the researcher documented a diagnosis based on the clinical symptoms and signs (day 1 FP diagnosis). Meanwhile, the microscopy slides were prepared

and examined by the duty Medical Laboratory Scientific Officer (MLSO) in the on-site GUM laboratory. This microscopy result provided the day 1 GUM diagnosis. The researcher was blinded to the microscopy-based diagnosis until the day 1 diagnosis from the FP strategy had been documented. Equally, the MLSO performing the microscopy was blinded to the clinical (FP) diagnosis until the day 1 GUM diagnosis was documented. To prevent sub-optimal treatment, day 1 management of each participant was based on the microscopy findings (day 1 GUM strategy diagnosis). The FP swabs and the GUM selective and non-selective gonococcal culture plates were then transferred to the local microbiology laboratory and the chlamydia swab was transferred to the virology laboratory. At the time of the study, the FP and GUM specimens were being analysed in two different microbiology laboratories. For the purposes of the study we obtained permission to have all specimens analysed in the same microbiology laboratory (Glasgow Royal Infirmary). On day 7, the participants were contacted with their final results, and offered further treatment if required. The questionnaire was completed during this telephone consultation. To determine strategy accuracy, day 1 and 7 diagnoses were compared with the reference standard of both strategies combined (Box 2.2.1).

This study received approval from the Greater Glasgow Primary Care Trust Research Ethics Committee.

Figure 2.2.1 Study protocol



Box 2.2.1 – The reference standard

- On-site Gram stain and microscopy of vaginal, endocervical and urethral specimens.
- On-site microscopy of vaginal wet mount (0.9% saline).
- On-site inoculation of selective and non-selective gonococcus agar (endocervical and urethral specimens) for culture.
- High vaginal and endocervical swabs transported in Aimes medium to local laboratory and: Gram stained for microscopy; cultured on Sabouraud's medium; cultured in Feinbergs medium; and cultured on selective and non-selective gonococcus agar.
- Endocervical swab for *Chlamydia trachomatis* (Nucleic acid amplification technique).

Statistics

The study power was set at 80% to detect a 10% difference in strategy veracity rates. Strategy accuracy was estimated by the difference of two paired proportions, together with 95% confidence intervals. Statistical significance was assessed by McNemar's test. Statistical comparison of FP and GUM participants and the randomised sequence groups was made using χ^2 tests and Wilcoxon tests.

Data collection and coding

Data were collected and stored anonymously in a secure SPSS database using a study number. Once the final results were obtained for each participant, the diagnostic data were coded. If a strategy obtained only one of the diagnoses in a participant with multiple diagnoses or misdiagnosed an infection then it was coded as either false positive or false negative. All false positives and negatives were combined to give a total number of incorrect diagnoses. Similarly, to be coded as a

correct diagnosis, the diagnoses made by the strategy in question had to completely agree with the diagnoses made by the reference standard (true positive or true negative). This method of data coding produced a total of 200 correct and incorrect diagnoses, despite some participants having multiple diagnoses.

2.3 Results

Characteristics of study participants

All participants completed the study. Table 2.3.1 describes the characteristics of all study participants, and those participants from FP and GUM. Characteristics and comparison of the participants in each randomised sequence group are shown in Table 2.3.2. The mean age of participant was 28 years (range 16 - 51 years). There were 185 white participants and 15 participants from other ethnic origins. No significant difference was found in age and ethnicity when the participants from each clinic and each randomised sequence group were compared using the χ^2 test. 132 participants had one sexual partner in the previous year. Statistical comparison of the number of sexual partners in FP and GUM participants showed that GUM participants had significantly more sexual partners in the last year ($p = 0.005$). Comparison of the number of sexual partners in the randomised sequence groups showed no significant difference. Approximately one quarter of participants had a history of a previous STI ($n = 54$). 32 of the participants had a history of *Chlamydia trachomatis*, 25 of genital wart infection (human papilloma virus), 5 of gonorrhoea, 4 of genital Herpes Simplex virus (HSV) and 1 of Human Immunodeficiency Virus (HIV) infection (FP participant). The number of FP and GUM participants with a previous STI was statistically similar, and the randomised sequence groups showed no difference. The COCP was the most commonly used method of contraception in

all (n= 95) and GUM and FP participants. 54 participants used the recommended "double Dutch" method of contraception (condoms and another form), and 39 participants used condoms alone. GUM participants were significantly more likely to use no form of contraception than FP participants (9 GUM vs. 2 FP, p = 0.030). Otherwise, there was no significant difference in the methods of contraception used by FP and GUM participants or by participants in each randomised sequence group. 73 study participants were current smokers, and significantly more of these were GUM attendees (45 GUM vs. 28 FP, p = 0.013).

Table 2.3.1 Characteristics of all, FP and GUM participants

		All Participants n=200	FP n=100	GUM n=100	p Value
Age	Median	25	25	25	
	Mean	28	27	28	*NS
	Range	16 - 51	17 - 43	16 - 51	
Ethnicity	White	185	92	93	
	Black African	5	2	3	
	Pakistani	4	3	1	
	Indian	2	0	2	*NS
	Chinese	2	1	1	
	Other	2	2	0	
Number of sexual partners (previous12 months)	None	5	3	2	
	One	132	75	57	
	Two	48	17	31	
	Three	8	2	6	†p=0.005
	Four - Six	6	3	3	
	More than ten	1	0	1	
Previous STI		54	23	31	*NS
Contraception	None	11	2	9	*p=0.030
	Condoms alone	39	16	23	*NS
	Condoms and another method	54	29	25	*NS
	COCP	95	50	45	*NS
	Progesterone methods	21	14	7	*NS
	IUD	17	11	6	*NS
	Sterilisation	14	4	10	*NS
	Cap/Billings	3	3	0	*NS
Current Smoker		73	28	45	*p=0.013

*χ^2 test. †Wilcoxon test. p value shows the significant difference between participants from each clinic. Sterilisation includes male and female.

Table 2.3.2 Characteristics of all participants and randomised sequence groups

		All Participants n=200	GUM first n=100	FP first n=100	p Value
Age	Median	25	24	27	
	Mean	28	27	29	*NS
	Range	16 - 51	17 - 50	16 - 51	
Ethnicity	White	185	92	93	
	Black African	5	1	4	
	Pakistani	4	3	1	*NS
	Indian	2	1	1	
	Chinese	2	1	1	
	Other	2	2	0	
Number of sexual partners (previous12 months)	None	5	2	3	
	One	132	64	68	
	Two	48	27	21	
	Three	8	3	5	†NS
	Four - Six	6	3	3	
	More than ten	1	1	0	
Previous STI		54	27	27	*NS
Contraception	None	11	6	5	*NS
	Condoms alone	39	20	19	*NS
	Condoms and another method	54	24	30	*NS
	COCP	95	45	50	*NS
	Progesterone methods	21	13	8	*NS
	IUCD	17	8	9	*NS
	Sterilisation	14	6	8	*NS
	Cap/Billings	3	2	1	*NS
Current Smoker		73	41	32	*NS

*χ^2 test. †Wilcoxon test. p value shows the significant difference between participants from each randomised sequence group. Sterilisation includes male and female.

Diagnostic accuracy of strategies

Table 2.3.3 summarises the number of correct and incorrect diagnoses made by each strategy on days 1 and 7. On day 1, the FP strategy produced 73 incorrect diagnoses and the GUM strategy produced 32 incorrect diagnoses. Statistical comparison using McNemar's test showed that the FP strategy produced significantly more incorrect diagnoses than the GUM strategy ($p<0.001$, difference -20%; 95% CI -27% to -14%). On day 7, the FP strategy produced 17 incorrect diagnoses and the GUM strategy produced 32 incorrect diagnoses. Statistical comparison showed that the GUM strategy produced significantly more incorrect diagnoses than the FP strategy ($p=0.019$, difference 7.5%; 95% CI 1.3% to 13.7%). In order to determine if the sequence of sampling influenced diagnostic accuracy, statistical comparison of the randomised sequence groups was performed. No statistically significant difference in diagnostic accuracy was found on days 1 or 7 ($p=1.000$ and $p=0.236$ respectively).

