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**THE PREVALENCE OF
REPRODUCTIVE TRACT
INFECTIONS IN RURAL
BANGLADESH**

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Thesis submitted to the Faculty of Medicine of the
University of London for the degree of Doctor of Philosophy

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PAGE

NUMBERING

AS ORIGINAL

*For Eric and Flo, my parents, who supported me in countless myriad
ways throughout the whole experience of this project;
For Kent who made me laugh, who made me love, who supported and
advised me, and who married me;
For Salvador who made it all worthwhile.*

Abstract

Reproductive tract infections (RTIs), including but not limited to the sexually transmitted infections (STIs), are currently high on the public health agendas of most low-income countries. The reasons for this are manifold, but important contributing factors include the need to control the spread of HIV, and the high costs to health care systems and infected individuals as a consequence of un- or mis-diagnosed infections. Strategies for the control and management of these infections in resource-poor settings have been advanced at a global policy level: syndromic management of symptomatic men and women is recommended in the absence of comprehensive laboratory facilities.

This thesis describes a large cross sectional survey assessing the population-based prevalence of RTIs in one rural area of Bangladesh. The prevalence of these infections was determined from random selections of women and men. Patterns of health-care seeking behaviour were analysed, and the correlation between reported symptoms and the presence of infection was investigated. The prevalence of syphilis in pregnant women, and the incidence of ophthalmia neonatorum were also determined, and the cost-benefit of control strategies for these two problems in this population were investigated.

Given that management of symptomatic persons forms a cornerstone of most national RTI/STI control programmes, the study described in this thesis also evaluated the efficacy of the most common syndromic algorithm in use (that for treating women with vaginal discharge). Training requirements for integrating the algorithm at primary health care level are also discussed as part of the findings, and finally the cost-effectiveness of the recommended algorithm was evaluated.

Using the results of the five arms of the study, recommendations are advanced for RTI/STI control programmes in areas with similar epidemiological characteristics to those found in the population described in this study. Finally, areas where further research is needed are highlighted in the discussion.

Acronyms in use in this report

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ARI	Acute Respiratory Infection
BV	Bacterial Vaginosis
CHW	Community Health Worker
CI	[95%] Confidence Interval
DFID	Department for International Development
DMPA	Depot MedroxyProgesterone Acetate
DSS	Demographic Surveillance System
ELISA	Enzyme-Linked Immunosorbent Assay
FP	Family Planning
GC	<i>Neisseria gonorrhoeae</i>
GIS	Geographical Information System (ICDDR,B)
GNP	Gross National Product
GoB	Government of Bangladesh
GUD	Genital Ulcer Disease
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
ICDDR,B	International Centre for Diarrhoeal Disease, Bangladesh
ICPD	International Conference on Population and Development
ISM	Indigenous Systems of Medicine
IUD	Intra-Uterine (contraceptive) Device
KG	Dr. Kaniz Gausia
KOH	Potassium Hydroxide
LFPV	Lady Family Planning Visitor
LMP	Last Menstrual Period
LSHTM	London School of Hygiene and Tropical Medicine
MA	Medical Assistant
MCH	Maternal and Child Health
NAD	No Abnormality Detected
NPV	Negative Predictive Value
OCP	Oral Contraceptive Pill
ON	Ophthalmia Neonatorum
OR	Odds Ratio
PCR	Polymerase Chain Reaction
PHC	Primary Health Care
PID	Pelvic Inflammatory Disease
PPV	Positive Predictive Value
RKS	Record Keeping System
RPR	Rapid Plasma Reagin
RTI	Reproductive Tract Infection
SD	Standard Deviation (about a mean)
SH	Sarah Hawkes
SMT	Selective Mass Treatment
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection

TBA	Traditional Birth Attendant
TPHA	Treponema Pallidum Heamagglutination Assay
TV	<i>Trichomonas vaginalis</i>
UN	United Nations
VDRL	Venereal Disease Reference Laboratory
WHO	World Health Organisation

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The subject of sexually transmitted infections, sex and sexuality was not an easy one to initially tackle in a relatively conservative setting, however, the hard work and dedication of all the people mentioned above made sure that the project ran its full course. I hope that the findings will be of use to programme managers, policy makers, policy advocates, public health personnel, and anyone else interested in working towards the improvement of sexual and reproductive health.

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CHAPTER ONE: INTRODUCTION

1. Introduction

There has never been a time when greater priority has been accorded to the public health control of sexually transmitted infections, than the position it currently occupies on the health agendas of many countries. Such an interest, however, has its historical analogies. At the beginning of the twentieth century, increasing public recognition of the ‘terrible havoc’ wrought by sexually transmitted (‘venereal’) diseases,¹ and the intercessions of the medical, military and newspaper-publishing establishments, prompted the British Government in 1913 to appoint a Royal Commission on Venereal Diseases. Fortuitously preceding the advent of the First World War by one year, the Royal Commission was supported by such figures as the venereologist Sir Malcolm Morris who himself believed that such diseases ‘threatened national security’ at a time of increasingly hostile inter-European relations. “In these days of a falling birth rate and of an international rivalry in which the weight of numbers are factors of international success or failure, a disease which is so frequent a cause of abortion, which at its best diminishes efficiency and at worst consigns its victims to asylums and infirmaries and workhouses and prisons, or to an early grave, cannot continue to be a matter of indifference to the state.”²

Whilst the analogy with a war-footing may be overstretched in the late 1990s (although many commentators talk in military-like tones of waging campaigns against at least one sexually transmitted infection – HIV), the fact remains that even in the absence of such an overt ‘stimulus’ as war, sexually transmitted infections (STIs) are now high on the public health agendas of most countries. The reasons for this relatively recent rise to prominence are multifactoral and will be explored in the following section.

1.1 Why aim to control reproductive tract infections and sexually transmitted infections?

In many parts of the developing world, it is now well accepted by health-policy makers, public health specialists and health-care service funders (national governments and international multilateral and bilateral funding agencies) that control of reproductive tract infections (RTIs) and especially the sexually transmitted infections (STIs) is an urgent health priority.^{3,4,5,6} The relatively recent addition of RTI/STI control to the global public health agenda has arisen from a variety of complementary developments in the field, including biological, political and economic ones.

Biological

The highly publicised results of trials and research programmes which have demonstrated that improved management of STIs can lead to a significant decrease in HIV incidence⁷ has had a profound impact on public health perceptions of the importance of STI control. The salience of this finding has increased with more recent results demonstrating the cost-effectiveness of the intervention in low-income, high prevalence areas.⁸ In countries such as Bangladesh, which are at the perceived early or middle stages of an HIV epidemic, the contribution of STI control to curbing the spread of HIV may be significant.

Political

Recommendations from the 1994 United Nations International Conference on Population and Development (ICPD) stated that: "All countries should strive to make accessible through the PHC [primary health care] system, reproductive health to all individuals of appropriate ages... [this] should include ... treatment of

reproductive tract infections; sexually transmitted diseases and other reproductive health conditions.”⁹ The ICPD declaration published after the Cairo-based conference, was the culmination of many years’ work by a variety of actors intent on lobbying for a change in the focus of reproductive health agendas. For example, women’s health activists throughout the world had for many years been calling for a shift away from the specific concentration on family planning and towards a broader, comprehensive reproductive health agenda. This proposed approach was deemed to be both more gender-sensitive and one which recognised the role of social, cultural and economic factors, as well as the more obvious biological ones, in determining reproductive well-being or morbidity (especially in women and girls).¹⁰

Both the international policy makers who determine much of the health policy agenda in Bangladesh,¹¹ and the Government of Bangladesh itself, had also long advocated such an approach. The focus of their agenda, however, was somewhat different to that agreed upon by the women’s health advocates. In 1985 the World Bank summary plans for the third national health project (to run from 1985-1990), noted that “The FP/MCH strategy has been modified and now emphasises MCH which was missing. ... [The] Government has come to accept the premises that... improvements in the range and quality of services offered will promote better relationships between health workers and clients and ... should lead to increased contraceptive prevalence rates and reductions in fertility.”¹²

Economic

Further weight is added to the argument for effective management of RTIs/STIs given the increasing recognition that these infections can contribute substantially to the overall disease burden of many low-income countries.⁴ The economic and

logistical consequences for health care systems seeking to provide effective management for the clinical manifestations and complications of these (preventable) infections can be significant. A report by Over and Piot (1993) showed that the burden of STIs in many urban (high prevalence) populations in the developing world, as measured by disability-adjusted healthy life years lost, is a substantial fraction of the entire disease burden of those populations.^{4,5} The contribution of STIs to the problems of foetal wastage, premature births, congenital infections, blindness, ectopic pregnancies, infertility, and genital cancers is now widely accepted^{1,13}. It is estimated that up to 80% of female infertility in low income countries is a consequence of reproductive tract infections (RTIs) including STIs.³⁶

Policy makers ideally set health sector priorities according to a number of variables: burden of disease; whether technical 'solutions' are available; and the calculated cost-effectiveness of those solutions.¹⁴ Most published estimates of the economic burden of sexually transmitted infections are based upon medium-high prevalence situations. The priority that should be accorded to RTI/STI management and control in low income countries with lower prevalence has not yet been calculated. Furthermore, the most appropriate management strategies (clinical and service delivery) for differing epidemiological settings have not been developed and tested.

A common agenda: How to control RTIs/STIs

Given that the ICPD Programme of Action was signed by most governments, including those of low-income countries, there is now a concerted push in many of these countries to move away from established programmes purely devoted to, for example, family planning and towards the provision of integrated,

comprehensive reproductive health programmes which include RTI/STI management. A move which has been widely discussed and generally supported in published literature and reports.^{15,16,17,18,19,20,21,22,23,24,25} However, many countries are hampered in this pursuit by a distinct lack of epidemiological data on which to base decisions concerning provision of RTI/STI services. Despite published recommendations that STI services should initially be directed at those groups in society with perceived or known higher rates of infection,³ most countries in the developing world lack even the most fundamental data about the scale and nature of their own RTI/STI problem, and, thus, about how and where services might be most effectively delivered. Consequently, although many countries are opting to pursue a policy of ‘integration’ of services – for example, training primary health care (PHC) workers and family planning workers in the management of RTIs/STIs (for current and planned examples of this policy see refs. ^{26,27,28,29,30,31,32}), in most cases the actual prevalence of infection among clinic attendees is not yet known, and the appropriateness of published management guidelines³³ has not yet been evaluated. Furthermore, the training requirements which will enable PHC-level staff to adequately and effectively manage all clients have yet to be established.

Like many countries in the developing world, Bangladesh is currently developing its first working national STI/HIV control programme.³⁴ Questions are being raised on the probable burden of disease in the population, and decisions are being made concerning the cost and cost-effectiveness of service provision. The need to develop a national programme for the control of STIs has been advocated by the Ministry of Health and Family Welfare.³⁵ Whilst the recognised need for such programmes in developing countries may be agreed upon by most actors involved both nationally and internationally, the strategies for organising services to

achieve optimal coverage and benefit are less clear. A central aim of the study described in this thesis was, therefore, to inform the decision-making process concerning the development of a national programme for RTI/STI management and control in Bangladesh.

1.2 What are Reproductive Tract Infections?

Reproductive Tract Infections (RTIs) encompass three main groups of infection in men and women:³⁶

1. **Endogenous infections** of the female genital tract – such as candida or bacterial vaginosis.
2. **Sexually transmitted infections** in both men and women.
3. **Iatrogenic infections**, acquired, for example, through unsterile trans-cervical procedures such as insertion of an intrauterine device, menstrual regulation or termination of a pregnancy. Aetiologically may be due to either endogenous or sexually transmitted infections.

The study only addressed the first two categories of infection. There are over 30 identified organisms which can infect the reproductive tract. The most common organisms are listed in Box 1 below. Of the three types of RTI, it is probably the endogenous infections (marked with a * in Box 1) which contribute most to the burden of perceived and reported symptoms, especially in women.³⁷ However, the sexually transmitted infections may have the greatest impact on both the individual sufferer (clinically and socially) and the health-care system dealing with management of infections (the latter due to the cost of managing complications of the mis- or un-treated infections – see for example, refs. ^{38 and 39}).

Box 1 – Micro-organisms which can infect the reproductive tract

Bacteria	Viruses	Mycoplasmas	Parasites	Protozoa	Fungi
<i>Chlamydia trachomatis</i>	Herpes simplex viruses	<i>Ureaplasma urealyticum</i>	<i>Sarcoptes scabiei</i>	<i>Entamoeba histolytica</i>	<i>Candida albicans</i> *
<i>Neisseria gonorrhoeae</i>	Human papilloma virus	<i>Mycoplasma hominis</i> *	<i>Phthirus pubis</i>	<i>Trichomonas vaginalis</i>	
<i>Gardnerella vaginalis</i> *	Molluscum contagiosum			<i>Giardia lamblia</i>	
<i>Treponema pallidum</i>	Hepatitis viruses				
<i>Haemophilus ducreyi</i>	Cytomegalo-virus				
	Human immuno-deficiency viruses				

1.3 Epidemiology of RTIs/STIs

1.3.1 Epidemiology of RTIs/STIs globally

Data on STI prevalence and incidence can be compiled both from published studies, and from reported cases recorded within surveillance systems. The latter will only be of use in countries with an efficient and widespread system of reporting – such countries and systems are small in number. As with most other disease categories, there is very little homogeneity in the published global prevalence of RTIs and STIs. However, recorded figures (mainly from research programmes rather than ongoing surveillance systems) and estimates consistently

show both a higher prevalence of STIs in low income countries, and higher absolute numbers.⁴⁰ Similarly, reviews of endogenous infections indicate that they too are found more commonly among women in lower income areas.

Recent WHO publications estimate that globally there were approximately 333 million new cases of the 4 major curable STIs (gonorrhoea, chlamydia, syphilis and trichomoniasis) in the 15-49 year old age group in 1995.⁴⁰ Highest absolute numbers of new cases were found in the regions of South and South-east Asia, and sub-Saharan Africa - a reflection of both the global population distribution, and the higher recorded prevalence estimates for these regions. Countries in Sub-Saharan Africa consistently appear to have the highest recorded and estimated levels of all STIs (including HIV). Other regions, meanwhile, acknowledge more specific STI problems – for example, the incidence of new syphilis infections in the countries of the former Soviet Union is reported to be increasing significantly.⁴²

It should be recognised that within any named geographical region there will be wide variation in infection prevalence/disease burden. Numbers of people infected will vary both between and within countries in any one region. For example, it is generally recognised that prevalence levels are higher in urban than in rural settings, and that even within areas of known high prevalence there are some populations who are more at risk of STI acquisition and transmission than others.

Looking more generally at both global and national STI prevalence, it is perhaps helpful to divide prevalence according to economic rather than geographical indicators, since the former may have a significant impact on the overall prevalence of STIs (for example through the ability of low income countries to

provide widespread effective clinical management, ensure an adequate drug supply, or undertake screening for asymptomatic infections; or through the ability of people in low income countries to pay for services on offer⁴³). In the following sections, countries are ranked as high, middle or low-income according to published indicators of national wealth.³

1.3.1.a Epidemiology in high- and middle-income countries

In many high- and middle-income countries, there has been a marked decline in the number of new cases of bacterial STIs seen and reported to surveillance centres by clinicians. Syphilis rates, for example, have decreased markedly in Western Europe and North America since the 1950s.^{44,45} However, there is evidence that the incidence of viral infections (such as human papilloma virus and herpes infections) in these countries is increasing.^{5,40} In the United Kingdom, gonococcal infections have been declining in both men and women since the mid-1970s (thus predating the advent of AIDS and increased efforts towards primary prevention).⁴⁶ During the same time period, however, the incidence of new viral STIs seen (notably warts and genital herpes) has increased substantially. New cases of genital warts, for example, increased more than 4-fold during the time period 1976-1992. These rather contradictory trends seem to suggest that the decreased prevalence of the treatable STIs is probably due to better treatment services (and access thereto), rather than any long-term alteration in patterns of sexual behaviour.

Across the countries of the former Soviet Union and Eastern Europe, there is every indication that the reported number of sexually transmitted infections (both viral and bacterial) is currently increasing.^{47,48} In many instances this may be a result of better diagnostics and improved surveillance, but the contribution of

social and economic factors (leading, for example, to increased income inequalities, social mobility and commercial sex) cannot be overlooked. The situation with respect to the diagnosis and prevalence of endogenous infections is more difficult to fathom, with very few published reports and non-existent surveillance data.

1.3.1.b Epidemiology in low-income countries

The picture in countries containing the majority of the world's population and classified as low-income is one of geographical heterogeneity. In general, it is acknowledged that rates in these countries (regardless of geographical zone) are higher than those in middle- and high-income areas. The reasons for the higher prevalences are multifactorial, but usually based in predisposing economic and social conditions:

- i. ***Increasing urbanisation.*** It is recognised that in most countries STI rates are higher in urban than in rural populations. This is probably due to increased possibilities for diverse sexual mixing patterns. Much of the developing world is currently undergoing a period of rapid urbanisation – with a large amount of internal migration from rural areas to cities. In many low-income countries this picture is exacerbated by the increasing discrepancy of the male to female ratios in cities. The sex ratio imbalance arises predominantly as a result of differential work opportunities for men and women in urban areas,^{49,50} and may be encouraged by restrictive employment practices, high urban rents and lack of social support for women living without their families. These and other factors may combine to force women to stay at home in rural areas looking after families whilst their husbands, brothers, sons and fathers migrate to cities in search of work.

- ii. *Population 'pyramids'*. STIs are predominantly found in younger age groups – a reflection, perhaps, of increased sexual mixing at an age associated with general experimentation of all aspects of life. Low-income countries (with higher fertility rates and shortened life expectancies) are generally characterised by larger numbers of young people.
- iii. *Changing notions of social norms*. Increasing urbanisation and the pervasive factors of 'globalisation' are, in many countries, leading to a relaxation in the previously strongly held social and cultural taboos and restraints which may have contributed significantly to controlling sexual behaviour patterns in the past.
- iv. *Status of women*. Many low-income countries have societal structures which discriminate against women. Such structures and attitudes result in a paucity of paid employment opportunities for women (sometimes forcing women into commercial sex activities in order to support their families), and an inequality in marital relationships. The latter means that many women will not have the power to either challenge their husbands/partners on the issue of multiple sexual relationships, or insist on the use of safer sexual practises.
- v. *Cultural and economic barriers to seeking treatment*. For many people (especially women), the symptoms of RTIs and STIs are associated with a sense of shame and embarrassment. Care from a qualified practitioner is not sought for fear of stigmatisation and a lack of privacy/confidentiality. Other people may not seek care due to the prohibitive associated costs: travel, lost work time, consultation fees, laboratory fees, and drug charges.⁴³
- vi. *Lack of adequate treatment facilities*. Even when a woman or man decides to seek care, in many low-income countries there is a dearth of qualified

and trained health care workers able to deal with the problem, few diagnostic facilities, and often a lack of drugs and essential supplies as well.

The combination of these factors may result in a higher prevalence of RTIs and STIs in the lower-income countries than in those countries with higher per capita incomes and relatively less restrictive social and cultural practices. Nonetheless, it would be premature to characterise all low-income countries as areas of high prevalence. In many cases the prevalence is simply not known as studies have not been carried out and ongoing surveillance data remains a pipe dream. General consensus in the published literature, however, seems to point to one recurring theme: higher RTI/STI prevalence in the low-income countries of sub-Saharan Africa than is found in either Asia or Latin America. Such broadsweeping statements are fraught with problems and pitfalls, but a comprehensive review of published literature carried out by Judy Wasserheit and published in 1989 seemed to confirm this theory.³⁷ It should be noted, however, that the review pertains only to women and the picture in men is not clear. Furthermore, many studies, as will be noted below, are carried out with inadequate clinical or laboratory diagnostic facilities, thus calling in to question the validity of some findings.

There are generally more peer-reviewed and published studies on the epidemiology of RTIs/STIs in sub-Saharan Africa than in Asia, or Latin America. However, this situation with respect to Asia is changing with increasing numbers of studies emerging from India (see section 1.3.2 below). Many of the larger studies carried out to-date in the Asian (excluding South Asia) and Middle Eastern regions have been published as internal reports rather than academic papers. The major findings from several such studies outside sub-Saharan Africa are detailed below. Only the laboratory-based findings are reported in this Table:

Table 1 – Selected prevalence data from community- and clinic-based surveys of women in Asia and the Middle East.

	China	Vietnam	Turkey	Egypt
Population studied	Population-based study of township women, southern China ⁵¹	Women attending urban MCH-FP centre, central Vietnam ⁵²	Population-based survey in one MCH-FP catchment area, Istanbul ⁵³	Community-based study in 2 rural villages, Giza ⁵⁴
Number screened for infections	2020	600	918	509
RTI/STI prevalence				
<i>Candida</i>	38.9%	12%	5.2%	11%
Bacterial vaginosis	14.7%	6.3%	4.8%	21.9%
<i>Trichomonas vaginalis</i>	16.2%	2.8%	2.9%	18.3%
Syphilis		1.2%		0.8%
<i>Chlamydia trachomatis</i>	5.5%	0.8%	4.9%	8.6%
<i>Neisseria gonorrhoeae</i>	0.3%	0.2%		0%
'Cervicitis' (exact microbiological diagnosis not stated)	58.2%*			9.7%
Cervical dysplasia				8%**

*Identified through visual examination of the cervix

** Defined as having both grade II (or greater) dysplasia and at least moderate dyskariosis.

As Table 1 illustrates, there is a divergent epidemiology of both the endogenous and sexually transmitted infections. However, the authors of the Turkish study point out that such differences in prevalence rates may owe as much to the lack of using a standardised definition for laboratory diagnosis (especially in the case of the endogenous infections) as to 'true' differences between populations.⁵³

Published reports of RTI/STI epidemiology in men (either population-or clinic-based) are even more scarce. One survey of men in rural Maharashtra (central India) has been recently carried out, and this is reported in section 1.3.2, Table 2.

1.3.2 Epidemiology of RTIs/STIs in the South Asian region (excluding Bangladesh)

Most countries in the South Asian region (comprising India, Pakistan, Bhutan, Nepal, Sri Lanka and the Maldives, as well as Bangladesh), suffer from a relative paucity of epidemiological data on many diseases – RTIs and STIs are but one example of the dearth of ongoing data collection. Programme and policy personnel in South Asian countries usually only have patchy results from *ad hoc* surveys and studies of RTI/STI prevalence available, and relatively few ongoing surveillance programmes in operation (except in the case of HIV in India^{55,56,57}). Nonetheless, even in the absence of accurate statistics on the burden of disease, fundamental decisions concerning levels of need and service provision are still undertaken.

During recent years, however, many more South Asian prevalence studies have been published – all of them from India, and all funded during the late 1980s. Most of these studies have been community-based estimates of prevalence, covering a wide variety of both geographical sites and communities in the surveys. A summary of these studies is presented below. Data is presented in three

different ways: firstly the details of the individual studies are outlined, including the sampling frames, sample sizes and different methodologies in use; secondly the prevalence of gynaecological morbidity is presented – both self-reported and that diagnosed by the clinician; and finally the results of laboratory-based tests are presented.

Table 2 - Location, sampling techniques and methodologies: community-based studies in India

Site of study	Study details		
	Population group	Sample size	Methodologies used
1. Gadchiroli District, Maharashtra ⁵⁸	Village women >13yrs. of age; symptomatic and asymptomatic.	650 women.	Interview; Clinical exam; Limited laboratory studies.
2. Slum area, Bombay ⁵⁹	Ever married women living in slum area.	756 women.	Interview; Clinical exam; Laboratory studies on a sub-sample.
3. Alipur, rural area, near Delhi ⁶⁰	Village women in a selection of 20 villages served by department of Maulana Azad Medical College, Delhi.	7123 women screened; 6273 women had clinical exam; 5366 PAP smears examined.	Interview; Clinical exam; PAP smear and HPV samples taken.
4. Rural West Bengal ⁵⁹	Quota sample of village women in 8 villages. Ever married and unmarried women aged 13-45 years.	500 women.	Interview; Clinical exam Laboratory diagnosis.
5. Baroda ⁵⁹	50% random sample from 2 urban slum areas. Ever married women aged 18-45 years.	840 women interviewed; 548 women clinical exam.	Interview; Clinical exam.

Site of study	Study details		
	Population group	Sample size	Methodologies used
6. Karnataka ⁶¹	Subsample of random sample of 48 villages and one town. Ever married women <35years with child <6months.	440 women interviewed; 385 clinical exam.	Interview; Clinical exam; Laboratory studies.
7. Rural Gujarat ⁵⁹	Ever married women >15 years of age, attending village health fairs.	1103 women interviewed; 324 women examined.	Interview; Clinical exam.
8. Rural Rajasthan ⁵⁹	100% sample of ever married women >15years, women in two rural villages.	274 women interviewed; 51 women examined.	Interview; Clinical exam.
9. Gadchiroli District, Maharastra ⁶²	Eligible men in ongoing community education programme.	233 men interviewed and examined.	Interview; Clinical exam; Laboratory diagnoses.

Morbidity

**Table 3 – Prevalence of gynaecological morbidity:
results from community-based studies in India
% of women with morbidity by geographical
locale**

	Rural Maharast ra	Rural West Bengal	Bombay	Baroda	Karnataka	Rural Gujarat	Rajasthan	Alipur
SELF- REPORTED								
*Menstrual Problems	60	33	41	58	65	59	48	7
*Abnormal discharge	13	50	31	22	22	57	78	32
*Lower abdo. Pain	13	17	21	9	16	NA	10	5
*Lower backache	30	5	39	24	NA	30	16	11
*Dyspareunia	7	2	NR	NR	1	NR	48	NR
*One or more conditions	55	65	74	65	NA	84	100	69

Morbidity

**Table 3 – Prevalence of gynaecological morbidity:
results from community-based studies in India
% of women with morbidity by geographical
locale**

	Rural Maharast ra	Rural West Bengal	Bombay	Baroda	Karnataka	Rural Gujarat	Rajasthan	Alipur
<i>CLINICALLY DIAGNOSED</i>								
*Vaginal infection	62	4	15	11	13	10	30	34
*Cervical infection	48	14	40	13	24	8	19	27
*Cervical erosion	46	2	21	5	10	20	30	21
*Pelvic inflamm. dis.	24	1	16	8	11	8	36	NA
Genital prolapse	0.5	17	18	5	3	NA	27	NA
One or more conditions	NA	43	74	26	70	43	77	93

Table 4 - Laboratory results from community-based studies*, India

Infection diagnosed	% of participants diagnosed at geographical locales				
	Alipur	Rural Maharashtra (women)	Bombay	Karnataka	Rural Maharashtra (men)
Candidal infection		34	16.5	5.2	
Bacterial vaginosis		62.2	13.4	18.2	
HPV	0.1				
<i>Trichomonas vaginalis</i>	4.6	14	7.7	7.5	5.6
<i>Neisseria gonorrhoeae</i>		0.3	1.1	0.8	1.7
<i>Chlamydia trachomatis</i>			14.5	0.5	15
Syphilis (VDRL+)		10.5	0.2	1.5	
HIV					0.4

* Not all of the studies mentioned in Tables 2 and 3 carried out laboratory-based diagnoses of infection. Therefore, only selected results are presented in this Table.

The above results highlight some of the inherent problems with both community-and clinic-based studies. Firstly, non-standardized definitions may have led to wide variations in prevalence estimates. For example, in the case of ‘cervical infection’ diagnosed clinically, the prevalence ranges from 8% in rural Gujarat to 48% in rural Maharashtra (neighbouring States). Whilst such differences in prevalence may indeed reflect a ‘true’ situation, it is also clear that confusion exists as to the exact definition of common clinical problems. For example, some of these studies diagnosed ‘cervicitis’ only when

there was laboratory evidence of infection, whilst others included “cervical inflammation with pus discharge and/or evidence of prior or present scarred cervix”. Given that several of the studies included more than one clinician (usually a gynaecologist), there is a possibility of intra-study variation as well as inter-study differences. Furthermore, self-reported morbidity in all these studies shows an equally (or greater) range of prevalence estimates – a possible reflection of the way questions are phrased during surveys, and who is asking the questions.

These problems of definition were well recognised by the central co-ordinators of seven of the above-reported studies in their summary report to an international conference held in the Philippines in September 1996.⁵⁹

Divergence among definitions used, and hence in reported prevalence, has led many researchers to look for a more objective measure of disease prevalence.

One strong contender is to consider laboratory-diagnosed infections as the gold standard and the only ‘true’ indicator of the presence or absence of infection. Although there are known to be some problems inherent with laboratory-based diagnoses (for example, standardised definitions of the presence of laboratory markers of bacterial vaginosis – see reference⁵³), this is possibly the most independent of all indicators of prevalence, and the only one which can be subjected to external validation.

In the study described in this thesis, self-reported morbidity, clinically-diagnosed morbidity and the presence of laboratory-diagnosed infections were all recorded. To overcome problems of definition (as found in the Indian studies), we standardised diagnostic criteria at the start of the study (see Chapter 3 – section 3.1.1), and also aimed to standardise the questions used in self-reports of morbidity. Furthermore, laboratory diagnoses were made according to standard internationally accepted guidelines and were subjected to external quality control. Correlations between the three different measures are assessed.

1.3.3 Epidemiology of RTIs/STIs in Bangladesh

Previous studies of RTI/STI prevalence in Bangladesh are more scarce than those reported from neighbouring India. A large community-based study of prevalence was carried out in the Matlab area in the mid 1980s by Dr. Judy Wasserheit.⁶³ Other studies have been undertaken in the 1990s in both clinic- and community-based populations. The composite results of these studies are presented in Table 5:

Table 5 – RTIs/STIs in Bangladesh

Site of study and executing agency	Matlab (rural), ICDDR,B (Dr. Wasserheit) ⁶³	Mirpur (peri-urban), Bangladesh Women's Health Coalition (BWHC) ⁶⁴	Rangunia (rural), Save the Children (USA) ⁶⁵
Year of study	1985/6	1991	1992
Population studied	Currently married non-pregnant women living in ICDDR,B intervention area; complaining of symptoms in the reproductive tract.	Women of reproductive age (18-40 years) attending the BWHC clinic for a variety of health services.	Married women of reproductive age in rural villages, selected by cluster sampling.
Sample size	472 women	601 women	613 women
Prevalence by laboratory diagnosis			
Candida	5%	4.7%	9%
Bacterial vaginosis	35%	44.4%	34.6%
<i>Trichomonas vaginalis</i>	5%	3.7%	
Syphilis		0.5%	0%
<i>Neisseria gonorrhoeae</i>	0.4%	3.8%	1.1%
<i>Chlamydia trachomatis</i>	2%		12.4%
'Cervical infection' ('mucopurulent cervicitis' on clinical and slide-based diagnosis)	19%	0.2%	
Genital warts			0.6%

Differences in prevalence in these studies may indeed reflect true differences in the populations under investigation. Alternatively, there may be differences in definitions used (especially for clinical diagnosis), or in laboratory techniques. For example, whilst the 1985 study carried out in Matlab used monoclonal antibody testing (Micro-Trak) and was subjected to external quality control, the Save the Children study used ELISA tests which had no external validation.

As discussed above, the relative paucity of data on either the community- or clinic-based levels of RTIs/STIs in Bangladesh, and the absence of any comprehensive data on men, clearly raised problems for the Government of Bangladesh in its proposed development of a national plan of action for STI control. The study reported in this thesis was, therefore, undertaken with the explicit backing of the Government agencies responsible for the proposed national STI/HIV control programme which expressed a keenness to use the data in subsequent planning activities.

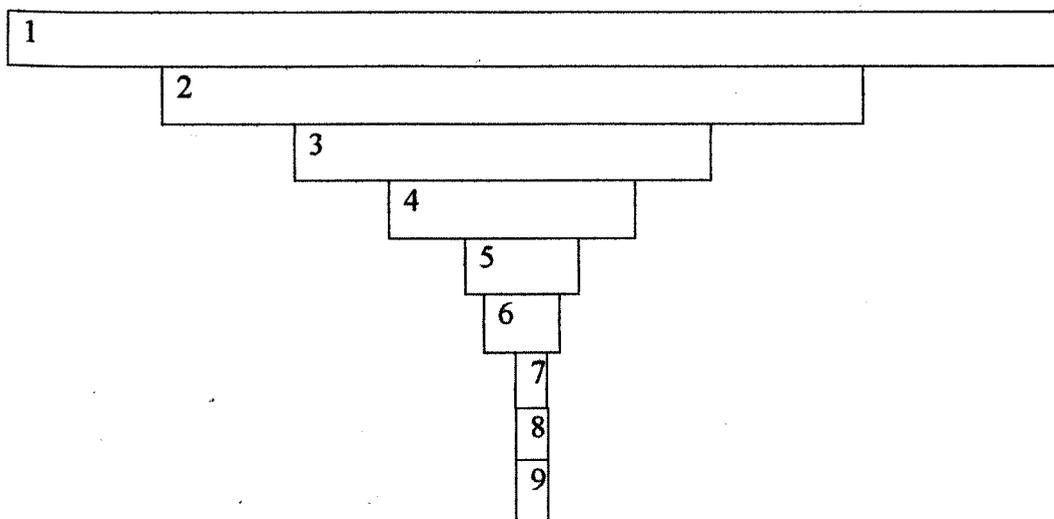
1.4 Management of RTIs/STIs – public health approaches

Despite the global acknowledgement that control of STIs is a worthwhile target (as exemplified by almost universal agreement on the Programme of Action from the United Nations International Conference on Population and Development, 1994) the tools available for achieving this goal in low-income countries are still limited. Accurate clinical management of people with established infections (including management of their partners) remains a cornerstone of most control programmes,^{66,67,68,69,70,71,72} along with campaigns of primary prevention, promotion of accurate symptom recognition, encouraging appropriate and timely health care seeking behaviour,⁷³ and promoting management of sexual partners. Such approaches aim not only to treat the infected individual but also to prevent the spread of the infection to

others. This obviously has the potential to reap benefits for the individual patient (who is less likely to suffer from the potential sequelae and complications of un- or mis-treated RTIs/STIs), and for society as a whole which benefits from a reduction in the amount of time an individual is potentially infectious to others.

The principle steps in achieving STD management are succinctly illustrated in the ‘inverse pyramid’ model of Piot and Fransen⁷⁴ - see Figure 1. This model, based on data from rural women in sub-Saharan Africa, highlights the areas where STD programmes may be failing in their attempts to reach infected women, and allows programme managers and policy makers to identify the steps needed to effectively manage more women. The model will be discussed in more detail in Chapter 5 in relation to the results from this study.

Figure 1: The Piot-Fransen model of STD management in rural women⁷⁴



Code:

- | | |
|--|---|
| 1: All women in the community | 6: Women treated correctly (6%) |
| 2: All women with an STD/RTI (100%) | 7: Women who comply with treatment (4%) |
| 3: All women with symptoms (50%) | 8: Treatment effective (3%) |
| 4: Women who seek treatment (35%) | 9: Partner also treated (1%) |
| 5: Women who go to a health unit (30%) | |

The evidence for interventions in each step in the pyramid of STD control is reviewed below, along with examples from countries where these interventions have been tried, plus a short review of primary prevention campaigns. This is followed by a brief outline of another important intervention in the field of STI control: the role of mass treatment in either whole communities or selected groups.

1.4.1 Primary Prevention

Primary prevention means a reduction in the risk of transmission of, or susceptibility to, infection through promotion and adoption of a number of risk reduction strategies:

- Reduction in the number of partners
- Mutual monogamy
- Engaging in non-penetrative sex
- Use of barrier methods of contraception (male or female condoms)
- Delaying the age at first marriage/first sexual intercourse
- Prompt treatment of symptomatic individuals and their sexual partners

Historically, most primary prevention campaigns have focused on modifying the sexual behaviour of the individual.⁷³ Such campaigns have been waged using a variety of techniques and media: central state communicators via radio, television and video^{75,76}; local communicators such as religious leaders,⁷⁷ opinion formers⁷⁸ and peer group educators (e.g. with self-identified gay men or commercial sex workers^{79,80,81,82}). The aim of modifying individual behaviour through directed communications campaigns has been criticised not least because the evaluation of such approaches has been less than rigorous.^{84,85} Furthermore, there is now increased recognition of the role of structural, economic and socio-cultural factors which may impede or prevent people from changing their own sexual behaviour.⁷³

Furthermore, campaigns are now recognising that whilst their primary focus may remain one of aiming to prevent people becoming infected, it is also important to ensure that those who are already infected should receive accurate and effective treatment as quickly as possible – see for example recent UK-based IEC campaigns targeting men who have sex with men. The importance of this is further highlighted in Figure 1, which shows that of the infected and symptomatic women in the rural areas studied, only 60% sought care from an appropriate source (defined as a health unit in this case).

Since a central focus of this thesis is on the management of established infections in primary health care settings, and given that primary prevention is a wide-ranging and diverse area, it will not be explored further in this chapter. Instead, I will now focus on the other layers of the Piot-Fransen pyramid: namely, management of symptomatic individuals once they have reached sites of health care. Further explorations of behaviour change communication are limited to its implementation in the primary health care setting – see for example, Sections 3.4.6.2 and 4.13.6.2.