Table 2.3.3 - Correct and incorrect diagnoses made by each strategy

Diagnoses (n=200)	**Day 1 FP Strategy** (n=200)	**Day 1 GUM Strategy** (n=200)	**Day 7 FP Strategy** (n=200)	**Day 7 GUM Strategy** (n=200)
True negative	59 (29.5%)	89 (44.5%)	75 (37.5%)	75 (37.5%)
True positive	68 (34%)	79 (39.5%)	108 (54%)	93 (46.5%)
False negative	32 (16%)	30 (15%)	17 (8.5%)	31 (15.5%)
False positive	41 (20.5%)	2 (1%)	0	1 (0.5%)
Correct diagnoses	127 (63.5%)	168 (84%)	183 (91.5%)	168 (84%)
Incorrect diagnoses	73 (36.5%)	32 (16%)	17 (8.5%)	32 (16%)
p Value*	p<0.001 (-20%)		p=0.019 (7.5%)	
95% CI	–27% to -14%		1.3% to 13.7%	

CI = confidence interval. *McNemar's test.

Specific diagnoses

Table 2.3.4 illustrates the specific diagnoses that were made in this study. There were no significant differences in the numbers of each infection diagnosed in participants from each clinic or in each randomised sequence group (χ^2 test). Of the 75 participants who had no microbiological abnormality detected, nine had a cervical ectopy, and one had an endocervical polyp.

Table 2.3.4 – Specific diagnoses made in all participants, FP and GUM participants and randomised sequence groups

Diagnoses	All Participants (n=234)*	FP† (n=113)	GUM† (n=121)	GUM strategy first † (n=119)	FP strategy first † (n=115)
No abnormality detected	75	39	36	34	41
Bacterial vaginosis	63	30	33	34	29
Candida albicans	60	28	32	34	26
Chlamydia trachomatis	16	7	9	7	9
Neisseria gonorrhoea	1	0	1	0	1
Trichomonas vaginalis	2	2	0	1	1
Streptococci	17	7	10	9	8

*27 participants had multiple diagnoses, hence total number of infections = 234
†Statistical comparison of the diagnoses made in participants from each clinic and in each randomised sequence group using the χ^2 test showed no significant difference ($p \geq 0.05$).

Non-sexually transmitted infections

There were 140 diagnoses of non- sexually transmitted infections. These consisted of 63 cases of Bacterial vaginosis, 60 of *Candida albicans*, and 17 streptococcal

infections. Of the 63 cases of Bacterial vaginosis the vaginal pH was greater than or equal to 5.0 in 61 cases. In the remaining two participants, the pH was 4.0. The vaginal discharge was described as 'offensive' in 27 of the 63 cases, profuse in 44 of the cases and thin and watery in 56 of the cases. The day 1 FP diagnosis (clinical) correctly identified 56 of these cases.

Of the 60 cases of *Candida albicans,* 33 had a normal vaginal pH (3.5 – 4.5). In the remaining 27 participants, the vaginal pH was elevated (> 4.5). The discharge was described as white in 44 participants, and 'curd-like' in 10. In 28 additional participants, the discharge was described as 'thick'. Forty of these women complained of a vulval itch. The FP strategy (clinical) correctly diagnosed 30 of the cases on day 1, and 58 of the 60 cases by day 7 (swab results).

The reference standard identified 17 cases of beta-haemolytic streptococcal infection. There were 12 cases of Lancefield Group B streptococci, 2 cases each of Lancefield group C and G streptococci, and 1 case of Lancefield group A streptococcus. At day 7 follow up these participants were offered treatment for streptococci if their symptoms persisted despite treatment for concurrent infections. Overall, eight participants were treated with antibiotics for streptococcal infections.

Sexually transmitted infections

Nineteen STI's were diagnosed in 19 participants. There were 16 cases of *Chlamydia trachomatis*. Seven cases were diagnosed in participants attending the FP clinic and nine in participants attending GUM. There was no significant difference in the number of chlamydia cases diagnosed in each clinic (χ^2 test). The mean age of the

participants with this infection was 23 years (range 18 – 40). Two of these women were married and the remaining 14 identified themselves as single. Three of these women had a history of a previous STI. One had a history of chlamydia infection only; one had a history of chlamydia infection and genital warts, and the third had a history of chlamydia, genital warts and *Neisseria gonorrhoea*. Of the 16 women diagnosed with chlamydia, 10 had a single sexual partner in the previous year, whilst 6 had 2 partners in this time period. The FP and GUM strategies used the same specimen for chlamydia analysis therefore both correctly identified all cases of this infection.

Two cases of *Trichomonas vaginalis* were diagnosed in the study. One participant was a 35 year old married Chinese woman. Her contraceptive method was condoms alone. She gave no history of a previous STI, was a non-smoker, and had one sexual partner in the year prior to study recruitment. The other participant was a 24 year old Caucasian woman who lived with her partner. She used depoprovera and condoms for contraception. This participant smoked 20 cigarettes per day, and had one sexual partner in preceding year. She gave no history of a previous STI. Both cases of *Trichomonas vaginalis* were diagnosed correctly by GUM on day 1. The vaginal pH in both participants was greater than six. Both infections were misdiagnosed as Bacterial vaginosis on day 1 by the FP strategy (clinical diagnosis). The diagnoses were however made correctly on day 7 by the FP strategy.

One case of *Neisseria gonorrhoea* was diagnosed in the study. This participant was a 29 year old Caucasian woman. She described herself as 'married/separated', was a non-smoker, and used the IUCD alone for contraception. She had no history of an

STI, and had three sexual partners in the year prior to the study. The vaginal pH in this participant was elevated at 5.2. This was explained at microscopy by the presence of semen on the slide. The diagnosis was missed on day 1 by the GUM strategy. The FP strategy incorrectly diagnosed Bacterial vaginosis on day 1. On day 7, both the FP and GUM strategies correctly identified *Neisseria gonorrhoea* on the culture plates.

Multiple diagnoses

98 participants had a single diagnosis, 21 participants had two diagnoses, and 6 participants had three or more infections diagnosed (Table 2.3.5). The total number of infections diagnosed was 234. Comparison of the number of multiple diagnoses made in participants from FP and GUM, and from each randomised sequence group was made using the χ^2 test, and no significant difference was found ($p = 0.411$ and $p = 0.629$ respectively).

Table 2.3.5 – Multiple diagnoses

Number of diagnoses	All participants (n=200)	FP (n=100)	GUM (n=100)	GUM first (n=100)	FP first (n=100)
0	75	39	36	34	41
1	98	50	48	52	46
2	21	10	11	10	11
3-4	6	1	5	4	2

Missed and incorrect diagnoses

The GUM strategy failed to diagnose 21 cases of *Candida albicans*, 11 of Streptococcus and 1 case of Bacterial vaginosis. 13 of these cases of *Candida albicans*, 5 of Streptococcus, and the case of Bacterial vaginosis were treated at day 7 follow-up. Of the 75 participants with no microbiological abnormalities detected, the day 1 FP strategy incorrectly diagnosed 21 of these participants with *Candida albicans*, 4 with Bacterial vaginosis and 1 with *Trichomonas vaginalis*. These participants were correctly identified as no abnormality detected by the FP strategy on day 7.

Sensitivity and specificity

Table 2.3.6 illustrates the overall sensitivity and specificity of each strategy on days 1 and 7.

Table 2.3.6 - Sensitivity and specificity of FP and GUM strategies

Strategy	Sensitivity (%)	Specificity (%)
Day 1 FP	68	59
Day 1 GUM	72	98
Day 7 FP	86	100
Day 7 GUM	75	99

FP = Family Planning, GUM = Genitourinary medicine

2.4 Discussion

Our study found that the strategy of on-site microscopy (GUM) was superior to the strategy of best clinical diagnosis (FP), in terms of initial diagnostic accuracy, but that the FP strategy of "triple swabs" was significantly more accurate than the GUM strategy in terms of final diagnosis.

This study demonstrated that in some patients, clinical findings can be difficult to interpret. Nearly all the cases of Bacterial vaginosis were correctly identified clinically (day 1 FP), however the majority of these participants had a typical watery discharge with a high vaginal pH. The cases of *Candida albicans* were not so typical. Almost half the participants with this infection had an elevated vaginal pH (27/60), and one third denied vulval itch. This may have made the clinical diagnosis more difficult and is reflected by the day 1 FP strategy identifying only half the cases of candida. Both cases of *Trichomonas vaginalis* were incorrectly diagnosed as Bacterial vaginosis by the day 1 FP strategy. This is perhaps because *Trichomonas vaginalis* is much less common than Bacterial vaginosis, and is also associated with an elevated vaginal pH and an offensive profuse discharge. Another factor, which may confuse the clinical findings, is the presence of more than one infection. This may cause a mixed pattern of symptoms and atypical signs. Although, the vaginal pH is a helpful diagnostic tool, it can also be altered by factors other than infections. Blood, semen and lubricating jelly can all elevate the vaginal pH (Sonnex 1996a). An example of this was the case of *Neisseria gonorrhoea,* which was diagnosed in the study. The vaginal pH in this participant was 5.2 and there was a watery vaginal discharge. A clinical diagnosis of Bacterial vaginosis was made by the day 1 FP strategy. At microscopy, the presence of sperm was noted. This could account for the elevated vaginal pH and the watery discharge. The participant had been questioned regarding timing of last sexual intercourse, however she had stated that this was more than one week prior to recruitment to the study. Microscopy findings are independent of these variables and this may explain why this was found to be more accurate than clinical diagnosis.

The day 7 FP diagnoses were found to be more accurate than day 7 GUM. The infections that the day 7 GUM strategy missed were all vaginal - *Candida albicans* , Streptococci and Bacterial vaginosis. This is because the vaginal specimen from the GUM strategy was only examined by microscopy in-house and not routinely plated onto culture media to yield growths of *Candida albicans* and Streptococci. Culture using Sabouraud's medium is the most sensitive diagnostic method for candida, with a sensitivity of 70% - 80% and a specificity of greater than 99% (Sobel 1997; Wilson 2003). A Gram stain, which is utilised in GUM, will identify up to 65% of symptomatic cases (Sonnex & Lefort 1999). Although traditionally, an HVS has not been part of the GUM strategy, practice is changing and in order to save time and reduce workload for microscopists an HVS is being used in place of near-patient testing in some departments in the UK (Robinson & Rogstad 2003). Another criticism of the 'triple swab' strategy is that the transit time to the laboratory and the delay in inoculation of specimens might result in a reduction in diagnostic accuracy. In our study there was a delay of up to 12 hours between sampling and transportation of genital specimens, however this did not result in any significant loss of accuracy. This finding has been reiterated by other studies (Beverly et al. 1999; FitzGerald & Bedford 1996; Human & Jones 1986; Peterson, Danielsen, & Renneberg 1999; Schwebke, Venglarik, & Morgan 1999; WHO 1999).

Characteristics of participants and infections

No significant differences were identified when the randomised sequence groups were compared in terms of characteristics, infections diagnosed, and diagnostic accuracy. The sequence of sampling was not shown to influence the findings of the study. Comparison of participants from the GUM and FP clinics revealed many

similarities such as age, ethnicity and previous STI. There were however some notable differences. Significantly more GUM attendees used no contraception, and participants from this clinic had significantly more sexual partners in the previous year. This was not associated with an increase in the number of STI's diagnosed in GUM participants. Similarities in women attending FP and GUM clinics have been previously demonstrated (Gunneberg, Mann, & Radcliffe 1996; Radcliffe et al. 1993). There were no significant differences in infections diagnosed in participants from each clinic (STI and non-STI). The diagnoses made in this study on the whole reflect the recognised order of frequency of occurrence and the typical reported prevalence of these infections (Hay 1999b). Many participants had no microbiological diagnosis found (n=75) and had complete symptom resolution with the reassurance offered by negative tests. Bacterial vaginosis was the most commonly diagnosed infection, closely followed by *Candida albicans*. Eight percent of participants were diagnosed with chlamydia and their mean age was less than 25 years. A low prevalence of gonorrhoea in the study population is noted. The prevalence found in our study is typical of that found in women in our region.

Strengths and weaknesses

The diagnostic accuracy of these strategies had not been previously compared. For this reason it was considered unethical to deny a GUM participant near-patient microscopy. We therefore employed a cross-over design in which all participants underwent both strategies thus minimising the chance of sub-optimal treatment. In order to eliminate sampling bias we randomised the sequence of strategies. The primary researcher performed all examinations thus avoiding observer variability. The researcher was blinded to the microscopy result until a clinical diagnosis was

documented. All microscopy was performed by the duty MLSO who was blinded to the clinical diagnosis until a microscopy result was documented. All specimens were analysed in the same laboratory and were not labelled as study specimens to reduce bias further. In order to extrapolate our findings to routine clinical care we must assume that the researcher's clinical acumen was representative of FP staff. To confirm this, the knowledge of a sample of FP staff was assessed, and found to be comparable with the researcher's knowledge (Melville, Bigrigg, & Nandwani 2003). To evaluate accuracy, the outcome of a test or strategy is compared with an independent reference standard. "Gold standards" providing full certainty are rare and sometimes no suitable independent standard is available (Knottnerus, van Weel, & Muris 2002). No independent reference standard existed therefore we utilised a combination of both strategies.

Our research was designed to compare strategy accuracy in terms of diagnosis. No comment can therefore be made regarding the clinical implications of the diagnosed infections. This is of particular relevance for the streptococcal and candida diagnoses. Group B Streptococcus is known to colonise the genital tract in up to 18% of healthy women (Rowen 1993). Mean vaginal isolation rates for *Candida albicans* from asymptomatic women have been reported as 8% (Sonnex & Lefort1999). All participants in our study were symptomatic at recruitment, and were only offered treatment for these infections on day 7 if still symptomatic. Although isolation of streptococci from the genital tract is often thought to be incidental (Shaw, Mason, & Scoular 2003), the vaginal micro-flora is a complicated environment and our understanding of conditions such as desquamative inflammatory vaginitis is limited (Donders et al. 2002). Further research could be performed in this area, with

participants being randomised to treatment or no treatment of these infections with post-treatment follow-up.

Implications for clinical practice

This study has shown that in terms of immediate diagnosis, microscopy is more accurate than clinical judgement. Managing patients solely on the basis of clinical diagnosis may result in over, or incorrect treatment. This will have cost implications and consequences for antibiotic resistance. The FP strategy did not miss any STIs. This is reassuring for clinicians who do not have access to near-patient testing. This strategy does however incur a delay of approximately seven days in obtaining results. This may be acceptable in areas of low female gonorrhoea prevalence, and is similar to the duration taken to obtain a chlamydia result. A delay of seven days in the diagnosis of Bacterial vaginosis and *Candida albicans* should not cause any serious morbidity. The exception would be Bacterial vaginosis in pregnant women.

In common with much of UK GUM practice, the vaginal specimen from the GUM strategy was examined by microscopy in-house but not routinely plated onto culture media. To increase accuracy of this strategy, a vaginal specimen could be sent to the laboratory for culture. We have found that FP and GUM attendees have many similar characteristics, and show no significant difference in the infections diagnosed. We therefore feel it is possible to develop a unified protocol for the management of women presenting with vaginal discharge. The findings of this study have already been used to alter our clinical strategies. A vaginal specimen is now taken from all symptomatic GUM attendees at our centre, and we are assessing ways to select those patients who would benefit from the addition of near-patient testing. We have

identified an area of the FP strategy where costs can be streamlined. Both the HVS and endocervical swabs were being tested for vaginal and endocervical pathogens. This duplication is unnecessary, and the monies saved from discontinuing this practice have been used to fund the HVS in GUM participants. A move away from near-patient microscopy is likely in the future with wider availability of non-invasive sampling techniques.

CHAPTER 3: CLIENT PERSPECTIVES ON SEXUAL HEALTH SERVICE PROVISION.

3.1 Introduction

In order to provide more holistic sexual health care, reorganisation and convergence of FP and GUM services in the UK is taking place. UK government policy has stressed the need for health services to be more responsive to the expressed needs and views of the public and service users (Department of Health 1989; Department of Health 1995). A recommendation made by the English National Strategy for Sexual Health and HIV is that service users should "play a big part in reshaping services" (Department of Health 2001). Reorganisation of services in some regions has led to the development of one-stop sexual health clinics (Dawson et al. 2000; Jones 2000; Stedman & Elstein 1995; Wilkinson, Hampton, & Bradbeer 2000). The Sandyford Initiative in Glasgow provides both GUM and FP services under the one roof. Integration and modernisation of services has necessitated changes in practice. Attention is being given to the development of unified clinical systems and common protocols. A particular area of interest is the role of near-patient testing, which is typically utilised in GUM, but not in FP clinics (Robinson & Rogstad 2003). One of the key principles of the Sandyford Initiative is to consult with service users to ensure equity and access in the development and delivery of services (Laughlin et al. 2001). A study was performed at the Sandyford Initiative to assess diagnostic accuracy of the current FP and GUM strategies for the management of women with vaginal discharge (Chapter 2), (Melville, Nandwani, & Bigrigg 2003). Thus the opportunity arose to carry out a questionnaire-based qualitative study to evaluate user views of our FP and GUM departments, attitudes towards near-patient testing

and general comments on our service prior to implementation of change. Although user views have been sought in independent FP and GUM settings (Evans & Farquhar 1996; Harris, Peckham, & Walsh 1997; Munday 1990; Rogstad 1991), no qualitative studies have been performed to draw a comparison between these two clinics.