1.4.2 Case management of symptomatic individuals

Traditionally the diagnosis and management of STIs has relied upon the results of laboratory tests or has been based upon the clinical judgment of the individual practitioner. In the absence of widespread laboratory facilities in most low-income countries, the World Health Organisation (WHO) has developed a set of management guidelines specifically for low-income, low-resource settings: syndromic management algorithms.⁸⁶ The three main management approaches are considered below:

1.4.2 a Laboratory diagnosis

Whilst this is the most accurate of the three diagnostic approaches, it is also generally the most costly. The depth and scale of laboratory testing can be adapted for appropriate use at different levels of a health care service (see, for

example ref⁸⁷); but it is important to recognise that even the most basic testing and diagnostic procedures (such as Gram stain or wet mount) are contingent upon the availability of trained personnel and ongoing adequate supplies of reagents and/or infrastructure (such as a microscope). Public sector health-care systems in some countries may have problems meeting such requirements.

1.4.2 b Clinical diagnosis

This relies on the individual health-care worker making a diagnosis after clinical examination. Studies have shown that this form of diagnosis generally has a low sensitivity and specificity when compared to ‘gold standard’ laboratory tests.^{88,89} The reasons for this are:

- low specificity of clinical symptoms and signs
- inaccurate interpretation of normal clinical features and signs, especially in the female genital tract
- occurrence of mixed infections

The misclassification of ‘normal’ features within the reproductive tract can have a significant impact on diagnosis rates. For example, classification of cervical ectopy (a normal response to hormone changes) as ‘cervicitis’ (an infection at the cervix) will lead to overdiagnosis and overtreatment.

1.4.2 c Syndromic management

Syndromic management is currently being promoted in many parts of the world as one (central) part of a low-cost, minimal-technology approach to the public health control of RTIs including STIs. This approach relies on being able to identify and treat the clinical syndrome caused by an endogenous infection or STI. A syndrome is defined as the set of symptoms and/or signs that an individual suffers from and presents with in health-care settings. The value of this approach is that it is relatively simple to use, and can be incorporated into all levels of the health care system – even at primary health care levels – and can be useful in both the public and private sectors.⁹⁰ The

syndromic approach recognises that there are several different organisms that can cause a particular set of symptoms or signs and recommends treatment for the most common group of aetiological agents which may be present.

The clinical syndromes which are most commonly seen in RTI/STI patients are presented in Box 2 along with their most common aetiologies

Box 2 – Aetiological agents causing common syndromes in the reproductive tract*

Vaginal discharge	Lower abdominal pain	Urethral discharge	Scrotal swelling	Genital ulcer disease	Inguinal bubo
<i>Chlamydia trachomatis</i>	<i>Chlamydia trachomatis</i>	<i>Chlamydia trachomatis</i>	<i>Chlamydia trachomatis</i>	<i>Treponema pallidum</i> (syphilis)	<i>Chlamydia trachomatis</i> (lympho-granuloma venereum)
<i>Neisseria gonorrhoeae</i>	<i>Neisseria gonorrhoeae</i>	<i>Neisseria gonorrhoeae</i>	<i>Neisseria gonorrhoeae</i>	<i>Haemophilus ducreyi</i>	
<i>Trichomonas vaginalis</i>	Organisms of bacterial vaginosis			Herpes simplex Viruses	
Candida				<i>Calymmatobacterium granulomatis</i> (donovanosis)	
Organisms of bacterial vaginosis					
β Haemolytic streptococcus					
Cervical lesions – warts, chancre, herpes					

* One additional syndrome not included in this Box covers the organisms most likely to cause ophthalmia neonatorum – *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

The syndromic management approach was initially developed for use in areas of relatively high RTI/STI prevalence. Studies have shown, however, that the most common presenting symptom in patients— vaginal discharge — is relatively poorly dealt with when using syndromic management.^{91,92}

The lack of specificity of this symptom, and the difficulty interpreting clinical signs may mean that women are over-diagnosed and over-treated for STIs when they are in fact only suffering from endogenous infections. Conversely, the common absence of clinical signs in the case of cervical infection with either *N.gonorrhoeae* or *C.trachomatis* can lead to a low sensitivity of the recommended algorithm in many cases. Such problems have been found among symptomatic women presenting for care in a variety of clinical settings (PHC, FP clinics, specialised STI centres).^{93,94,95} The algorithms perform even less well among women seeking other services (such as family planning or antenatal care) in whom opportunistic screening is undertaken.^{96,97} Similarly, in higher prevalence situations the recommended algorithms have been shown to be poorly predictive of the presence of cervical infection, and hence of questionable use for screening programmes among more at-risk populations.^{98,99}

An additional problem is that the ability of health workers to adhere to the recommended clinical algorithms has been shown to be poor, especially in the case of vaginal discharge.⁹² Furthermore, trained and experienced clinicians have been shown to achieve a higher sensitivity for detecting cervical infections during clinical diagnosis, than other health workers.¹⁰¹ This latter finding carries clear implications for resource management and personnel placement in health-care programmes.

Behavioural risk assessment has been introduced to try and distinguish between those women with an STI as a cause of their symptoms, and those suffering from an endogenous infection. Evaluations of behavioural risk

assessment have been carried out in several settings in sub-Saharan Africa,^{91,102,103} and elsewhere in the world,¹⁰⁴ and have shown that the introduction of this step into the syndromic algorithm increases its specificity and positive predictive value, but sensitivity may remain a problem. Similarly, other researchers have found clinical examination variables (such as bimanual examination) which improve the diagnostic performance of adapted algorithms.⁹⁴

Other evaluations of syndromic algorithms have shown that they can work well in the case of clients with genital ulcers^{89, 105} and for symptomatic men with urethral discharge,^{93, 106} and possibly for men with dysuria (pain passing urine) as their main symptom.¹⁰⁷ It should be noted, however, that most evaluations have been undertaken in areas with a reasonably moderate to high prevalence of STIs. Clearly a main determinant of the ability of health workers using the algorithms to accurately detect STIs, or to confidently pronounce the absence of infection, will be the underlying prevalence of infections in the population receiving services: in epidemiological terms, both positive and negative predictive values are dependent on prevalence.

One aim of this study (see sections 3.6.6 and 5.8) was to evaluate the efficacy of the most common syndromic algorithm in use (that for treating women with vaginal discharge) in a rural Bangladeshi population. Training requirements for integrating the algorithm at primary health care level are also discussed as part of the findings, and finally the cost-effectiveness of the recommended algorithm was evaluated.

1.4.3 Partner Notification

Partner notification is premised upon the fact that if only the 'index patient' (that is, the client presenting for care) is treated, then s/he is likely to be reinfected if her/his sexual partners are not simultaneously treated.

Notification can either be patient-led or provider-led. Provider-led referral is

likely to be both time-consuming and expensive, it may also be unlikely to yield higher numbers of contacts than patient-led strategies. Hence, the success of partner notification strategies may lie with educating the index patient about the importance of simultaneous treatment regimes. Such strategies may be particularly important in reaching female partners of male index patients – women who are likely to be asymptomatic and otherwise ‘hard to reach’.¹⁰⁸ Indeed, this may be one of the few ways of reaching such women in the absence of large-scale screening programmes.

Studies of the effectiveness of different strategies of partner notification are limited, but highlights include:

- **Rwanda** - Steen and colleagues¹⁰⁹ demonstrated that 58% of clients at a primary care facility accepted a partner referral coupon, which included the patient’s identification number and a code for the STD syndrome involved. The referral rate among those who accepted the coupons was 45%.
- **Port-au Prince, Haiti** launched a partner referral program in its antenatal clinics. Pregnant women found to have an STD were educated, treated, and encouraged to refer their partners to the clinic for treatment. More than 90% of these women agreed to inform their partner. The 384 women treated for an STD named 331 partners, of whom 101 went to the clinic for treatment after referral by the women, while 38 men sought treatment following health worker referral.¹¹⁰
- **Kenya** - an STD program implemented in 10 medical centres in Nairobi allows nurses to diagnose syphilis based on symptoms, and counsel on the importance of partner treatment and sexual abstinence during treatment.¹¹¹ Once syphilis is confirmed, the nurse educates the pregnant woman about syphilis and emphasises the need to treat the woman’s sexual partner(s). Each pregnant woman receives several partner notification cards asking the partner to go a health centre. Of a total 13,131 pregnant women

screened for syphilis, 87.3% of seroreactive women were treated on site and 50% of partners returned to the clinic and were treated.

- Studies of provider-led partner notification in both **Nigeria**¹¹² and **Zimbabwe**¹¹³ showed that provider-led referral yielded very few extra partners presenting for treatment, but was estimated to cost between four and eight times as much per partner compared to client-led referral.
- However, ICDDR,B's own primary health care programme in **Matlab, Bangladesh** used family planning workers to visit couples at home following diagnosis of an STI in any woman coming for treatment at one of the static women-only primary health care clinical facilities. The family planning workers gave drug treatment (at home) to any man who had not previously received treatment following his wife's diagnosis. Over the period 1990-1995, of the more than four thousand couples seen, 70% of the men (and 95% of the 'index women') said that they had completed their course of treatment.¹¹⁴ Clearly such an impressive recorded outcome is not without financial implications, especially for a low-income country such as Bangladesh.

1.4.4 Mass Treatment

Whilst outside the domains of the Piot-Fransen model of STD management (Figure 1), the role of mass treatment strategies is one which is currently gaining prominence as a possible method of STD control. The few published examples of mass treatment trials will be explored below. It should be noted, however, that this strategy was outside the realm of inquiry for the study described in the remainder of this thesis.

Mass treatment refers to the provision of epidemiologic treatment to a population or community. Epidemiologic treatment refers to treatment when the diagnosis is likely on behavioural, clinical, or epidemiological grounds, but before the results of confirmatory tests, if any, are known. Selective mass

treatment (SMT) is based on epidemiological grounds and given to a selected group of the community at high risk of infection.¹¹⁵

Whilst epidemiologic treatment to individuals is common, it is recommended only for those cases where it is given to the named sexual contacts of patients with a diagnosed STI “after a history of exposure to infection but without or in advance of confirmatory pathological test results”.¹¹⁶ In such cases, epidemiological treatment is given only when the risk of morbidity is high and the possibility of delayed treatment needs to be avoided. Since 1950 the Centers for Disease Control has recommended epidemiological treatment for female contacts of men with gonorrhoea, and similarly male contacts of gonorrhoea-infected women have been recommended to receive such treatment since the early 1970s. Nonetheless, even those patients receiving epidemiological treatment are still advised to have a full STI screening, subsequent tests of cure, and for further partner notification to be carried out.

There are relatively few examples of the provision of mass treatment or SMT to whole communities. Published work shows that selective mass treatment of sex workers has been tried in the Philippines,¹¹⁷ California¹¹⁸ and Indonesia.¹¹⁹ These campaigns (the earliest of which, in Indonesia, started in 1958) have shown some success not only in reducing STI incidence and prevalence in the sex workers themselves but also in their male clients and further into the sexual networks: prevalence fell concomitantly in pregnant women in the general population. Population-based mass treatment and control has been undertaken in China¹²⁰, Greenland¹²¹, and most recently in Uganda.¹²² Whilst the results from the Ugandan trial have been disappointing in terms of their ability to reduce HIV incidence and STD prevalence, historically in both China and Greenland the population-based interventions had more success. In the case of China, however, this was accompanied by the reported eradication of prostitution, and in Greenland, mass treatment was supplemented by clinical examination and contact tracing.

Given the current debate over the role and effectiveness of mass treatment, global attention is still firmly fixed on improving the management of individuals with established infections, through promotion of more appropriate health care seeking behaviour, and improving the clinical management of infected people. The study undertaken for this thesis, concentrated on understanding patterns of health care seeking, and looked at strategies for improving clinical management against a background of determining the population-based levels of infection.

1.5 Site of the study

1.5.1 Bangladesh

Bangladesh ranks amongst the poorest and most densely populated of all low-income countries. Most tables ranking common indicators of development (income levels, literacy, status of women, nutritional levels, health indicators such as infant or maternal mortality) find Bangladesh nearing the bottom of global leagues. With an estimated population of 111.4 million in 1991,¹²³ and an annual population growth rate of 2.17%, in an area of only 144 thousand square kilometres, Bangladesh has a population density of 735 persons per square kilometre, the highest in the world outside the city states.¹²⁴ Despite recent fertility decline (current total fertility rate = 3.4) the population of Bangladesh is estimated to double within the next 30 years.

Such a high population density and low GNP per capita (US \$220 in 1991)³ contribute to the enormity of health problems faced by the entire population – planners, providers and recipients of services alike. With an infant mortality rate of 87.4 per 1000, an under-five mortality rate of 133.1 per 1000 children, maternal mortality ratio (number of deaths per 100,000 live births over a period of time) between 440 and 710,¹²⁵ 76.1% of children classified as malnourished or undersized,¹²⁶ and only 22% of the female population estimated to be literate,³ the scale of problems and challenges faced by health planners, service providers and

behaviour change communicators in this country should not be underestimated.

1.5.2 Matlab field study area

The study described in this thesis was undertaken in the Matlab area of southern/central Bangladesh. This area has been the site of ongoing demographic surveillance and field trials conducted by the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) since the early 1960s. ICDDR,B is a United Nations affiliated research organisation dedicated to finding low-cost solutions to the public health problems of low-income countries.

Geography and economy of Matlab

Matlab town is situated about two and a half hours travel by road and river transport from Dhaka. It is in an area that is representative of the river delta system formed by the joining of the large Meghna and Padma rivers (See Map 1). The area is subject to large seasonal fluctuations in water level of several metres and the agricultural subsistence economy is based on rice cultivation and river fishing. Travel within the area is mainly by local roads, on foot, and by 'country' boats (small wooden punts), particularly during the rainy months of June to September.

In the Matlab area about 88% of the population are Muslims and most of the remainder are Hindu. Literacy is approximately 55% for males and 25% for females and the commonest occupation is as 'wage labourers' (i.e., landless workers) on farms or for other manual work. The majority of households possess two rooms in houses built of traditional materials, but with brick, concrete and metal roofs being commonly used as well. Most households use tube-well water for drinking in both dry and monsoon seasons but the majority also use surface water for cooking and washing. However, less than 10% use a sanitary latrine. Malnutrition is widely recognised to be common and more

frequent in girls than boys, with about two thirds of children having weight-for-age less than minus two Z scores.¹²⁷

Matlab is one of the larger thanas (political districts) in Bangladesh, with approximately 500,000 people. Government of Bangladesh (GoB) health services are organised from the thana health complex in Matlab town itself. The nearest government referral hospital is in the district town of Chandpur, about 45 minutes by road from Matlab. Besides the government and ICDDR,B services there are a wide variety of allopathic practitioners, in both the formal and informal sectors, together with private pharmacists, indigenous systems of medicine practitioners and drug sellers. However, the Matlab ICDDR,B hospital is widely recognised for treating diarrhoeas and many patients come from long distances to receive care at the hospital.

1.5.3 Matlab demographic and geographical surveillance systems

The study population of 210,000 people, who are resident in 142 villages, have been included in the Centre's demographic surveillance system (DSS) since 1966. The bari is a local demographic unit formed by some 6-7 households that share a common courtyard and there were 7,194 in 1994 in the full DSS area. Each individual in the DSS area has a unique identification number, which locates them to a specific village, bari and household. The present DSS utilises male health assistants (HAs) and female Community Health Workers (CHWs) to collect data every two weeks through household visits and, based on the unique individual identification number, records are kept on all marriages, births, deaths, in- and out-migration, and internal movements.¹²⁸

In 1977 the DSS geographical area was divided into two equal populations. The 'intervention area' is where the Maternal, Child Health and Family Planning (MCH-FP) Programme has carried out health and population intervention studies since that time, while remainder of the area has served as a demographic 'comparison area' – see Map 2. The MCH-FP Programme

holds computerised household information on all women aged 15-44 years and children aged 0-4 years in its area, called the Record Keeping System (RKS). In addition to the DSS and RKS there is a geographical information system (GIS) which shows the delineation of 142 villages and the location of the total Matlab population of 210,000 by their bari. Both demographic and epidemiological data can be demonstrated spatially by the GIS. Further descriptions of the work of the CHWs, RKS and DSS are given below.

1.5.4 Demographic characteristics of the Matlab population

Some relevant demographic information on the population, dating from 1994, is given in Table 6 below. Analysis of the 1994 DSS data shows that the male to female ratio is approximately equal at all ages and that more than 10% of the population is aged 0-9 years. In the intervention and comparison areas the total fertility rates have fallen to 3.0 and 3.8 respectively and the average expectation of life at birth is now more than 60 years for both males and females in both study areas.

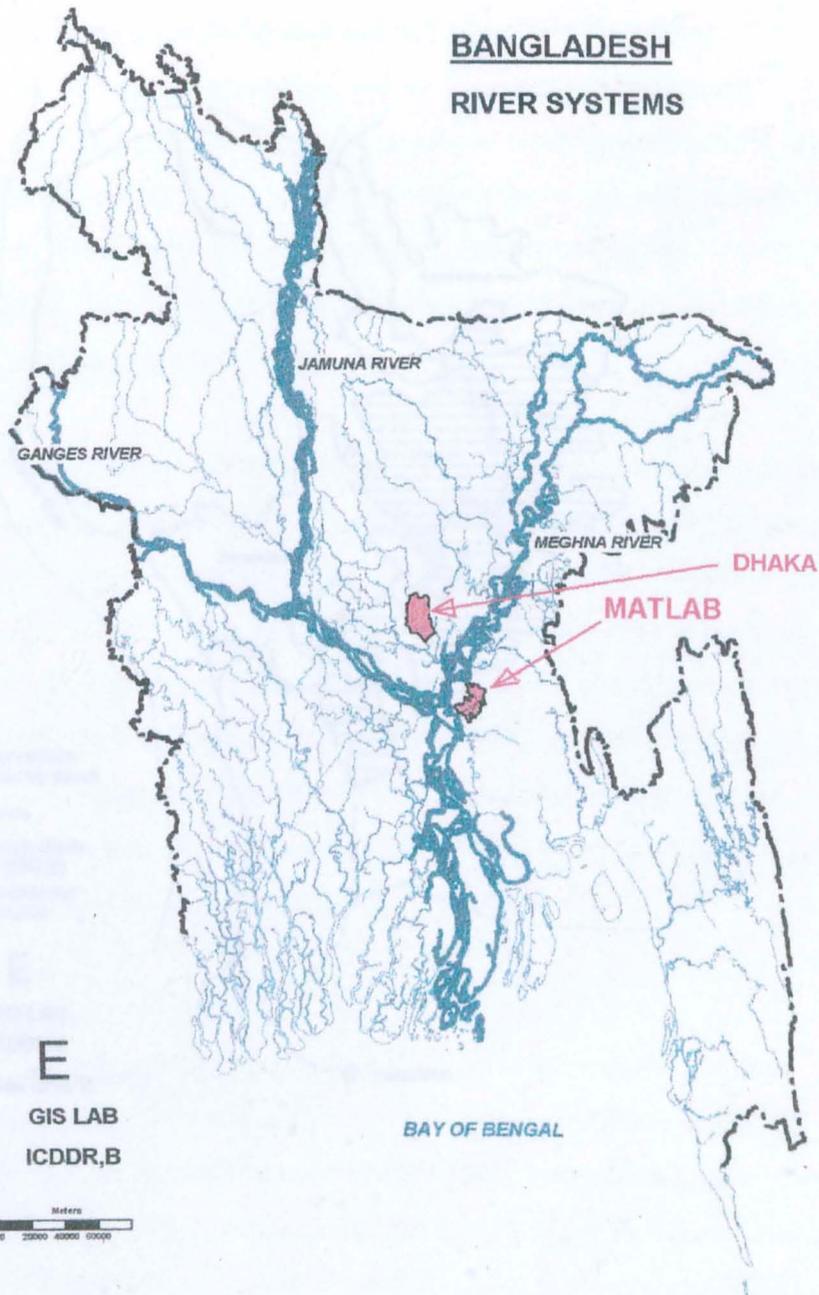
The mean age of first marriage in both areas is now about 25.5 and 19.5 years for men and women respectively. Contraceptive prevalence in the MCH-FP area is more than 66%, compared to the national average of about 45%, and the preferred methods are injectable contraceptives (52%), the oral pill (25%) and female sterilisation (14.0%). Prenatal care in the MCH-FP area is mainly from the programme midwives (86%) whereas in the comparison it is from government facilities (23%) and for deliveries in these areas the main birth attendants are traditional birth attendants (TBAs) and midwives (80.3% and 8.5% for the MCH-FP area compared to 97.6% and 0.1 % for the comparison area respectively). Stillbirths have been estimated to be 3.1% and 3.9% of all births in these areas and the miscarriage rates are 7.0% and 10.5% respectively. In 1994 these two populations had crude birth rates of 25.6 and

29.4 per 1000 women/year respectively, resulting an estimated 2,730 and 3,030 live births per year, or 5,760 for the whole DSS area.

Table 6: Matlab DSS study population, 1994 (Rates per 1000 population).

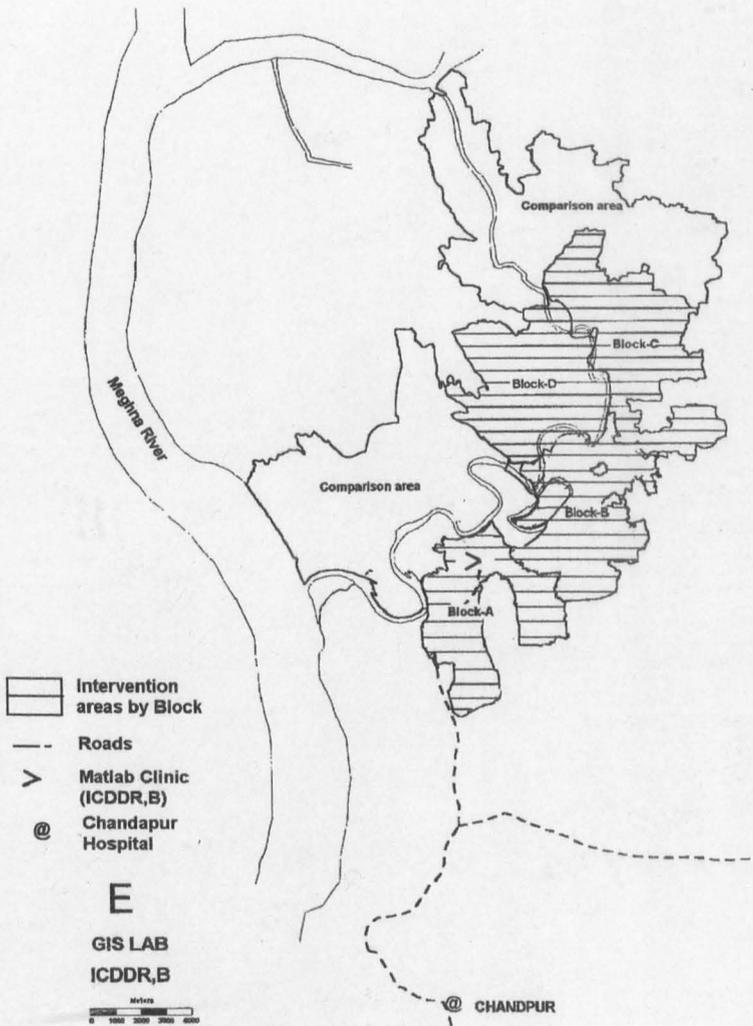
Study Populations	MCH-FP Intervention	Comparison Area
Total number	106,786	103,032
Crude birth rate	25.6	29.4
Total fertility rate	3.0	3.8
Infant mortality rate	64.8	86.2
Child mortality rate (0-4 years)	84.4	113.2
Maternal mortality ratio (1993 figures for deaths per 100,000 live births ¹³⁰)	497	368

MAP 1 – Position of MATLAB



MAP 2 - MATLAB THANA :

Demographic Intervention and Comparison Areas



1.5.5 Matlab maternal, child health and family planning programme

Since 1977, the Centre's MCH-FP Programme has utilized more than 80 CHWs to provide a range of health and family planning services to mothers and their young children in their own baris.¹²⁹ The CHWs currently visit each household in their area every two weeks in order to collect population based incidence data on common childhood and maternal illnesses, record information on their case management and to deliver preventive health services. A referral system ensures that severely ill children and mothers are referred on to health subcentres staffed with nurse-midwives and medical assistants and, if necessary, patients are then again referred to the Centre's Matlab hospital. The Centre provides emergency speed-boat transport for severely ill patients needing referral.

The data collected by all the CHWs is maintained in record books as a part of the record keeping system (RKS), from where it is collated and computerised monthly. The computerised RKS data is complete since 1986. Close monitoring of HAs and CHWs ensures that household coverage is high and that there are good quality data available. The RKS includes information on dates of vaccinations and vitamin A supplementation, diarrhoea and ALRI episodes and their case management in infants, reproductive morbidity in women (including complaints of abnormal vaginal discharge), patient referrals, nutritional status and temporary absenteeism.

1.6 Funding for the study

Most funding was received from the British Department for International Development (DIFD, formerly known as ODA) via their Dhaka-based Aid Management Office. During the course of the study, extra funding was generously given by DFID to ensure that the microbiology laboratory was fully established and the technician properly trained. Furthermore, DFID awarded 4 training grants, enabling members of staff to be sent abroad for

training in data management and analysis (10-week course at the University of Reading, UK); male sexual health counselling (10-week course in West Bengal, organised by the British Council); STI molecular diagnostics (10-week course at London University); Masters level degree in STDs at the London School of Hygiene and Tropical Medicine/University College London. The Reproductive Health Programme of the Ford Foundation in Bangladesh awarded extra funding for HIV and hepatitis B testing.

1.7 Study personnel

A full list of study personnel is attached in Appendix One. It should be noted that a large number of ICDDR,B staff, although not directly employed by the RTI project, regularly contributed to the daily running of the project at the field level.

CHAPTER TWO: OBJECTIVES

2. Study Objectives

As outlined in the introductory chapter, the study took place with the explicit backing of the Government of Bangladesh, the bilateral funding agency (Department For International Development), and ICDDR,B. During the development stage of the study (October 1994 to May 1995), the objectives of the research were agreed upon by all actors involved. These are recorded below:

- 1. To determine the prevalence and aetiology of reproductive tract infections (RTIs) in a rural population of men and women, and investigate risk factors for infection*
- 2. To determine the prevalence of morbidity and perceived ill-health related to infections of the reproductive tract, and to further understand health-care seeking behaviour in relation to RTIs*
- 3. To ascertain the antimicrobial resistance patterns of the infections most commonly seen*
- 4. To work towards the development of a replicable and sustainable programme of training health-care workers in the recognition, management and prevention (primary and secondary) of RTIs.*

During the course of the study, it became clear that the original objective to look at antimicrobial resistance patterns (Objective no. 3) could not be fulfilled owing to the low number of STIs found in the population. Such a low level meant that little meaningful data could usefully be garnered from studies of antibiotic resistance. The other three objectives, however, remained valid for the duration of the study.

Given that the study took place at a time when the Government of Bangladesh was developing a national programme for RTI/STI management and control, output of the study was expected to inform the decision-making process for the national programme.

CHAPTER THREE: METHODS

3 Methods

3.1 Study Design

There were five separate arms to the study:

- i. Population-based survey of women
- ii. Population-based survey of men
- iii. Survey of pregnant women
- iv. Survey of neonates
- v. Evaluation of management in symptomatic women

Parts (i) and (ii) were cross-sectional surveys of RTI/STI prevalence in the general population. These surveys also addressed issues of perceived versus actual morbidity, health-care seeking patterns, and risk factors for the presence of infection. The survey of pregnant women (iii) looked at the prevalence of syphilis infection in these women in a defined geographical area over a one year time span. During the same time period, newborn babies in a separate geographical area were included in a study of the incidence of ophthalmia neonatorum (iv).

The final arm of the study (v) was carried out in the four ICDDR,B primary health care centres in Matlab. Health care workers were trained in the syndromic management of symptomatic women, and subsequent evaluations of the effectiveness of training and the efficacy of the syndromic flow charts were undertaken. Furthermore the cost-effectiveness of the flow charts was analysed.

The study was undertaken in several stages, each of which is reviewed in the following sections:

- Training of staff
- Selection of populations to be interviewed
- Questionnaire development and pilot phase of the study
- Data collection and data management
- Data analysis

In this chapter, detailed consideration is also given to the establishment of the laboratory facilities in Matlab, and the piloting of sexual health clinics for men.

3.2 Review procedures

ICDDR,B has two review committees in operation. Every study undertaken by ICDDR,B must be approved by both the ethical and research review committees. Once the proposal and all questionnaires and consent forms had been developed for this study it was put before the ethical review committee. We experienced a number of difficulties with gaining ethical clearance, but this was finally given on the third submission. The committee had raised objections to the following issues:

- Title of the project
- Exact monetary value of incentives given to women in the population-based study (this covered the cost of food only)
- Inclusion of unmarried girls and women in the population-based study
- Testing for HIV

All the points raised by the ethical committee were answered to the satisfaction of the committee members before the study was reviewed by the research review board. This latter committee raised no objections or queries on the proposed study design and conduct.

3.3 Staff selection and training

ICDDR,B has two categories of professional staff working in Matlab: regular clinical service providers and formally recruited project staff. Both types of staff were involved in the RTI project from the middle of 1995 onwards.

3.3.1 Regular staff

The maternal and child-health and family-planning (MCH-FP) programme of ICDDR,B has existed in its current format since 1986. It was established as the integrated natural successor of preceding separately organised large-scale family-planning and more modest MCH services. As previously described, staff in the MCH-FP programme work at a variety of levels: in the community (household visits); at static primary health care centres (PHC centres, known as 'subcentres'); and at the central Matlab referral hospital. Clinical staff above the community-health worker (CHW) level were all designated to

receive training in the syndromic management of RTIs/STIs. Most of these staff were based in the PHC centres, all had completed 10 years of basic school education, and were either: nurse-midwives (3 years of nursing training plus 1 year of midwifery training); lady family planning visitors (18 months of family planning training); or medical assistants (male workers – one per subcentre, with three years of basic medical training). Their regular daily workload would usually involve seeing CHW-referred (female) patients and children with a range of common illnesses and family planning problems. Clients with complicated problems are referred to the central Matlab hospital, although occasionally they are referred directly to Government clinics and hospitals in the Matlab thana.

Many staff at PHC level had received previous training in RTI/STI management from Dr. Judy Wasserheit in 1985. Thus, they were already keeping detailed records of women attending their PHC centres with symptoms suggestive of RTIs, and were treating them according to basic principles of syndromic management. It was felt, however, that since the training had been ten years before and had never been updated, all staff should receive a basic training programme.

Two training sessions of one week each were held in the central Matlab hospital in May and June 1995. These training weeks were based on the published WHO syndromic management training modules¹ and were run by myself, one Bengali physician/translator (Dr. Kaniz Gausia), and one Bengali specialist in behaviour change education (Ms. Veena Lakhmalani from the British Council in Calcutta). Methods in use in the training sessions included interactive lectures, group discussions and role play. A variety of media were used including slides and videos.

A total of 32 staff participated in the training sessions, not just the PHC-level clinical staff, but also the male interviewers (whose regular work in ICDDR,B included supervision of subcentre activities, and monitoring of CHW work/achievements) who carried out the population-based survey of men. A variety of topics were covered including : basics of RTIs/STIs/HIV

(epidemiology, clinical); education and counselling techniques; diagnosis and management; partner management; and infection prevention. Each member of staff received their own copy of the WHO training modules, plus English and Bengali versions of the recommended clinical algorithms and leaflets and information on HIV and STIs. At the end of each training session, staff were asked to design a one-day training programme for the community health workers.

Given the findings from previous studies in the South Asian region and beyond, that lack of standardised clinical definitions could lead to problems in inter-observer variation (see Section 1.3.2), standard clinical definitions were used from the start of the project. These were especially important in the case of cervical infection and pelvic inflammatory disease. The definitions used throughout the entire project are detailed below:

Table 7: Standardised clinical case definitions in use in Matlab RTI project

Condition	Accepted Criteria for Diagnosis
Cervical Infection ('Cervicitis')	Mucopurulent discharge present at the endocervix <i>Or</i> Easily induced endocervical bleeding (= cervical friability)
Pelvic Inflammatory Disease ^{2,3}	<i>Basic criteria:</i> (Excluding a surgical or pregnancy related cause) Lower abdominal pain <i>Plus</i> Signs of a lower genital tract infection <i>Plus</i> Cervical/adnexal motion tenderness

3.3.2 Supervision of regular staff and monitoring of clinical practice

Following the theoretical training courses, staff returned to work at their regular PHC subcentres. For the next 18 months, each subcentre was visited

monthly by one of the project physicians (SH or KG). During these regular visits, staff would be observed in their clinical practice, and current problems in syndromic management would be discussed. Supplies of drugs were monitored, and it was continually ensured that each subcentre had sufficient drugs available to adequately manage both the regular RTI/STI patients and any extra patients who may be identified through the RTI study protocol.

One month after the initial training (that is, in July 1995), the record books were amended and more details on each presenting client were collected. For the rest of the project time, clinic record books were reviewed, and the pattern of diagnoses was monitored. All clinic records were computerised at the end of the study. These records were then compared with the computerised lists of RTI/STI diagnoses made in the five years preceding the start of the RTI study.

3.3.3 Training of regular community health workers

After the initial training of PHC-level staff had been completed, all 80 regular CHWs received a one-day training course (in batches of 20), designed and executed by their more senior colleagues from the PHC subcentres. At the start of each training day, the CHWs were asked to complete a basic written questionnaire assessing their pre-existing knowledge of RTIs and STIs (including HIV). The training courses were run in Bengali by the subcentre supervisors, and covered a variety of topics: the basics of RTIs/STIs (symptoms and signs, management, complications, prevention); and an outline of the forthcoming RTI study. Since each CHW was to participate in the RTI study (by accompanying women to and from the central hospital), the reasons behind the study and an explanation of what would happen to each woman in the study were provided. Finally, each CHW was given her own Bengali version of all overheads used in the training day (covering the basics of RTIs as outlined above).

3.3.4 Selection of project staff

Many of the staff working on the RTI project were assigned from the regular 'core' of project staff working in the central Matlab field station. These staff

included field supervisors, male interviewers, data manager, data coders. However, the remainder of the project staff (physician, laboratory technician, 6 field CHWs) were recruited through the regular ICDDR,B process of open advertising and interviews.

3.3.5 Training of Project Staff

(a) Project Physician

Dr. Gausia had previously worked in the fields of both MCH-FP and obstetrics, and therefore had a good pre-existing knowledge of women's reproductive health care. She required clinical training in basic STI/genitourinary medicine, and this was provided through a two-week attachment to one Dhaka-based NGO providing reproductive health care to women, including women with RTIs/STIs plus hands-on supervision (by SH) of the first 100 women seen as part of the population-based survey of women.

(b) Laboratory Technician

Mr. Nazmul Alam was recruited after several previous unsuccessful attempts to recruit a suitable microbiology technician. Bangladesh has a dearth of microbiologists trained in the field of STIs/RTIs, it was therefore expected that we would recruit a general microbiologist and send her/him on a training course in the United Kingdom. An ODA training grant was obtained for this purpose. After several attempts, however, (including one technician who came to the UK and then left, without warning, after four days), and given the constraints on time, it was felt that we would need to bring a microbiology trainer to Bangladesh. Mr. Alam was recruited in July 1995, and the next month an STI/RTI diagnostic specialist (Mr. Trevor Sykes) came to Matlab from the UK. Mr. Alam received three months of training in RTI/STI diagnostics, and a laboratory manual was prepared specifically for use in the Matlab laboratory.

(c) Project CHWs

Six (female) CHW-level staff were recruited from the Matlab area in June 1995. All six women were educated with at least 10 years of schooling, and two of them had previous training as Lady Family Planning Visitors. These 6

women were to carry out the field work for the survey of pregnant women, and the survey of neonates. All 6 participated in a month-long training course which, among other topics, covered questionnaire filling and specimen collection. The end of the training period was marked by the completion of a written questionnaire covering the basics of reproductive health care and more specific questions relating to the RTI project itself (for example, listing the signs of ophthalmia neonatorum).

(d) Male interviewers

Given a lack of finances which would have enabled the recruitment of new staff to work on the population-based survey of men, the male interviewers were assigned to the project from among the regular staff already working in ICDDR,B. These 5 men had been working for ICDDR,B for many years, and their regular posts involved field supervision of the MCH-FP CHWs and ensuring logistical supplies to the field. Although many had worked on previous projects in ICDDR,B, very few had worked in such a socially 'explicit' field as RTIs/STIs before. Some of the men assigned to work on the project appeared to have a degree of discomfort when dealing openly with issues of sexual behaviour and sexuality, and initially appeared reluctant to ask such questions of men. During the supervision of the pilot project, it was noted that some of the interviewers left 'difficult' parts of the questionnaire blank. Over the course of the next year, I met regularly (approximately once per month) with the 5 male interviewers and we would go through their completed questionnaires in great detail. It took a great deal longer for some of these interviewers to feel comfortable with the subjects under discussion, than any of the other staff (in the project or regular).

(e) Training of other staff in the project

All other project-staff (field supervisors, data manager, data coder, etc.) were trained during the first two months of field operation (and before the start of the data and specimen collection). Regular training sessions were held in June and July 1995, in which the objectives and running of the project were discussed, and the specific duties and role of each member of staff was outlined and discussed in detail. These sessions also provided the opportunity

for discussion and development of the questionnaires to be used in the project (see below – Section 3.5).

3.4 Selecting the populations to be interviewed

3.4.1 Population-based surveys (of men and women)

The basic demographic surveillance systems of ICDDR,B Matlab field station have been operating since 1966. There are two types of surveillance system in operation: the Demographic Surveillance System (DSS) and the Record Keeping System (RKS). A full description of these systems is given in Section 1.5.3. The survey lists of these systems were used as the basis for selecting the population-based samples of the project.

a. Calculation of Sample Size

Sample sizes were calculated in order to measure the prevalence of infection with acceptable precision. Assumptions on the likely prevalence of infection were based on the results of previous surveys in the South Asia region and in Bangladesh in particular.^{4,5} It was assumed that in a population-based survey (among both men and women), 1% would have syphilis, 3% gonorrhoea, 5% chlamydia and 30% of women would have bacterial vaginosis. A sample of 800 would be expected to give the following numbers of cases:

PREVALENCE	95% C.I.	EXPECTED CASES
1%	0.3 – 1.7	8
3%	1.8 – 4.2	24
5%	3.5 – 6.5	40
30%	26.8 – 33.2	240

Furthermore, it was assumed that between 25% and 30% of men and women would decline to participate in the study (compatible with the figure from Wasserheit's study in 1985⁴). Thus, sample size lists of 1200 were drawn each from the RKS and DSS databases (for women and men, respectively).

b. Selection from the existing database lists

i. Women

As noted above, the ethical committee of ICDDR,B had mandated certain changes in the study design before allowing the study to proceed. For reasons of perceived cultural non-acceptability, the ethical committee did not feel that it was appropriate to include unmarried women/girls in a survey of RTI/STI prevalence. Given this restriction we used the RKS lists as the basis for sample selection. These lists, updated monthly, are restricted to coverage of ever-married women of reproductive age resident in the Matlab intervention area. In August 1995, a sample list of 1216 women was drawn from that month's RKS list. The basis of selection was:

- Exclusion of pregnant women (again, for reasons of cultural non-acceptance in performing internal speculum examinations on non-symptomatic pregnant women)
- Age between 15 and 50 years
- Even distribution of women between all CHWs in the intervention area (in order not to unfairly disrupt the working days of any of the CHWs)

Given the first two exclusions, the RKS list for August 1995 contained a total of 17,820 eligible women. The RKS list is based on household residence – i.e. a geographical basis which, therefore, results in the list being split almost equally among all CHWs since each one covers a reasonably equal number of households. Thus, in order to split the workload evenly, it was decided to choose every 15th woman from the August 1995 list (i.e. 17820/1200). This systematic sampling scheme also ensured that there was an even geographical spread of women and that the sample contained women from villages in the same proportion as that found in the general population.

ii. Men

Men are not included in the RKS lists, but only in the DSS database. This is a census-derived database, the most recent dating from 1993. The 1993 list formed the basis of the sampling frame for men. Unlike the survey of women, including unmarried men was not felt to pose the same ethical dilemmas.

Thus, criteria for inclusion of men in the survey were:

- Married or unmarried
- Age 15-50 years

In August 1995, a random selection of 1200 men was drawn from the 1993 DSS list of 25,650 men. These 1200 men were targeted for interview over the course of the next year. However, during the year it was noted that approximately 30% of the men who were included in the survey reported that they had never had sexual intercourse. It was felt that this would adversely affect the calculation of STI prevalence, since the level would obviously be lower if a large number of men had never been possibly exposed (assuming all men were reporting the truth). In October 1996, therefore, a second list of a further 400 men was drawn from the original 1993 DSS list (after excluding the 1200 drawn in August 1995). These men were targeted over the next three months until the end of the project. A total sample of 1626 eligible men was drawn over the course of the project and all were targeted for interview.

3.4.2 Survey of pregnant women

One of the functions of RKS is to register reproductive events in the lives of eligible women in the survey (e.g. pregnancy, contraceptive use and associated morbidity events, lactational status). Every month, computerised lists of pregnant women are produced for use at the fortnightly CHW supervisory meetings (which take place at the PHC subcentre level). A woman is recorded by her CHW as being pregnant when she has missed two consecutive periods (no diagnostic tests are undertaken).

For reasons of logistical ease it was decided to carry out the survey of pregnant women in 2 of the 4 blocks in the Matlab intervention area (see Section 1.4.3). In the other two blocks, the survey of ophthalmia neonatorum incidence would be carried out (see below). Every 2 weeks, two of the project CHWs would attend the subcentre meetings in Blocks C and D and collect lists of pregnant women in the area, and talk to the regular CHWs about arranging to visit each pregnant woman at home.

3.4.3 Incidence of ophthalmia neonatorum

The RKS and DSS both record the birth of infants in the Matlab intervention area. These events are computerised and at fortnightly meetings the regular CHWs are given lists of children requiring post-natal visits. These computerised lists were used by the RTI project CHWs as the basis for visiting neonates in Blocks A and B. Details were collected at the subcentre meetings and arrangements made with the regular CHWs to inform the mothers that the project CHW would visit her at home to see the baby.

3.4.4 Survey of symptomatic women in the subcentres

One year after the initial training of PHC-level clinical staff (health assistants, Lady Family Planning Visitors (LFPVs) and nurse-midwives) in the syndromic management of RTIs/STIs, an evaluation of their syndromic management practices in symptomatic women was carried out. This is fully described in Section 3.6.6. Eligibility for symptomatic women to be included in the study was:

- Any age
- Married or unmarried
- Self-referred or referred by regular community health worker to the primary health care centre
- Complaining of any symptom which may be attributable to infection of the reproductive tract (for example, vaginal discharge, abnormal smell, genital itching, lower abdominal pain not associated with diarrhoea, dyspareunia).

A sample size of 500 symptomatic women was aimed for after the calculation of expected numbers of cases based on the assumption of a higher prevalence among these women than among those men and women seen as part of the population-based surveys.

The study was carried out in all 4 of the PHC subcentres by the regular ICDDR,B PHC clinical staff (under supervision of one of the project physicians, SH or KG).

3.5 Development of questionnaires and piloting of study

Questionnaires were written for all five arms of the study, and piloted by both the field supervisors and field-level interviewers (project CHWs and 5 male interviewers) during the months of June and July 1995. The questionnaires employed a mixture of pre-coded and open questions. Since ICDDR,B has a long history of surveys of family-planning use, many of the pre-existing code plans were used in this study since project and regular staff were already familiar with these codes (for example, occupation, education levels, contraception in use). Code plans for the open questions were mostly developed during the course of the data entry once the replies were recorded.

Three of the arms of the study (population-based men, population-based women, and symptomatic women) used questionnaires written in English. The other two arms of the study (pregnant women and neonates) were to be completed by non-English-speaking CHWs, therefore these questionnaires were translated into Bengali. In order to check the validity of the translated questionnaires, they were then re-translated back to English from their Bengali versions. These questionnaires used only pre-coded questions, with no open questions requiring interpretation.

Copies of all questionnaires (English and Bengali, plus the re-translation back to English, versions) are included in Appendix 2.

Each questionnaire was piloted on a minimum of 20 people. Those chosen for piloting were residents of Matlab living near the main hospital, and women attending the main MCH-FP referral clinic in the central hospital. Once the questionnaires had been tried on a number of people, all interviewers, data coders and supervisors were invited to a number of meetings to discuss any problems with the questionnaires, and to look for possible alternatives. Most of the suggested changes were in the male questionnaires – two of the male interviewers felt that there were not enough questions included on male sexual behaviour. The omission was rectified by asking the male interviewers which

questions would be deemed suitable. Subsequently, questions on male-to-male sex and commercial sex were added.

Once the questionnaires had been agreed upon, the final versions were again sent to the ICDDR,B ethical committee for approval (see Section 3.2 above). Before data collection started, there were further pilot phases to test the procedures and mechanisms for client recruitment, transport of clients and samples, sample collection and laboratory processing. This secondary pilot phase incorporated a further twenty participants in each arm of the study. For these participants, full clinical and treatment services were provided (as in the main body of the study), but their results were not included in final data entry and analysis.

Interviewers for the population-based surveys participated in repeated training sessions, concentrating specifically on the following areas:

- Confidentiality of the questionnaires
- Non-directive questioning
- Asking questions of sexual behaviour in a non-judgemental manner
- Referring symptomatic people for treatment (men only)

These points were emphasised at regular meetings with interviewers during the entire course of the study. The last of these four points (referral of symptomatic men) raised the issue of where these men could be referred to. All public-sector (including ICDDR,B) reproductive health services available in the Matlab area were women-only services as they were concentrated within the MCH-FP system. The idea was raised that in order to ensure equality within the project, we should establish our own sexual health services for men – in this way we could treat those men identified as symptomatic and/or infected in our community-based surveys, and we would also treat any symptomatic men who came to the clinics as ‘walk-in’ patients. This subject is dealt with in more detail in Section 3.9.

3.6 Data collection

3.6.1 Population-based women

On specified days selected women were recruited at home by their regular CHWs, who accompanied them to and from the central hospital where all interviews and tests were carried out (see photograph 1). Prior to recruitment, the purpose of the study was explained, by the regular CHW, to the selected woman, and to members of her family (husband, mother-in-law, etc.). The entirely voluntary and confidential nature of the study was emphasised. All transport costs for the woman (and any accompanying children she might bring along) were borne by the RTI project, and although women did not receive any monetary payment, they were given food for the whole day plus a small amount of food to take home. During their time spent at the central hospital (on average, 6 hours), the issue of RTIs and STIs was discussed informally with them by members of the project staff, the objective being to impart health education in an informal setting.

With the woman's recorded consent (consent form was read in full to each woman, who then either signed or gave a thumb imprint), interviews were administered by our trained interviewers in a private room. These interviews (Form A – Appendix 2) covered demographic and reproductive histories, current and past clinical symptoms of the reproductive tract, treatment seeking history, and sexual behaviour history.

Subsequently each woman was seen by one of the project physicians (KG,SH) and underwent a general clinical examination and detailed gynaecological examination – the details of which were recorded on Form B (Appendix 2). Clinical samples were collected from each woman as follows:

- (i) the ectocervix was cleaned using sterile cotton wool, and two swabs were taken from the endocervix – one for antigen detection of *Chlamydia trachomatis* (DAKO) and one dacron-coated swab which was immediately plated onto Modified Thayer Martin Medium and placed in a candle extinction jar (for culture of *Neisseria gonorrhoeae*);
- (ii) a high vaginal swab was taken for Gram-staining, and then placed in a drop of saline for immediate wet mount examination;

- (iii) a further swab from posterior vaginal fornix was placed in *T.vaginalis* culture medium^a;
- (iv) a cervical smear was taken and immediately fixed according to procedures recommended by the manufacturer of the cell-fixative;
- (v) on removal of the speculum, the vaginal fluid was tested with both pH paper and potassium hydroxide (KOH)^a;
- (vi) a bimanual examination was carried out, and if the woman had cervical motion tenderness, or adnexal tenderness, and an abnormal discharge she was diagnosed as having pelvic inflammatory disease, according to published and pre-defined clinical criteria^b;
- (vii) a finger- prick blood sample and a first-void urine sample were collected.

All women with symptoms and signs of infection in the reproductive tract were treated immediately according to the syndromic management flow charts in use in the project (see Appendix 3). Any woman who was clinically diagnosed as having a sexually transmitted infection was given the option of asking her husband to come in for treatment, or of taking treatment home to him.

Following laboratory analysis of the clinical samples (see Section 3.8 below), all women who were found to have an endogenous infection or STI, and who had not been treated on the day of interview, were given treatment by project staff who visited them at home. All women with a laboratory-diagnosed STI, and all symptomatic women with a clinical diagnosis of cervical infection, genital ulcer or pelvic inflammatory disease, were asked to return for a check-up one week later (or earlier if the symptoms worsened).

^a Problems were experienced in maintaining a regular supply of both potassium hydroxide and *T.vaginalis* culture swabs. These deficiencies have been taken into account in the final data analysis

^b See Table 7 in this chapter.

3.6.2 Population-based men

Men were recruited to the population-based survey by interviewers who visited them at home (see photograph 2). The purpose of the study was explained both to the man selected for interview, and to other members of his household if necessary. During the course of the explanation, the existence of the newly-established male sexual health clinics was highlighted, and all symptomatic men in the village were encouraged to attend. After obtaining consent (methods as above), interviews were administered in private (as far as possible) in the men's homes, covering similar topics to the women's interviews – see Form E, Appendix 2. Symptomatic men were encouraged to attend the male sexual health clinics in ICDDR,B.

A finger-prick blood sample and first void urine sample were collected from each man, the urine sample was immediately tested with a leucocyte esterase dipstick and the result recorded. Samples were transported back to the central laboratory in Matlab on the same day as collection, for immediate separation and then refrigeration at +2 to +4°C.

After laboratory analysis, any man found to be infected with either *Chlamydia trachomatis* or syphilis was asked to attend the male sexual health clinic for treatment. Any infected man who did not attend the clinic within a reasonable space of time (two weeks), was then visited at home by a male health assistant (PHC-level staff) and treatment was given at home. Treatment of partners (where possible) followed the same guidelines as for the population-based survey of women. Where appropriate and possible, blood samples were collected from the wives of syphilis-infected men before and after treatment.

3.6.3 Pregnant women

All pregnant women in Blocks C and D were seen at home by project CHWs who, after explaining the nature of the study to the woman herself and members of her family, obtained consent (same procedure) to interview the woman and collect blood from a finger-prick blood test (see photograph 3). All blood samples were transported back to Matlab central hospital on the same day, for immediate separation and refrigeration.

All women found to be either RPR+/TPHA+ or RPR-/TPHA+ were immediately visited at home by the field supervisor, and the recommended dose of benzylpenicillin was given (to non-allergic women). A further blood sample was taken on the day of treatment. Women found to be only RPR positive on laboratory analysis were visited again at home and a repeat blood sample was taken for analysis before treatment was started. Infected women (with either active or latent syphilis) were followed up for the entire course of the study. Blood was taken from them, their husbands, their new-borns and their co-wives (where appropriate). Treatment was administered according to recommended guidelines. The results of this longitudinal assessment of serostatus and partner status are in Section 4.10.

3.6.4 Neonates

Women who had given birth within the preceding two weeks were visited at home by project CHWs who, with consent, interviewed the mother and examined the baby looking for signs of ophthalmic infection. The two week cut-off point was chosen since the vast majority of infants will show clinical signs of infection during the first 12 days after birth⁶. Any baby with clinically obvious signs of infection was visited again the next day and had swabs taken for detection of Chlamydia antigen and for *N. gonorrhoeae* – swabs for gonorrhoea culture were immediately plated onto modified Thayer Martin medium and placed in a candle jar; a swab of conjunctival exudate was taken for Gram staining and examination looking for intracellular diplococci. All specimens were transported back to the central laboratory in Matlab on the same day. The mother and baby were accompanied that day to the nearest PHC subcentre and treatment was given according to published guidelines.⁷

After the study had been running for approximately 3 months a quality control check was carried out to ensure that the CHWs were not overlooking any cases of ophthalmia neonatorum. For a period of 3 months (during which time approximately 150 babies were seen), swabs were taken from all babies seen, irrespective of signs and symptoms. In this way we were able to monitor not

only the accuracy of the CHWs' diagnoses, but also were able to check for any asymptomatic carriage of either *N.gonorrhoeae* or *C. trachomatis*.

3.6.5 Additional surveys in the population-based groups

As indicated in Tables 8 and 9, we undertook serological screening for HIV and hepatitis B in the population-based groups. Furthermore, cervical PAP smears taken from population-based women were read looking for evidence of cervical dysplasia, carcinoma or other abnormalities.

Owing to a lack of funds, we were not able to carry out testing for these infections/conditions on everyone recruited as part of the population-based surveys of men and women. Numbers were limited purely by the financial resources available to us.

HIV: Using established methods for unlinking samples from their identifying study numbers⁸, we tested a random selection of serum samples from the 2 population-based groups (men and women). Any samples which were positive on initial ELISA screening were subsequently tested using Western blot in ICDDR,B's Dhaka laboratories and PCR at the Public Health Laboratories, London.

Hepatitis B: Again, a random selection of serum samples were taken from the population-based surveys of men and women. Any samples which were positive on testing for hepatitis B anti-core were subsequently tested for the presence of hepatitis B surface antigen. All testing was carried out in Dhaka. The testing procedures depleted the serum supplies making quality control testing impossible.

Cervical cytology: A random selection of cervical smears taken from population-based women were sent to Dhaka Medical College for initial readings. Any smears which showed a possible abnormality were then sent, along with double the number of negative smears, to King's College London for confirmation of the results.

Undertaking population-based surveys



Photo 1 - population-based survey of women

Photo 2 - population-based survey of men

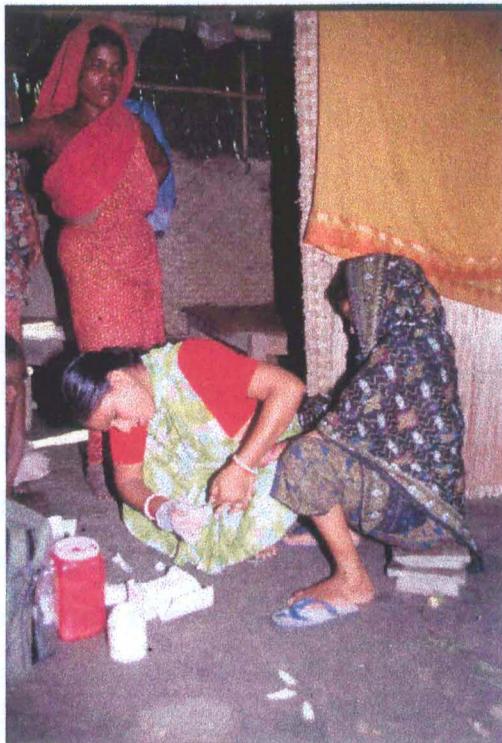


Photo 3 - survey of pregnant women

3.6.6 Absentees/refusers in the population-based surveys

In selecting the original sample sizes for all population-based parts of the survey (including the surveys of pregnant women and neonates), an allowance was made for an estimated 25% refusal rate. In the course of the entire project, almost every person eligible to be included in the study (determined from the original sample lists, or from information given to project CHWs concerning eligible pregnant women and mothers of neonates) was visited by members of the project staff. The following data was recorded about each visit:

- Interviewed
- Absent
- Declined
- Out-migrated

Special categories were in use for the surveys of pregnant women and neonates:

<i>Pregnant women</i>	<i>Neonates</i>
Already delivered by time of visit	Over 15 days old at time of visit
Died	Died/Stillborn

Men and women who declined to take part in the survey were visited on at least two more occasions by the project staff, and reasons for refusal were recorded in all cases.

The largest number of absentees was found among the population-based men – a reflection of the number of men who travel to the neighbouring towns and cities in search of work. In every case, the family of the absent man was asked if and when he was likely to be coming home (a man absent for one year or more is recorded as an ‘out-migration’, not an ‘absentee’), and a special effort was made to visit the men at home during this period. In February 1996 during a period of great political turmoil and civil unrest in Bangladesh, many usually absent men came home to their villages for the Muslim Eid celebrations. Immediately following Eid there was a general strike and transport throughout the country was halted for many days. At this time we

were able to interview many of the men usually absent from their homes but now forced to remain in their homes for an extended period.

3.6.7 Symptomatic women

a. Evaluation of syndromic management algorithm

In 1995, all clinical staff running the PHC subcentres had received recommended training in the syndromic management of symptomatic women (and men) with possible RTIs/STIs. Most of these staff had received training in prototypes of syndromic management in 1985 (see Section 3.3.1). The previous training programme had included the use of a speculum and pH paper for the diagnosis of vaginal infections. Therefore, in order to continue existing practices we adapted the recommended WHO algorithms to include a speculum examination and the use of both pH paper and potassium hydroxide— both of which may act to increase the sensitivity and specificity of diagnosis of vaginal infections.⁹ Furthermore, we did not limit ourselves to only asking the recommended WHO standard questions on possible STI risk (see Appendix 3 for WHO risk assessment questions). Instead we collected a variety of information as part of a more detailed questionnaire on social, demographic and risk behaviours (see Appendix 2), and subsequently analysed all variables as possible predictors of infection (see Appendix 5 for full details).

One year post-training, a validation study of the use of the syndromic algorithms was carried out investigating both the accuracy of diagnosis (compared to laboratory-diagnosis) and the accuracy of behaviour change messages given by the PHC workers.

The study was conducted in all four subcentres, with most women seen in Block C (the largest of the four PHC level facilities). PHC-level staff (nurse-midwives, and Lady Family Planning Visitors) in the subcentres were trained to interview symptomatic women using the study questionnaire (see Form C, Appendix 2), and to carry out a full clinical examination and specimen collection. Clinical examination and specimen collection followed the same procedures as outlined in Section 3.6.1 above, except that there was no

collection of cervical smears and blood was only tested for syphilis. For the first one month of the study in Block C (the largest of all the subcentres), all clinical examinations were supervised by SH. Subsequently, examinations were carried out two days a week without supervision, and two days with supervision. At no stage was the recorded diagnosis of the PHC-worker contradicted by the study physician. However, if the physician felt that the PHC-worker had overlooked a clinical diagnosis, this was rectified immediately by giving treatment to the woman, but leaving the recorded diagnosis of the PHC worker unchanged.

In the other three subcentres in the Matlab intervention area, the study of symptomatic women was supervised by the two project physicians (SH,KG). The physicians visited each subcentre for an equal number of days, and all symptomatic women reporting to the subcentres on those days were asked to participate in the study. Each symptomatic woman was interviewed in private by one of the trained study interviewers. Clinical examination was carried out by the PHC-level health worker, but specimen collection was by one of the project physicians. Subsequent diagnosis was made by the PHC-worker (with the same proviso as detailed above).

At the end of the study period, the following analyses were undertaken:

- Comparison PHC-level health workers' diagnoses with laboratory findings
- Comparison of health workers' recorded clinical signs with known laboratory diagnoses

b. Cost-effectiveness of vaginal discharge algorithm in Matlab

More detailed analyses of the use of syndromic management by PHC level workers and the cost-effectiveness of this approach are examined in a separate paper (submitted for publication) – see Appendix 5. In summary, the drug costs of treating symptomatic women according to our modified algorithm (see previous page) were compared to the drug costs of using the WHO recommended algorithm. Costs for both flow charts were calculated and compared to the actual cost of treating the laboratory-diagnosed infections in

the same symptomatic women. All costs refer to the market prices of drugs in Bangladesh and do not include the costs of training as this was assumed to be similar for both algorithms.

c. Assessment of behaviour change messages given to symptomatic clients

Central to the training course in syndromic management was an emphasis in the importance of giving correct information about behaviour change, and encouraging the client to talk openly (without fear of judgement) about sexual behaviour and issues of sexuality. As part of the assessment of the effectiveness of the syndromic management training course, one year post-training we undertook an evaluation of the consultations between the PHC-level workers and their symptomatic clients. This survey was carried out in both the male and female clinics (the latter excluded those women who were otherwise part of the clinical evaluation of the algorithms in use since their interviews were conducted using our project questionnaires).

In collaboration with the Social and Behavioural Sciences unit of ICDDR,B, one social scientist was recruited to work full-time with the RTI project. After obtaining clearance from the ethical and research committees of ICDDR,B, the study undertook to use tape-recordings of the actual clinical interviews and to analyse the tapes post-hoc. PHC service providers were each given a tape recorder and asked to record all interviews with symptomatic clients for a period of one month. In each case, the permission of the client was to be sought before the tape-recorder was switched on, and the client was to be reassured of the confidentiality of the records. The tape-recorder was never concealed from the client, and the recording could be ended at any time at the client's request.

After one month, all tapes were collected from the subcentres and transcribed by a member of secretarial staff at ICDDR,B. Under guidance (from myself), the transcripts were then analysed by the social scientist and records made of the following:

- Presenting complaint(s)

- Questions asked about the client's symptoms
- Asking about spouse's symptoms
- Questions asked about client's and spouse's sexual behaviour
- Responses to all questions on sexual behaviour
- Information given to the client concerning exposure, treatment and prevention
- Language and style of interview

All data was entered into the ANTHROPAC programme and results were analysed by both the social scientist and myself together.

3.7 Data management and data entry

For all parts of the study, the following procedures were followed to ensure the highest possible standards of data entry and data management:

- Data was stored in locked filing cabinets throughout the entire course of the study to ensure restricted access and maintain confidentiality
- At the end of every working day, every questionnaire was checked by the data-coder to ensure that all parts had been correctly completed and there were no obvious problems with the questionnaire
- All unclear/inconsistent answers were clarified the next day with the original interviewer
- Every questionnaire in the population-based and symptomatic studies was then checked again independently by two people (SH and data coder) looking for breaches of internal consistency, and clarifying the codes in use for open questions
- Any common problems or difficulties with the questionnaires were discussed at regular monthly meetings which were attended by all interviewers together
- Data entry programmes (written in FoxPro, Version 3.0, Microsoft) included logical checks of consistency and range
- Every questionnaire was entered twice. Two separate data entry persons were employed. Double entry was then validated using the validation

programme of Epi-Info (Version 6.0, Stone Mountain, GA). Any inconsistencies were checked with the data coders by referring in each case to the original questionnaire. The inaccurate data entry was then modified accordingly.

3.8 Establishment of laboratory and diagnostic techniques in use

Matlab central hospital had a pre-existing laboratory, mainly devoted to the study of diarrhoeal disease pathogens. This laboratory was used to house a newly established facility for RTI/STI diagnosis. The facilities were set up at the start of the project, and the microbiologist worked full-time in the Matlab laboratory for the entire duration of the study.

The pathogens looked for in each part of the study, and techniques used are outlined in Tables 8 and 9 below.

Table 8 Survey section and pathogens/conditions looked for

Table 9 Diagnostic methods in use for each pathogen (including confirmatory testing and quality control procedures).

TABLE 8 Survey section and pathogens/conditions looked for

Pathogen/Condition	Populn. – based survey of men	Populn. – based survey of women	Pregnant women	Neonates	Clinic-based symptomatic women
1. <i>Chlamydia trachomatis</i>	X	X		X	X
2. <i>Neisseria gonorrhoeae</i>		X		X	X
3. <i>Treponema pallidum</i>	X	X	X		X
4. Hepatitis B virus	X	X			
5. Human immunodeficiency virus	X	X			
6. Herpes simplex virus		X			
7. <i>Trichomonas vaginalis</i>		X			X
8. Bacterial vaginosis		X			X
9. Candida		X			X
10. Cervical dysplasia		X			

TABLE 9 Diagnostic and confirmatory methods used, plus quality control measures

Pathogen	Diagnostic method	Confirmatory testing	Quality control measures
<p>1. <i>Chlamydia trachomatis</i></p>	<p>ELISA kits used (DAKO diagnostics, Denmark)</p>	<p>Antigen blocking (DAKO diagnostics, Denmark)</p>	<p>All specimens (urine, cervical and ophthalmic) initially tested for <i>C. trachomatis</i> were shipped to the Laboratory Centre for Disease Control, Canada, for PCR confirmation. Specimens were tested using Amplicor <i>C. trachomatis</i> PCR assay^{10,11,12,13}. All positive specimens were re-tested with another PCR assay targeting a different chlamydial gene, the <i>C. trachomatis</i> major outer membrane protein¹⁴</p>
<p>2. <i>Neisseria gonorrhoeae</i></p>	<p>Initial screening of cervical and ophthalmic specimens with Gram stain. Culture on modified Thayer Martin medium. Incubation at 36-37°C in CO₂ for a maximum of 48 hours.</p>	<p>Oxidase positive, Gram-negative samples were confirmed as <i>Neisseria gonorrhoeae</i> by carbohydrate degradation tests.</p>	<p>Known <i>N. gonorrhoeae</i> positive plates were included regularly in candle jars used in the field and in the clinics to ensure that growth of the organism continued under field conditions. Urine samples were tested by PCR.*</p>
<p>3. <i>Treponema pallidum</i></p>	<p>i. Rapid plasma reagin (RPR, Human diagnostics, Germany) ii. <i>Treponema pallidum</i> haemagglutination (TPHA) test on <u>all</u> specimens screened for RPR</p>	<p>i. Quantification of RPR if positive ii. All positives for both RPR and TPHA were repeat tested on fresh serum samples at least once.</p>	<p>All subjects found to be either RPR+/TPHA+ or RPR-/TPHA+ were followed serologically for the entire course of the study, thus both monitoring response to treatment and confirming the specificity of their original result</p>

Table 9 contd. Pathogen/ Condition	Diagnostic method	Confirmatory testing	Quality control measures
4. Hepatitis B virus	All samples screened for Hepatitis B anti-core by ELISA (Organon Technica)	Anti-core positive samples screened for Hepatitis B surface antigen (Organon Technica)	No QC was possible as serum was fully depleted during the first round of testing.
5. Human immunodeficiency virus	All samples screened with ICE HIV-1.O.2 (Murex Diagnostics, Dartford, England) to detect all known subtypes of the virus. ^{15,16}	ELISA positive samples confirmed with Western Blot (Murex Diagnostics, Dartford, England) according to published guidelines. ¹⁷	All ELISA positive samples sent to Public Health Laboratory Service, London, for PCR testing.
6. Herpes simplex virus	Women with genital ulcer disease screened for HSV using ELISA kits (Murex diagnostics, Dartford, England)		
7. <i>Trichomonas vaginalis</i>	Immediate wet mount of vaginal fluid on all women	Vaginal swab collected from all women on specific <i>T. vaginalis</i> transport kits (Medical Wire and Equipment Co., England), incubated at 36°C for 5 days and read every 24 hours.	
8. Bacterial vaginosis	Amsel's ^{18,19} diagnostic criteria used: <ul style="list-style-type: none"> • Consistency and character of vaginal fluid noted • PH of vaginal fluid noted • KOH test carried out on vaginal fluid • 'Clue cells' looked for on Gram stain 	All 'clue cell' positive (and an equal selection of negative) slides re-read in Dhaka by a second laboratory technician.	All slides from symptomatic women sent to Louisiana State University for confirmatory reading using Nugent's criteria ²⁰

Table 9 contd. Pathogen/ Condition	Diagnostic method	Confirmatory testing	Quality control measures
9. Candida	<ul style="list-style-type: none"> • pH of vaginal fluid noted • Consistency and 'clumpy' vaginal fluid looked for • Budding hyphae looked for on all Gram stains of vaginal fluid. 	All slides diagnosed as candida positive (plus a selection of the negatives) checked in Dhaka by RTI/STI microbiology specialist	
10. Cervical dysplasia	All slides read by professor of Obs/Gynae at Dhaka Medical College		Any slide showing any degree of abnormality (plus an equal number of the 'normal' slides) read in Department of Cytopathology, King's College Hospital, London

*** Note on PCR testing for *N.gonorrhoeae***

We had originally hoped to test all urine and cervical samples for both *C.trachomatis* and *N.gonorrhoeae* using PCR²¹. However, during the course of the confirmatory testing (carried out in the Laboratory Centre for Disease Control, Winnipeg, Canada), it was discovered that there was a previously unrecognised cross-reactivity with *N.meningitidis*, with which the samples had been contaminated. Thus, we were not able to use PCR as confirmation for *N.gonorrhoeae*, and have relied upon culture results. As a result of this finding, Amplicor PCR for *N.gonorrhoeae* has been withdrawn from use in Canada until further notice (R.Peeling, Laboratory Centre for Disease Control, Winnipeg, Canada, personal communication).

3.9 The establishment of sexual health clinics for men

In Section 3.5, it was noted that during the development of the questionnaires to be used in the male and female population-based surveys, both the male and female staff felt that there would be a discrepancy in possible outcomes for men and women in the community. Men identified in the course of the project as either symptomatic and/or infected would have to be immediately referred to non-ICDDR,B services as ICDDR,B does not usually provide basic primary health care (including reproductive health care) for men. Men were eligible to receive health services from ICDDR,B only if they were

suffering from acute diarrhoea. All other health problems were dealt with either by the Government services in Matlab thana, or, more usually, by the private sector. A possible solution was put forward in the establishment of sexual health clinics for men, to be based within the pre-existing MCH-FP facilities.

3.9.1 Researching and marketing the clinics

The male sexual health clinics were opened only after the community had been consulted both formally and informally, and acceptability, nomenclature and need had been discussed. This was carried out in several ways: by the male medical assistants going out into their local communities and holding focus group discussions with various sections of the male population; by the male interviewers from the project talking about service provision with the men being interviewed for the STI prevalence survey; and by the female community health workers informing their regular (female) clients that a new service for men would be opening, and asking their clients to encourage their partners/husbands to attend if they had any symptoms. By the time the clinics opened, the communities they served had been made aware of the existence of this new service through the use of word-of-mouth and person-to-person communication networks. This, rather than a written poster or leaflet campaign, was felt to be an appropriate method of communication in a situation where only 43% of men and 22% of women are literate,²² and access to any form of mass media is low.

Four clinics were opened between August 1995 and January 1996. It was agreed that the clinics would initially open for one afternoon per week, although this was later expanded to a full day per week. They were located within the existing MCH-FP subcentre buildings as these were equipped with basic facilities for examination, and were also well recognised as sites of health-care provision. The clinics were open to all men in the local community, both married and unmarried, and were free of charge.

3.9.2 Clinical care in male sexual health services

Men are treated according to WHO syndromic management flow-charts for STIs – male medical assistants working at subcentre level had participated in the initial syndromic management training courses in May/June 1995. Owing to a lack of funds in the original budget (as male sexual health clinics had not been foreseen at that stage), it was not possible to carry out any clinical or laboratory surveys in the clinics. However, careful records of client attendance were kept, and the aggregate data from all record books is presented in Section 4.13.

One year after the clinics opened, it was noted that a large proportion of men in both the population-based survey, and those self-referring to the clinics, were complaining of psychosexual problems rather than obvious physical infections or problems. Male staff running the clinics felt ill-prepared to deal with such psychosexual disorders. There are remarkably few sexual health services for men in Bangladesh (indeed, our own clinics in Matlab were the first such services opened in either the public or NGO-sectors), thus no detailed training possibilities for our staff existed in Bangladesh. Therefore, a British Council training grant was applied for and one member of staff went on a three-month study tour of male sexual health services in India – in the neighbouring state of West Bengal which has a history of more developed services for men. On returning to Bangladesh, the medical assistant ran training programmes for his 3 male colleagues.

3.10 Statistical analysis

Data from questionnaires was entered into specially designed FoxPro entry screens. As stated above (Section 3.7), these entry screens contained logical checks for data range, and looked for internal consistency in each questionnaire. Validation was carried out through the use of double data entry, and validity checks in Epi-Info 6.0.

Risk factor analysis for all sexually transmitted and endogenous infections was undertaken with all social and demographic variables included in the

model. Risk factors for all infections were first examined individually using cross-tabulations and X^2 tests (or Fisher's exact test if the assumptions for the X^2 test were violated) in Epi-Info 6.0. For endogenous infections and for hepatitis B infection, independent risk factors were determined using a logistic regression model in Stata (Version 5, Austin, TX) to control for confounders. Those risk factors which had achieved statistical significance on bivariate analysis ($p < 0.1$) were included in the multivariate models. The number of cases of sexually transmitted infections was too small in all groups (population-based women and men, and symptomatic women) to allow more detailed analyses of risk factors to be undertaken.

CHAPTER FOUR: RESULTS

4 RESULTS

4.1 Time-frame of the study

Data collection in the study ran from July 1995 – December 1996. This was longer than originally forecast owing to political disturbances in the period November 1995 – March 1996 which severely disrupted the running of the study, and resulted in over 70% of working days being lost at this time. Extra time was allowed for data collection in order to achieve the original survey sample size estimates.

4.2 Data validation

All questionnaires were double-data entered (original entry on the day the questionnaire was administered, second entry up to one year later by a second person) into specially designed Fox Pro data entry screens which included logical checks of consistency and range (see Section 3.5). The double data entry was compared (validated) using Epi-info 6.0, resulting in the following percentages of differences:

Population-based survey of women:	8.1% of records differed
Population-based survey of men:	8.1% of records differed
Survey of neonates:	14.4% of records differed
Survey of pregnant women:	1.9% of records differed
Survey of symptomatic women:	9.2% of records differed
Laboratory forms:	1.6% of records differed

The high discrepancy rates (8 – 14%) in some parts of the survey were in the most part due to post-hoc changes in the original coding plans. Very few of the discrepancies were due to actual problems in data entry (as indicated by the low rates in 2 parts of the survey where the coding plans remained unchanged). Where differences were found, we returned to the original forms and checked the completed questionnaires. Information on both the data entry screens was then adjusted to ensure consistency with the original responses.

4.3 Participation in the study

At the time of drawing our sample frames, there were 17,820 married women of reproductive age on the RKS list, and 25,650 eligible men on the DSS census list. Using the methodology outlined above, we drew sample frames of 1216 women and 1618 men, all of whom were eligible for interview during the study. A total of 1626 women in 2 geographical Blocks were recorded as being pregnant during the survey, and in the other 2 Blocks 1676 infants were born. These pregnant women and mothers of neonates were all eligible for inclusion in the study. One pregnant woman seen at the start of the study was later also included in the survey of population-based women. This was the only case of overlap (inclusion in two parts of the study) in the entire study. Table 10 shows participation rates for the four population-based arms of the study.