3.2 Methods

200 consecutive women presenting with the main complaint of vaginal discharge were recruited to a study to compare the FP and GUM strategies for the management of vaginal discharge (Chapter 2). 100 women were recruited from each clinic between December 2001 and June 2002. Once recruited, all women were invited to participate in a researcher administered structured questionnaire which was completed during the consultation process (Appendix III). A brief telephone interview was completed one week after the initial consultation. The questionnaire covered: access to and choice of service, attitudes towards near-patient testing, views on time spent in the clinic, and open questioning regarding overall views of the service and suggestions for change.

Statistical comparison of the characteristics of participants from the two clinics was made using the χ^2 test and the Wilcoxon test. This study received approval from the Greater Glasgow Primary Care Trust Research Ethics Committee.

3.3 Results

All 200 women completed the study and follow-up. Table 3.3.1 shows the characteristics of the study participants. The mean age of participant was 28 years, and there were no significant differences in the mean age of participants from each clinic. The participants included 5 black-African women, 4 Pakistani women, 2 Indian women and 2 Chinese women.

No statistically significant differences in age, ethnicity and previous sexually transmitted infections between the populations of GUM and FP participants were demonstrated. GUM participants were significantly more likely to use no form of contraception and had significantly more sexual partners in the last year than FP clinic participants. There was no significant difference in the number of previous STI's in the two groups of participants.

Table 3.3.1 – Characteristics of study participants

		All Participants n=200	FP n=100	GUM n=100	p Value
Age	Median	25	25	25	*NS
	Mean	28	27	28	
	Range	16 - 51	17 - 43	16 - 51	
Ethnicity	White	185	92	93	*NS
	Other	15	8	7	
Number of sexual partners (previous12 months)	None	5	3	2	†P=0.005
	One	132	75	57	
	Two	48	17	31	
	Three	8	2	6	
	Four - Six	6	3	3	
	More than ten	1	0	1	
Previous STI		54	23	31	*NS
Contraception	None	11	2	9	*P=0.030
	Condoms alone	39	16	23	*NS
	Condoms and another method	54	29	25	*NS

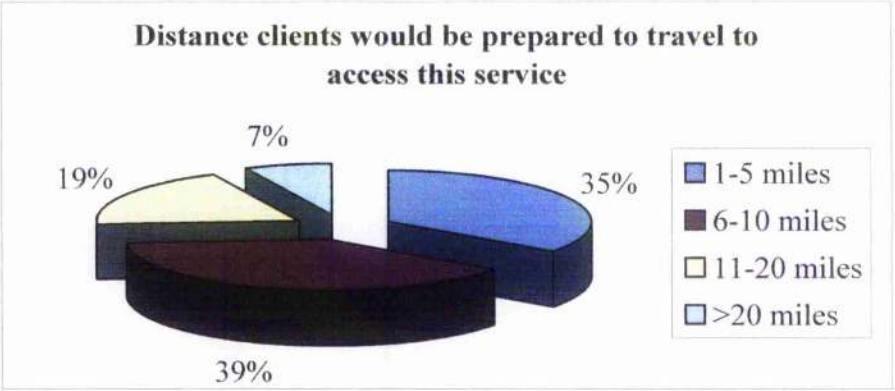
*χ^2 test
† Wilcoxon test.

Access to, and choice of service

Participants were asked how far they felt it was reasonable to travel to access a service such as the Sandyford Initiative. These results are summarised in Chart 3.3.1. 70 participants would only travel up to 5 miles; 78 participants would travel between

6 - 10 miles; 38 participants would travel 11 - 20 miles, and 14 participants would be prepared to travel more than 20 miles to access such a service.

Chart 3.3.1



The participants were questioned regarding the service provider that they would prefer to access for a similar problem if the choice was available. The categories offered were: a GP, a hospital clinic, a local FP clinic, a local GUM clinic, a central FP clinic, or a central GUM clinic (such as the Sandyford Initiative). Table 3.3.2 summarises these results. 86 participants (43%) chose the central FP clinic option; 66 participants (33%) chose the central GUM clinic option; 23 participants (11.5%) chose the local GUM clinic option; 13 participants (6.5%) chose the local FP clinic option; 12 participants (6%) chose the GP option, and no participant expressed a preference to attend a hospital-based clinic.

Table 3.3.2 – Clients' preference of service provider

Service provider	**Preference** (%) (n=200)
GP	12 (6%)
Hospital clinic	0
Local FP clinic	13 (6.5%)
Local GUM clinic	23 (11.5%)
Central FP clinic	86 (43%)
Central GUM clinic	66 (33%)

The responses to this question were split and analysed according to the clinic the client attended on the day of study participation (central FP or central GUM). The majority of participants expressed a preference for that same service provider, with 81 of the 100 FP participants expressing a preference for the central FP clinic option, and 63 of the 100 GUM participants expressing a preference for the central GUM clinic option (Charts 3.3.2, 3.3.3).

Chart 3.3.2

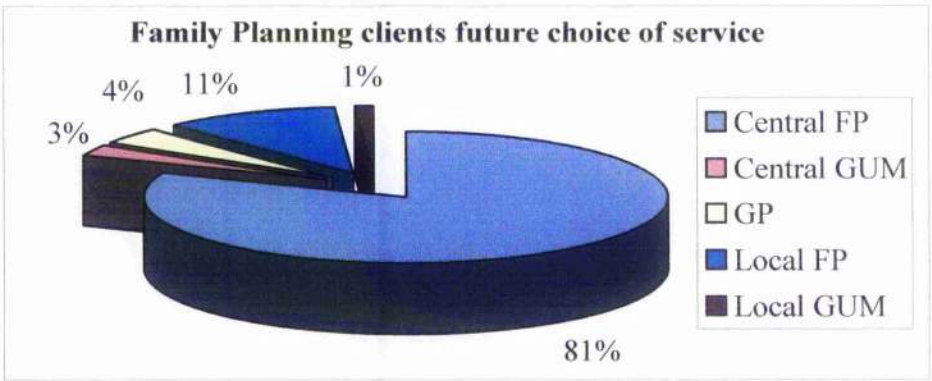
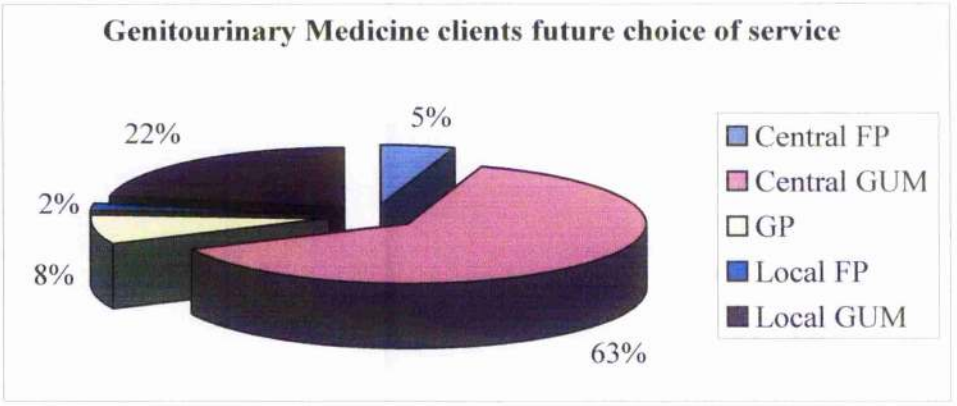


Chart 3.3.3



Views on near patient testing

All participants had undergone both current strategies of near-patient testing (at the time of the study only available in GUM), and provisional clinical diagnosis offered by FP (with confirmed results in 7 days). We sought their views regarding the different approaches. Although most participants said that near-patient testing resulted in a longer time spent in clinic, 99% (n=198) said they would prefer to wait for these immediate results and receive initial treatment based on microscopy whilst awaiting confirmatory culture results. Comments included: " I liked receiving immediate results even if they were negative" and "I was previously treated in the FP clinic for my symptoms. Although they thought I had thrush, it turned out this was wrong and I think it is much better to wait for accurate results". Only two participants said that they would prefer to wait seven days for their results and treatment. These two participants felt that the wait for a microscopy-based diagnosis would be too long.