Refusal rates for 3 parts of the study were much lower than had been originally estimated; only the population-based survey of women had a refusal rate approaching that of the original estimate (18.4% of the original sample frame; estimated at 25% when drawing the sample size). Nonetheless, there were higher numbers of absentees and out-migrants than had originally been estimated – especially in the population-based survey of men. Many men were repeatedly absent from their homes despite at least two, and usually three, visits to them. Between 8-11% of new mothers and pregnant women were also repeatedly absent from their marital homes – a reflection of the common practice of returning to the parental home around the time of childbirth. A further 27% of post-partum mothers were beyond the set 15-day time limit when seen by project staff. They were thus excluded from the study. One fifth of pregnant women (20%) had delivered before the project staff visited them.

Table 10 – Participation in four population-based arms of the study (showing numbers and %)

	Population-based women	Population-based men	Pregnant women	Mothers and neonates
Number eligible	1216	1618	1626	1676 (neonates)
Interviewed	804 (66.1%)	969 (59.9%)	1021 (62.8%)	1008* (60.4%)
Declined to participate	224 (18.4%)	37 (2.3%)	16 (1%)	0
Absent	77 (6.3%)	383 (23.7%)	177 (10.9%)	130 (7.8%)
Out-migration	46 (3.8%)	153 (9.5%)	5 (0.3%)	16 (1%)
Baby overage before interview conducted				446 (26.7%)
Woman suffered spontaneous miscarriage or stillbirth				17 (1%)
Woman died before interview			2 (0.1%)	5 (0.3%)
Pregnant woman delivered before interview			323 (19.9%)	
Woman misclassified as pregnant			7 (0.4%)	
No information available	65 (5.3%)	76 (4.7%)	75 (4.6%)	46 (2.8%)

* a total of 995 mothers were interviewed; including the 13 sets of twin births this gave us data on 1008 neonates.

4.4 Basic demographic variables

These are presented in Table 11 for all arms of the population-based studies.

Table 11 – Demographic variables of participants in population-based arms of the study

		Population-based survey of women (N=804)	Population-based survey of men (N=969)	Survey of pregnant women (N=1021)	Mothers of neonates (N=995)
Mean Age (SD)		32.68 (7.67)	31.45 (9.69)	26.82 (5.52)	27.01 (5.58)
Marital status	Single	0%	42%	0%	0%
	Married	99.5%	57.5%	100%	100%
	Divorced/ widowed	0.5%	0.5%	0%	0%
Occupation	Housewife	95.6%		97.1%	97.1%
	Fish-trade (fishing, trading, etc.)		4.9%	0.1%	
	Farmer		18.2%		0.1%
	In service	1.2%	17.6%	0.7%	0.8%
	In business	0.5%	13.8%	0.3%	
	Student	0.3%	10.9%	0.6%	0.8%
	Skilled labourer	0.1%	8.9%	0.2%	
	Labourer	0.2%	4.9%	0.1%	0.2%
	Unemployed		17.6%	0.4%	
	Other	2.1%	3.2%	0.5%	1%
Level of education mean years (S.D.)		2.66 (3.14)	5.11 (4.26)	2.83 (3.36)	3.57 (3.73)
Total number of pregnancies (S.D.)		3.59 (2.18)	-		
Contraceptive use *	None	21.4%	19.4%		
	OCP	16.2%	22.8%		
	DMPA	43.3%	41%		
	IUD	2.7%	2%		
	Tubectomy	11.1%	6.3%		

		Population-based survey of women (N=804)	Population-based survey of men (N=969)	Survey of pregnant women (N=1021)	Mothers of neonates (N=995)
	Condom	4.1%	2.5% ^a		
	Vasectomy		0.2%		
	Other	1.1%	5.8%		

* Contraceptive use asked of married men only (n=558)

^a The issue of condom use and attitudes to condoms is explored further in Section 4.8.6

4.5 Comparison of demographic variables of participants and non-participants

The DSS and RKS datasets were used to collate information regarding the basic demographic variables for both participants and the sample frames from which the participants were drawn, as well as their spouses (where applicable). The prevalence of demographic variables for all those originally eligible for inclusion in the study are presented in Appendix 4.

Comparisons of means of demographic variables between the participants, sampling frames and census lists yielded the following results:^a

i. Population-based survey of women

The only significant differences between all groups in the stratified sampling frame (participants, refusers, absentees, out-migrants) were found in contraceptive use: refusers were more likely to not be using any contraception at all (37.5% vs. 27.9%; $p=0.004$); absentees and refusers were less likely to

^a Decisions on whether to use the overall demographic datasets (DSS or RKS) as baseline for comparison with participants' data, or the stratified sampling frames as baseline, were made on the data available to the study. Some difficulty was experienced in obtaining baseline demographic variables especially for the DSS (census) lists. In these cases, comparisons were made between participants and other groups in the sampling frame (refusers, out-migrants, absentees, or those not interviewed for other reasons such as lack of time). Otherwise, comparisons were made between participants and the demographic dataset. Similarly, comparisons were also made between those in the sampling frame who did not participate, and either the participants themselves or the demographic datasets.

be using DMPA (injectable long-acting contraception) when compared to participants. Comparison of the sampling frame and the original dataset (RKS list) did not yield any significant differences.

ii. Population-based survey of men

Differences were found between the group of out-migrants (n=153) and the other groups in the sampling frame: they were younger (mean 26.4 years vs. 31.5 years; $p<0.0001$), less well educated (mean 0.9 years education vs. 3.9 years; $p<0.0001$) and more likely to never have been married (90.2% vs. 40.1%; $p<0.0001$). The smaller number of men who declined to take part (n=37) were older than average (mean 35.1 years vs. 31.5 years; $p=0.02$), but other demographic variables were no different to the sample frame. When comparing participants (969 men) with all those in the original demographic dataset (DSS list), participants were better educated than average (mean 5.1 years education vs. 3.9 years; $p<0.0001$).

iii. Pregnant women

During the course of the study, 1626 women in 2 of the Matlab Blocks (see Chapter 3) were registered as pregnant and therefore eligible for inclusion in the study. Comparisons between those interviewed or not and the total eligible group of 1626 women, showed that the interviewees were slightly better educated (mean 3.1 years education vs. 2.8 years; $p=0.03$); whilst the group of eligible women who were not interviewed (due to lack of time) were younger than average (24.3 years vs. 26.5 years; $p<0.0001$). The 1626 eligible women were younger than the total RKS data-file of 17,820 women (mean 26.5 years vs. 31.5 years; $p<0.0001$).

iv. Mothers of neonates

A total 1670 babies were registered as being born during the course of the study in the other two Matlab blocks, and therefore eligible for inclusion. Absent women were again younger (23.5 years vs. 26.4 years; $p<0.0001$), and they were also slightly better educated than the entire group of 1670 eligible pregnant women (mean 4.6 years education vs. 3.5 years; $p=0.001$). Again, the

eligible mothers were younger than the total RKS data-file of women (26.4 years vs. 31.5 years; $p < 0.0001$).

4.6 Prevalence of RTIs/STIs (all groups)

Tables 12 and 13 presents the overall prevalence data for all 5 arms of the study, showing laboratory results. Exact prevalence is presented along with 95% confidence intervals^b. Note that laboratory results are not available for every test on every participant. The reasons for this are outlined below:

- *Chlamydia trachomatis*: confirmatory PCR testing was carried out on as many samples as possible, but we were unable to send 100% of all samples to Canada owing to a shortage of money for dry-ice transport;
- *T.vaginalis* culture kits were not available to us at the start of the project;
- Bacterial vaginosis – we experienced occasional shortages of pH paper, and more frequent shortages of potassium hydroxide, during the project. Since we were using Amsell’s criteria to diagnose BV in the population-based survey of women, we do not have BV results on all these women. However, we do have microscopy results for every woman in this part of the survey. For the survey of symptomatic women, vaginal slides which had been read according to Amsell’s criteria were then sent to the United States (Louisiana State University) for confirmatory diagnosis according to Nugent’s criteria – see Section 3.8, Table 9. A shortage of funds precluded us from being able to read the population-based slides using these criteria.
- Candida – similarly, we do not have candida results for all women in the survey since we occasionally lacked pH paper and this was included in our definition of candida (see Table 9).
- Cytology, HIV and Hepatitis B infection - results are available for approximately 500 randomly selected women and men for each of these diagnoses. The numbers reflect the amount of money available to us to carry out tests for these infections/diagnoses.

^b In the case of HIV, since no positive infections were found (prevalence = 0%), the upper limit of the 95% confidence interval refers to the hypothetical result obtained when using Hanley’s formula to estimate the probability of an event which has not yet occurred. In this case, the upper limit of the 95% confidence interval (maximum risk) is calculated from the equation $3/n$. Ref: Eypasch E, Lefering R, Kum CK, Troidl H. Probability of adverse events that have not yet occurred: a statistical reminder. *BMJ* 1995; 311(7005):619-620

Main findings from these results are as follows:

- The prevalence of STIs in all groups is low (around 3% have a current STI, including those with active syphilis);
- The prevalence of endogenous infections in the population-based group of women is also relatively low;
- Symptomatic women attending clinics have a moderate-high level of endogenous infections;
- The prevalence of active syphilis across all groups is similar (0.5-0.9%);
- 1.2% of neonates suffer from ophthalmia neonatorum.

As stated, further laboratory tests were carried out on subsets of the population-based groups of men and women. The results of these tests are shown in Table 13. The main findings from these studies are:

- No HIV-infected persons were identified in the course of the study
- The prevalence of both hepatitis B anticore (past infection) and surface antigen (potentially infectious to others, and possibility of future chronic/fatal liver disease) is high in this population
- There is a low prevalence of cervical dysplasia in the female population

The RTI/STI prevalence and associated risk factors will be further explored for each study group in turn in the remainder of this chapter. Each of the following sections also outlines the main findings in the five arms of the study: population-based surveys of women and men, pregnant women, mothers of neonates, symptomatic women. The chapter then concludes with a review of the newly established male sexual health clinics

Table 12 Prevalence of named RTIs/STIs showing percentage and 95% confidence intervals

	PREGNANT WOMEN (N = 1021)	NEONATES (N = 964 babies and N= 995 women seen)	POPULATION-BASED WOMEN (N = 804)	SYMPTOMATIC WOMEN (N = 465)	POPULATION-BASED MEN (N = 969)
<i>Neisseria gonorrhoeae</i>		3/964 = 0.3% [0.08 - 0.8]	4/804 = 0.5% [0.16 - 1.20]	1/465 = 0.2% [0.01 - 1.11]	
<i>Chlamydia trachomatis</i>		9/964 = 0.9% [0.45 - 1.71]	4/753 = 0.5% [0.17 - 1.3]	4/449 = 0.9% [0.28- 2.13]	3/607 = 0.5% [0.13 - 1.33]
Active syphilis (RPR+/TPHA+)	7/1021 = 0.7% [0.30-1.35]		6/804 = 0.7% [0.30 - 1.55]	4/465 = 0.9% [0.27 - 2.10]	9/942 = 0.5% [0.19 - 1.17]
Latent or treated syphilis (RPR-/TPHA+)	1/1021 = 0.1% [0.00 - 0.48]		4/804 = 0.5% [0.16 - 1.20]	1/465 = 0.2% [0.01 - 1.11]	6/942 = 0.6% [0.26 - 1.32]
<i>Trichomonas vaginalis</i>			5/661 = 0.8% [0.28 - 1.67]	6/395 = 1.5% [0.62 - 3.13]	
Bacterial vaginosis *			28/478 = 5.9% [4.00 - 8.24]	79/418 = 18.8% [15.36 - 22.87]	
Candida			53/796 = 6.7% [5.11 - 8.55]	58/460 = 12.6% [9.81 - 15.88]	

* Bacterial vaginosis diagnosed according to Amsell's criteria for population-based women and Nugent's criteria for the symptomatic women

Table 12 contd. – prevalence of any current infection (selected groups)

	NEONATES (n = 964 babies and n= 995 women seen)	POPULATION -BASED WOMEN (n = 804)	SYMPTOMATIC WOMEN (n = 465)
Any current cervical infection (gonorrhoea or chlamydia)		8/753 = 1.1% [0.49 – 2.01]	5/449 = 1.1% [0.41 – 2.45]
Any current STI (gonorrhoea, chlamydia, active syphilis or trichomonas)	12/964 = 1.2% [0.67 – 2.11]	19/630 = 3.1% [1.91 – 4.66]	14/385 = 3.6% [2.08 – 5.88]
Any endogenous infection (candida or bacterial vaginosis*)		56/475 = 11.8% [9.11 – 14.92]	133/418 = 31.8% [27.48– 36.40]

* Bacterial vaginosis diagnosed according to Amsell's criteria for population-based women and Nugent's criteria for the symptomatic women

Table 13 – Prevalence of selected STIs/Conditions (percentage and 95% confidence intervals)

	Women			Men		
	<i>Number tested</i>	<i>Number positive</i>	<i>% and 95% C.I.</i>	<i>Number tested</i>	<i>Number positive</i>	<i>% and 95% C.I.</i>
Abnormal cytology	482	3	0.62% [0.16 - 1.68]			
HIV	458	0	0% [0 - 0.65]	444	0	0% [0 - 0.67]
Hepatitis B anti-core	494	189	38.3% [33.98 - 42.61]	483	256	53.0% [48.54 - 57.43]
Hepatitis B surface antigen	82	12	5.6% *	122	23	9.9% *

* Insufficient serum precluded the testing of all anti-core positive samples – see Section 4.10.2 for a full explanation.

4.7 Population-based survey of women

4.7.1 Symptoms reported by women

Table 14 details the reported current symptoms from women in response to unprompted open questioning about their current reproductive health concerns. Responses were coded for up to three separate symptoms. It can be seen that the majority of women (63.6%) reported at least one abnormal reproductive symptom on the day of interview. The most common symptom was that of abnormal vaginal discharge (38.7%); other common symptoms were lower abdominal pain (18.4%), genital prolapse (12.3%) and genital itching (11.6%).

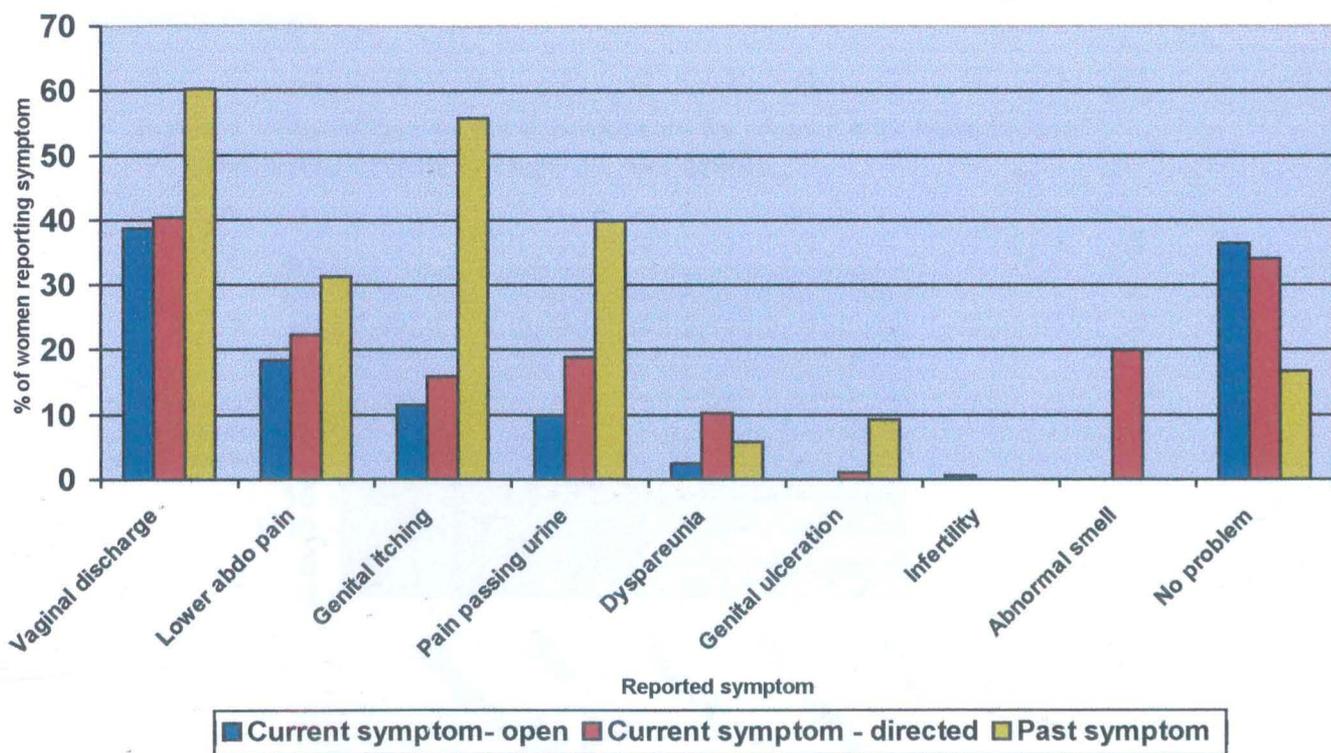
Table 14 – Current symptoms reported by women in the population-based survey

Reported symptom(s)	% of women reporting symptom (N = 804)
No problem	36.4%
Abnormal vaginal discharge	38.7%
Lower abdominal pain	18.4%
Genital prolapse	12.3%
Genital itching	11.6%
Pain passing urine	10%
Dyspareunia	2.5%
Infertility	0.6%

Any current abnormal symptoms were more likely to be reported by women using IUDs as contraception, and less likely to be reported by women using DMPA ($p=0.004$). There was no relationship between reported symptoms and the woman's age, educational level or occupation.

Further questions were directed towards establishing how many women would respond positively to directed questioning concerning named symptoms (as opposed to open questioning) and how many had suffered from any reproductive health symptoms in the past. For all named symptoms, more women responded positively to a directed than to an open question – see Figure 2. A minority of women (16.7%) stated that they had never suffered from a reproductive health problem in the past.

Figure 2 – Prevalence of current and past RTI/STI symptoms among population-based women

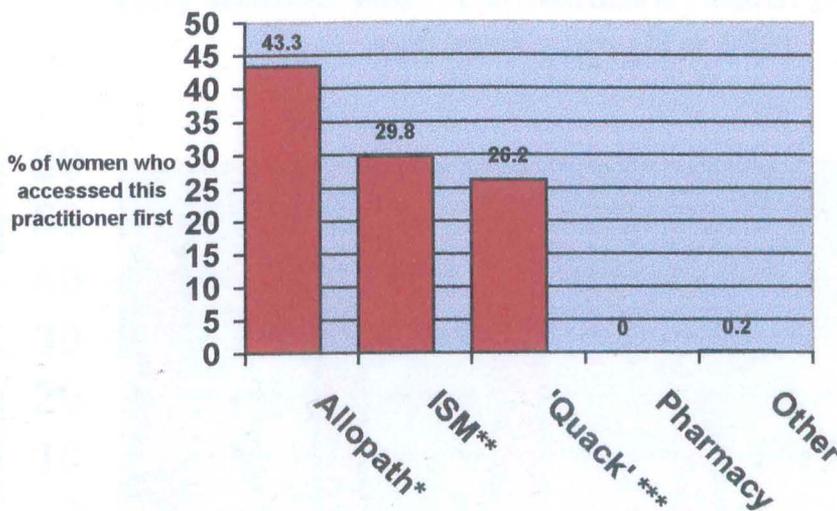


Note that in the above Figure the women who openly reported a current symptom (blue column) are all included within the group recorded as responding positively to a directed question on current symptoms (red column).

4.7.2 Treatment-seeking histories in women

Women in the population-based surveys were asked to state (whether and) where they had first sought treatment for current or previous symptoms of the reproductive tract (but excluding symptoms concerned with irregular or abnormal menstruation). They were asked in general about any of a number of symptoms they may have suffered from. Figure 3 outlines the treatment-seeking histories of the 543 women who said that they had ever sought care for an abnormal current or past symptom in the reproductive tract – possibly due to an RTI. The most common site of health care was outside the public sector/ICDDR,B system. Common sources of health care included indigenous systems of medicine practitioners, village-based ‘quacks’ and private allopathic doctors.

Figure 3 – Site of first access to health care for women with reproductive health problems (current or past). N= 543 women



* Allopathic practitioners here usually refer to the ICDDR,B system of medical care. However, it also includes the Government sector and any private allopathically qualified medical practitioners visited.

** Indigenous systems of medicine (ISM) practitioners include those practising herbal and homeopathic medicine, amulet sellers, and traditional healers.

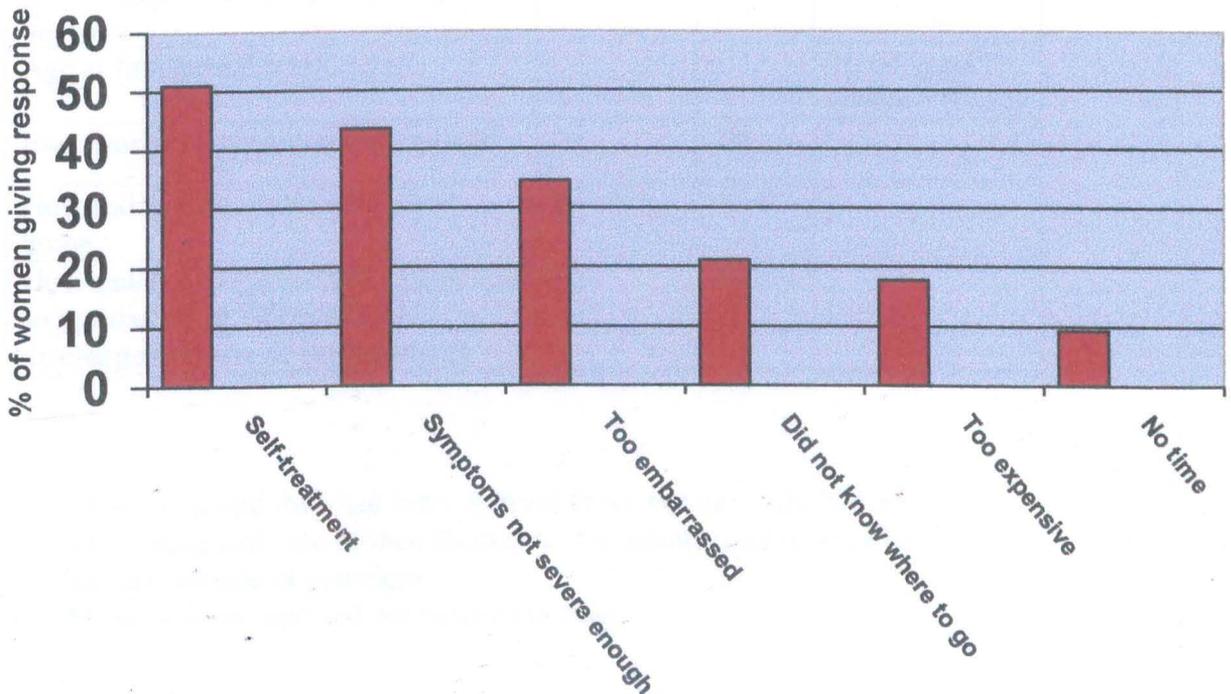
*** ‘Quacks’ are village-based practitioners with little or no formal medical training (often people who have, for example, worked as a drug-seller at some point) who usually dispense allopathic medicines.

4.7.3 Why treatment was not sought

If a woman had suffered from any abnormal symptom of reproductive health but had not sought care, reasons why were explored through the use of pre-coded questions and one open question- see Figure 4. A total of 502 women said that they had experienced abnormal symptoms but had not sought care for them. The most common reason women did not seek outside care was self-treatment at home. Large numbers of women reported that they were too embarrassed to seek care, and up to one fifth of respondents said they did not know where to go for treatment. Between 15 and 31% of respondents stated that outside treatment was too expensive, hence they had not sought care.

Figure 4

Why women with reproductive health problems did not seek care (N = 502)



4.7.4 Sexual behaviour reported by women

Women were asked a number of questions relating to possible risk factors for STI transmission and the presence of STIs: number of sexual partners in lifetime/past one year^c, age at first sexual intercourse, number of marriages, occupation and mobility of self and spouse, symptoms present in spouse. These were then investigated as possible risk factors through bivariate analysis of association – see Section 4.7.5. The prevalence of the possible risks and indicators of STIs among women is presented in Table 15.

Table 15 – Prevalence of possible STI risk factors and/or indicators among women

Possible Risk Factor (N = 804)	N	%	Mean
Age at first marriage			16.51 years (range = 9-30)
Any sexual intercourse before marriage	0	0	
More than one marriage in lifetime	58*	7.2%	
More than one sexual partner in lifetime	49*	6.1%	
More than one sexual partner in past one year	0	0	
Age at first sexual intercourse			16.64 years** (range =10-30)
Ever worked outside her own village	16	2%	
Husband spends nights away from home	371/799	46.4%	
Husband/sexual partner has symptoms suggestive of an STI (urethral discharge, dysuria or genital ulcer)	269	40.6%	

* 9 women said they had been married twice but had only had sexual intercourse with one of their husbands. No women told us they had ever had sex outside of marriage.

** No women reported sex before marriage.

^c Whilst the published WHO syndromic management algorithms recommend asking about sexual behaviour in the preceding three months, the female health care workers felt that this short time-scale would yield few positive results in this population of women. Therefore, they recommended increasing the question time-frame. However, see results on following page.

It can be seen that no women reported non-marital sexual behaviour - in marked contrast to the reported behaviour of men, see Tables 22 and 23. One woman did, however, decline to answer the question on her number of sexual partners within the past year. However, a large number of women reported proxy indicators of risk or infection in their husbands – 46% of husbands had spent some or most nights away from home in the last month, and 40% were reported to have symptoms of urethral discharge, genital ulcer disease or pain passing urine.

4.7.5 Prevalence of RTIs/STIs in population-based women, and risk factor analysis

The prevalence of both endogenous and sexually transmitted infections in the 804 women in the population-based survey is shown in Tables 12 and 13. It can be seen that the prevalence of STIs is low: 3.1% (19/620) of women, for whom all test results are available, have a current STI (gonorrhoea, chlamydia, trichomonas or active syphilis). This includes 8 women with cervical infections (gonorrhoea or chlamydia), and 6 women who were RPR+/TPHA+. The prevalence of endogenous infections was at a moderate level – 11.8% of women had either candida or bacterial vaginosis (only one woman had both infections) diagnosed.

Table 13 shows that the population-based prevalence of abnormal cytology in these women was also low – only 3 of the 482 slides tested showed any abnormality: one showed mild dyskaryosis; one had koilocytosis; and one showed signs of possible adenocarcinoma. All three women were referred to the Gynaecology Department of Dhaka Medical College (a free public sector hospital). It should be noted that a further 3.4% of smears showed signs of inflammatory changes. Results of the surveys of both hepatitis B infection (linked survey) and HIV (unlinked anonymous) will be explored further in Section 4.10.

Results of risk factor analysis for endogenous infections in population-based women are presented in Table 16. Unadjusted ORs are derived from bivariate analysis; any variables with $p < 0.10$ were then included in a logistic regression model. Given the large number of missing test results (see Section 4.6), in

order to make maximum use of the data, if any one infection was present in any woman, but results from other tests are missing, the woman is still included in the analysis. Risk factor analysis data is available for a total 499 women, although row totals may be lower in some cases owing to some missing data for risk factors.

Table 17 details the results of risk factor analysis for the presence of current sexually transmitted infections (*N.gonorrhoeae*, *C.trachomatis*, *T.vaginalis* and active syphilis) in the same women. Owing to the low prevalence of STIs it was not possible to control for possible confounders, therefore, unadjusted odds ratios (ORs) are presented.

Table 16 – Risk factors for endogenous infections – population-based women (N=499)

Possible risk factor		r/n	Percentage of women with endog.inf.	Unadjusted OR	Adjusted OR	P
Religion	Muslim	61/431	14.2%	1	1	0.015
	Hindu	19/68	27.9%	2.35	2.99	
Contraception	None	24/123	19.5%	1	1	
	DMPA	24/212	11.3%	0.53	0.73	0.69
	IUD	6/12	50%	4.12	2.73	0.21
	Condom	2/23	8.7%	0.39	0.18	0.11
	Tubectomy	11/46	23.9%	1.3	1.02	0.98
	OCP	13/78	16.7%	0.82	0.38	0.05
Age group	< 25 years	14/105	13.3%	1		
	25-34 years	35/213	16.4%	1.28		0.47
	35+ years	31/181	17.1%	1.34		0.4
Schooling	0 years	43/240	17.9%	1		
	01-05 years	29/176	16.5%	0.9		0.7
	06+ years	7/76	9.2%	0.46		0.07
Season when seen	Cold, dry	23/73	31.5%	1	1	
	Hot, dry	24/185	13%	0.32	0.37	0.047
	Hot, wet	33/241	13.7%	0.34	0.41	0.058
Sanitary protection	Cloth/towel made at home	62/331	18.7%	1	1	0.41
	Other	18/167	10.85	0.52	0.69	
Number of times per day that she changes sanitary protection	1	2/8	25%	1	1	
	2	22/192	11.5%	0.39	0.25	0.22
	3+	56/297	18.9%	0.7	0.29	0.28
Days since LMP	<11	15/47	31.9%	1	1	
	11-20	21/138	15.2%	0.38	0.37	0.02
	21+	11/46	23.9%	0.67	0.72	0.55
Having regular menstruation	Yes	47/229	20.5%	1	1	0.98
	No	33/270	12.2%	0.54	0.97	

Table 17 – Risk factors for sexually transmitted infections – population-based women (n=620)

Possible risk factor		R/n	Percentage of women with STI	Unadjusted OR	P
Religion	Muslim	18/522	3.5%	1	0.34
	Hindu	1/98	1.0%	0.29	
Contraception	None	5/129	3.9%	1	0.95
	DMPA	8/272	2.9%	0.75	
	IUD	1/15	6.7%	1.77	
	Condom	1/26	3.9%	0.99	
	Tubectomy	2/71	2.8%	0.72	
	OCP	2/99	2.0%	0.51	
Age group	< 25 years	4/116	3.5%	1	0.83
	25-34 years	7/268	2.6%	0.75	
	35+ years	8/236	3.4%	0.98	
Schooling	0 years	10/290	3.5%	1	0.85
	01-05 years	6/228	2.6%	0.76	
	06+ years	2/95	2.1%	0.6	
Occupation	Housewife	19/562	3.3%	-	1.00
	In service	0/8	0%	-	
	Other	0/27	0%	-	
Working outside her village	Yes	0/0		-	-
	No	19/620	3.1%	-	
Marital status	Married	18/596	2.9%	1	0.17
	Divorced/ Widowed	1/6	16.7%	6.6	
Number of marriages in lifetime	1	15/564	2.6%	1	0.03
	2+	4/41	9.8%	4.06	
Husband's occupation	Manual labour	9/315	2.9%	1	0.007
	Skilled labour	3/116	2.6%	0.9	
	Business	4/174	2.3%	0.8	
	Irregular	2/9	22.2%	9.7	
Husband spent nights away in the past month	Most/all	6/219	2.7%	0.8	0.65
	Occasional	1/72	1.4%	0.4	
	None	11/324	3.4%	1	
Husband symptomatic	Yes	5/209	2.4%	0.8	0.7
	No	9/304	3.0%	1	

Highlights of the identified risk factors for the presence of endogenous infections (after adjusting for possible confounders), and sexually transmitted infections (no logistic regression possible) are presented below:

i. Endogenous infections (candida and bacterial vaginosis) were more commonly found in the following women:

- Hindu women

The following situations were associated with a reduced risk of endogenous infection:

- Use of the oral contraceptive pill
- Hot season of the year
- Time since last menstrual period (mid-cycle)

Endogenous infections were found slightly more commonly in older women, and in women with fewer numbers of years of education, but neither of these associations was statistically significant. Women who used shop-bought sanitary protection were less likely to suffer from an endogenous infection when compared to those women who made their own cloths/towels; again this association did not reach statistical significance. Other demographic and behavioural variables (age, education, other menstrual hygiene practices) were not associated with an increased or decreased risk of endogenous infections in the women seen.

ii. Sexually Transmitted Infections were found slightly more commonly in women who had been married more than once in the course of their lifetime, and whose husbands were in irregular occupations (domestic labour, begging or unemployed). No other statistically significant risk associations for the STIs were found in the population-based survey of women. However, there were several possible risk factors with larger (but non-significant) odds ratios on analysis:

Increased risk:

- divorced/widowed women (although note that this higher risk refers to only one woman. This woman had been widowed four weeks prior to

participating in the survey, and told us that her husband had been having an affair prior to his suicide)

- IUD users

Decreased risk:

- Hindu women
- OCP users
- Women whose husbands are occasionally away from home (compared to those who are always at home)
- Women with more years of schooling

4.7.6 Clinical examination of women

The population-based survey of women was undertaken in three main stages – a private interview using a mixture of precoded and open questions (results presented above), a full clinical examination (including but not limited to an examination of the reproductive tract), and microbiological diagnosis of clinical samples looking for the presence of RTIs/STIs (results presented in Tables 12 and 13). The following section outlines the results of the clinical examination of women – carried out by one of the two project physicians (SH or KG). The standard criteria used for the diagnosis of abnormality are outlined in Section 3.1.1, Table 7.

Selected clinical signs and reported (open, i.e. not directed questioning) symptoms were then analysed as possible predictors of the presence of infection in the 804 population-based women. The results of this analysis (sensitivity, specificity and positive predictive value of each variable) are presented in Table 18. For comparison of these results with the findings from symptomatic women, see Tables 29 and 34.

Table 18 - Clinical signs recorded by physicians on 804 population-based women

Clinical Sign	Number of women with clinical sign/ abnormality (N= 804)	%
<i>Non-reproductive tract signs</i>		
Pyrexial	68 (8.5%)	8.5%
Hypertensive (diastolic >95mm Hg)	14 (1.7%)	1.7%
Breast problem		
• Lump (probably benign)	1	0.1%
• Lump (poss. malignant)	0	0
• Mastitis	2	0.2%
• Fibroadenosis	2	0.2%
• Other abnormality	3	0.4%
<i>Reproductive tract signs</i>		
Lower abdominal tenderness	12	1.5%
Genital ulcer seen	5	0.6%
Genital warts	1	0.1%
Inguinal lymphadenopathy	25	3.1%
Vulval candida	16	2%
‘Abnormal-looking’ vaginal discharge	131	16.3%
Vaginal discharge looks ‘clumpy’	49	6.1%
Cervical mucopus	11	1.4%
Cervical friability	39	4.9%
Cervical ectopy	202	25.1%
Cervical motion tenderness	11	1.4%
Genital prolapse	81	10.1%
<i>Diagnostic tests on site</i>		
pH of vaginal discharge > 4.7	402	50%
KOH (‘whiff’) test positive	33/408	6.9%

Table 19: Association of microbiological infection with reported symptoms (on open questioning*) and recorded clinical signs (N=804)

Variable (symptom or sign) as predictor of the presence of any infection and/or a specific named infection	Sensitivity of variable	Specificity of variable	Positive Predictive Value
<i>Symptoms reported^a/possible infection present</i>			
Any symptom in reproductive tract/Any infection present	68.8%	38%	16.3%
Complaint of abnormal discharge			
• Any infection	43.3%	62.1%	13.4%
• Endogenous infection	41.3%	62.3%	17.3%
Complaint of itch/candida	13.2%	95.8%	18.4%
Complaint of lower abdominal pain			
• Any infection	13.3%	81.1%	8.7%
• Cervical infection	37.5%	81.9%	2.2%
Complaint of dyspareunia/Any infection	3.3%	97.6%	15.8%
Complaint of genital ulcer disease/Active syphilis	0%	100%	0%
Complaint of abnormal smell/Bacterial vaginosis	25%	82%	8%
<i>Recorded signs on clinical examination/ possible infection present</i>			
Cervical pus/Cervical infection	12.5%	98.7%	9.1%
Cervical ectopy/Cervical infection	0%	74.9%	0%
Genital ulcer disease/Syphilis	0%	99.4%	0%
Clumpy discharge/Candida	15.1%	94.5%	16.3%
pH vaginal fluid > 4.7/Bacterial vaginosis ^b	100%	53.1%	11.7%
KOH (whiff) test positive/Bacterial vaginosis ^b	82.1%	97.8%	69.7%

Legend for Table 19:

Any infection = chlamydia, gonorrhoea, syphilis, *Trichomonas vaginalis*, bacterial vaginosis or candida

Cervical infection = chlamydia or gonorrhoea

Endogenous infection = bacterial vaginosis or candida

^aall questions were open except for 'abnormal smell' which was not reported by any women and was therefore asked directly as a prompted question

^b Amsell's criteria for diagnosing BV includes these two criteria – therefore the sensitivity and specificity of these signs would be expected to be high

Table 19 shows that none of the recorded elicited symptoms or clinical signs were good predictors of the presence of infection – either endogenous infections or sexually transmitted infections (cervical or serological evidence of syphilis). The positive predictive values of the recognised clinical signs for cervical infection (cervical pus and/or ectopy) were particularly insensitive and had 0% PPV. Bedside diagnostics were of use in detecting bacterial vaginosis – pH paper and KOH were both sensitive and specific, but it should be noted that this refers to diagnosis of BV using Amsell’s criteria (which includes vaginal pH and KOH testing as part of the criteria). In the case of symptomatic women self-presenting to PHC centres, in order to avoid the problems of interpretation with Amsell’s criteria and the use of pH paper or KOH as diagnostic tools, Nugent’s criteria were used to diagnose BV. See Table 34 for comparative results.

4.8 Population-based survey of men

4.8.1 Symptoms reported by men

The population-based survey of men utilised the same mixture of open and directed questions as that used in the survey of women. Results are presented as current symptoms – open question (Table 20); current symptoms - directed questioning - and past symptoms (both in Figure 5).

Table 20 – Current symptoms reported by men in the population-based survey: open question

Reported symptom(s)*	% of men reporting symptom (n =969)
No problem	74.2%
Psychosexual problem**	16.7%
Pain passing urine	7.9%
Urethral discharge	3.1%
Urethral discharge plus dysuria	1%
Painful coitus	1.7%
Genital ulcer	0.6%
Genital itching	0.5%

Referring to Table 20:

* Men were coded for a maximum of three symptoms

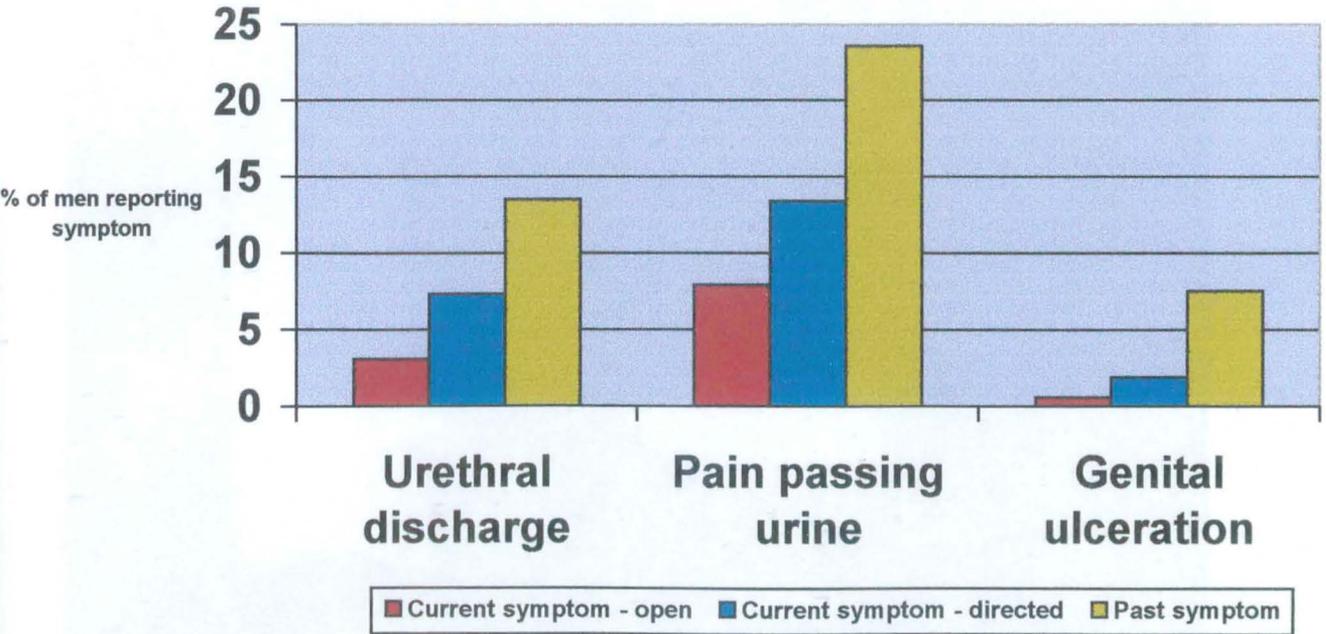
** Psychosexual problems include the following: premature ejaculation; impotence; 'dissatisfaction with sexual intercourse'; difficulty in maintaining an erection; "night pollution" (nocturnal emissions).

A majority of men (74.2%) on unprompted interviewing stated that they had no current problem. In contrast to the women who only reported physical symptoms, the most common group of problems in men related to psychosexual difficulties (premature ejaculation, 'dissatisfaction with sexual intercourse', difficulty in maintaining an erection, and nocturnal emissions). Physical symptoms were mainly those relating to a possible STI: 7.9% complained of pain passing urine and 3.1% said they had an abnormal urethral discharge.

Comparison of those reporting any current symptoms (on unprompted interviewing) against those who reported no sexual/reproductive health problems, showed that they were more likely (at statistically significant levels, $p < 0.05$) to be employed in agricultural/fishing work, manual labouring (unskilled and skilled work) or factory work, when compared to all other occupations, and were less likely to have ever been to school. There was no relationship with age and the likelihood of reporting symptoms.

Further interviewing asking direct (prompted) questions about 3 specific symptoms possibly indicative of an STI (urethral discharge; dysuria; and/or genital ulceration) again resulted in an increase in the numbers of all men reporting a specified current problem— as shown in Figure 5. This finding corresponds with that in the population-based survey of women, where directed questioning resulted in an increase in all positive responses when compared to open questioning. Also shown in Figure 5 are the number of men who reported having suffered from the symptoms at any time in the past.

Figure 5 - Possible STI symptoms reported by men



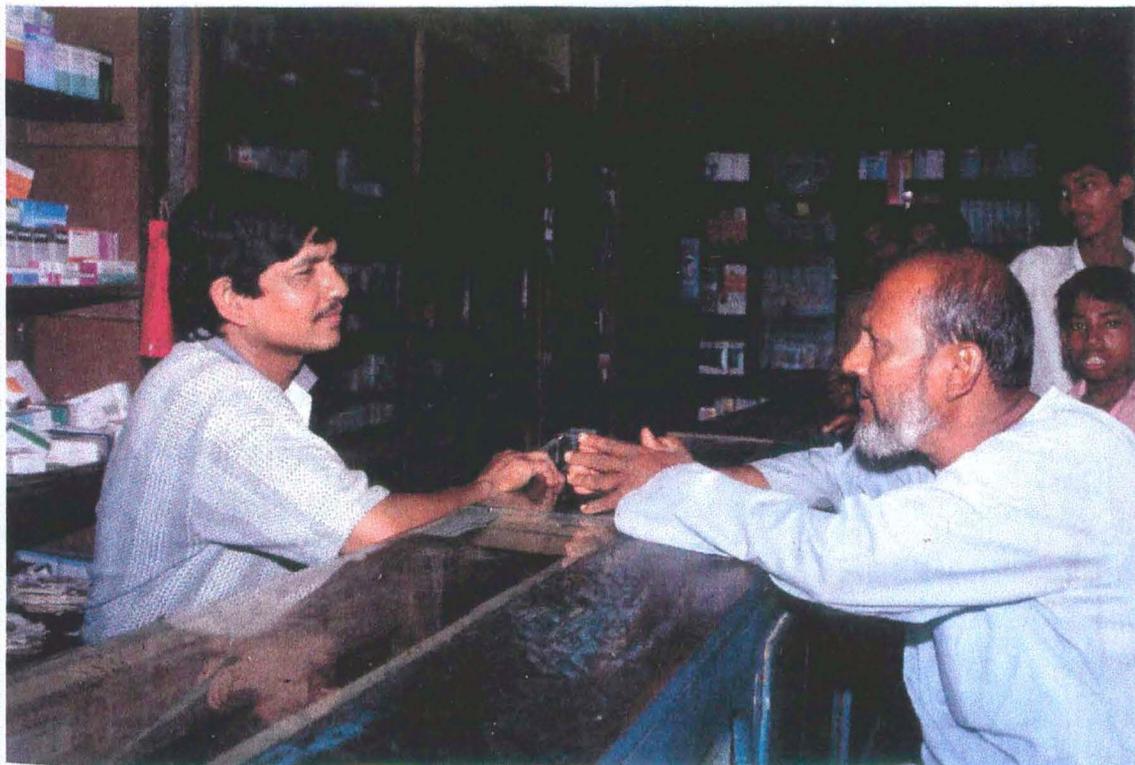
4.8.2 Treatment seeking histories among men

Men were asked about the site they first sought health care if they had suffered from any one of three named symptoms (see Figure 5, above) in the past. At the time the survey was started, no easily accessible public sector (allopathic) services existed for men with possible STIs. Thus, men who sought allopathic care were forced to use private sector providers. Photographs 4 and 5 were taken in the Matlab market and show typical unlicensed health care providers. This situation may have changed during the course of the survey with the establishment of the male sexual health clinics – see Section 4.14. However, men were specifically asked about past not current symptoms in order to avoid a time-bias during the survey.

Where men seek health care



Photograph 4 - herbal medicine seller



Photograph 5 - market pharmacist

Table 21 – Treatment-seeking histories for past symptoms, population-based men

	Urethral discharge (n = 146)	Pain passing urine (n = 273)	Genital ulcer disease (n = 82)
% with symptom who have sought health care	60.3% (88/146)	56.8% (155/273)	84% (69/82)
Site where health care was sought	n=88	N=155	n=69
Indigenous systems of medicine practitioner	53.4%	43.8%	27.6%
Village 'quack'	15.9%	16.8%	13.0%
Pharmacy‡	5.7%	11.6%	15.9%
Private allopathic doctor	23.9%	27.1%	27.5%
Self-treatment	0%	0.6%	2.9%

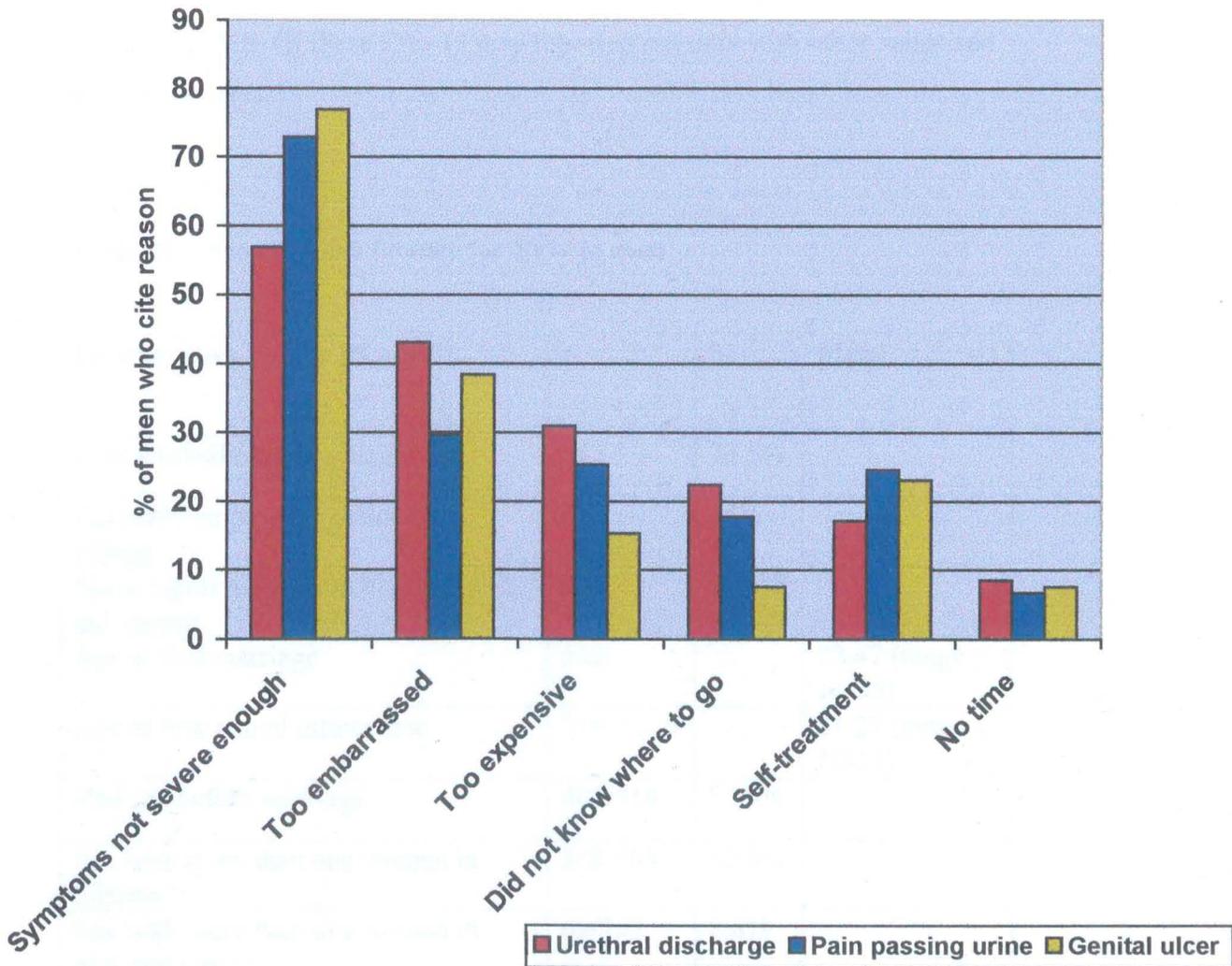
Same descriptions of informal medical sector apply as in footnotes for Figure 3, except that men could not use ICDDR,B services for reproductive/sexual health problems in the past.

‡ Pharmacy refers to a private drug seller – usually in a market place.

4.8.3 Why treatment was not sought

It can be seen from Table 21 that in a large minority of cases, symptomatic men did not seek health care. Using a set of pre-coded questions plus one open question (same format as for the survey of women), the most common reasons for not seeking care were explored. These results are presented in Figure 6:

Figure 6 - Why symptomatic men do not seek care



4.8.4 Risk behaviour reported by men

As with the surveys among women, men were asked a variety of social, demographic and sexual behaviour questions which were then analysed in terms of their possible risk association for the presence of STIs. Questions on sexual behaviour were more frequently answered positively by male respondents than the findings among their female counterparts (see Table 15 for comparison). This was despite the fact that male interviews took place in the man's home (as compared to a private interview at the clinic for women),

and privacy could in no way be guaranteed. Of the 969 men interviewed, a total of 716 reported that they had ever had sexual intercourse at any point during their lives. Therefore, the denominator for the sexual behaviour questions is 716. Of these 716, 13 men reported sex only with other males and not with females.

Table 22 – Possible risk factors for STIs in men

Possible Risk Factor (N = 969)	n	%	Mean
Ever worked outside village	712	73.5%	
Currently employed outside own village	330	34%	
Spent nights away from home in past one month	351	36.3%	
Age at first marriage	562		22.47 (range = 16-36)
Age at first sexual intercourse	716		21.27 (range = 10-36)
Had sex before marriage	400/716	55.9%	
Sex with more than one woman in lifetime*	368/703	52.3%	
Sex with more than one woman in past one year**	62/703	8.8%	
Ever paid for sex	127/705	18%	
Sexual relations with another man or boy***	55/716	7.7%	

* 277 men reported 2-4 sexual partners; 68 reported 5-9; and 23 reported 10+ female sexual partners. A majority of single men who had sexual experience (n=142) have had more than one sexual partner (92/142)

** This includes 28 married men who had sex with more than one non-spousal partner in the past year; and one man with two wives who had sex with three women during the year

*** 13 men reported sexual intercourse only with other men/boys and never with women.

4.8.5 Prevalence of STIs and risk factor analysis for population-based men

Table 12 outlines the prevalence of STIs found in men. We were only able to test men for two STIs: chlamydia and syphilis. We were unable to test men for *N.gonorrhoeae* as originally planned (using PCR on urine samples) owing to a newly-discovered lack of specificity in the PCR test kit – see Section 3.6, Table 9.

It can be seen that the prevalence of the 2 STIs in men did not differ significantly from the rate found in the population-based sample of women; 0.5% of men were RPR+/TPHA+ and 0.5% had *Chlamydia trachomatis* confirmed by PCR testing.

On analysis we found that one 29 year old man with active syphilis (RPR+/TPHA+) reported never having had sexual intercourse. Therefore, we used all participating men as the denominator for prevalence (i.e. 969 men) rather than restricting numbers to those who reported any sexual activity. However, for risk factor analysis we only included in the model those men who reported sexual activity.

Risk factor analysis in men was undertaken with all social, sexual behaviour and demographic variables included in the model (including those outlined in Tables 10 and 22). Again, given the low prevalence of STIs, bivariate analysis only was undertaken looking for risk associations for the presence of STIs.

Results of this analysis are presented in Table 23.

Table 23 - Risk factors for sexually transmitted infections, population-based men (Results only available for a maximum of 607 men with PCR results of whom 453 were sexually experienced, therefore sexual behaviour questions have a lower denominator)

Possible risk factor		r/n	Percentage of men with STI	Unadjusted OR	P
Religion	Muslim	7/516	1.4%	1	0.66
	Hindu	1/91	1.1%	0.81	
Contraception (used by man or his wife)	None	1/71	1.4%	1	0.20
	DMPA	4/140	2.9%	2.06	
	IUD	0/10			
	Condom	0/9			
	Tubectomy	2/20	10%	7.78	
	OCP	0/82			
Age group	< 25 years	0/217	0%		0.032
	25-34 years	5/182	2.8%	-	
	35+ years	3/207	1.5%	-	
Schooling	0 years	3/147	2.0%	1	0.21
	01-05 years	4/207	1.9%	0.95	
	06+ years	1/247	0.4%	0.19	
Occupation	Manual labour	1/47	2.1%	1	0.54
	Skilled labour	1/68	1.5%	0.69	
	Business	2/97	2.1%	0.97	
	Student	0/106	0%	-	
	Irregular	4/289	1.4%	0.65	
Marital status	Single	1/250	0.4%	1	0.19
	Married	7/353	2%	5.04	
	Divorced/ Widowed	0/4	0%		
Where working	In own village	6/406	1.5%	1	1
	In other rural area	1/97	1.0%	0.69	
	In urban area	1/014	1.0%	0.65	
Symptoms in female partner	Yes	2/108	1.9%	1.34	0.54
	No	3/213	1.4%	1	
Pre-marital sex	Yes	5/254	2%	1.98	0.47
	No	2/199	1%	1	
Number of female sexual partners in lifetime	1	2/197	1%	1	0.1
	2-4	2/185	1.1%	1.07	
	5-9	2/45	4.4%	4.53	
	10+	1/17	5.9%	6.09	

Table 23 contd.

Possible risk factor		r/n	Percentage of men with STI	Unadjusted OR	P
Number of female sexual partners in past one year	0	0/34	0%		0.25
	1	5/362	1.4%	-	
	2+	2/47	4.3%	-	
Sex with men (in lifetime)	Yes	1/36	2.8%	1.96	0.44
	No	6/417	1.4%	1	
Payment for sex (in lifetime)	Yes	3/84	3.6%	3.31	0.13
	No	4/362	1.1%	1	

STIs (syphilis and chlamydia) were found significantly more frequently in men aged 25-34 compared to the younger (<25 years) age groups.

Whilst no other variables proved to have a statistically significant association with the presence of STIs, it should be noted that the STIs were found more commonly in men reporting higher levels of sexual behaviour :

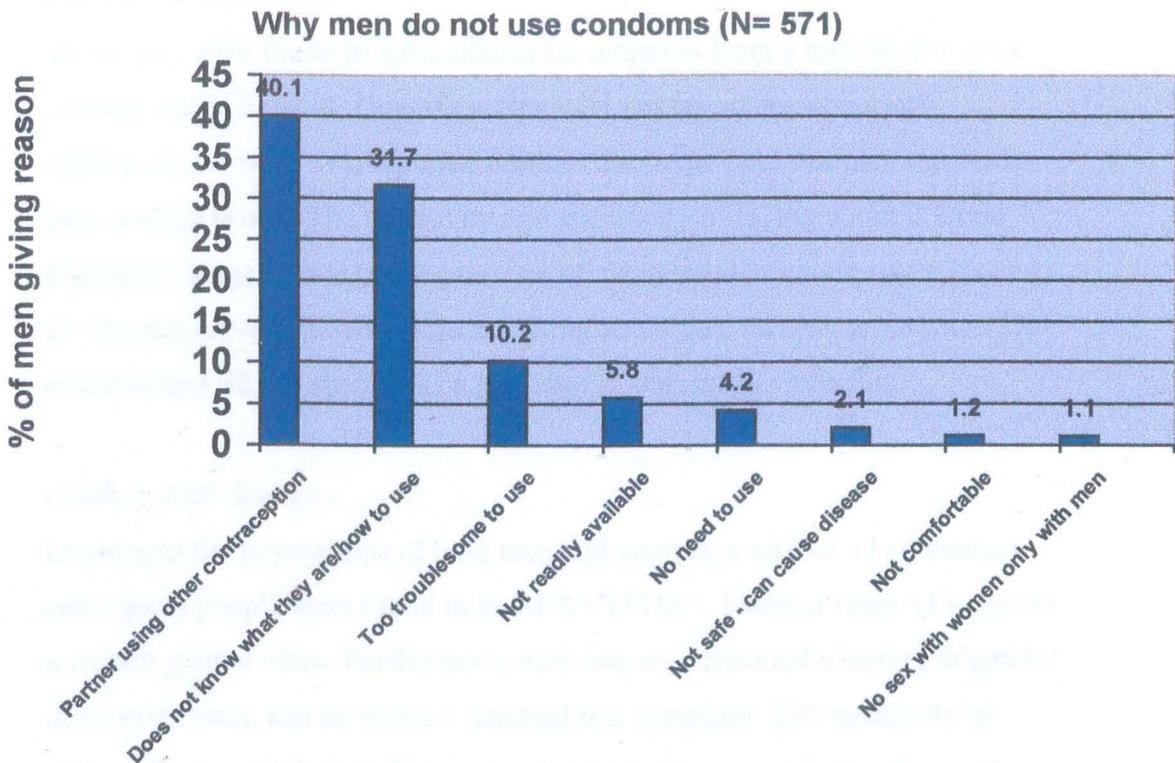
- Those who had experienced pre-marital sex
- Men who had sex with more than one woman (non-spousal) in the past year
- Men who reported 5 or more lifetime female sexual partners (note the trend of higher STI rates in men reporting more sexual partners)
- Men who had exchanged money and/or gifts etc. in return for sex
- Men who reported a history of sex with other men/boys.

4.8.6 Protection against risk – reported use of condoms

Table 11 indicates that 2.5% of the 558 married men interviewed about current contraceptive practice used condoms as their primary method of family planning. All men in the survey who had been sexually active (n=716) were asked whether they had ever used condoms at any time. A total of 145 (20.3%) sexually active men had used condoms at some point in their lives. If sexually active men had not used condoms they were asked why not – this was an open question and men were given the opportunity of reporting two separate reasons why they had not used condoms. The commonest reasons given for not using

condoms (n=571) were: partner using another form of contraception (40.1%); man does not know what condoms are or how to use them (31.7%); condoms are 'too troublesome' to use (10.2%); or they are 'not readily available' (5.8%). Very few men responded with other reasons: 'not easily disposed of' (0.5%); 'wife does not like them' (0.4%); or a perceived religious barrier to their use (0.2%). These results are presented in Figure 7.

Figure 7



4.9 Asymptomatic carriage of sexually transmitted pathogens

The population-based surveys of both men and women asked open and directed questions about current and past symptoms. Two-by-two table analyses of the reported symptoms and the laboratory-diagnosed presence of infection revealed the following:

Population-based women

Eight women (1%; 8/804) had either chlamydia or gonorrhoea. Half of the women (4/8) did not report any symptoms in the reproductive tract on either open or direct questioning. The four symptomatic women all reported abnormal vaginal discharge, and three of them also reported abdominal pain. The sensitivity and specificity of asking about other reproductive health questions as predictors for the presence of any RTI is outlined in Table 19.

Population-based men

Three men were found to have chlamydia infection from a total of 607 urine samples tested by PCR. One of the three did not report any abnormal symptoms; the other two reported urethral discharge (and one also reported pain passing urine). The sensitivity and specificity of asking about urethral discharge as a predictor of the presence of chlamydial infection was 67% and 97.1% respectively. In comparison, asking about pain passing urine was 33% sensitive and 92.7% specific as a predictor of chlamydial infection.

Genital ulcer disease

Looking at the populations of both men and women, a total of 11 (6 women and 5 men) people were found to be RPR+/TPHA+. None of these 11 reported a current genital ulcer. Furthermore, only one man reported a history of genital ulcer in the past, and no women reported this symptom. The sensitivity of asking about genital ulcer disease (past symptom) as a predictor of current active syphilis is therefore 9%, and the specificity is 96%. A similarly low sensitivity and positive predictive value of asking about these symptoms was found during the survey of pregnant women – see section 4.11 below.

4.10 HIV and Hepatitis B Infections

4.10.1 HIV Infection

A random selection of 458 female and 444 male serum samples were tested for HIV infection (1,2 and sub-type O) using unlinked anonymous procedures. Four serum samples were positive on initial ELISA testing. However, none of

these four were positive by Western Blot or PCR testing. Therefore, in this study, no cases of HIV were found among all the samples tested.

4.10.2 Hepatitis B infection

In the population-based survey of women, a total of 494 randomly selected serum samples were tested for hepatitis B anticore (HBAc). Thirty-eight percent (189/494) were anticore positive. Sufficient serum remained in 83 of the 189 anticore positive samples to be tested for hepatitis B surface antigen (HBsAg). Twelve of the 83 were HBsAg positive. Projected calculations of the number who would have been positive if we had been able to test all 189 serum samples suggested that 27 samples would have been HBsAg positive: i.e. 5.5% (27/494) of the female population were estimated to be HBsAg positive.

Similar tests and calculations among the population-based survey of men yielded the following results: a random selection of 483 serum samples were tested, of which 53% (256/483) were positive for HBAc. One hundred and twenty-seven of the 256 anticore positive samples were then tested for HBsAg, and 23 were positive. Back calculations yielded an estimated 46 men who would have been HBsAg if we had tested all 256 men, i.e. 9.5% (46/483) of the male population.

In summary:

	Women	Men
Hepatitis B Anticore positive	38.3%	53%
Hepatitis B surface antigen positive (estimates for the entire population)	5.5%	9.5%

Analysis of risk factors for evidence of both past exposure (hepatitis B anticore positive) and current infection or chronic carriage (hepatitis B surface antigen positive) yielded the following significant associations on bivariate analysis (Tables 24 and 25):

Table 24 - Risk associations for Hepatitis B anticore

Possible risk factor		Women (N=494)				Men (N= 483)				
		r/n	%	OR	p	r/n	%	OR	P	
Religion	Muslim	163/427	38.2	1	0.92	211/400	52.8	1	0.81	
	Hindu	26/67	38.8	1.03		45/83	54.2	1.06		
Age group	< 24 years	21/88	23.9	1	0.007	83/171	48.5	1	0.53	
	24-34 years	89/220	40.5	2.17		62/138	44.9	0.86		
	35+ years	79/186	42.5	2.36		111/172	64.5	1.92		0.003
Schooling	None	87/218	39.9	1	0.07 (<5 years compared to 6+ years)	67/114	58.8	1	0.09	
	01-05 years	74/185	40	1.00		89/183	48.6	0.66		
	06 +	25/85	29.4	0.63		97/180	53.9	0.82		0.41
Contra-ception	None	41/108	37.9	1	0.16	34/60	56.7	1	0.44	
	OCP	21/75	28	0.64		40/63	63.5	1.33		
	DMPA	88/216	40.7	1.12		62/111	55.9	0.97		0.92
	IUD	4/17	23.5	0.5		2/5	40	0.51		0.48
	Condom	7/22	31.8	0.76		4/9	44.4	0.61		0.49
	Tubectomy	27/52	51.9	1.76		11/15	73.3	2.1		0.25
Length of sexual exposure	0-9 years	40/138	28.9	1	0.11	82/165	49.7	1	0.41	
	10-19 years	67/178	37.6	1.48		65/119	54.6	1.22		
	20+ years	80/171	46.8	2.15		58/85	68.2	2.17		0.006
Marital status	Single	0	-		0.49	92/196	46.9	1	0.02	
	Married	187/490	38.2	1		164/285	57.5	1.53		
	Divorced/ Widowed	2/4	50	1.6		0/2	-			
Number of marriages	1	173/458	37.8	1	0.43	NA	-			
	2+	16/36	44.4	1.32						
Number of female sexual partners ever	1	NA	-			96/176	54.5	1	0.84	
	2-4					78/140	55.7	1.05		
	5-9					23/37	62.2	1.37		0.39
	10+					8/14	57.1	1.11		0.85
Number of female sexual partners past one year	0	NA	-			9/24	37.5	1	0.14	
	1					176/307	57.3	2.24		
	2+					19/33	57.6	2.26		
Paid money for sex	Yes	NA	-			28/57	49.1	1	0.11	
	No					178/310	57.4	1.4		

Table 25 - Risk associations for Hepatitis B surface antigen

Possible Risk Factor		Women (N=387)				Men (N= 359)			
		r/n	%	OR	P	r/n	%	OR	p
Religion	Muslim	12/339	3.6	-	0.19	16/290	5.5	1	0.13
	Hindu	0/48	-	-		7/69	10.1	1.92	
Age group	<24 years	0/75			0.03 (trend)	6/135	4.4	1	
	25-34 years	4/163	2.5			5/103	4.9	1.1	0.88
	35+ years	8/149	5.4			3/119	10.1	2.4	0.09
Schooling	None	8/168	4.8	1	0.38	6/76	7.9	1	
	01-05 years	4/143	2.8	0.58		9/145	6.2	0.77	0.64
	06+	0/71	-			8/134	5.9	0.74	0.59
Contra-ception	None	1/81	1.2	1		3/43	6.9	1	
	OCP	0/63				5/45	11.1	1.67	0.5
	DMPA	6/171	3.5	2.9	0.33	4/75	5.3	0.75	0.72
	IUD	1/15	6.7	5.7	0.23	0/3			
	Condom	1/17	5.9	5	0.26	1/9	11.1	1.66	0.68
	Tubectomy	3/37	8.1	7.1	0.09	1/12	8.3	1.2	0.87
	Other					2/5	40	8.89	0.05
Length of sexual exposure	0-9 years	0/111			0.05 (trend)	4/121	3.3	1	
	10-19 years	4/133	3.0			8/84	9.5	3.1	0.07
	20+ years	8/137	5.8			6/62	9.7	3.1	0.09
Marital status	Single	0	-		0.91	7/153	4.6	1	0.22
	Married	12/384	3.1	-		16/204	7.8	1.78	
	Divorced/ Widowed	0/3	-	-		0/2	-		
Number of marriages	1	11/359	3.1	1	0.59	NA	-		
	2+	1/28	3.6	1.18					
Number of female sexual partners ever	1	NA	-			7/129	5.4		
	2-4					7/97	7.2	1.36	0.58
	5-9					3/28	10.7	2.1	0.31
	10+					1/9	11.1	2.18	0.49
Number of female sexual partners past one year	0	NA	-			1/19	5.3	1	
	1					14/220	6.4	1.2	0.85
	2					3/23	13.0	2.7	0.41
Paid money for sex	Yes	NA	-			3/43	6.9	1.05	0.97
	No					15/220	6.8	1	

Given the relatively high prevalence of hepatitis B infection among both men and women, multivariate analysis was undertaken. Unadjusted ORs in Tables 24 and 25 are derived from bivariate analysis; any variables with $p < 0.10$ were then included in a logistic regression model. This yielded the following results:

Hepatitis B anticore positive

Men	Women
<ul style="list-style-type: none"> • Age confounds the association with other variables which were significant in the bivariate analysis. After adjusting for age, these variables no longer contribute significantly to the model. • The only explanatory variable is age; a significantly higher risk in >35 year olds compared to younger age groups (OR=1.93, $p=0.003$) 	<ul style="list-style-type: none"> • On multivariate analysis, age is still significantly associated with higher risk: OR=1.94, $p=0.001$ for >30year olds vs. <20 year olds. • After adjusting for age, tubectomy was no longer associated with higher risk, but OCP was protective relative to no protection (OR=0.54, $p=0.03$)

Hepatitis Surface Antigen Positive

Men	Women
Too few cases for adjusted analysis	Too few cases for adjusted analysis

4.11 Results from survey of pregnant women

A total of 1021 pregnant women out of an eligible 1626 were interviewed (see Table 10) and gave finger-prick blood samples which were tested for serological evidence of syphilis infection. Of these 1021, 7 (0.7%) were RPR and TPHA positive, and a further one woman was TPHA positive only. Risk factor analysis was carried out for all women against those who were found to be both RPR and TPHA positive (7/1021) – i.e. those women with active syphilis. Further analysis was undertaken to see if there was any association between complaints of clinical symptoms (current or past genital ulcer) and serological evidence of syphilis infection – see Table 26.

Table 26 – Demographic and clinical variables in pregnant women with and without serological evidence of syphilis (RPR+/TPHA+)

Possible risk factor		r/n	%	Unadjusted OR	P
Religion	Muslim	4/796	0.5	1	0.2
	Hindu	3/225	1.3	2.68	
Age group	15-20 years	0/95	-	-	-
	20.1 – 25 years	4/335	1.2	-	
	25.1 – 30 years	0/313	-	-	
	30.1 – 35 years	1/184	0.5	-	
	>35.1 years	2/94	2.1	-	
Schooling	0 years	4/457	0.9	1	0.48
	01-05 years	2/330	0.6	0.55	
	06+ years	0/234	-	-	
Occupation	Housewife	7/957	0.7	-	-
	In service	0/57	-	-	
	Other	0/7	-	-	
Has ever worked outside her village	Yes	0/29	-	-	-
	No	7/992	0.7	-	
Husband's occupation	Manual labour	2/585	0.3	1	0.38
	Skilled labour	1/101	1.0	2.91	
	Business	3/297	1.0	2.97	
	<i>Irregular</i>	1/38	2.6	7.88	
Husband spent nights away in the past month	Yes	0/234	-	-	-
	No	5/462	1.1	-	
	Not applicable – husband not living at home	2/325	0.6	-	
Complains of current genital ulcer	Yes	0/67	-	-	-
	No	7/954	0.7	-	
Previous genital ulcer	Yes	0/96	-	-	-
	No	7/925	0.8	-	

Risk factor analysis was undertaken looking for predictors of infection, using demographic and clinical variables in the model. The low prevalence of active syphilis (0.7%) meant that bivariate analysis only was undertaken. No demographic variables were highly associated with the presence of syphilis, although ‘husband not in regular occupation’ tended towards significance ($p=0.095$). Sixty seven women complained of a current genital ulcer and 96 said that they had suffered from such a problem in the past. There was no association between complaints of a past or present genital ulcer and evidence of infection with syphilis.

We were able to take blood from both the spouses and children (of current pregnancy) of those women found to be RPR and/or TPHA positive, and monitor responses to treatment over a maximum period of 18 months. The results of partner and children infection studies are presented in Table 27:

Table 27 – Evidence of syphilis in husbands and children of pregnant women with RPR and/or TPHA positive serology

	Husband’s serological results	Child of current pregnancy
7 women RPR and TPHA positive	3/7 show evidence of current or past infection. 4/7 have no evidence of syphilis.	6/6 children tested found to be serology positive at birth (1 TPHA positive only; 5 RPR and TPHA positive). 1 child not tested at birth but presumptively treated.
1 woman TPHA positive only	Husband serology negative.	Child born TPHA positive.

All husbands and children were treated according to recommended guidelines whether or not they showed evidence of infection. Responses to treatment for mothers and children were monitored for a maximum period of 15 months – this is presented in Figures 8 and 9. Data is presented on 7 of the 8 pregnant women with syphilis; the eighth woman was seen in the last month of data collection and only one serum result was available for her. Note that the black arrows on each Figure indicate the date of treatment.