Time spent in clinic

This was calculated from the time of arrival, and included any time waiting to be seen, and waiting for microscopy results. Although the participants presented to different clinics, all underwent an identical consultation process. The time spent in clinic ranged from 40 minutes to 4 hours, with a mean time of 99 minutes. The mean time spent by those participants who presented to the GUM service was 113 minutes (range 40 - 180 minutes), versus a mean time of 85 minutes (range 45 - 240 minutes) at the FP service. Nine participants spent greater than 160 minutes in clinic. A single participant spent 4 hours in clinic (FP), however in addition to investigation of vaginal discharge she underwent counselling for, and insertion of a contraceptive implant. 78% (n=156) of participants felt that the time they spent in clinic was "about right", and 22% (n=44) felt that this was too long. No participant felt that the time spent in clinic was too short. The mean time spent in clinic by those participants who felt it had been "too long" was 122 minutes (range 60 – 180 minutes) compared with a mean time of 88 minutes spent by those who felt it was "about right" (range 40 – 240 minutes).

Future use of the service

Participants were asked if they were likely to reuse this service in the future should the need arise. 181 participants (94 FP, 87 GUM) stated that they would be "very likely" to use this service again in the future. 18 participants would be "quite likely" to reuse the service. Only 1 participant stated she would be "unlikely" to re-attend this service (GUM) because she was moving away from Glasgow.

General views and suggestions for improvement

Overall the participants' views of the service were very encouraging (Box 3.3.1). 57 participants' felt that the consultation was "fine" and 40 felt that is was "good". Others commented that it was a "non-judgemental and friendly environment" and the staff "put me at ease". Many felt "relieved to know what was wrong".

Box 3.3.1 - Positive feedback from users

- 'Excellent service'
- 'Completely satisfied'
- 'They were very informative and non-judgemental'
- 'I appreciated all the help and advice'
- 'Reassuring – very comfortable and relaxed'

When asked if they had any suggestions regarding how the service could be improved, we received useful feedback (Box 3.3.2). 10% of those questioned felt that we needed more staff as the waiting time was too long in both clinics and it was difficult to get appointments. Many participants offered practical suggestions about the clinics' amenities and environment. Better parking facilities were requested and clearer signage inside the building to direct patients to the relevant clinic. One user stated, "I came in the wrong door and it was quite a shock to see all these men". Some participants had concerns regarding the 'check-in procedure'. The general feeling was that the area was not discrete enough and there were concerns that private information might be overheard. This concern has been expressed in previous qualitative reports of GUM user views (Evans & Farquhar 1996).

Box 3.3.2 – Some suggestions for change and improvement

- 'The drop-in (clinic) was too busy. More staff would be helpful'
- 'Need better links between family planning and genitourinary medicine'
- 'Waiting area was not discrete enough'
- 'Need better parking facilities'
- 'Music and a coffee machine in reception would be good'

3.4 Discussion

Clients attending FP and GUM clinics are often thought to have quite different characteristics. This study found that the two populations shared many similarities. There were however some significant differences such as use of contraception and number of sexual partners, which may be important. GUM attendees were more likely to use no form of contraception than FP users. This may reflect a lack of contraceptive services in the GUM setting. This must be taken into consideration when developing our clinics.

The majority of participants would choose to re-attend either a central FP or GUM clinic. This response was unsurprising as we were asking women who had already chosen to attend our service and therefore this question was subject to bias. We were interested to learn that very few women in this study would opt to see their GP for a similar problem and that none would attend a hospital based clinic if given a choice. Expansion of sexual health services into primary care has been recommended (Department of Health 2001), however other authors have similarly reported that patients may prefer to attend GUM or FP clinics (Cassel & Brook 2002; Dawson &

Greenhouse 1996; Stedman & Elstein 1995). We should be aware of this when developing sexual health services at a local level.

The time spent in clinic included the time to undergo the study, however this added only 15 minutes to the total time. The majority of time was spent waiting to be seen initially (most women were recruited from 'drop-in' clinics), and waiting whilst near patient microscopy was performed. The participants of this study considered a total time of 90 minutes spent in clinic as acceptable. 120 minutes spent in clinic was however considered too long. The longer time spent in the GUM clinic appears to reflect an increased waiting time. This is mirroring the increase in the number of STI's and resulting attendances at GUM clinics, which has occurred over the past 10 years in the UK (Adler 2003). Since this study was completed we have reviewed our check-in procedure and are streamlining the service by a variety of means including nurse triaging.

Reducing routine microscopy minimises the workload for staff and decreases waiting times for clients. This study demonstrates overwhelmingly that if given a choice, clients prefer to receive immediate results from near-patient microscopy, even if this increases their time spent in clinic. This has major implications for resources in departments offering sexual health care. Some clinics have introduced a policy of no microscopy for patients fulfilling certain conditions. This saves time for patients in clinics and reduces workload for microscopists (Andrews et al.1994). In the longer term the introduction of non-invasive diagnostic techniques, which utilise nucleic acid technology may offer a solution. Our 'one-stop' sexual health service was

established three years ago and it is essential that we continue to seek feedback from our users as we strive to integrate and modernise our services.

CHAPTER 4: IMPACT OF THE SEXUALLY TRANSMITTED INFECTIONS FOUNDATION COURSE ON THE KNOWLEDGE OF FAMILY PLANNING NURSES AND DOCTORS

4.1 Introduction

Staff involved in the provision of sexual heath care will require training and educational support in order to facilitate implementation of the English National HIV and Sexual Health Strategy. Modernisation of sexual health services has meant altered and expanded roles for health care workers. Many disciplines are now involved in the provision of sexual health care including family planning nurses and doctors, youth clinic staff, GP's and practice nurses (Department of Health 2001). It is vital that staff are equipped with the knowledge and skills to confidently and competently extend their roles (Miles 2002).

The Diploma of the Faculty of Family Planning and Reproductive Healthcare (DFFP) is widely recognised as the optimal training route for gaining knowledge and skills in contraception and reproductive health. It is generally attended by GP's, trainees in Obstetrics and Gynaecology, FP nurses and doctors, and trainees in GUM. In 2000, the General Training Committee of the FFPRHC recommended that the DFFP syllabus be re-written, with a particular emphasis on enhancing the STI module to provide course participants with skills appropriate for sexual health consultations to Level one of the National Strategy for Sexual Health and HIV.

The Sexually Transmitted Infections Foundation (STIF) course was developed by the Medical Society for the Study of Venereal Diseases (MSSVD) as a UK-wide initiative to support the implementation of the English National HIV and Sexual Health Strategy. In March 2002, the first Scottish STIF course was run in Glasgow. The duration of the course was two days, and the programme consisted of a combination of short lectures and workshops. The aim of this course was to provide the participants with the basic knowledge, expertise and attitudes for the effective management of STI's. GUM and FP staff and GP's attended the course.

As the STIF course had recently been introduced, no previous studies had assessed the educational value of the course. This study was therefore undertaken to determine the impact of the STIF course on the knowledge of FP doctors and nurses. For the purposes of the study we chose to assess the knowledge of cervical and vaginal infections, which is taught as a workshop in the STIF course.

4.2 Materials and methods

This prospective study was performed in the department of FP at the Sandyford Initiative in Glasgow. Non-sessional core FP staff who had applied for a place on the STIF course were invited to undergo knowledge assessment prior to and following attendance at the course. A variety of different grades of doctors participated in the study, including clinical medical officers, FP trainees and consultants. The nurses were all full-time members of staff. No member of staff declined to take part in this study.

Design

16 family planning doctors and 4 family planning nurses were assessed prior to the STIF course. The researcher administered four clinical case scenarios. The cases were: *Candida albicans*, *Trichomonas vaginalis*, Bacterial vaginosis, and *Chlamydia trachomatis* (Box 4.2.1). Each case consisted of a patient history which included symptoms typically associated with the infection concerned (Appendix IV). The history was accompanied by a clinical photograph of the condition concerned. The photographs showed the typical signs associated with each infection.

Box 4.2.1 – Case topics

Candida albicans
Trichomonas vaginalis
Bacterial vaginosis
Chlamydia trachomatis

The participants were asked to answer three questions relating to each case (Box 4.2.2). The vaginal pH was provided for question two. A point was awarded for each of these three stems, allowing a maximum of 12 points. The participants were asked to give a primary (not differential) diagnosis. Within 3 months of the STIF course, each doctor and nurse were re-tested with the initial scenarios. Answers and feedback were provided on completion.

Box 4.2.2 – Questions asked of participants

1) What is your provisional diagnosis based on the history and photograph?
2) The vaginal pH is now provided - does this alter your diagnosis (and to what)?
3) How would you manage this patient?

Statistical analysis

Two sample t-tests and confidence intervals for the difference of two means were employed to compare all participants and the doctors and nurses scores before and after attendance at the course. One sample t-tests and confidence intervals for the difference of two means were employed to compare the doctors and nurses scores. As the numbers in the study were small we did not perform sub analysis of the results for different grades of doctors.

4.3 Results

Two of the 20 initial participants in this study (one doctor and one nurse) were not re-assessed, as they did not attend the course. They were therefore excluded from the analysis. 18 members of staff were re-tested. Table 4.3.1 shows the mean (and standard deviation), median pre- and post-course scores, and mean difference in scores.

All participants

There was a mean increase of 2.5 points in all participants' scores. Comparison of the pre- and post-course mean scores revealed a statistically significant improvement ($p = 0.001$).

Table 4.3.1: The mean (and standard deviation), median pre- and post-course scores, and mean difference in scores

		Pre-course score	Post-course score	*Mean difference (95%CI)	p value
All participants (n=18)	Mean (SD)	8.2 (2.3)	10.7 (1.8)	+2.5 (1.1 – 3.9)	0.001
	Median	9.0	12.0		
Doctors (n=15)	Mean (SD)	8.6 (1.9)	10.6 (1.8)	+2.0 (0.7 – 3.3)	0.006
	Median	9.0	12.0		
Nurses (n=3)	Mean (SD)	6.0 (3.0)	11.0 (1.7)	+5.0 (-3.6 – 13.6)	0.130
	Median	6.0	12.0		

*t-test

Nurses

The nurses' knowledge showed improvement following attendance at the STIF course, with two of them gaining full marks and none of them gaining less than their initial scores. Their mean increase in score was 5.0 points. Comparison of their pre- and post- course scores however, failed to show a statistically significant increase in mean score ($p = 0.130$). This is likely to be due to the small number of participants.

Doctors

Two of the doctors gained full points at both assessments. Nine of the doctors' scores improved after the STIF course, however the score of two doctors' who had

high baseline result decreased (from 9 to 7 and from 9 to 8). The mean increase in all doctors' scores of 2.0 points was statistically significant (p = 0.006).

Comparison of doctors and nurses

A comparison of the mean increase in scores of the doctors and nurses failed to reach statistical significance (-3.0; -6.4 0.4; p = 0.08). The data suggests that the nurses may have benefited more, however as the numbers were small this was inconclusive.

Knowledge of individual infections

All participants correctly diagnosed and managed the candida vulvovaginitis case scenario pre- and post-STIF course. The Bacterial vaginosis question was the most frequently incorrect (16 participants pre-course answered this incorrectly), with all wrong participants confusing this with candida infection. Provision of the typical vaginal pH associated with Bacterial vaginosis (pH >5.0) did not change the participants' answers. Post-course the Bacterial vaginosis question was still incorrectly diagnosed as candida vulvovaginitis by six of the participants.

4.4 Discussion

In recent years, FP and GUM services have become more integrated (Dawson et al. 2000; Jones 2000; Kane & Wellings 1999; Stedman & Elstein 1995; Wilkinson, Hampton, & Bradbeer 2000). This move towards integrated sexual health service provision is in line with the recommendations of the English National Strategy for Sexual Health and HIV (Department of Health 2001). With the introduction of 'one-stop sexual health clinics' such as the Sandyford Initiative in Glasgow, FP doctors

and nurses will be required to assess and manage clients with vaginal discharge and STI's more frequently. Courses such as the STIF course run by the MSSVD play a vital role in providing staff with the education and training they need to competently extend their roles. In addition, a revised DFFP syllabus has now been introduced. Attendance at the STIF course will exempt a candidate from the theoretical part of the DFFP Sexually Transmitted Infections module.

The main weakness of our study was the small size. In addition, there are limitations of assessing knowledge by this somewhat artificial method. Examination of a patient will reveal more details than a photograph and in clinical practice a differential diagnosis would often be made. To compensate for this, we endeavoured to use pictures and case histories, which were as representative and realistic as possible. The same scenarios were used before and after the course. All core members of staff were invited to attend the STIF course, and to participate in the study, thus minimising selection bias.

It was interesting to confirm our suspicions that candida vulvovaginitis is frequently over diagnosed, perhaps at the expense of diagnosing other conditions such as Bacterial vaginosis. Vaginal pH measurement is not universally employed in the family planning setting. This was reflected by the participants' uncertainty regarding the normal vaginal pH as well as that found in association with infections. This area of knowledge did however show improvement following attendance at the STIF course.

Our study suggests that knowledge increased following attendance at the STIF course. The STIF course is an important educational tool for staff working in the field of sexual and reproductive healthcare. A larger study of this type assessing a wider range of subject matter would enable further evaluation of the STIF courses' impact on knowledge.

CHAPTER 5: DISCUSSION

Over the past decade in the UK, GUM and FP services have become more integrated. Commissioners and care providers realised that whilst functioning separately, these services failed to provide client centered care. Service duplication also meant that resources were not being optimised. Closer links between providers of sexual health care have been encouraged by the government in the English National Sexual Health and HIV Strategy, and have been supported by professionals working in both fields (Department of Health 2001; Wilkinson, Hampton, & Bradbeer 2000).

In June 2000, central FP and GUM services in Glasgow became housed together as the Sandyford Initiative. This change in practice created an opportunity to evaluate the services we provided. Our strategies for patient care were assessed and attention given to implementing new protocols which could be used throughout the Sandyford Initiative. It was vital that our evolving service was responsive to the needs and views of users. Consultation with our clients was therefore undertaken. We recognised the importance of ensuring our staff were equipped with the knowledge and skills to confidently extend and alter their roles in this newly integrated environment. Accordingly staff were provided with the opportunity to attend educational initiatives such as the STIF course. The studies presented in this thesis were performed in order to evaluate the proposed changes prior to implementation.

Traditionally departments of GUM have utilized near-patient microscopy for examination of genital specimens from their patients (Andrews et al. 1994). The benefit of this strategy is that it confers immediate results for patients. This can eliminate a delay in treatment and may offer prompt reassurance to the anxious patient. Microscopy is the recommended method of diagnosis for Bacterial vaginosis, however culture is a more sensitive diagnostic method for *Candida albicans*, *Trichomonas vaginalis* and *Neisseria gonorrhoeae* (Bickley et al. 1989; Daniels & Forster 1999; FitzGerald & Bedford 1996). It must therefore be noted that the immediate results offered by the GUM strategy are preliminary only, and the confirmatory *Neisseria gonorrhoeae* result will take at least 48 hours. *Chlamydia trachomatis* is diagnosed by a NAAT and this result will not usually be available within seven days.

Huge demands have been placed on sexual health services in the UK over the past decade. All STI's have increased in England over the past six years and this has resulted in a doubling in attendances at GUM departments (Adler 2003). Services have been unable to cope with this increased demand. Neither adequate resources nor manpower have been available. The Department of Health's Monk Report set a target that all patients should be seen at a GUM service within 48 hours (Monks et al. 1998). The length of waiting time to be seen at a GUM clinic within the UK has increased by eight days for women and seven days for men from 2001 to 2002 (House of Commons Health Select Committee 2003). This has major public health implications, as STI's are communicable diseases. Methods of tackling these problems are being addressed and sexual health providers are assessing innovative

methods in which to streamline their services. Primary care teams who will provide 'level one care' may meet some of the increased demand (Department of Health 2001). Other modifications to practice include the introduction of patient triage and an expanded role for nurses (Miles 2002). In order to shorten clinic visits, some GUM departments are selecting patients who do not require near-patient microscopy (Andrews et al. 1994).

Although the conventional function of the FP clinic was contraception, this remit has changed, and amongst other services, sexual health care and management of STI's are now provided in most departments. FP services remain on the whole based in the community and do not typically have access to on-site microscopy services. Instead, local laboratories are utilized. Patients seeking sexual health care advice may chose to attend their GP or an FP clinic rather than a GUM service, to avoid the perceived stigma associated with GUM (Scoular, Duncan, & Hart 2001).