Figure 8 Response to syphilis treatment: mothers and infants

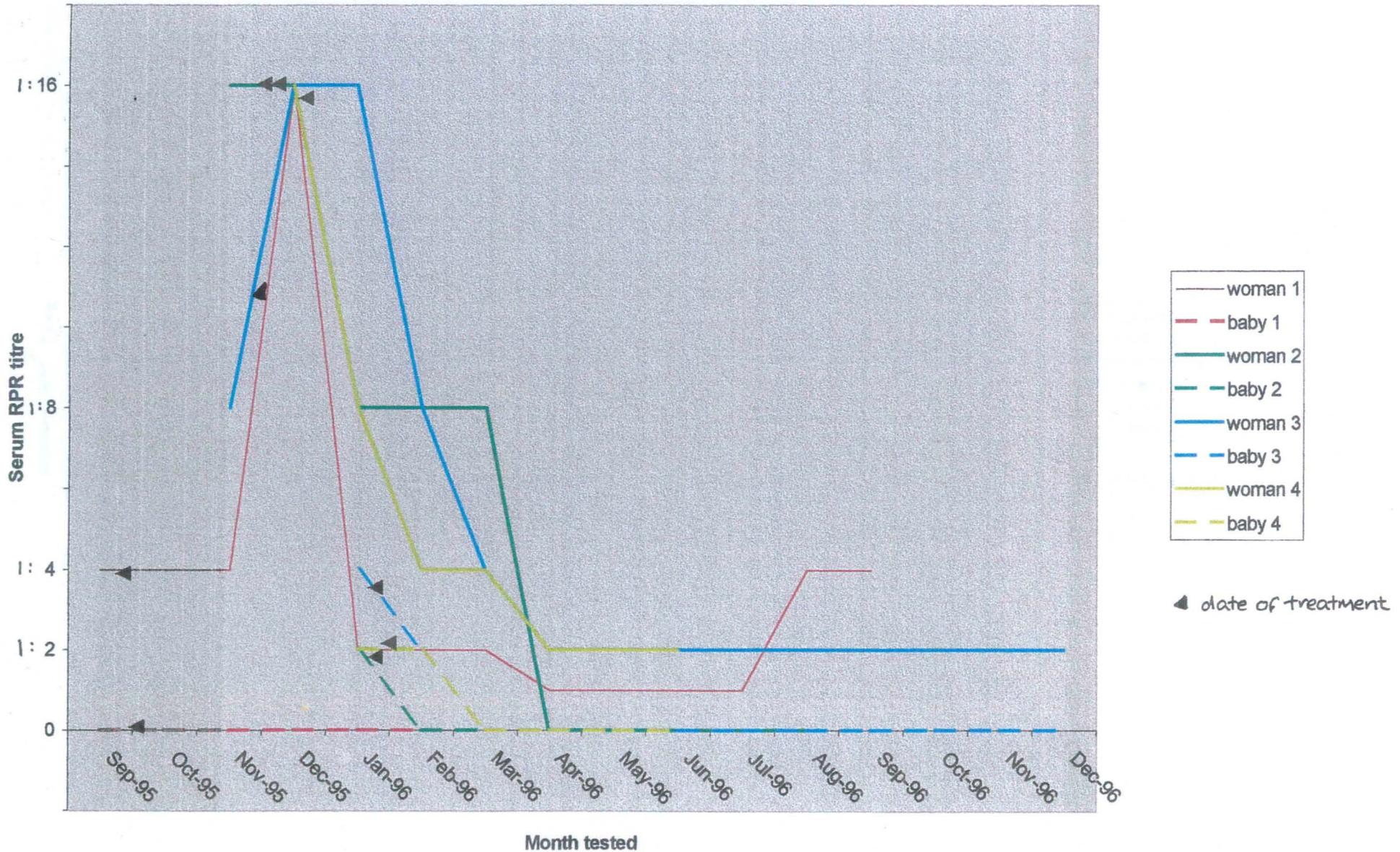
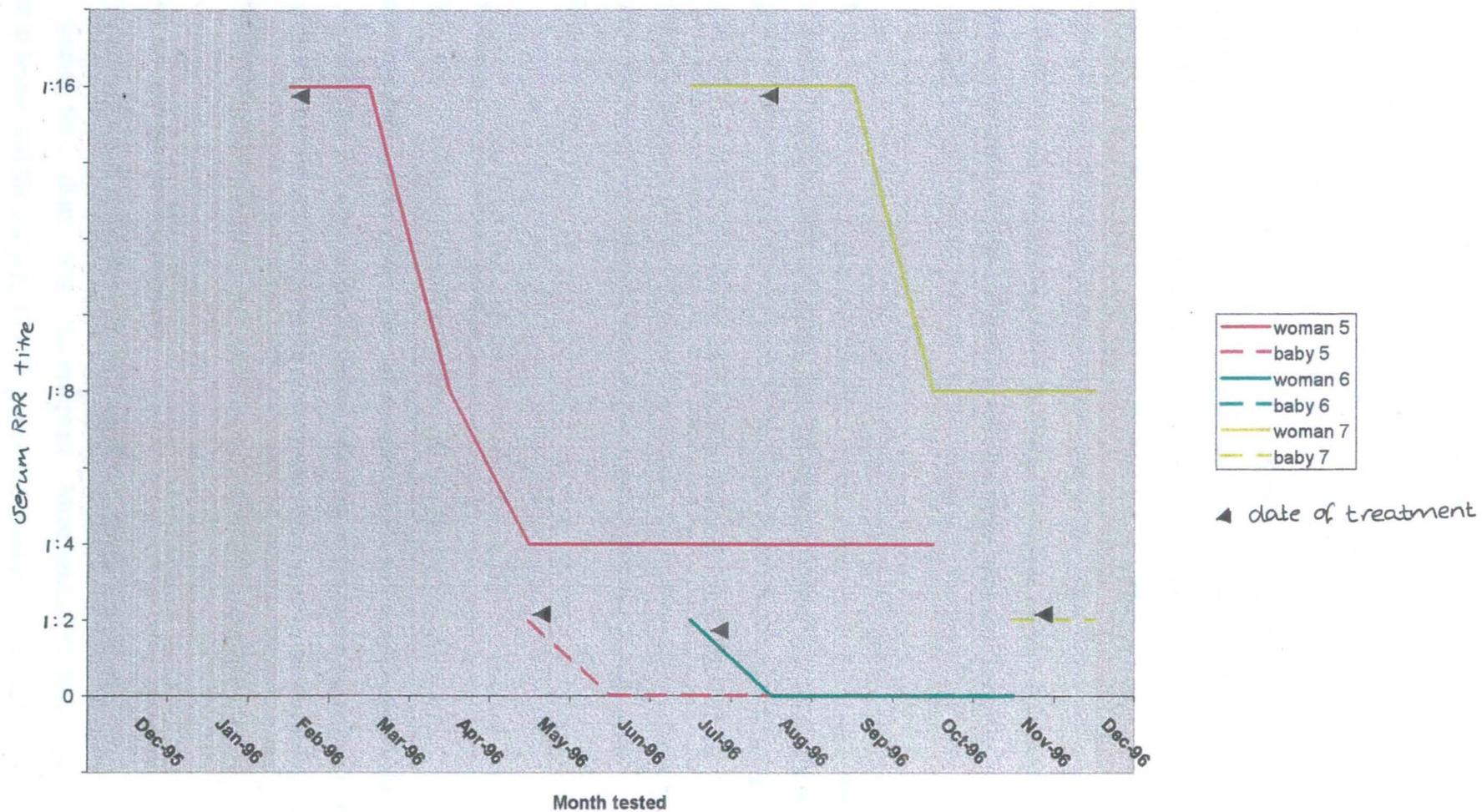


Figure 9 Response to syphilis treatment: mothers and infants



4.12 Mothers of neonates and incidence of ophthalmia neonatorum

During the course of the study, a total of 1676 babies were born in the two Blocks under study. Results are available for 1008 babies recorded as being born in the two blocks (see Table 10 for reasons for non-participation in the study). Whilst the majority of deliveries (94%) were recorded as being normal with a healthy live baby, 17 (1.9%) were stillbirths and a further 25 (2.5%) of neonates had died within 15 days of birth. Mothers of stillborn children or those who had suffered a neonatal death were interviewed by our study personnel. Eighteen (1.8%) infants were recorded as suffering from a congenital abnormality. All mothers were interviewed regarding demographics and symptoms - giving a total of 995 mothers (including 13 who had given birth to twins) interviewed and 964 babies who were seen and clinically examined.

Almost one fifth of babies (201/964; 20.8%) were recorded as suffering from eye redness/swelling plus discharge. Eye swabs were collected from all these babies. In addition, at one point early in the study, every baby seen during a two month period had eye swabs taken and processed, irrespective of the presence or absence of clinical signs of infection. This allowed us to check for any asymptomatic carriage of infection in a total of 105 non-symptomatic babies.

Prevalence of infection in infants

A total of 1.2% (12/964) of infants were found to have either *Neisseria gonorrhoeae* (0.3%) or *Chlamydia trachomatis* (0.9%) infection – see Table 12. None of the 105 asymptomatic babies who had swabs taken were found to be suffering from ophthalmia neonatorum in the absence of overt clinical signs of infection.

Place of birth and birth attendants

Women were asked about demographic variables, the circumstances surrounding the birth and post-natal symptoms. Most babies (91.4%) were born at home, and the majority (79.8%) were delivered by traditional birth attendants (TBAs).

Symptoms in mothers

Two percent of mothers (22/995) said that they were suffering from an abnormal foul-smelling vaginal discharge. Similar numbers of women (19/995; 1.9%) reported a fever.

Predictors of infection

No association was found between the presence of reported symptoms in the mother and the probability of ophthalmia neonatorum (ON) being present. Similarly, analysis of the demographic variables (age, place of delivery, birth attendant) recorded for each mother did not find any single or combination of variables associated with ON.

4.13 Evaluation of syndromic management in symptomatic women

For a five month period in 1996, a total of 465 women attended the four primary health care centres in Matlab complaining of symptoms suggestive of a possible RTI/STI: abnormal vaginal discharge, genital itching, abnormal smell, lower abdominal pain (plus discharge), dyspareunia - see Table 28. All 465 women agreed to take part in the survey. Comparison of demographic variables between these symptomatic women and the 804 women in the population-based survey of women revealed that they were similar in all respects except in the following significant ways ($p < 0.05$):

- symptomatic women were more likely to be Hindu
- symptomatic women were more likely not to be using any contraception, were less likely to be DMPA users and more likely to be condom users
- more symptomatic women were having regular menstruation, were more likely to use home-made sanitary protection, but changed their sanitary protection less frequently

Comparison of the prevalence of infections microbiologically-diagnosed in the 2 groups of women showed that only the rates of endogenous infections (candida and bacterial vaginosis) were statistically significantly different in the

two groups. Both were found more commonly in symptomatic women ($p < 0.0005$). The STIs were not found at any higher rates in symptomatic versus population-based women

Table 28 – Presenting complaints, 465 symptomatic women

PRESENTING COMPLAINT(S)	% of women reporting the symptom
Abnormal vaginal discharge	94%
Genital itching	55%
Lower abdominal pain (plus discharge)	40%
Abnormal smell	29%
Pain passing urine	20%
Painful coitus	7%
Genital ulcer	1%

4.13.1 Clinical signs in symptomatic women

As with the population-based women, questionnaires were administered (in private) to every woman and a full clinical examination was undertaken by trained health care workers (usually under the observation of one of the project physicians). The prevalence of clinical problems diagnosed in the 465 symptomatic women taking part in the survey is shown in Table 29 below. These are signs recorded by trained primary health-care workers.

Table 29 - Clinical signs recorded by primary health-care workers on 465 symptomatic women

Clinical Sign	Number of women with abnormality (n= 465)	Percentage
<i>Non-reproductive tract signs</i>		
Pyrexial	36	7.7%
Hypertensive (diastolic >95mm Hg)	4	0.9%
Breast problem		
• Lump (probably benign)	0	
• Lump (poss. malignant)	0	
• Mastitis	0	
• Fibroadenosis	0	
• Other abnormality	3	0.6%
<i>Reproductive tract signs</i>		
Lower abdominal tenderness	9	1.9%
Genital ulcer seen	7	1.5%
Genital warts	2	0.4%
Inguinal lymphadenopathy	16	3.4%
Vulval candida	47	10.1%
'Abnormal-looking' vaginal discharge	162	34.8%
Vaginal discharge looks 'clumpy'	98	21.1%
Cervical mucopus	6	1.3%
Cervical friability	15	3.2%
Cervical ectopy	105	22.6%
Cervical motion tenderness	10	2.2%
Genital prolapse	40	8.6%
<i>Diagnostic tests on site</i>		
PH of vaginal discharge > 4.7	249 (53.5%)	53.5%
KOH ('whiff') test positive	73/424 (17.2%)	17.2%

4.13.2 Sexual and other risk behaviours/indicators reported by symptomatic women

All symptomatic women were asked a series of questions relating to sexual and other risk behaviours (in themselves or their sexual partners) - similar to the questionnaire administered to the population-based women. In this case, however, the questionnaire was administered in private by a primary health care worker rather than by a trained interviewer. The sociodemographic variables which may indicate risk are recorded within Table 11. Table 30 below indicates the prevalence of other reported risks:

Table 30 – Prevalence of possible STI risk factors among symptomatic women

Possible Risk Factor (N = 465)	n	%	Mean
Age at first marriage			16.84 (range = 7-26)
Any sexual intercourse before marriage	3*	0.6%	
More than one marriage in lifetime	35	7.6%	
More than one sexual partner in lifetime	28**	6%	
More than one sexual partner in past one year	2	0.4%	
Age at first sexual intercourse			16.07 (range = 9-26)***
Ever worked outside her own village	10	2.2%	
Husband spends nights away from home	206	45.2%	
Husband/sexual partner has symptoms suggestive of an STI	118/388 (rest = 'don't know')	30.4%	

* Includes one currently unmarried girl

** Includes 23 women with 2 marriages and 2 sexual partners, 1 woman with 3 marriages and 3 sexual partners, and 4 women with 1 marriage and 2 sexual-partners

*** 61 women answered 'Don't Know' to this question

4.13.3 Laboratory results and risk associations of infection

On laboratory analysis (see Table 12), the symptomatic women were found to have a low level of STIs (gonorrhoea or chlamydia = 1.1%; syphilis = 0.9%; trichomonas = 1.5%) and a moderate-high level of endogenous infections (candida and/or BV defined by Nugent's criteria = 31.8%). One further result not reported in Table 12 is that one woman with a genital ulcer was found to be herpes simplex virus positive on ELISA testing of an ulcer swab.

Of the 385 women for whom all STI results are available, 14 (3.6%) were found to be suffering from a current STI. This included 5 women with a cervical infection (4 with chlamydia and 1 with gonorrhoea) and six with *Trichomonas vaginalis*. The prevalence of the endogenous infections in all the women was higher: 32% of women had an endogenous infection including 18.8% (79/418) with bacterial vaginosis (diagnosed using Nugent's criteria) and 12.6% (58/460) with candida.

Risk factor analysis for both STIs and endogenous infections was undertaken with all social, demographic and behavioural variables included in the model. Again, given the low prevalence of STIs, bivariate analysis only was undertaken looking for risk associations for the presence of STIs. Logistic regression analysis was undertaken to explore risk-associations with the endogenous infections. Results of risk factor analysis for both the endogenous and sexually transmitted infections are presented in Tables 31 and 32. The following associations were statistically significant in symptomatic women:

Endogenous infections:

- More common in Hindu women
- More common in IUD users and women with a tubectomy
- More common in women whose husbands do not have symptoms
- Less common in more educated women

Sexually transmitted infections:

- More common in women in 'service' professions (e.g. cook, teacher)
- More common in women working outside their own village (p=0.07)

These two variables are probably linked, since women working in service professions are likely to do so outside their own villages.

A summary of statistically significant risk factors in both the population-based and symptomatic women's surveys is presented in Table 33 below

Table 31 – Risk factors for endogenous infections – symptomatic women (N=418)

Possible risk factor	r/n	%	Unadjusted OR	Adjusted OR	P	
Religion	Muslim	115/378	30.4	1	1	
	Hindu	18/40	45.0	1.87	2.32	0.02
Contraception	None	40/125	32.0	1	1	
	DMPA	38/132	28.8	0.86	1.33	0.39
	IUD	8/15	53.3	2.43	4.05	0.018
	Condom	3/26	11.5	0.28		
	Tubectomy	17/38	44.7	1.72	2.47	0.047
	OCP	27/76	35.5	1.17	1.62	0.19
Age group	< 25 years	30/97	30.9	1		
	25-34 years	69/215	32.1	1.06	0.84	
	35+ years	34/106	32.1	1.05	0.86	
Schooling	0 years	65/177	36.7	1		
	01-05 years	42/154	27.3	0.65	0.07	
	06+ years	25/86	29.1	0.71	0.22	
Season when seen	Cold, dry	56/167	33.5	1		
	Hot, dry	16/70	22.9	0.59	0.11	
	Hot, wet	61/181	33.7	1.01	0.97	
Sanitary protection	Cloth/towel made at home	100/321	31.2	1		
	Other	33/95	34.7	1.18	0.51	
Number of times per day that she changes sanitary protection	1	12/30	40.0	1		
	2	62/176	35.2	0.82	0.62	
	3+	56/206	27.2	0.56	0.15	
Days since LMP	<11	14/45	31.1	1		
	11-20	50/155	32.3	1.05	0.89	
	21+	19/40	47.5	2.00	0.12	
Having regular menstruation	Yes	81/232	34.9	1		
	No	52/186	27.9	0.73	0.13	
Male partner symptomatic	Yes	25/103	24.3	1	1	
	No	82/243	33.7	1.59	1.74	0.046
Last sexual intercourse	1 day – 1 week	27/88	30.7	1		
	>1 week - < 1 month	51/188	27.1	0.84	0.54	
	> 1 month - < 1 year	31/74	41.9	1.63	0.14	
	> 1 year	22/64	34.4	1.18	0.63	

Table 32 – Risk factors for sexually transmitted infections – symptomatic women (N= 385)

Possible risk factor		r/n	%	Unadjusted OR	P
Religion	Muslim	12/351	3.4	1	0.35
	Hindu	2/34	5.9	1.77	
Contraception	None	4/116	3.5	1	0.14
	DMPA	3/121	2.5	0.71	
	IUD	2/13	15.4	5.09	
	Condom	0/27	0	-	
	Tubectomy	1/38	2.6	0.76	
	OCP	3/64	4.7	1.38	
Age group	< 25 years	4/78	5.1	1	0.58
	25-34 years	6/207	2.9	0.55	
	35+ years	4/100	4.0	0.77	
Schooling	0 years	5/169	3.0	1	0.72
	01-05 years	7/145	4.8	1.66	
	06+ years	2/70	2.9	0.96	
Occupation	Housewife	11/358	3.1	1	0.008
	In service	3/10	30	13.5	
	Other	0/14	0	-	
Working outside her village	Yes	1/2	50	28.46	0.07
	No	13/383	3.4	1	
Marital status	Single	0/1	0	-	1.0
	Married	14/379	3.7	-	
	Divorced/ Widowed	0/5	0	-	
Number of marriages in lifetime	1	13/352	3.7	1	0.89
	2+	1/31	3.2	1.15	
Husband's occupation	Manual labour	7/201	3.5	1	0.80
	Skilled labour	2/68	2.9	0.84	
	Business	5/104	4.8	1.4	
	Irregular	0/4	0	-	
Husband spent nights away in the past month	Most/all	4/139	2.9	1	0.84
	Occasional	1/32	3.1	1.1	
	None	9/208	4.3	1.53	
Husband symptomatic	Yes	6/98	6.1	2.34	0.14
	No	6/221	2.7	1	

Table 33 - Risk factors for RTIs in women in two arms of the survey

Risk Factor	Endogenous infections		Sexually transmitted infections	
	Popn. women	Sympto. women	Popn. women	Sympto women
Hindu	Increased	Increased	NS	NS
Use of oral contraceptive	Decreased	NS	NS	NS
Tubectomy	NS	Increased	NS	NS
Use of IUD	NS	Increased	NS	NS
Hot season	Decreased	NS	NA	NA
Mid-cycle when seen	Decreased	NS	NA	NA
Married twice in lifetime	NA	NA	Increased	NS
Working 'in service'	NA	NA	NS	Increased
Working outside village	NA	NA	NS	Increased
Husband in 'irregular' occupation	NA	NA	Increased	NS
Male partner asymptomatic	NS	NS	NS	Increased

NS = Not significant

NA = Not Analysed

4.13.4 Predictors of infection in symptomatic women – presenting complaints and clinical signs

As with the population-based survey of women, all recorded presenting complaints and clinical signs were analysed as possible predictors of the presence of any infection. The sensitivity, specificity and positive predictive value of each variable is recorded in Table 34.

Compared to the analysis for population-based women, some of the reported symptoms had higher sensitivities and PPVs, viz: abnormal discharge, genital itching, lower abdominal pain. Clinical signs and bedside tests for the endogenous infections gave reasonably high sensitivities and specificities, and

PPVs in the range 31.4% - 34.3%. For the STIs (cervical infections or syphilis), however, clinical signs were insensitive with values of 0% for both sensitivity and PPV.

Table 34 – Clinical symptoms and signs as predictors of infection (N=465)

Variable (symptom or sign) as predictor of the presence of any infection and/or a specific named infection	Sensitivity of variable	Specificity of variable	Positive Predictive Value
<i>Symptoms reported and possible infection present</i>			
Complaint of abnormal discharge			
• Any infection	93.5%	5.1%	30.2%
• Endogenous infection ^α	93.2%	6.0%	31.6%
Complaint of itch/candida	93.3%	4.3%	61.1%
Complaint of lower abdominal pain			
• Any infection	36.2%	59.2%	28.1%
• Cervical infection	60.0%	60.8%	1.7%
Complaint of dyspareunia/Any infection	9.4%	94.3%	41.9%
Complaint of genital ulcer disease/Active syphilis	9.6%	93.7%	38.5%
Complaint of abnormal smell/Bacterial vaginosis ^α	29.1%	70.9%	18.9%
Complaint of pain passing urine			
• Any infection	19.6%	80.6%	30.7%
• Cervical infection	60.0%	80.9%	3.4%

<i>Recorded signs on clinical examination and possible infection present</i>	Sensitivity of variable	Specificity of variable	PPV of variable
Abnormal looking discharge/Any infection	41.3%	68.1%	36.3%
Cervical pus/Cervical infection	0%	98.9%	0%
Cervical ectopy/Cervical infection	0%	77.5%	0%
Genital ulcer disease/Active syphilis	0%	98.5%	0%
Clumpy discharge/Candida	53.4%	83.3%	31.6%
pH vaginal fluid > 4.7/Bacterial vaginosis ^α	88.5%	54.9%	31.4%
KOH (whiff) test positive/Bacterial vaginosis	30.8%	85.8%	34.3%

Legend for Table 34:

Any infection = chlamydia, gonorrhoea, syphilis, *Trichomonas vaginalis*, bacterial vaginosis or candida

Cervical infection = chlamydia or gonorrhoea

^αEndogenous infection = bacterial vaginosis (diagnosed by Nugent's criteria) or candida

4.13.5 Efficacy of training health-workers in syndromic management

In the sections above I have outlined the presenting complaints, clinical signs and possible sociodemographic risk factors of the 465 symptomatic women and their relationship with the presence of laboratory-diagnosed infections in the reproductive tract. The central aim of this part of the study, however, was to look at the accuracy of the health workers' diagnostic skills – that is, how well did each health worker use the combination of presenting symptoms, signs and elicited possible risk factors within the recommended algorithm (see Appendix 3 for the algorithms in use) to arrive at a possible diagnosis? The primary health workers in Matlab had all been trained in the use of syndromic management flow charts in May/June 1995. Post-hoc assessments of the effectiveness of training took place in July-November 1996: see Sections 3.6.7a and 3.6.7c for full details of the methods used.

Of the 465 women seen as part of the survey of symptomatic women, full laboratory results are available for only 320 presenting with vaginal discharge – the most common presenting complaint. Therefore, all assessments of the effectiveness of training, accuracy of health workers' diagnoses and cost-effectiveness of management are based on the findings from these 320 women only. Table 35 shows the sensitivity, specificity and PPV of the health workers' diagnoses when compared to laboratory findings.

Table 35 – Accuracy of health care workers' diagnoses when compared to laboratory results (N=320)

Diagnosis	Sensitivity of diagnosis	Specificity of diagnosis	Predictive Value of a Positive diagnosis
Bacterial vaginosis^α	(19/60) 32%	(213/260) 82%	(19/66) 29%
Candida	(23/39) 59%	(221/281) 79%	(23/83) 28%
Trichomonas infection	(2/6) 33%	(250/314) 80%	(2/66) 3%
Cervical Infection*	(0/3) 0%	(309/317) 97%	(0/8) 0%

^α Defined according to Nugent's criteria

* gonorrhoea or chlamydia

It can be seen that whilst the health workers were reasonably good at finding women with candida (as evidenced by the relatively high sensitivity) the same is not true for the more serious cervical infections (gonorrhoea or chlamydia), or for bacterial vaginosis. None of the women with laboratory-diagnosed cervical infections were picked up on health worker screening, and the eight women who were told they had a cervical STI were subsequently proven to be uninfected on laboratory analysis. In the case of BV, whilst the actual health worker diagnosis (based on a combination of pH, potassium hydroxide result and diagnosing an 'abnormal looking discharge') had a fairly low sensitivity and PPV when compared to laboratory results (Nugent's criteria), it can be seen from Table 34 that with the use of pH alone, the sensitivity and PPV are higher.

Health workers' diagnoses of genital ulcers gave similarly poor results when compared with serological evidence of active syphilis infection: 0% sensitivity, 99% specificity and 0% PVP.

4.13.6 Cost-effectiveness of syndromic management in Matlab

Section 3.6.6b outlines the methods used for evaluating the cost-effectiveness of treating women complaining of vaginal discharge. This part of the analysis was carried out in collaboration with Dr. Susan Foster of the London School of Hygiene and Tropical Medicine. We compared the cost of using either the algorithm recommended by the WHO, or the modified algorithm in use throughout this study. Full details of the cost analysis are given in Appendix 5. This is a paper which has been submitted for publication. The costs of the two approaches are shown in Table 36 below:

Table 36 – Costs of treating vaginal discharge using different flow charts

	No. of women	WHO algorithm	Matlab algorithm used in study
Total cost	320	\$384.95	\$57.86
Overspend per woman	320	\$0.76	\$0.09
Total cost per cervical infection treated (GC, CT)	3	\$128.32	Infinity
Total cost per STD treated (GC, CT, TV)	9	\$42.77	\$28.93
% of total cost on true cases	101	8.1%	25%
% of total cost on overtreatment		91.9%	75%
% of STIs treated		100%	22.2%
% of cervical infections treated		100%	0%
% of endogenous infections treated		100%	42.4%

Using the WHO algorithm, all cases of STIs (cervical infections plus trichomoniasis) and endogenous infections (candida plus bacterial vaginosis)

were treated in the 320 women seen. However, 92% of the total drugs expenditure on these women was wasted on overtreatment.

For the actual algorithm used in the study, whilst the actual expenditure and cost per woman were lower than with the WHO algorithm, only 42% of women with endogenous infections received the correct diagnosis and treatment. Furthermore, the poor predictive values of the health workers' diagnoses meant that no cases of cervical infection in women were correctly treated (thus resulting in a result of 'infinity' for the amount of money spent per cervical case correctly treated). All women who received a diagnosis of cervical infection and were treated for it, were subsequently found to be uninfected on laboratory analysis.

The importance of these results for both the individual patient seeking care, and the health system providing care is explored more fully in Appendix 5.

4.13.7 Outcomes of training health workers in syndromic management

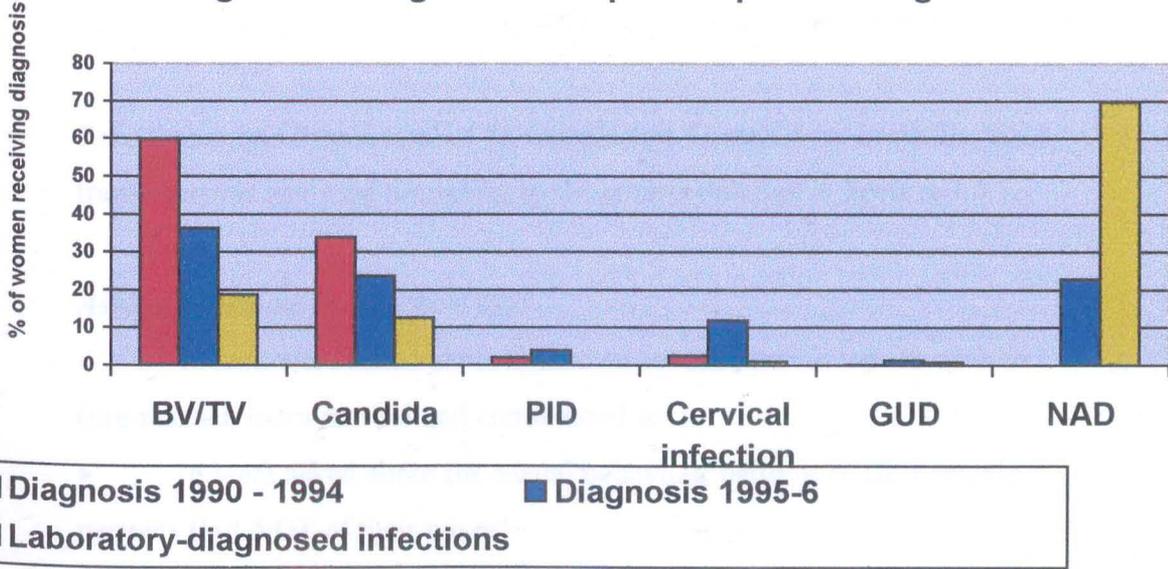
Apart from the accuracy and cost of syndromic diagnosis post-training, other outcomes of training were also measured during the course of the study:

- i. diagnostic rates in all clinics post-training
- ii. the accuracy of behaviour change messages

a. Diagnostic rates pre-and post-training

Clinic figures were available for a five-year pre-training period (1990-1994) for a total of 4267 women. These are shown in Figure 10 along with the diagnostic rates in the same clinics for the 18-month period post-training (1995-6) when 2673 women were seen. For comparison, the rates of laboratory diagnosed infection on the subset of 320 symptomatic women (for whom all laboratory results are available) are also presented in the Figure.

Figure 10 - Diagnosis rates pre-and post-training



Key:

BV = Bacterial vaginosis

TV = *Trichomonas vaginalis*

NAD = no abnormality detected

PID = pelvic inflammatory disease

GUD = genital ulcer disease

Post-training, there has been an increased willingness for PHC workers to diagnose women as not suffering from any infection/abnormality. This has been accompanied by a noticeable increase in the number of women diagnosed as suffering from a cervical infection (from 2.5% up to 11.9%) or from a genital ulcer infection (up from <0.1% to 1.4%), and a decrease in the number of women diagnosed with endogenous infections (candida diagnoses down from 34% to 23.7%; BV/TV down from 60% to 36.3%). The accuracy of these diagnoses (as compared against a laboratory ‘gold standard’) was outlined in Table 35.

b. Behaviour change information given by PHC workers

Results of the analysis of behaviour change information given to male and female clients by PHC workers are presented below. This work was presented to the International Conference on STDs held in Seville in October 1997.^d

Tape transcripts from a total of 83 women and 41 men were available. Each transcript was analysed according to the criteria detailed in Section 3.6.3.

Asking questions of men (n = 41):

- 40 men were asked about their own sexual behaviour with women (pre-marital, extra-marital and commercial sex)
- 16 were asked about the sexual behaviour patterns of their female partners (but NOT of their wives)
- none were asked about same sex relationships, although one man mentioned voluntarily

Asking questions of women (n = 83)

- 22 were asked about their own pre- or extra-marital sexual relations
- 21 were asked about their husband's sexual relationships
- 61 were not asked any questions about sexual behaviour (self or spouse)

Sexual behaviour reported by men

33 married men were seen

- 18 reported pre-marital sex
- 7 reported extra-marital sex
- 4 reported paying for sex

8 unmarried young men were seen

- all 8 reported sexual activity
- 3 reported paying for sex
- 1 reported same sex relations

^d Hawkes S, Gausia K, Chakraborty J, Rahman H, de Francisco A, Mabey D. Training requirements for RTI/STI management at the PHC level. Oral presentation, International Society for STD research, Seville, October 1997.

Sexual behaviour reported by women

- None reported pre- or extra-marital sexual relationships
- 5 reported that their husbands have other sexual partners
- 1 unmarried girl was seen; she did not report any history of sexual activity

Language and style of interviews:

The following quotes come directly from the tapes analysed. They give examples of the language used by the PHC workers and nature of the interviews as they actually took place:

Men:

“You had sex with a lady before marriage. This is not good.....never do this with any other girls”

“Men can get AIDS through sexual contacts. One must die if one gets AIDS. Also people get syphilis and gonorrhoea. If you get it your wife will get it and the baby will get it. It will make the baby blind or crippled. Your wife will have a stillbirth, so people shouldn't make love with bad girls.”

Women:

“Do you know why you have got it? You don't keep clean. People get this disease when they....use dirty cloths, don't shave or share needles with others”.

“It's good you have come for treatment. If you did not come you could develop AIDS eventually” (this to a woman complaining of and treated for vaginal candida).

4.14 The establishment of male clinics

A full description of the establishment and findings from the first year of running the male sexual health clinics in Matlab is presented in Appendix 6. This paper was published in *Health Policy and Planning*, June 1998. The major findings are highlighted below:

4.14.1 Seeking health-care prior to the opening of the clinics

A full description of patterns of health care seeking behaviour (for sexual health problems) in the population-based men is given in section 4.8.2.

4.14.2 Attendance at the clinics

The clinics were open to all men in the local community, both married and unmarried, and were free of charge. During the first 18 months each clinic (in each primary health care subcentre) saw, on average, 4 men per session - a similar figure to the number of women with RTI/STI symptoms presenting weekly to each subcentre. More than 80% of the men are self-referred, and smaller numbers were either identified through the population-based prevalence survey or were the partners of infected women. Attendance rates of women seeking MCH-FP services during the period that the male clinics have been open do not appear to have been affected in any significant way.

4.14.3 Diagnoses in clinic attendees

Table 37 presents data from the first year of running the four clinics. A total of 622 men attended the clinics during this time, and their presenting complaints/symptoms are shown along with the syndromic (and other) diagnoses made by the medical assistants. Each man could be recorded as having more than one symptom and/or diagnosis. The most frequent diagnostic categories relate to possible STIs: 28.2% of men received treatment for urethral discharge, genital ulcer disease, scrotal swelling, inguinal bubo or pain passing urine^e.

Over two fifths of men presented with problems which fall into the psychosexual category: impotence, premature ejaculation, 'sexual dissatisfaction', difficulty in maintaining an erection, and "night pollution" (nocturnal emissions). However, the number of men who were eventually diagnosed as having a predominantly psychosexual condition was much smaller (8.5%), and all of but one of these men were diagnosed in only one of the four subcentre clinics by one medical assistant.

^e Whilst symptoms of urethritis (urethral discharge or pain passing urine) may be due to non-sexually transmitted causes, the majority are probably due to STIsⁱⁱ.

Table 37 - Presenting complaints and health worker diagnoses among 622 men attending sexual health clinics in Matlab.

Morbidity	% of 622 men who complain of this symptom	% of 622 men who receive this diagnosis after clinical exam.
Pain passing urine	41.8%	8.5% ^a
Psychosexual problem^b	41.5%	5.9%
Urethral discharge	37.8%	10.8%
Skin problem	9%	18.2%
Partner management^c	7.1%	7.1%
Genital ulcer disease	3.9%	3.9%
Urethral pain	3.9%	0%
Scrotal swelling	1.4%	2.3%
Blood in urine	1.3%	0%
Inguinal bubo	0%	2.7%
Other, non-reproductive health morbidity^d	18.3%	3.5%
No abnormality detected		37%

a – men were diagnosed with a urinary tract infection

b – such as premature ejaculation, impotence, “night pollution”, dissatisfaction with sex, etc.

c – female partner received the initial diagnosis of an STI

d – other morbidities/complaints such as cough, weakness etc.

CHAPTER FIVE: DISCUSSION

5 Discussion

5.1 Participation in the study

This study was the largest epidemiological survey of reproductive tract infections ever undertaken in Bangladesh – both in terms of the number of participants and the range of issues looked at. The overall level of participation by the community was surprisingly high, especially given the sensitive nature of the topic. Indeed, in four of the five arms of the survey, the number of people declining to participate was under 3% (see Chapter 4, Table 10). The higher rate of refusal in the population-based survey of women may reflect a number of factors: social sanctions on women participating in activities which take them away from home (in this case a full day's trip to the central Matlab hospital); fear or unwillingness to have a clinical examination which involved an internal speculum examination; or reluctance to submit to an in-depth and very personal interview with ICDDR,B staff who have a long-standing role in the daily lives of all women in the area. Nonetheless, the high overall participation rates are perhaps both a reflection of the depth of concern about this subject within the community itself, and the degree of enthusiasm and hard work undertaken by all the ICDDR,B staff in tackling this new subject.

5.2 Representativeness of the participants

In interpreting the results of this study, it must always be borne in mind that Matlab is an area of Bangladesh which has received a more intensive input of demographic surveys and health services for the past twenty years than almost any other part of the country. In this respect, the results from this area may not be seen as entirely representative of the rest of rural Bangladesh, and certainly do not give any indication of prevalence of RTIs/STIs in urban settings or among so-called 'core groups'.¹ Nevertheless, it is still pertinent to remember that the established MCH-FP services in Matlab have not, until now, focused on RTI/STI primary prevention and have never previously provided services for men. Furthermore, it is well accepted that stand-alone STD services in developing countries have little impact on overall STI incidence and

prevalence in the absence of campaigns aimed at primary prevention or improvements in health-care seeking behaviour² (see Section 1.4). There would therefore not seem to be any strong reason to believe that the prevalence results are totally unrepresentative of what might exist in other rural areas in Bangladesh.

A more pertinent omission from the study is the almost total absence of younger and unmarried females. It is known from studies in other areas of the world that adolescent girls may be particularly vulnerable to STIs – both socially³ and physiologically,⁴ and their absence from this study is unfortunate. We were precluded by the Ethical Committee of ICDDR,B from including either unmarried girls or those married girls who were younger than 18 years of age. Whilst we may have expected to see some adolescent unmarried girls in our study of symptomatic women (which did not have the same restrictions imposed by the Ethical Committee) we soon discovered that social pressures currently preclude them from availing services – indeed, in the entire study we only saw three unmarried girls.