Integrating our FP and GUM services at the Sandyford Initiative has offered many challenges. The departments initially functioned in parallel and therefore methods were assessed in which to deliver a unified service. Each department had separate protocols and strategies for patient care. These had evolved mainly by custom and practice rather than from an evidence base. This was an area where change was considered achievable and beneficial. Both departments had a strategy for the management of vaginal discharge. Neither of these were evidence based and we could find no previous studies comparing these strategies in terms of diagnostic accuracy (Miles et al. 2002). The study presented in Chapter 2 was therefore

performed. The conclusion that the GUM strategy offered greater initial diagnostic accuracy and the FP strategy offered greater final diagnostic accuracy was reached. On the basis of the findings of this study our practice at the Sandyford Initiative has been modified. An HVS is taken from all symptomatic women and microscopy is not performed on asymptomatic women. This study also showed that there were no significant differences in the infections diagnosed in GUM and FP attendees. This would suggest that these populations have similar needs as far as sexual health care is concerned.

Consultation with patients regarding service provision is now encouraged throughout the NHS (Department of Health 1989; Department of Health 1995). As part of the process of change at the Sandyford Initiative, we thought it vital that we determined the views of our users. The majority of participants in the study presented in Chapter 3 said they would travel up to 10 miles to access a sexual health service. Most stated a preference to attend a GUM or FP clinic rather than attend their GP. This may be due to the anonymity and confidentiality afforded by these services (Cassel & Brook 2002). This has implications for implementation of the National Sexual Health and HIV Strategy, as primary care teams will be playing a more active role in the management and preventions of STI's. Participants in our study overwhelmingly voiced a preference for receiving near-patient microscopy as offered in GUM. These patients were all symptomatic (of vaginal discharge) at presentation. Asymptomatic patients may not uphold this view. Nevertheless these views should be considered when modifying our services, and a balance between patient choice, and cost-benefit should be reached.

Finally, in Chapter 4, we evaluated the educational impact of the STIF course. FP nurses and doctors attended this course, and we evaluated their knowledge prior to and after attendance. Although only a small section of the STIF course syllabus was assessed (cervical and vaginal infections), staff knowledge did show significant improvement. It is important that educational interventions are part of an ongoing evaluation cycle (Wilkes & Bligh 1999), and that staff are regularly updated on developments in their field of work.

CHAPTER 6: CONCLUSIONS

- The FP and GUM strategies for the management of vaginal discharge both have advantages.
- The GUM strategy is more accurate in terms of initial diagnosis.
- The FP strategy is more accurate in terms of final diagnosis.
- The addition of an HVS for culture to the GUM strategy would result in increased accuracy of the final diagnosis.
- Diagnosis based solely on clinical symptoms and signs results in over- and mis-diagnosis of infections and over-treatment of patients.
- GUM and FP users share many characteristics.
- Symptomatic GUM and FP users prefer to receive immediate results from near-patient microscopy even though this requires a longer time spent in clinic.
- The STIF course is of educational value to FP nurses and doctors.

Future research

- A further study assessing the pathogenicity of streptococci and their relationship with vaginal discharge could be performed. Women presenting with vaginal discharge could be randomized to treatment or no-treatment of these conditions, with prolonged follow-up.

- Further evaluation of users choice of sexual health service could be undertaken. It would be interesting to determine the rationale for choosing to attend FP, GUM or primary care. This will be important for commissioning future services.

- Additional areas of the STIF course syllabus could be evaluated and the educational needs of staff assessed by means of further knowledge appraisal.

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APPENDIX I

Gram-staining method

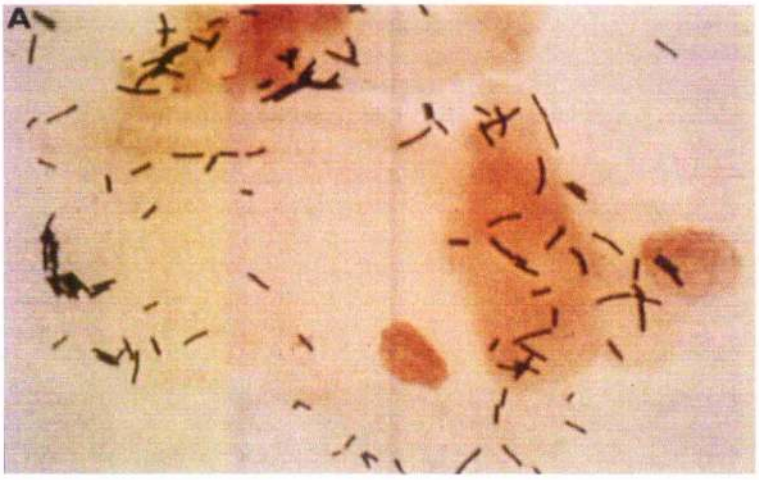
After fixing the specimen on a glass slide by heating, four reagents are then applied in the following order:

1. A basic pararosaniline violet dye, such as crystal violet
2. An aqueous solution of iodine
3. A decolourising agent, such as acetone
4. A red counterstain, such as diluted carbol fuschin

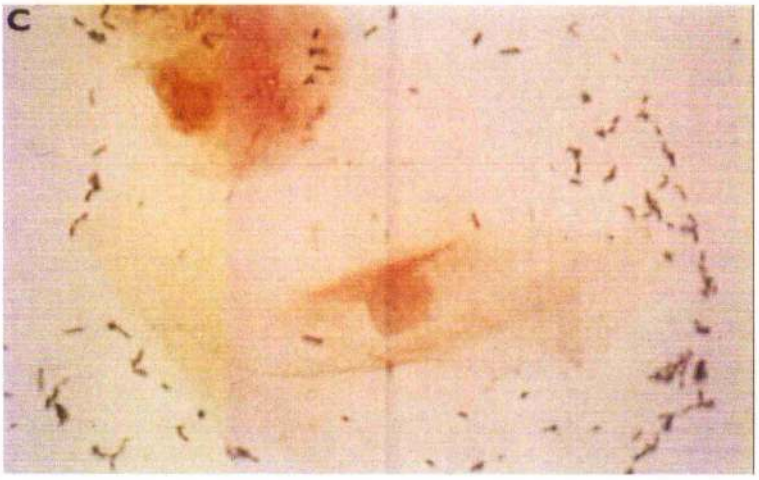
The two dyes and the iodine should be kept on the slide for at least 15 seconds. The time during which the specimen is exposed to the decolourising agent is critical. This depends on the thickness of the specimen, and the agent used. Acetone decolourises within 3 seconds.