During the course of both the population-based and symptomatic women's studies, 3% of women interviewed in each arm were in the age group 15-19 years. By comparison, the total percentage in this age group in the general rural population is approximately 11.4%.⁵ None of the adolescent girls seen in our study had any sexually transmitted infections. However, it should be noted that the women interviewed as part of the studies of syphilis in pregnancy and ophthalmia neonatorum among neonates, were significantly younger than the total population registered as part of the ICDDR,B record keeping system (of married eligible women) – mean ages 26.82 years and 27.01 years respectively, compared to 31.51 years for RKS women. The discussion of STI prevalence in these women is explored below in Sections 5.5 and 5.6.

The lack of younger girls (either married or unmarried) in our study obviously carries implications for the representativeness of the results for the whole population. Despite this, studies among at least three arms of the population

(pregnant women, mothers of neonates and symptomatic women) do reflect women who currently use and are covered by public sector health and family planning services in Bangladesh⁶ and the findings from these groups may still carry considerable policy and programme relevance in the country.

Interestingly, the Ethical Committee did not prevent us from interviewing unmarried boys/men in our population-based study. Nonetheless, we did find that a large number of such men had migrated out of the rural area and were thus unavailable for interview – see below. Of the 969 men available for interview, 15% (144/969) were in the age group 15-19 years (our lower age limit in this part of the study was 15 years, in comparison to 18 years for girls); only 6 of whom were married. The figure of 15% is closer to the national population figure for this age group (10.4% in rural areas⁵) than that noted for adolescent girls in our study.

Reviewing the results highlighted in Appendix 4, the following points are noteworthy with respect to the representativeness of the survey participants:

Population-based women

A comparison of those women who were interviewed, against those eligible women who, for whatever reason, were not interviewed, shows that the interviewees were not only more likely to be using contraception, but were also slightly older and had more children. The interviewees may therefore represent a population of women who are more ‘compliant’ with health service utilisation. The effect of these characteristics on risk of STI/endogenous infection is unknown but is likely to be minimal given the low impact that use of health services alone have on the overall control of STIs² (see Sections 1.4 and 5.9 below for an assessment of the Piot/Fransen model of STI control in this population), and in the absence of programmes of primary prevention and changing health care seeking behaviour (e.g. to decrease the time from onset of symptoms to when care is sought). Such was the situation in Matlab at the start of this study.

Population-based men

The group found to be noticeably different from the general population was the population of men who had migrated out of the Matlab area: they were younger, less well educated and more likely to be single (unmarried) than the general population. Given that such characteristics may define a group of men at generally higher risk of STIs^{7,8,9} (when they migrate to towns and cities in search of work), it is perhaps pertinent to consider whether such young men could be targeted for STI prevention campaigns *before* they leave their rural areas. Equally, policies for redressing the unequal sex ratios increasingly common in urban settings in developing countries need to be fully explored.

Pregnant women/Mothers of neonates

The finding that pregnant women and mothers of neonates were younger than the general population is probably a reflection of the younger age at which women give birth within the total population of women. Indeed, national statistics show that the proportion of women who do not want any more children rises rapidly with age⁶— thus reflecting the comparatively younger age at which one might expect women to be pregnant. In some societies, younger age is associated with an increased risk of STIs. The relevance of this to the Matlab survey will be explored in Sections 5.5 and 5.6 below.

The remainder of this chapter will discuss results from individual sections of the study in turn, looking generally at the meaning of the results in terms of future policy and programme decisions for STI control/RTI management in the country, future research strategies in STI control will then be addressed, concentrating on the management of symptomatic women attending primary health centres in similar situations.

5.3 Population-based survey of women

5.3.1 Current and past symptoms

On the day of interview, a majority (65%) of women reported an abnormal symptom in the reproductive tract, the most common symptom being abnormal vaginal discharge (reported by over one third of all women). The

high prevalence of reported symptoms but relatively low prevalence of STIs and endogenous infections, and the lack of any correlation between the two (see Tables 12 and 19, Chapter 4) may reflect a number of different factors:

i. We were using the incorrect terminology and women did not understand the question

Whilst this may account for some of the reported problems, it is unlikely to explain the high prevalence in its entirety. We asked both open (“do you have a problem today?”) and closed questions (“are you suffering from an abnormal vaginal discharge today?”). Local terminology was always used (*‘Meho’*, *‘Promeho’*, *‘Saada Srab’*) and the female interviewers were all from the local community. The nature and terminology of questioning was discussed at length in the pilot phase of the study, and subjected to constant review during the course of the study. Whilst the use of closed questions slightly increased the number of women reporting an abnormal discharge (see Chapter 4, Figure 2), nonetheless over 38% of women reported this as a current symptom on open questioning.

ii. Women suffer frequently from symptoms in the reproductive tract

Previous work in the Matlab area supports the view that reproductive health problems are rated as serious health concerns by women. A 1995 study on women’s health priorities found that reproductive health problems (predominantly ‘white discharge’) were ranked third in a ‘free list’ of all health concerns¹⁰. Highest on the list was asthma; arthritis and high blood pressure were joint second in the level of overall concern. During the course of the study, researchers noted that although women rated reproductive health problems as serious, they also felt that they could not speak freely about them to others.

Such findings are similar to others carried out in neighbouring India: ‘white discharge’ was found to be among the most common of all complaints expressed by women in five separate studies of illness and health perceptions.¹¹ It is unclear, however, what the exact meaning attached to the term ‘white discharge’ might be. Whilst it is recognised that this is a

significant health concern of women in this area, the most appropriate health service response to this complaint has yet to be determined since the cause of the complaint remains to be identified. This conclusion arises from the finding that the sensitivity and positive predictive values of all reported symptoms were low for predicting the presence of a laboratory-diagnosed infection – see Chapter 4, Table 19. Thus, if RTIs are not the predominant cause of the reported symptoms, another explanation must be sought. For example, it may be important to note that any current abnormal symptoms in the reproductive tract were significantly more likely to be reported by women using intrauterine devices as contraception, and less likely to be reported by DMPA users, when compared to non-users of contraception. This is explored further in Section 5.10.1 below.

5.3.2 Prevalence of infections in women

In contrast to the high level of reported symptoms, the prevalence of both the endogenous and sexually transmitted infections was, pleasingly, lower than we had originally estimated in our sample size calculations (see Chapter 3, Section 3.2.1.1). Such findings are consistent with increasing numbers of published results from the Asian region,^{12,13,14} although some researchers have found higher levels of individual STIs or of vaginal infections in the populations studied.^{15,16} Differences in prevalence in these studies may be true differences, alternatively this may reflect sample bias, or differences in the laboratory definitions¹⁷ or diagnostic tests used.¹⁸ The overall prevalence results are in marked contrast to the figures reported from many studies in the sub-Saharan African region.^{7,19}

5.3.3 Risk of Infection in Population-Based Women

5.3.3.1 Endogenous infections

Endogenous infections were found more commonly in Hindus than Muslims, and were less common in OCP users (compared to those using no contraception), among women seen in the middle of their menstrual cycles and in the hot seasons. The explanations associated with such risk factors are not entirely straightforward, but the following factors may have played some part:

i. *Cultural factors*

In Bangladesh, Muslim men are more likely to be circumcised than Hindu men – indeed, circumcision is usually compulsory for Muslim boys before the age of 10 years (and is usually carried out between the ages of 3 and 7),²⁰ whilst Hindu boys are only rarely circumcised. There is published evidence that the risk of sexually transmitted infections – especially HIV – is higher in men who have not been circumcised,^{21,22} and also in the female partners of such men.²³ The exact nature of the risk is still debated, however, and the exact public health implications of the association remain to be determined.²⁴ The association between the female endogenous infections and male-partner's circumcision status does not feature in the published literature. However, there is some evidence that bacterial vaginosis may be more common among more sexually active women,^{25,26} and the pathogens associated with infection in women have frequently been cultured from their male sexual partners.²⁷ Some researchers have therefore hypothesised that BV is a sexually transmitted infection,²⁸ although this hypothesis is contested by others.²⁹ If BV was found to be more common with increasing sexual activity then a possible association with the partner's circumcision status *may* become more feasible as BV might then share similar epidemiological characteristics with other STIs.

ii. *Hormonal factors*

The association between OCP use and rates of endogenous infections usually works in the opposite direction to the one noted in this study. Generally, women using the high oestrogen oral contraceptives (as are used by women in the Matlab area) suffer from higher rates of vulvovaginal candidiasis.³⁰ The risk association noted here (less risk in OCP users) holds for both BV and candida in this population of women, and is difficult to explain. Similarly, most studies do not find an association between stage of the menstrual cycle and the risk of endogenous infection,³¹ although it should be recognised that recent research has noted a link between stage of the menstrual cycle and the likelihood of recovering *Chlamydia trachomatis* from the female genital tract.³² Both these findings require confirmation and further exploration.

5.3.3.2 Sexually transmitted infections

On univariate analysis, STIs were found more commonly in women who had been married more than once, and those with partners in ‘irregular’ occupations (that is, house to house domestic labour, people who beg, disabled persons, or those listed as unemployed). As with other reported variables on sexual behaviour, most interpretation of the data here would be conjecture as the number of women with infections is very low, and no women in this part of the study reported sexual relations outside of marriage, and we did not ask them about the possible extra-marital relationships of their husbands.

5.3.4 Asking women about sexual behaviour

As noted above, no women in this part of the study reported having non-marital sexual activities (either pre-marital or extra-marital). Whilst this may represent reality, it is perhaps more likely a reflection of both the insensitivities of the methodologies used in the study, and of the difficulty women face in answering questions about socially sanctioned behaviour (for women). Such findings are not uncommonly reported in the literature on sexual behaviour³³ – nonetheless the findings in this study do seem rather extreme (especially when the reported behaviour in women is compared with that reported by men). These findings have the following implications for future work in this population:

- i. Reliable reports on sexual behaviour can probably only be obtained through a variety of techniques,^{34,35} including in-depth qualitative interviewing,³⁶ probably carried out over a longer time frame and involving multiple visits by the same interviewer in order to build up trust with the interviewee;
- ii. The use of sexual behaviour questions as part of a recommended ‘risk score’ assessment for clinical management may be compromised – this is further explored in Section 5.8.1 below;
- iii. Other, less subjective, measures of sexual exposure may be of use in this population, for example, biomedical markers of exposure.³⁷ It is important to recognise that STIs in this population will have a low incidence,

therefore cumulative prevalence STI levels may be of more interest than incident rates (herpes simplex virus antibodies, for example).

5.3.4 Clinical examination of women

Women in the population-based surveys were examined only by physicians, who also made any diagnoses of RTIs/STIs or other problems. Both clinicians in the study were using the same standardised definitions of clinical findings to diagnose abnormality – see Chapter 3, Section 3.1. As with the lack of correlation between reported symptoms and the presence of infection, there was both a low sensitivity and PPV of recorded clinical signs and laboratory-diagnosed infections (see Chapter 4, Table 19). In higher prevalence situations in South Asia, researchers have found a much better correlation between clinical signs and the presence of laboratory-diagnosed infection than that found in this study.³⁸ This illustrates the difficulty which may be expected in making non-laboratory-based diagnoses in such a low-infection prevalence area. Even when clinicians with a high level of training are making the diagnoses, the accuracy of clinical or syndromic management is unlikely to be high due to both asymptomatic carriage of the major STIs and the difficulty in interpreting physical signs of low specificity in the female genital tract against a background of low STI prevalence. These issues are further explored in the evaluation of syndromic management undertaken as part of the study – see Section 5.8.

5.3.5 Treatment seeking behaviour

Most women who reported a current or past symptom of the reproductive tract had sought care for this symptom. Commonly cited reasons for not seeking care included not perceiving the symptoms as severe enough, embarrassment and not knowing where to go for treatment. Amongst those who had sought care, a majority had first gone to the informal private sector – indigenous healers and/or village ‘quacks’. These findings carry implications for service provision in the public sector.

The use of the private sector (especially the informal sector) was more extensive than expected. The reasons why women choose to use the private

rather than the public services are obviously multiple. However, in the light of the fact that ICDDR,B has been providing 'high quality' and free public sector reproductive health care for women in the Matlab area for more than 20 years, it is somewhat surprising that a majority of women do not avail themselves of these services first. Clearly cost is a major determinant of health-care choice in general and for STI treatment in particular^{39,40} but it seems not to be the only one in this population. It should not be forgotten that the literature on out-of-pocket expenditure on health services draws attention to the high opportunity costs associated with foregone income as well as the direct costs of travel when seeking treatment.⁴¹ This should be borne in mind when assessing why women do not use services which are 'free at the point of delivery'. It may, in fact, be less costly for such women to visit the untrained 'quack' residing in their village than to spend more time and resources visiting ICDDR,B services which are less conveniently located.

One fifth of interviewees said that they did not know where to go for treatment. Both this finding and the previously highlighted finding of the possible expenses associated with seeking (free at the point of delivery) services may in part highlight a failure of the ongoing ICDDR,B programme to advertise itself well enough as a provider of comprehensive, free reproductive health care. It may be the case that in terms of reproductive health care most women associate the ICDDR,B services only with family planning provision and not with other types of services. Indeed, ICDDR,B and Matlab in particular have often been the subject of external criticism which charges that the programme is too FP-focussed and does not provide enough in the way of health (and specifically reproductive health) services.⁴² This finding carries lessons for those programmes in other parts of the world which are seeking to move away from vertical FP services towards integrated horizontal programmes of comprehensive reproductive health care. The recipient population should be made fully aware of the nature (and cost, or absence of cost) of services on offer.

The second most common reason why care had not been sought was that symptoms were not perceived as severe enough by the women themselves. This may indicate a lack of general understanding about the possible aetiologies and importance of such symptoms. Programmes of information and education may be able to change this, and may also help women decide what is a normal symptom and what is potentially abnormal, and when care should be sought. As with other primary prevention interventions, programmes are probably more effective if they are started at an early age, although the exact timing and nature of such programmes has yet to be established.⁴³

5.4 Population-based survey of men

In the following sections, I will summarise the main findings from the population-based survey of men, and then discuss the meaning of findings in relation to STI control programmes in Bangladesh.

5.4.1.1 Symptoms reported by men

Men in the survey reported a lower level of symptom prevalence than women. Nonetheless, a quarter of those surveyed said that they had a current problem on the day of interview. Rather unexpectedly, the majority of reported symptoms were of a psychosexual nature. Symptoms of a possible STI (pain passing urine, urethral discharge and/or genital ulcer disease) were the second most common group of symptoms. When men were prompted about specific symptoms of a possible STI, more reported abnormalities (see Chapter 4, Figure 5).

5.4.1.2 Treatment seeking histories

As with the survey among women, most men who had suffered from a symptom of a possible STI in the past, or were currently suffering from such a symptom, had sought care. In the absence of public sector services, all men reported going to the private sector – most commonly to indigenous healers. Again similarly to the reports from women, the most common reason men did not seek care was that they did not perceive the symptoms as severe enough.

5.4.1.3 Risk behaviour reported by men and risk of STIs

Unlike the surveys among women, men in the population-based surveys more readily told us about their past and current patterns of sexual behaviour: see Chapter 4, Table 22 for details. The only variable significantly associated with risk of an STI in men was being in the age group 25-34 years (see Table 23). It should be noted, however, that men with a history of non-spousal sexual relations were at increased (but non-significant) risk of chlamydia and syphilis in our study population. This finding helps to objectively validate the reported sexual histories of the men in the survey. However, caution should be exercised in this conclusion since 1 of the 9 men confirmed to have syphilis reported during the interview that he had never had any sexual relations during his lifetime

5.4.1.4 Protection against risk

Of the ever-sexually active men interviewed, a large majority (80%) had never used a condom. The most common reason given for not using condoms was that their female partners were already using another form of contraception. Among the 13 men who reported sexual activity only with other men and none with women, 8 reported that they did not use condoms because they 'do not have sex with women', perhaps reflecting the status of condoms as methods of contraception rather than helping to reduce risk of STI transmission.

5.4.2 Interpretation of results from men

These findings taken together raise a number of issues for health service providers and planners:

- i. Where to site primary prevention measures/campaigns against STIs?
- ii. How to change treatment seeking behaviour?
- iii. Whether clinical services for men should be provided in the public sector?

These three areas will each be explored separately in the following sections.

5.4.2.1 Primary prevention of STIs

In Bangladeshi society, as in many others, it is probably men rather than women who have a greater likelihood of being involved in non-marital sexual relationships.⁴⁴ Indeed, whilst earlier in this chapter I acknowledged the likelihood of underreporting of female sexual activity (see section 5.3.4), the possibility still exists that men in our survey report significantly more sexual partners than women as this is, in fact, reality. Rural Bangladesh is, in general, an extremely conservative society and sanctions against non-marital sexual relationships are harsh – especially for women. It is therefore feasible that not only can women not report their extra-marital relationships, but that, in general, such relationships are perhaps less likely to take place than might be the case in other, more liberal, societies, or is the case for men in rural Bangladesh. After all, it is men who are more able to travel away from their homes and who are more likely to engage in purchasing commercial sex – see below.

The sexual behaviour patterns reported by men in our survey correspond very closely with findings from a study of sexual behaviour in Matlab carried out in the 1970s.²⁰ In that study during in-depth interviews with 32 men, 17 (53%) reported pre-marital sexual intercourse, and the same number reported extra-marital sex. Corresponding figures in our own study were 56% and 49.2% respectively. Interestingly, the authors of the earlier study found that although 6/33 (18%) of the women interviewed reported pre-marital sex, none reported extra-marital sexual relations.

These results in both our own study and the 1970s study add support to findings from other researchers that in many societies it is primarily the behaviour of married men which puts their wives at risk of STIs.^{23,45, 46} The reasons for this in a society such as Bangladesh are undoubtedly multiple: firstly, men are more likely to be mobile and involved in intra- or inter-country migration patterns in pursuit of employment. Indeed, more than 165,000 men go abroad from Bangladesh each year to work,⁴⁷ generally to the countries of south-east Asia or the Gulf States. Moreover, the largest non-participant group (due to absence) in our study was the young, unmarried and

under-educated men who had generally migrated to cities in search of work. Secondly, men are more likely to be the purchasers of commercial sex – in our own study 18% of sexually active male respondents said that they had paid for sex at some point in their lives – this included 14.5% of married men and 32% of the unmarried respondents. These figures contrast with a total of 6.8% in the population-based British National Survey of Sexual Attitudes and Lifestyles,⁴⁸ and 64% among Thai military recruits.⁴⁹

A recent survey of condom use at last sexual episode in a brothel in an urban area in Bangladesh found that less than 6% of such episodes were protected through condom use.⁵⁰ Given that there are an estimated 100,000 girls and women engaged in the commercial sex trade in the country,⁵¹ each with an average of three male customers per night,⁵² high levels of STIs (28% of girls and women infected with gonorrhoea and/or chlamydia in one brothel-based survey of commercial sex workers⁵³), and reports of large numbers of male sex workers,⁵⁴ there is a potentially high burden of STI risk through unprotected commercial sex in Bangladesh.

Condom use among the general population in Bangladesh is low. National figures suggest that only 4% of married women use condoms as their primary contraceptive method– attempts to increase this figure have so far met with mixed success: condom use is up from 0.7% in 1975, compared to an overall increase in contraceptive use from 5% to 41.5% over the same time frame.⁵⁵ Despite the acknowledged sexual behaviour risk factors in men, a disappointingly small number in the survey reported ever having used condoms, although other measures of sexual hygiene were more common - 68% of men reported washing (mainly with plain water) immediately after sexual intercourse. The main reason given for not using condoms was that the man's sexual partner was using another form of contraception. Second most common reason was that the man did not know what they are and/or how to use them (see Chapter 4, Figure 6).

These findings taken together may have an important role to play in aiding the design of appropriate primary prevention campaigns (especially, increasing condom use) in the country. In particular:

- i. General prevention campaigns against STIs should be targeted at least equally, and probably primarily, at men since it is more likely to be men who are at risk of contracting STIs in the first place.
- ii. Concentrating behaviour change campaigns within the family planning services is likely to miss the more at-risk group: men. There is, therefore, a strong case for widening the current target group of FP services in the country to ensure that more men are included as service users.
- iii. Accessing men once they are mobile (for example, in search of employment either in Bangladesh or overseas) is probably more difficult than providing information and education to boys and men who are in rural areas where there is a high household coverage of 'doorstep-delivered' family planning services, such as that found in Matlab and copied elsewhere in the country. Thus, there would seem to be a case for ensuring that young men (as well as young women) are included in the FP programme before they reach an age at which migration starts.
- iv. Basic information about condom use (for example, what condoms are for (disease prevention as well as contraception) where to buy them, how to use them correctly, lack of side-effects, etc.) is still lacking among sizeable numbers of the population of men interviewed. Clearly this information gap needs to be rectified.

Such recommendations are in line with internationally agreed programme and policy guidelines, and with research from other areas of the world which has highlighted the increased effectiveness of targeting men for primary prevention campaigns rather than women in FP service settings. The 1994 Programme of Action of the International Conference on Population and Development,⁵⁶ stated that "Special efforts should be made to emphasise men's shared responsibility and promote their active involvement in

....prevention of sexually transmitted diseases, including HIV; [and] prevention of unwanted and high-risk pregnancies". The effectiveness of targeting different sections of the population for primary prevention campaigns (men or women in the general population, or commercial sex workers as a 'core group' for example) has been studied through the use of mathematical modelling. Researchers have shown that in countries with 'serial monogamy with some commercial sex' (such as may be found in populations similar to Matlab) the highest impact for prevention campaigns is primarily obtained from those targeted at the sex workers themselves, and then those focused on men in the population. Least impact came from only targeting women in FP settings.⁵⁷

5.4.2.2 Changing health care seeking behaviour

As expected in an area (Matlab) where, until now, no reproductive health services have been provided for men (except vasectomies and distribution of condoms), most men who had sought care for their possible STI symptoms, had done so in the informal private sectors – visiting indigenous healers and village-based 'quacks'. This finding is similar to results from surveys in urban areas in Bangladesh: 90% of surveyed drug sellers in one urban-based study said that they regularly treat and advise STD patients.⁵⁸ It can be assumed that most health-care providers in these sectors have not received formal training in STI management, therefore the quality and efficacy of care that men receive is open to question.

The most common reason why men had not sought care was a self-assessment that the symptoms were not severe enough. Given the recognised paucity (or even absence⁵⁹) of symptoms among men infected with STIs, there is clearly a need to persuade men that all abnormal symptoms (or worries about risk exposure) in the genital area should be taken seriously and advice/treatment sought.

In order to ensure that men benefit from sexual health care, however, it is important that they visit trained providers. Whilst sexual health/STI training programmes are more common in the public and private allopathic sectors

(the latter is especially found in the NGO sector in Bangladesh), currently these are not sites where men seek health care for STIs. Clearly, changing health care seeking behaviour to encourage men to visit trained providers will entail reform of the current content of public sector primary health care service provision in Bangladesh, and making services more accessible to men.

5.4.2.3 Provision of services in the public sector

After the liberation of the state of Bangladesh in 1971, public sector priorities in the health and population field were predominantly focused towards population control programmes.⁶⁰ Such a programme was clearly supported by the multilateral and bilateral donors who dictate much of the health and population sector priorities in Bangladesh.^{42,61,62} The results of such focus and pressure were twofold: the use of incentives and even coercion in the family planning programme became widespread,⁴² and the primary care services became synonymous with family planning services. Indeed, it has been clearly stated that 'Despite its commitment to "Health for All by the Year 2000", Bangladesh has been so preoccupied with the pressing problem of its population explosion that the general health situation has not received enough attention. However, ...the stated policy [of the Government] is to provide essential minimum health care through PHC'.⁶³ A further outcome of this acknowledged bias of population and health programmes in Bangladesh towards FP services, has been the almost exclusive focus of primary health care on provision of maternal and child health services⁶⁴ to the exclusion of more comprehensive services, including reproductive health services for men.

The development of one version of selective primary health care (concentrating on MCH-FP) in Bangladesh, rather than comprehensive care for all (a subject of much published debate in the global health policy literature^{65,66,67}) has led to the almost total exclusion of men as recipients of reproductive health care services at the PHC level. However, it should be noted that since the inception of the health and population programmes with their limited scope and content in the early 1970s, there has been an ongoing move towards a broadening of the service content – a movement which has become more forceful since the 1994 International Conference on Population

and Development. The impetus for this change in service provision has come from a variety of directions, not least the women's health advocates who operate inside and outside the country.^{68,69}

The current content of the MCH-FP programme in Bangladesh already offers a reasonable array of services, most of these are directed towards women and children: female methods of contraception, safer birth practices (safe delivery kits, TBA training), some ANC care, expanded programme of immunisation, oral rehydration and treatment of other childhood infections.⁷⁰ Other activities at the MCH-FP and PHC levels include nutritional supplementation, control of vector-borne diseases, control of diarrhoeal diseases and ARI, and tuberculosis and leprosy control.⁷¹ No reproductive health services are specifically on offer to men at PHC level, except for condom provision and vasectomies. It may be equally noted that most recent published estimates of access to PHC indicate that only 62% of the population is covered by public sector PHC services at all.⁷²

As noted in Section 5.4.1.2 above, one outcome of the lack of public sector service provision for men, is that those men with reproductive and sexual health concerns/problems are forced to seek care in the multi-faceted and unregulated private sector. This situation has arisen in spite of the fact that a large part of the MCH services in the country are, in fact, provided by male health assistants or male medical officers.^{64 a}

Thus, there are existing male workers in the public sector system who could be trained to provide STI management for symptomatic men – for example through the use of syndromic management algorithms. We have shown in this project that the establishment of sexual health clinical services for men, based within the existing MCH-FP service facilities, has not resulted in either community hostility (one pre-establishment fear which was voiced) or a

^a Although the current Government plan is to phase out the medical assistant posts, it has been shown in this study that workers of this existing cadre can be trained to provide relatively competent management of sexual health problems in men at PHC level.

reduction in the number of women attending the centres. For a description of these clinics, see Appendix 6.

The provision of reproductive and sexual health services for men carries financial and other resource implications for any public sector system undertaking such an endeavour, and should perhaps be weighed against the costs of training providers who are already treating such men (in the private sector). However, the Government of Bangladesh has made clear its commitment to increase male involvement in reproductive health care issues,^{70,73} including as participants in programmes of behaviour change and through increasing condom use.⁷⁴ Thus, the issue of providing clinical sexual health services for men is one which is topical in Bangladesh at present, and a debate towards which this study may contribute.

5.5 Syphilis in pregnant women

Untreated syphilis in pregnancy is associated with a number of adverse outcomes: pregnancy loss; stillbirth; congenital syphilis. It is estimated that only one third of pregnancies in mothers with untreated syphilis will result in a normal healthy baby. A further third will end in spontaneous abortion or neonatal death, and the remaining third will produce children with congenital syphilis.⁷⁵ Such a high rate of materno-fetal transmission, the severe physical, mental and emotional consequences of congenital syphilis,⁷⁶ combined with the relative ease, high sensitivity and specificity, and low cost of both screening and treatment, have established screening programmes as a cornerstone of syphilis control.

The cost of syphilis screening is low: at current market prices in Bangladesh, initial screening tests (see below) are approximately 7 Taka (US \$0.16) each. Costs of blood-taking equipment (lancets) need to be added to this, along with the price of a mechanical rotator (solar-powered versions are available for use in developing countries, thus obviating many associated costs and worries about the supply of electricity). Similarly, the cost of treatment for each serologically reactive woman is also low: 52 Taka (US \$1.21) per full dose of

injectable penicillin per person, at current market prices. It has been shown that even when the prevalence of syphilis is as low as 1 in 1000, screening pregnant women is still a cost-effective intervention⁷⁷ compared with not screening and treating women at all.

Screening programmes for syphilis rely upon the use of simple, inexpensive tests (most usually rapid plasma reagin, RPR, or Venereal Disease Research Laboratory, VDRL) which can be undertaken at the PHC level.^{78,79} Treatment is then administered to any woman with reactive serology and she is encouraged to bring her partner in for treatment. A review of the economic benefit of screening in MCH-FP centres, carried out by ICDDR,B's health economist using the data from this study, found that given prevailing market conditions in Bangladesh, if the prevalence of syphilis is less than 6% in the population then screening plus confirmation (RPR followed by TPHA) is more cost-effective than performing RPR only.⁸⁰ Clearly such a recommendation carries other potential costs – such as loss to follow-up if women are asked to come back for their TPHA results and not treated immediately on site at their first visit.

Whilst there is a possibility of a low level of overtreatment if only screening test results are used, (due to the lower specificity of RPR or VDRL compared to the confirmatory test⁸¹), it is felt that this is usually outweighed by the benefit of treating a woman immediately instead of asking her to return, collect results and then have treatment.⁸² Indeed, in our own study, the false-positive rate of the RPR test was only 1 in 1000. However, such an approach is also reliant upon the woman seeking and obtaining adequate and effective antenatal care (ANC). Given that almost three-quarters of women in Bangladesh do not currently receive any antenatal care (and only 20% receive more than one antenatal check-up⁸³) the effectiveness of siting syphilis screening solely as part of the ANC services at the PHC level may be called into question. Other strategies to reach women and men through screening programmes need to be considered: for example, linking screening to provision of FP services; screening as part of occupational health; and establishing screening services in the private sector. Alternative strategies

which have been considered in some countries include the 'mass treatment' of all pregnant women.⁸⁴ Whilst this may obviate the need for screening programmes to be set up, it is currently only being considered (as a research topic⁸⁵) for populations with higher rates of infection than we found in this population.

In our study we found active syphilis in 0.7% of 1008 women (95% C.I. = 0.3-1.35). This figure was remarkably similar to the percentage of people found infected in the other population-based surveys in the study: 0.7% of women and 0.5% of men. The only risk association for serological reactivity was that syphilis was found more commonly in women whose husbands were in 'irregular' employment (similar to the STI risk association for population-based women), see Section 4.11, Table 26. Interestingly, as shown in Chapter 4, Table 27, only a minority of the husbands of infected women were seroreactive for syphilis (on either RPR or TPHA testing). It is possible that some of the seronegative men had been successfully treated in the very early stages of infection, or were incubating syphilis at the time of testing.⁸⁶ These explanations would, however, seem unlikely to account for all seronegative results, as this would imply that men with genital ulcers sought immediate care and received adequate and effective treatment. The possibility should be considered that some of the women themselves were primarily infected, and they had not yet infected their husbands. Anecdotal and published²⁰ accounts of sexual behaviour in the Matlab area suggest that it is sometimes 'easier' for married women to engage in extra-marital relationships (often with younger members of their own extended family) than for younger girls/women. Such women are subject to less strict social controls of their sexuality and behaviour.²⁰ This topic requires both confirmation of the results and in-depth qualitative research on patterns of sexual behaviour among married women in the community.

Over 6% of pregnant women stated that they were suffering from a current genital ulcer, and over 9% said they had suffered with an ulcer in the past. However, none of these women were seroreactive for syphilis on either screening or confirmatory testing. Among the pregnant women found to be

serologically reactive for syphilis, none complained of any current or past genital ulceration. These findings would suggest that syphilis control programmes in Bangladesh must undertake actual serological screening and cannot solely rely upon infected and symptomatic people seeking care.

5.6 Prophylaxis of ophthalmia neonatorum

Ophthalmia neonatorum (ON) is a potentially sight-threatening eye infection in infants, due to *Neisseria gonorrhoeae* or *Chlamydia trachomatis* transmitted from the mother at the time of delivery. Signs of infection begin usually within 2 to 12 days after birth,⁸⁷ although some later cases have occasionally been reported in the literature. Whilst the exact incidence of blindness resulting from untreated gonococcal infection remains open to debate, there is little doubt that the widespread introduction of ophthalmia neonatorum prophylaxis has resulted in a decline in the numbers of children rendered blind from these infections.^{88,89} Chlamydial infections are usually less severe although the associated conjunctivitis can last several weeks, and untreated infection can result in eye changes similar to those found in mild trachoma.⁹⁰

Strategies for the control of ON include: (a) preventing infection in the mother; (b) treating infected pregnant women before they give birth; (c) managing individual cases of infection in neonates; and (d) prophylaxis in all neonates at birth.⁹¹ Whilst the first of these four options remains the ultimate goal of most STI control programmes, programme managers are currently faced with the question of how to manage or prevent infection in infants. This situation arises in part because the possibility of screening all pregnant women before birth and finding all those who are infected remains low (active case management rather than screening would not suffice in a situation where up to 50% of infected women will be asymptomatic^{92,93}).

Thus, the choice for most programmes (especially in areas of low ON incidence) will be between case management of infected infants, or ocular prophylaxis of all infants. Active case management of a child with gonococcal or chlamydial ophthalmic infection generally presents a much larger challenge

to the health-care system. Correct management of the neonate ultimately relies on the parents/carers seeking treatment from a trained provider who can correctly diagnose and manage ON. It is felt by many experts that this assumption is too great a risk to take when the possibility of preventing infection in the first place is both simple and inexpensive.⁸⁸

In areas of higher incidence of ON, it is clear that prophylaxis is the most cost-effective intervention.⁹¹ ON prophylaxis is both cheap and simple to administer. The choice between using 1% silver nitrate drops and 1% tetracycline ointment will depend to some extent on the local cost of the drugs, the incidence of ON (both drugs have some degree of failure – higher for silver nitrate than for tetracycline), and the ability of health care personnel to correctly manage the storage and handling of the silver nitrate in order to minimise the likelihood of chemical conjunctivitis.⁹⁴

Given that ON prophylaxis should be administered within the first few hours after birth,⁹⁵ it is clear that any programme to prevent ON through the use of topical prophylaxis will be dependent upon those most likely to be involved in the delivery of infants. In our own study, 91% of infants were born at home and 80% were delivered by a traditional birth attendant (TBA). Any programme to reduce the incidence of ON, will need to concentrate first on training TBAs in administering simple prophylaxis – for example through the provision of tetracycline or silver nitrate with the TBA safe-delivery kits.

The relative lack of any predictive variables associated with infection in either pregnant women or mothers of neonates suggests that targeting of programmes to these women (e.g. selected screening of pregnant women for syphilis, or selected prophylaxis against ON) is not going to be appropriate, and universal programmes should be applied.

5.7 Special Cases – HIV, Hepatitis B and cervical cytology

5.7.1 HIV

We found no evidence of HIV infection in the 930 serum specimens tested using unlinked and anonymous procedures. Such testing policy is well recognised as providing an unbiased assessment of HIV population prevalence.^{96,97,98} The pleasing results of the survey should not, however, be used as an excuse for complacency. It is well recognised by many people in Bangladesh that the country has a number of possible risk factors which could result in a rapid increase in HIV incidence and prevalence:⁹⁹ extreme poverty; internal and external migration (more than 165,500 men go abroad each year to work);⁷⁰ large numbers of female and male commercial sex workers coupled with a very low rate of condom use (see Section 5.4.2.1 above); high numbers of unscreened blood transfusions every year, many of them from professional blood donors;⁹⁹ proximity to areas of high HIV incidence and prevalence (India and Myanmar), with a large amount of cross-border traffic; and low level of current knowledge among both the “at-risk”⁵⁰ and general¹⁰⁰ populations about the nature of HIV/AIDS and self-protection strategies.

Given the low levels of HIV infection reported from Bangladesh thus far, the country has a perhaps unique opportunity to act to prevent a widespread epidemic. Strategies for HIV prevention are not the subject of this thesis, but should be viewed as an urgent priority in Bangladesh.

5.7.2 Hepatitis B

Hepatitis B virus (HBV) can be transmitted via a number of routes: materno-fetal; childhood (exact mode of transmission still unclear); parenterally (e.g. non-sterile injections or surgical procedures); and sexually. The importance of infection with HBV lies in the potential development of the carrier state (persistence of hepatitis B surface antigen, HBsAg, more than six months after exposure) with its concomitant increased risk of chronic liver disease, cirrhosis and hepatocellular carcinoma.

Whilst it is well recognised that many countries in the Asian region have a high prevalence of HBV infection, exact population-based prevalence data from Bangladesh has been lacking until now. Several studies have looked at the prevalence of infection among selected 'risk groups' (surgical patients,¹⁰¹ commercial sex workers,¹⁰² injecting drug users¹⁰³), and found high levels of previous exposure and infectivity. The results from this study are the first in Bangladesh to show population-based prevalence in an unbiased sample.

We found a high rate of both previous exposure to HBV (54% of men and 38% of women), and chronic carriage (estimated 9% of men and 6% of women are HBsAg positive). Multivariate analysis showed that the prevalence of hepatitis B infection rose significantly with age in both men and women. It should be emphasised that the prevalence of HBsAg is an estimate since we did not have enough remaining serum to be able to test all those who were found to show evidence of previous exposure to HBV. Thus we have extrapolated results found in the numbers we were able to test (see Chapter 4, Section 4.10.2 for exact numbers tested). Caution should therefore be exercised with these results. However, corroborating evidence has come from a recent (unpublished) population-based study carried out on stored maternal serum in Matlab, which indicates that the prevalence of both hepatitis B anticore (previous exposure) and HBsAg in these women is very similar to the results we have found among women in our survey.¹⁰⁴

The data would seem to indicate that there is a strong case to consider the feasibility of undertaking an HBV vaccination programme in Bangladesh. It is well known that the age at infection has a strong impact on the likelihood of developing a carrier state with all its attendant risks.¹⁰⁵ Those who are infected earlier in life will be more likely to become chronic carriers. Thus, most experts would recommend mass vaccination in childhood as the most effective means to delay the average age of infection and hence reduce the number of new carriers in the population. Studies carried out recently in India have found an average estimated carrier rate of 4% in the general population,¹⁰⁶ and researchers have recommended universal immunization of neonates as the appropriate strategy for their country.¹⁰⁷ Further analysis is

needed in Bangladesh to determine the most appropriate and cost-effective public health strategy against this problem.