APPENDIX II – Photomicrographs

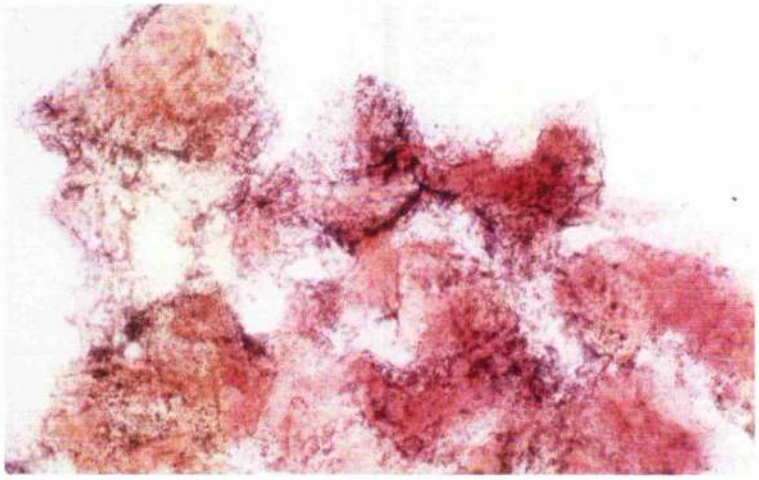
Normal vaginal flora



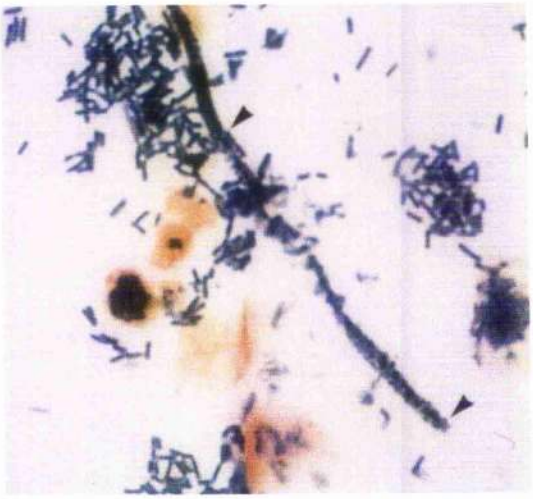
Intermediate vaginal flora



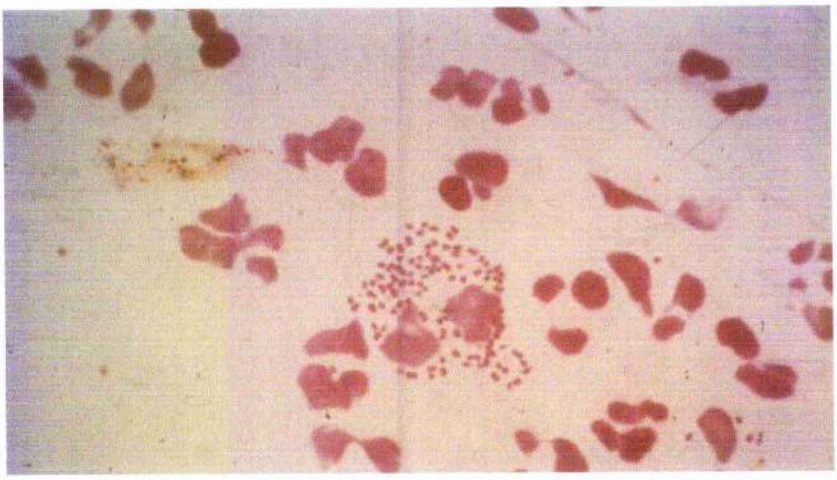
Bacterial vaginosis



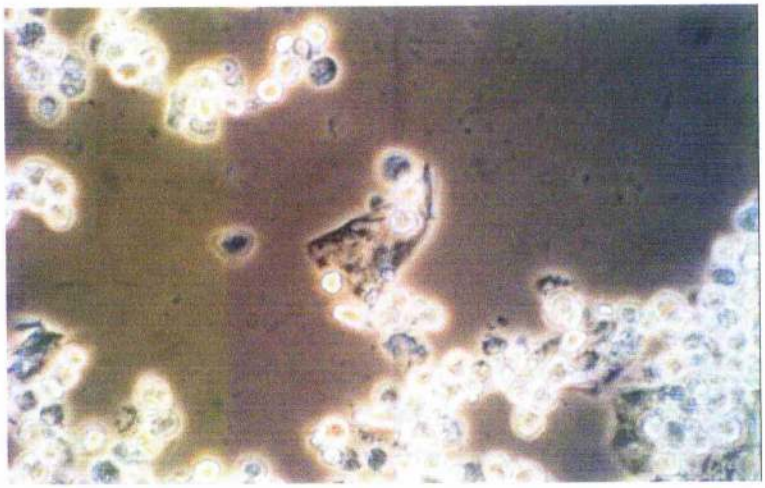
Candida albicans



Neisseria gonorrhoeae



Trichomonas vaginalis



APPENDIX III

Patient Questionnaire (to be administered by the researcher)

1) How far do you think it is reasonable to travel to a clinic, which offers this service? _____(miles)

2) In which setting would you prefer to have your swab tests taken?

At your family doctor/GP ☐
At your local family planning clinic ☐
At your local GUM/sexual health clinic☐
At a central family planning clinic ☐
At a central GUM/sexual health clinic ☐
At hospital ☐
Other (please specify)

3) Which of the following do you most agree with?

I would prefer to wait today to get some of my results ☐
I would you prefer to wait 7 days for my final results ☐

4) Which of the following do you most agree with?

I would prefer treatment today before all my results are available ☐
I would prefer treatment once I have all my results ☐

<u>At end of Day 1 clinic visit</u>

5) Approximately how long have you spent in the clinic today? _____

6) How do you feel about the length of time you have spent in the clinic today?

Too long ☐
About right ☐
Too short ☐

7) How likely is it that would you come to this clinic again?

Very likely ☐
Quite likely ☐
Unlikely ☐
Very unlikely ☐

8) Overall, how do you feel about your visit to the clinic today?

_____

9) Do you have any suggestions on how your visit could have been improved? _____

Questions for day 7 telephone follow-up

10) Has the reason you attended the clinic fully resolved? | Yes/No |

11) How satisfied overall have you been with the service you have had?

Very satisfied ☐
Quite satisfied ☐
Not satisfied ☐
Very unsatisfied ☐

APPENDIX IV

Case Scenarios

Case 1- Bacterial Vaginosis

This 25 year old woman presented to the FPC complaining of vaginal discharge. She described the discharge as heavy, offensive, and white. She denied vulval itch but complained of some irritation.

1) What is your provisional diagnosis based on the history and photo?
2) The vaginal pH is 5.5 – does this alter your diagnosis (and to what)?
3) How would you manage this patient?

Case 2 - Trichomoniasis

This 29 year old woman presented to the FPC complaining of an offensive vaginal discharge associated with vulval soreness and itching. She described the discharge as yellow.

1) What is your provisional diagnosis based on the history and photo?
2) The vaginal pH is 6.3 – does this alter your diagnosis (and to what)?
3) How would you manage this patient?

Case 3 – Candidiasis

This 21 year old woman presented to the FPC complaining of a white vaginal discharge associated with superficial dyspareunia and vulval swelling.

1) What is your provisional diagnosis based on the history and photo?
2) The vaginal pH is 4.0 – does this alter your diagnosis (and to what)?
3) How would you manage this patient?

Case 4 - Gonorrhoea

This 35 year old woman presented to the FPC complaining of dysuria and slight increase in vaginal discharge. She had also noticed that her discharge was blood stained on occasion. Her symptoms had been present for 2 weeks. She denied vulval itch.

1) What is your provisional diagnosis based on the history and photo?
2) The vaginal pH is 4.5 – does this alter your diagnosis (and to what)?
3) How would you manage this patient?

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Sex Transm Infect 2003;79:0

Impact of the Sexually Transmitted Infections Foundation course on the knowledge of family planning nurses and doctors

There has been convergence of genitourinary medicine and reproductive healthcare services in the United Kingdom to produce "one stop sexual health clinics" such as the Sandyford Initiative in Glasgow.[1 2] As part of service development a number of educational initiatives such as the Sexually Transmitted Infection Foundation (STIF) course have been initiated to ensure that minimum skills and competencies are obtained. Training programmes such as the STIF course coordinated by the Medical Society for the Study of Venereal Diseases (MSSVD) play a vital part in providing staff with the education required to competently extend their roles. The first Scottish STIF course was run in Glasgow in March 2002. The course was developed as a UK-wide initiative to support the implementation of the English national strategy for sexual health and HIV.[3]

In order to evaluate the impact attendance at the STIF course had on the knowledge of family planning staff, a prospective study was performed in Glasgow. Eighteen members of family planning staff (15 doctors and three nurses) were assessed on their knowledge of vaginal and cervical infections before and after attendance at the course, using four clinical case scenarios with accompanying clinical pictures. A maximum score of 12 was awarded for each assessment. The cases comprised candida, trichomonas, bacterial vaginosis, and chlamydia. The participants were asked to provide a provisional diagnosis based on the history and a clinical picture. The vaginal pH was then provided and each participant was given the opportunity to alter their diagnosis in the light of this additional information. They were then asked about the management of each condition. Within 3 months of the STIF course, each doctor and nurse were retested with the initial scenarios. Answers and feedback were provided on completion.

Table 1 The mean (SD), median precourse and post-course scores, and mean difference in scores

	Precourse score	Post-course score	Mean difference (95% CI)
All participants (n=18)			
Mean (SD)	8.2 (2.3)	10.7 (1.8)	+2.5 (1.1 to 3.9)
Median	9.0	12.0	
Doctors (n=15)			
Mean (SD)	8.6 (1.9)	10.6 (1.8)	+2.0 (0.7 to 3.3)
Median	9.0	12.0	
Nurses (n=3)			
Mean (SD)	6.0 (3.0)	11.0 (1.7)	+5.0 (−3.6 to 13.6)
Median	6.0	12.0	

Two sample *t* tests and confidence intervals for the difference of two means were employed to compare all participants and the doctors and nurses scores before and after attendance at the STIF course. One sample *t* tests and confidence intervals for the difference of two means were employed to compare the doctors and nurses scores. As the numbers in the study were small a subanalysis of the results for different grades of doctors was not performed. Table 1 shows the mean (SD), median precourse and post-course scores, and mean difference in scores. The mean increases in all participants' and the doctors' scores were statistically significant ($p = 0.001$, and $p = 0.006$, respectively). The mean increase in the nurses' score was 5.0 (95% CI −3.6 to 13.6), however the number of nurse participants was small (n=3).

This study suggests that knowledge increased following attendance at the STIF course. Educational initiatives such as the STIF course are important tools for development of staff working in the field of sexual and reproductive health care. A larger study of this type assessing a wider range of subject matter with longer follow up would enable further evaluation of the STIF courses' impact on knowledge.

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