5.7.3 Cervical cytology

It has been estimated that cervical cancer is the most common cancer among women in the developing world.¹⁰⁸ There is a strong association between the presence of certain sub-types of (sexually transmitted) human papilloma virus (especially HPV types 16 and 18) and the development of cervical¹⁰⁹ and other anogenital¹¹⁰ cancers. Screening (using PAP smears) at PHC (as undertaken in this study) and other levels can detect the presence of early pre-cancerous lesions. In order to be useful, however, screening must be backed up by the presence of established referral centres where women can be sent for appropriate management and treatment.

We found a low prevalence of cervical dysplasia (possible pre-cancerous changes seen in cells on the PAP smear) in these women – perhaps a further indication of the low prevalence of STIs in general. Nonetheless, early treatment of women with pre-cancerous cytology could avoid the risk of developing (usually fatal) invasive cervical cancer at a later stage. The cost-effectiveness of siting cervical screening services at the PHC level may be questionable in a population with a low prevalence of dysplastic changes as we have found, but will need further consideration before being dismissed as too expensive. Experts recommend that targeting women at higher risk of dysplasia may be successful in decreasing the incidence of cervical carcinoma in the entire population.^{111,112} It should be reiterated, however, that in order for screening to be worthwhile, referral systems and treatment centres must be in place. During the course of this study whenever we identified a woman with cervical dysplasia, we were left with few options for further management owing to the distinct lack of referral sites and low possibility of the women actually reaching the few sites available.

Finally, it should be emphasised that whilst the establishment of screening and treatment services for cervical cancer may still be some way off in the future for low-income countries with a low population-prevalence, this

remains predominantly a problem associated with sexual transmission. The use of barrier methods of birth control may act as the most effective intervention in those populations where other secondary and tertiary prevention services are not yet available.

5.8 Evaluation of the syndromic flow charts

Although there is global acknowledgement that control of STIs is a worthwhile target^{56,113,114} (see Chapter 1 for a more detailed exploration of this topic), the tools available for achieving this goal in low-income countries are limited. Epidemics of STIs are dependent upon a number of parameters, some fixed (the infectivity of the pathogen) and some open to modification: the rate of partner change (interaction between infected persons and susceptible individuals); and the duration of infectiousness.^{115,116} Accurate clinical management of infected persons remains a cornerstone of most STI control programmes.⁸² It aims not only to cure the infected individual, thus preventing possible complications and sequelae, but also to decrease the duration of infectiousness and thus prevent the spread of infections to sexual partners. Such an approach not only reaps benefits for the individual patient (and potentially for his/her partners), but also for society as a whole which benefits from a reduction in the amount of time an infected person is infectious to others.

Traditionally, diagnosis and management of STIs has relied either upon the clinical judgement of the individual clinical practitioner, or has been based upon the results of laboratory findings from individual patients. The latter approach carries high initial costs to both the service providing the laboratory facilities and possibly to the client purchasing care.

In the absence of either laboratory facilities or cheap, effective and simple-to-use diagnostics, the World Health Organisation has developed a set of syndromic management algorithms for use at the primary health care level.¹¹⁷ An evaluation of a modified flow chart for symptomatic women complaining of abnormal vaginal discharge was undertaken during the course of the study (see Chapter 3, Section 3.8). We investigated not only the effectiveness of the

flow chart itself (including the use of risk assessment), but also the cost of using the chart in Matlab. Further investigations were undertaken looking at the effectiveness of clinical training and the dissemination of behavioural change messages. The main findings of this part of the study can be summarised thus:

- i. PHC-level staff can be trained to diagnose and manage endogenous infections (bacterial vaginosis and candida) in symptomatic women, although the most cost-effective method of diagnosing BV is not clear. Diagnosis is aided by the use of simple, inexpensive technology such as pH paper, but such a technique depends upon the PHC worker carrying out a speculum examination on every symptomatic woman. With this precondition met during this study, and using a triad of conditions to diagnose BV (pH>4.7, 'whiff test' positive and discharge 'looks abnormal') the PHC workers were able to correctly diagnose 59% of candida infections and one third (32%) of BV [as judged against BV diagnosed by Nugent's criteria¹¹⁸]. The rate of overdiagnosis was relatively low with specificities of 79% and 82% for the two infections respectively (see Table 35). It should be noted that the use of pH paper alone had a sensitivity of 88.5% for the detection of BV, although overdiagnosis was higher with a specificity of 54.9%. Cost analyses of the two diagnostic approaches for BV (use of pH paper, potassium hydroxide and diagnosis of an 'abnormal looking discharge' versus using pH paper alone) will help programmes decide which technique is most cost-effective for the management of this endogenous infection by PHC level workers;
- ii. The ability of PHC workers to diagnose and manage women infected with cervical STIs (chlamydia or gonorrhoea) is compromised in this population by the low level of infection, the lack of cheap and effective diagnostic tools, and by the low specificity or absence of clinical signs of infection.^{92,93} Indeed, in this study, none of the 5 women with a cervical infection were correctly identified by the health workers, and the 9 women treated for an infection were subsequently proven to be uninfected on laboratory analysis;

- iii. The use of behavioural risk assessment to identify STI-infected women (a strategy recommended by the WHO and previously positively evaluated in several settings in sub-Saharan Africa^{119,120,121,122} and elsewhere¹²³) did not improve the sensitivity of STI diagnosis in a population where there are severe social and cultural consequences of reporting non-marital sexual relationships. The other recommended risk assessment question (whether the woman's sexual partner had any symptoms suggestive of an STI) was answered positively by 30% of women, thus making it a highly non-specific tool. We did investigate other possible markers of risk in this population, and the results are explored in Section 5.8.1 below;
- iv. Training of health workers in syndromic management has led to an increase in the number of women mistakenly diagnosed as being infected with an STI. Overdiagnosis carries a number of consequences:
- Financial for the health system providing unnecessary treatment (see below)
 - Financial for the client buying unnecessary drugs
 - Social/cultural for women (and potentially for men) being asked to tell their partners they need to seek treatment for a (non-existent) sexually transmitted infection
 - Clinical/microbiological with the possibility of increased drug resistance through the unnecessary use of antibiotics¹²⁴
- v. Whilst STI diagnosis rates have risen post-training, concomitantly, the diagnosis rates for endogenous infections have fallen (see Chapter 4, Figure 10). They now favourably approach the level of laboratory-confirmed infection in the clinic population;
- vi. The accuracy of behaviour change information given to symptomatic clients (male and female) was disturbingly low (see Chapter 4, Section 4.13.7b). In a majority of cases, women were not asked any questions about their sexual behaviour. Men, however, were asked a number of detailed questions and the response rate to these questions was high. Information given to the clients, however, was often inaccurate, and was frequently provided in a judgmental manner. Thus, before PHC

level workers can be expected to undertake roles of counselling and information sharing, they will need a more intensive level of training than that currently recommended (it should be noted that PHC staff on our training programme received a relatively more intense level of training from a noted behaviour change communications expert than that recommended in the training modules in use). Increased training requirements carry resource and financial implications for a national programme;

- vii. Owing to a lack of resources, we did not evaluate the syndromic flow charts for men in our sexual health clinics. Studies in other populations have shown that men infected with either gonorrhoea¹²⁵ or chlamydia⁹³ will often have symptoms, although these findings are now being challenged in more recent studies.⁵⁹ The symptoms and signs of infection are more specific in men than the equivalent syndromes in women, thus making the validity of syndromic management flow charts higher.^{126,127} An evaluation of the management charts in men is now needed in Bangladesh.

5.8.1 Risk assessment in symptomatic women

As stated above, the use of conventional risk assessment (as recommended by WHO¹¹⁷ – see Appendix 3 for further details) among the symptomatic women seen in the survey was unsuccessful: only three women in the survey reported non-marital sexual activity, whilst a large number of women (30%) reported that their husbands were symptomatic with possible symptoms of an STI. Application of the recommended criteria for risk assessment would thus have resulted in a large degree of over-treatment for STIs in these women.

During the course of the study we investigated other possible social and demographic markers of STI risk in symptomatic women. As Chapter 4 highlights, other markers were found, namely: working ‘in service’ and working outside of her own village. Both variables were associated, on bivariate analysis, with an increased risk of an STI being present. Use of an IUD was found to have a high but non-significant odds ratio (5.07) for

increased risk. The results of this survey should clearly be interpreted with caution since the percentage and absolute numbers of infected women in the population is low. The specificity of the diagnostic tests in use for the STIs was generally high, which may compensate somewhat for the lower prevalence in determining risk associations.¹⁸ Several points here deserve further discussion:

a. Working environment

The vast majority of women taking part in all sections of the study were listed as being 'housewives'. Among the symptomatic women, the percentage of housewives was 92.3% (compared with 95.6% of the population-based women), and only 2.6% of the women were classified as being 'in service' – saleswoman, teacher, public sector work, etc. The STI rates in the two groups (housewife and 'in service') were 2% and 27% respectively ($p=0.005$). As stated, given the low rates of STIs overall, it is difficult to interpret the data in a meaningful way. However, it is possible that women who work outside the home are older than the general population of women, and therefore less strictly subjected to social sanctions. It should be noted that the women classified as working 'in service' were mainly ICDDR,B health workers. These women came to seek care because they knew that a foreign doctor would supervise the clinical examination. Clearly, selection bias cannot be ruled out in this case. The study needs to be repeated in other areas of Bangladesh, in order to both confirm the results and look in more detail for explanations.

b. IUD use

I have included a discussion of the finding that symptomatic women with an IUD in situ were more likely to have an STI (high odds ratio but not statistically significant, although the association with endogenous infections of the reproductive tract was significant) when compared to women not using contraception, as this finding may carry programme implications for the FP services in the country. The results of this study add to the body of published literature which debates whether IUDs increase the risk of a woman acquiring a genital infection. Past studies which found a link between IUD-use and the

risk of PID have often been flawed by methodological shortcomings as they failed to control for possible confounders or to confirm a clinical diagnosis with laparoscopic evidence.^{128,129} In this study we adjusted for confounders for endogenous infections and found an increased risk in women using IUDs.

One of the largest studies of infection-risk in IUD users found that PID-risk (i.e. infection of the upper reproductive tract) was most strongly related to the actual insertion process and to the background risk of STIs in participating women.¹³⁰ Many practitioners currently only recommend IUDs in women who are considered to be at low risk of acquiring an STI.¹³¹ With regards to lower reproductive tract infections, there is some evidence that rates of endogenous infections may be higher in women who have a IUD,¹³² especially with respect to organisms which are associated with BV.¹³³

In the light of the current debate about IUDs and risk of infection, and given that approximately 2% of married women use IUDs as a method of contraception in Bangladesh,⁵⁵ perhaps the most important current issues for programme planners and managers in the country are how to ensure the lowest possible level of iatrogenic infections at the time of insertion, and how to ensure that women with IUDs and concomitant RTIs receive appropriate treatment. The latter point was repeatedly raised by family planning providers during the course of this study, as they felt that women with IUDs were having them removed unnecessarily as the symptoms they complained of (e.g. abnormal vaginal discharge) were often attributed to the IUD itself rather than to a simultaneous infection.

5.8.2 Cost-effectiveness of syndromic management in Matlab

Estimation of the costs of using either the WHO recommended algorithm or the amended algorithm used in the study showed that among the 320 women with abnormal vaginal discharge, and for whom all laboratory results were available, most of the drug expenditure (92% and 75 % respectively) was wasted on overtreatment.. Use of the WHO algorithm would have resulted in all infected women receiving treatment, whilst use of the amended algorithm

failed to adequately manage any of the women with cervical infections, and less than half of women with endogenous infections received appropriate care.

Overdiagnosis of STIs and overtreatment of all reproductive tract infections in this society carries both financial and social costs. Adoption of the WHO algorithm in areas of Bangladesh with a similar RTI prevalence has been calculated to waste US\$0.76 per symptomatic woman managed at PHC level (see Appendix 5 for full details). Since the Government of Bangladesh and donors together only spend US\$3.1 per capita annually on health care,¹³⁴ US\$0.76 per woman represents an unacceptable level of health expenditure wastage. Furthermore, in socially conservative and restrictive societies such as that found in rural Bangladesh, telling women that they have an STI and expecting them to tell their male partners may expose them to a risk of domestic violence. If the original diagnosis was wrong, this is potentially an unacceptable risk to women's health and wellbeing.

Difficulties such as those outlined above may be overcome if and when simple, cheap and effective diagnostic methods for chlamydia and gonorrhoea become available. However, it should be recognised that health-expenditure savings will only be made if uninfected women do not seek care. Otherwise resources will again be wasted on diagnostics. Therefore, given the findings of this study, more effort is needed to understand why such a large percentage of uninfected women report symptoms and seek care.

5.9 Implications of the study results from population-based and symptomatic women surveys

This study has provided a unique opportunity to look critically at current strategies for STI/RTI control in lower prevalence situations. The generally accepted model of STD management and control is illustrated in Figure 1 (Chapter 1). This model, known as the Piot-Fransen model, was arrived at using data from women in rural Africa (Uganda, Zaire and Tanzania). It presupposes that approximately 50% of sexually active women in the

community have an RTI at any point in time, and that only about two thirds of these women will be symptomatic.² It can be seen from the pyramidal shape of Figure 1 that the percentage of women who seek care, visit a trained health care provider, receive appropriate treatment and comply with it, or persuade their partners to seek treatment, is an ever diminishing number. Consequently, the percentage of infected women who are adequately treated is estimated to be only 3%, and most will be reinfected in the absence of adequate partner management.

Figure 11 shows the application of the data from the Matlab study to the Piot-Fransen model of STD control. In this figure, the left-hand side of the 'pyramid' applies to women who have a microbiologically diagnosed infection: 15% in this population. Thus, 85% of the general population of women do not have an infection (result from our own cross-sectional survey). These two populations of women (infected and uninfected) are treated separately in this model, but the same data is extracted for each side of the pyramid, and the steps are followed exactly according to the Piot-Fransen model.

Reviewing each step using data from the population-based and symptomatic women surveys in this study:

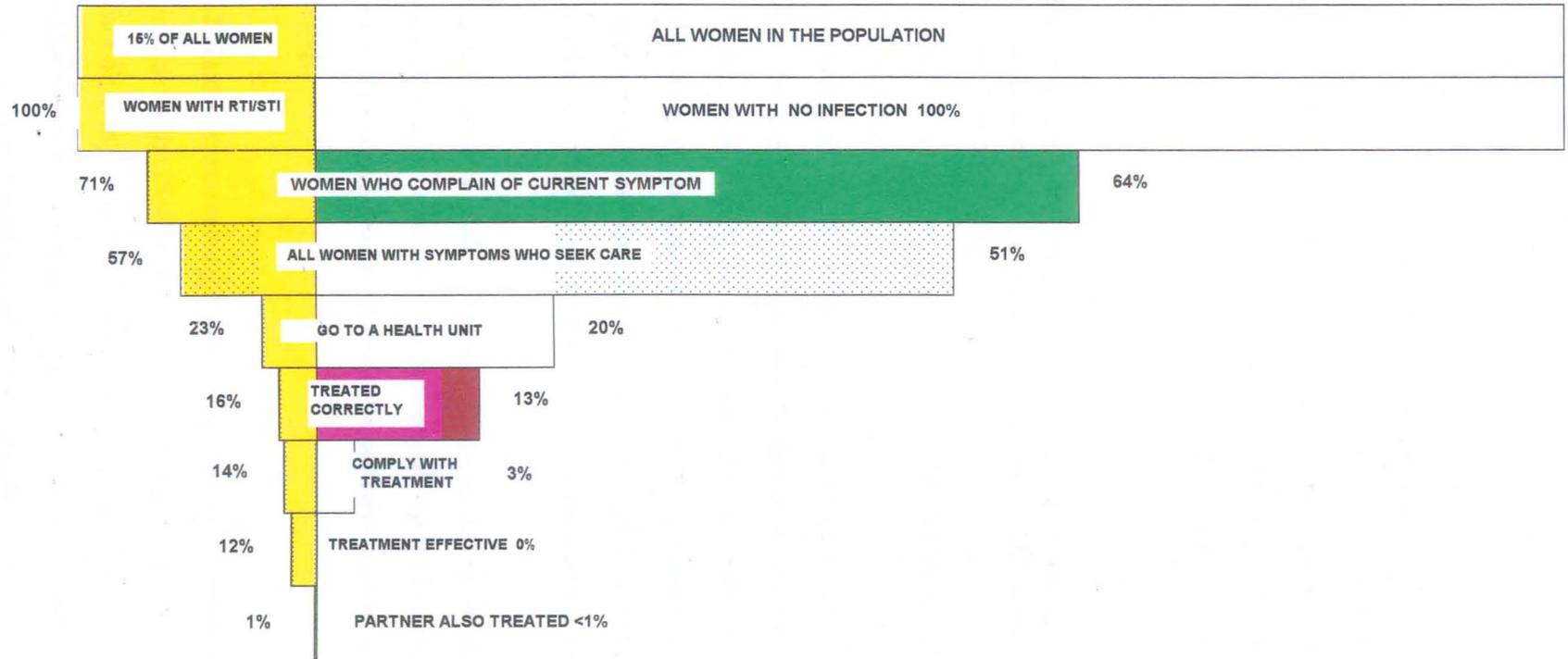
- i. A majority of women complain of a current symptom in the reproductive tract, on open questioning: 71% of infected women and 64% of the uninfected.
- ii. Most women with a symptom (approximately 80%) will seek care.
- iii. Most women seek care in the private sector, only 40% of those with a symptom (regardless of infection-status) will go to a public sector health centre.
- iv. Treatment received from trained health workers shows that of all those women with an infection, most will receive appropriate care. It should be remembered, however that NONE of the women with an STI received appropriate care in our study. The majority of correct care was administered to women with an endogenous infection. Furthermore, a large number of women in the review of symptomatic women received treatment in the

absence of an infection – this included ALL women who were told they had an STI on clinical diagnosis.

v. Compliance rates in this population are known to be high: 98% of women and 79% of their partners comply with treatment according to one Matlab-based study of 4,267 women followed up during a 4 year period.¹³⁵

The steps outlined above point to a variety of programme and research implications in settings such as the one found in Matlab (i.e. a low STI prevalence, high symptomatology area). The research questions are further discussed in the next section, whilst the policy and programme implications of these findings are outlined in Chapter 6.

REAPPLYING THE PIOT-FRANSEN MODEL TO
MATLAB



■ Why do these women complain of a current symptom in the absence of infection?

▨ Why do these women go to the private sector?

■ These women are treated in the absence of infection

■ These women are told that they have no problem

■ These women have an RTVSTI
-2.5% with an STI and 12.5% with an endogenous infection

In all cases where the partner is treated, the woman does NOT have an STI

Figure 11

5.10 Using the Matlab results to formulate a future research strategy in RTI/STI management in Bangladesh

The results in each of the steps outlined in Section 5.9 above, and throughout this discussion, highlight where the greatest impact might be achieved in attaining more appropriate public health management strategies for RTIs (including STIs) in rural Bangladesh. Solutions may not be immediately forthcoming, but the following questions can be raised in the hope that they will indicate where further and more appropriate studies need to be undertaken:

5.10.1 Why do a majority of women report an abnormal reproductive tract symptom, even in the absence of infection?

Do we need to address the issue of:

- (i) changing the way we train health providers to ask questions about ‘abnormal symptoms’?
- (ii) improving girls’ and women’s understanding of the ‘range of normality’ as far as the functioning of their own bodies is concerned?
- (iii) finding another non-infective basis of their symptoms. Is it, for example, linked more to contraceptive usage than to the presence of RTIs? Or do practices around menstruation and hygiene impact on symptom perception? Or are all three possibilities impacting on the prevalence survey results?

Research strategies might, therefore, focus on: (a) in-depth qualitative assessments of a community’s beliefs regarding RTIs and physical symptoms; (b) a more thorough review of the links between contraception and symptom reporting.

5.10.2 Health-care seeking behaviour: why the private sector?

Again, use of the Piot/Fransen model (Figures 1 and 11) highlights the fact that not all symptomatic women or men will seek care – although in this population a majority do, in fact, seek treatment. However, most of the men and women interviewed in this study stated that their first choice of health care provider is outside the public sector. This may be due to a number of factors:

- (i) Lack of opportunity – non-availability of the service, distance to travel, time, cost, ease of access, etc. This is especially the case for men in many areas where STI services in the public sector are only provided through the MCH-FP system and are thus only available for women;
- (ii) Fear of recognition/ sanctioning in public sector – e.g. for unmarried adolescents who may be deterred or even explicitly barred from seeking care in public sector clinics;
- (iii) Embarrassment associated with knowing that a trained provider may carry out a physical examination; and/or
- (iv) Perceptions regarding quality of care in the public sector.

If we are to advocate training programmes for public- and private-sector workers, we need to more fully understand the motivations leading people to choose one type of practitioner over another type. This may influence the choice of provider to whom training is given – e.g. in some areas it may be more appropriate to first train pharmacists rather than PHC/MCH-FP workers in RTI/STI management.

Research area: More in-depth community-based studies (outside the Matlab area) on health-care seeking behaviour and reasons for choice of provider with respect to RTI/STI symptoms, including understanding why people do not choose the public sector.

5.10.3 Provider-based research: What are the training needs?

It can be seen from the Piot/Fransen pyramid (original data and revised Matlab model) that activities at the provider-end of the model actually have a smaller impact on STI prevalence than those directed at the community and aimed at influencing either symptom perception or health-care seeking behaviour. Nonetheless, provider-based research, training and intervention carries the potential to: (a) improve overall quality of care for all presenting clients; (b) improve management of people with infections; (c) reassure those who are not infected (and potentially avoid overtreatment, and possibly

overspending in private care); and (d) provide opportunities for messages of primary prevention to be disseminated in a one-to-one setting.

Such improvements, however, are predicated on the belief that providers will want to receive and participate in training programmes. This is a perhaps naïve assumption as in many cases the needs of providers themselves have not yet been identified. Before wide-scale national training programmes are set in motion, it is important to focus directly on the needs of providers to avoid potential failure due to perceived 'top-down imposition'.

Research questions: What are the self-perceived training needs of all types of health-care providers? What are the incentives and motivations for those in the private sector to participate in training programmes? What are the disincentives and how can these be overcome? Which parts of the private sector are most likely to participate in training programmes and why?

5.10.4 Health systems research

(a) *What are the obstacles to adoption of known-to-be-effective interventions?*

This study has shown that there are several interventions in STI control which are both cost- and clinically-effective in the context of Bangladesh and could be implemented immediately. For example, screening pregnant women for syphilis, vaccination programmes against hepatitis B virus, and prophylaxis against ophthalmia neonatorum. However, these interventions have proven unpopular with policy makers in the country (L. Messersmith, UNAIDS Country Representative, personal communication on future STI control plans in Bangladesh). Given that these measures may actually act to decrease both prevalence and incidence of new infections, we need to fully understand why policy makers do not see them as a high priority.

Research questions: How do we communicate findings more efficiently from the research setting into the policy-making arena? What are the obstacles and opportunities for developing nationally appropriate RTI management and STI

control programmes? What lessons can be learnt from understanding how the policy decision-making process works in a country such as Bangladesh?

(b) *What guidelines and controls need to be implemented with respect to the private sector?*

If we acknowledge that private providers need to be included in programmes designed to improve quality of care for STI/RTI patients. How do we:

- i. Ensure ongoing quality of care in a sector which is often outside public sector scrutiny and control?
- ii. Enable all sections of the private sector to participate in such programmes – not only clinical service providers, but also, for example, private laboratories.
- iii. Facilitate more appropriate linkages between the private and public sectors to assure, for example, more direct referrals of patients requiring higher levels of medical care.

5.10.5 Moving out of the MCH-FP clinics

As discussed throughout this thesis, much global and national policy attention has so far been focused on the question of integrating RTI/STI management in to the MCH-FP setting. In areas of the world where the prevalence of these infections is high in such clinic settings, this is obviously one of the most effective ways of reaching infected women (although, again, men are often excluded from care in such settings). The results from Matlab, however, indicate that not all clinic populations are equally at risk, and in some cases these may not be the most appropriate recipients of full-scale public health control programmes for STIs. Issues raised by the findings in this thesis include:

- i. Are those women who attend MCH-FP clinics necessarily the same target group for both FP and STI services or are these two separate populations (with some degree of overlap for clinical services)?
- ii. At what prevalence of STIs in the general population should we think about targeting services to groups known or perceived to be at higher risk?

Research questions: These questions raise a number of possible future research areas:

- i. How do we ensure that unmarried adolescents (as a possible 'at-risk' group), receive appropriate and acceptable services given their current difficulties in accessing MCH-FP care?
- ii. When does it become cost-effective to target services/interventions? At what prevalence of STIs does it make more sense to focus attention on 'core groups' rather than the general population?
- iii. How do we establish programmes for 'core groups' in a non-stigmatising way?
- iv. What effect do programmes targeted at 'core groups' have on prevalence in the general population? For example, if a programme was established to treat (either prophylactically or clinically) STIs in female commercial sex workers, what effect does this have on STI prevalence in the wider community of women (e.g. among the MCH-FP attendees)?

These latter questions are especially important in a country such as Bangladesh where the possibility of social sanctions meted out against identifiable 'core groups' remains a valid and often cited reason for not acting to identify and provide services for such groups.

Whilst the section above highlights areas for possible future research, the final chapter in this thesis builds upon the results and discussion of the Matlab findings to recommend policy guidelines for STI control/RTI management which could be implemented in Bangladesh.

**CHAPTER SIX:
POLICY
IMPLICATIONS**

6 Policy Recommendations

The final chapter in this thesis uses the findings from all arms of the study to outline policy initiatives which could be incorporated into a national STI control/RTI management programme in a country such as Bangladesh. Whilst recognising that Matlab itself is not entirely typical of the rest of rural Bangladesh, the results from the work undertaken there highlight what types of interventions against STIs might be effective, for example in other areas with a low STI prevalence, and lead to suggestions of where these interventions might be placed in a national programme.

1. Management of symptomatic women at rural primary health care facilities

(a) Over 30% of symptomatic women complaining of an abnormal vaginal discharge and presenting for care were found to have an endogenous infection of the reproductive tract, whilst only a small number (1.1%) had a cervical sexually transmitted infection. Diagnosis and management of those women with endogenous infections was improved through the use of low cost diagnostics – such as pH paper. None of the women with STIs were correctly identified through the use of currently recommended management strategies (syndromic flow charts), including the use of risk assessment. Recommended WHO flow charts were found not to be cost-effective in this population. Thus, in order to improve the management of symptomatic women, and decrease costs spent on overdiagnosis of STIs in women attending PHC centres in areas of low STI prevalence, it would be worthwhile to initially concentrate on diagnosis and management of endogenous infections.

Recommendation: In areas of low STI prevalence, symptomatic women presenting to PHC level facilities, complaining of an abnormal vaginal discharge, should be treated first for endogenous infections of the reproductive tract. To ensure adequate and effective management of these women, PHC-level workers require:

- i. adequate training in the diagnosis and management of endogenous infections in symptomatic women;**

- ii. **Flow charts need to be developed for the management of endogenous infections in women at PHC level. The flow charts should initially be premised upon the non-availability of speculae;**
- iii. **However, it is recognised that diagnosis is helped by the use of low-cost diagnostics such as pH paper. This approach requires a speculum examination, therefore, simple flow charts incorporating use of a speculum and use of low-cost diagnostics also need to be developed for use at PHC level. The availability of these diagnostic tools needs to be ensured as part of a national programme;**
- iv. **The flow charts need periodic evaluations of their effectiveness.**

(b) A small number of symptomatic women will not respond to first line treatment for endogenous infections. In other cases, PHC level workers will be unsure of the appropriate management strategies for individual women (e.g. when they are unsure of the diagnosis). Both groups of women require adequate and effective management, and this may not be available at PHC level. These women should be referred to secondary or tertiary levels of the health service.

Recommendation: Women who do not respond to first line treatment at PHC level, or about whom staff are unsure/worried, should be referred to a facility with more specialised diagnostic and management capabilities.

This means ensuring that:

- i. **women who do not respond to treatment are encouraged to return for follow-up care;**
- ii. **adequate referral mechanisms exist within the health service to ensure women reach higher levels of care;**
- iii. **staff at secondary or tertiary level facilities are trained in RTI/STI diagnosis and management;**
- iv. **at higher levels of the health service, trained staff have access to adequate laboratory facilities.**

If women who do not respond to first line treatment, cannot or will not attend higher levels of health care, they should be treated for STIs at the primary health care level.

- (c) Syndromic flow charts other than the one used for management of women with an abnormal discharge were not evaluated in this study. However, they are thought to perform well, especially for the management of women with genital ulcers.

Recommendation: PHC level workers should be trained to manage women presenting with genital ulcer disease. Recommended flow charts are probably adequate for this purpose.

2. Non -clinical training requirements

Results from this study show that the adequacy, accuracy and hence efficacy of behaviour change messages given by PHC level staff was open to question. This was the case even after they had received recommended training.

Recommendation: Any staff engaged in programmes aiming to improve sexual health in both women and men need adequate training in behaviour change communications. The scope, depth and effectiveness of such training needs to be fully explored. Once trained staff are in place, programmes should monitor the type, accuracy and nature of information given out by staff.

3. Control of sexually transmitted infections

This study has shown that in areas of low STI prevalence, current management strategies are both inadequate and not cost-effective. However, the control of STIs *per se* is not in question. Other areas and populations in a country such as Bangladesh will probably have higher levels of STIs. These might include, for example, urban populations and those at risk from their profession (e.g. commercial sex workers) or their social activities (those who purchase commercial sex). However, in Bangladesh most current policy activity for STI

control is aimed at integration of STI services at the PHC level, and into the MCH-FP system. Concentration on such a policy may miss those at highest risk of STIs.

Recommendation: Populations at higher risk of STIs should be targeted at least equally and probably primarily for STI services and prevention strategies. Geographical and group targeting of services needs to be carried out without risk of stigmatisation.

4. Inclusion of men

In a country like Bangladesh, it is probably men rather than women who are at highest initial risk of contracting STIs. Furthermore, treatment of STIs in men is clinically simpler than management of the equivalent infections in women. Strategies to treat men, whilst being worthwhile in themselves, may also act to incorporate infected but asymptomatic women into the treatment framework – as partners of infected men.

This study has shown that there is a high level of unmet need in the provision of comprehensive sexual health services for men. Establishment of such services at PHC level was successful in Matlab – symptomatic and infected men sought care, others came for counselling only. When men seek care from trained providers, there is an opportunity for them to receive other sexual health services: behaviour change communication; psychosexual counselling; contraceptive services.

Recommendation: Men should be included in policies and programmes for improving reproductive and sexual health. Not only as the partners of infected women, or as the targets of condom promotion campaigns, but as people with unmet service needs in their own right. Establishing comprehensive sexual health clinics for men in rural Bangladesh has been shown to be successful in terms of persuading men to come forward for treatment and care from trained providers. A policy to establish more widespread public sector sexual health services for men may not only

improve the sexual health status of men, but will also be a more effective strategy in STI control than targeting women alone.

5. Changing health-care seeking behaviour

In this study, most women and men who had sought care for symptoms of possible RTIs had done so in the private sector. The reasons for choice of provider are not fully clear, but ease of access, cost and perceived quality of care may have all played a part. Meanwhile, most symptomatic women who sought care did not have an infection as a cause of their problem. Given that behaviour change campaigns should encompass strategies to improve health care seeking, these findings suggest the following:

Recommendations:

- i. When quality of care in the public sector is improved through training and strengthening of the programme (see recommendations above), the public themselves need to be made fully aware of the changes in the programme. Perceptions about the quality of public sector care need to be understood and changed, otherwise people will not seek care in this sector;**
- ii. general knowledge and understanding of RTIs/STIs needs elucidating and improving. In time, this will act to decrease the number of uninfected people who seek care (for physiologically normal discharges, for example).**

6. Training the private sector

Recognising that, in the short term at least, most people will continue to seek care from the private sector (formal and informal), providers in this sector should be included in training and quality of care improvement strategies. Other strategies for regulation of this sector also deserve consideration.

Recommendation: The needs, expectations and motivations of the private sector need elucidating. Such knowledge should then be used to design appropriate programmes to improve quality of reproductive and sexual health care in this sector.

7. Screening and prophylaxis against STIs

Adequate management of symptomatic adults seeking care is only one aspect in the public health control of STIs. Other strategies for control include: screening pregnant women for syphilis; prophylaxis of neonates against ophthalmia neonatorum; childhood immunisation against hepatitis B virus. This study has highlighted these strategies as being worthwhile of policy consideration in a country such as Bangladesh. The prevalence levels found in the population studied do not call into question the cost-effectiveness of the interventions.

Recommendation: All cost-effective aspects of STI control should be implemented in a country such as Bangladesh:

- i. screening all pregnant women for syphilis;**
- ii. prophylaxis of newborns against ophthalmia neonatorum;**
- iii. childhood immunisation against hepatitis B virus.**

8. Primary Prevention

Sexually transmitted infections are first and foremost preventable infections. The range of intervention strategies in a country such as Bangladesh can be as 'simple' as condom promotion, or as 'complex' as working towards the equality of opportunities and right for girls and women to ensure that they are not forced into commercial sex, or developing policies to ensure that urban sex ratio inequalities are minimised so that young men migrating to cities in search of work are not faced with environments which make the purchase of commercial sex more likely.

Recommendation: Prevention rather than treatment of STIs should remain the ultimate goal of any programme.

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APPENDIX ONE: STUDY PERSONNEL

Appendix One

STUDY PERSONNEL

Sarah Hawkes	Principal Investigator, ICDDR,B
Jyotsnamoy Chakraborty	Co-Investigator, ICDDR,B
Andres de Francisco	Co-Investigator, ICDDR,B
Linda Williams	Co-Investigator, LSHTM
David Mabey	Co-Investigator, LSHTM

Matlab-Based Staff (employed directly by RTI Project)

Kaniz Gausia	Project Physician
Nazmul Alam	Microbiology Laboratory Technician
Shamim Sufia Islam	Data Manager
Parimalendu Saha	Field Supervisor (male study)
Jahanara Begum	Field Supervisor (study of pregnant women and neonates)
Jahan Akhter	Interviewer/Supervisor (female study)
Milka Kunder	Interviewer
Khaleda	Data Entry
Masuda Sarif	Community Health Worker
Ferdousi Begum	Community Health Worker
Mallika Saha	Community Health Worker
Subhadra Gosh	Community Health Worker
Diplai Rani Das	Community Health Worker
Kodeza Akhter	Community Health Worker
Jhorna Majumder	Community Health Worker
Kashem Ali	Male Interviewer
Dinesh Saha	Male Interviewer
CR Das	Male Interviewer
Abu Taher	Male Interviewer
Alauddin Khan	Male Interviewer

PHC-Level Based Staff (evaluation of syndromic management in women and running male sexual health clinics)

Block A

Eva Talukder	Nurse Midwife
Kamrun Nessa	Lady Family Planning Visitor
Hasina Begum*	Nurse Midwife
Chandra Shekar Das*	Medical Assistant

Block B

Molina Roy	Lady Family Planning Visitor
Sufia Khatun	Nurse Midwife
Musarrat Hussain	Medical Assistant

Block C

Hena Begum	Lady Family Planning Visitor
Shebika Hadima*	Nurse Midwife
Santi Rani Gosh	Nurse Midwife
Haroun-ur Rashid	Medical Assistant

Block D

Dilara Sultana	Nurse Midwife
Janema Begum	Lady Family Planning Visitor
Mohammed ShahJahan	Medical Assistant

Matlab MCH-FP Clinic

Rokshana Parvin	Lady Family Planning Visitor
Anowara Khanam	Lady Family Planning Visitor

* = PHC-level staff employed directly by the RTI Project.

Dhaka-Based Staff

Zubaida Nasreen	Secretary
Farid Ahmed	Computer Programmer and Data Manager
Habibur Rahman	Social Scientist attached to Social and Behavioural Sciences Programme, ICDDR,B. Working part-time with RTI project.

**APPENDIX TWO:
QUESTIONNAIRES/
CONSENT FORMS**

Appendix 2

Questionnaires and Consent Forms

For sections A (population-based women), C (symptomatic women) and E (population-based men), questionnaires were used in an English version during the study as all health workers (PHC level) were literate in English. For sections F (pregnant women) and H (mothers/neonates), however, the English version was translated into Bengali (and then re-translated back again). The retranslated English versions are presented here.

All consent forms were written in Bengali and read to participants in Bengali. The English translations of the consent forms are presented here.

All questionnaires and consent forms were passed by the Ethical Committee of ICDDR,B.

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**TEXT
BOUND INTO THE
SPINE**

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH,
 BANGLADESH.
 MATERNAL CHILD HEALTH AND FAMILY PLANNING PROJECT.
 Matlab, Chandpur.

REPRODUCTIVE TRACT INFECTION STUDY
 POPULATION BASED QUESTIONNAIRE FOR WOMEN

Note: Y = 1
 N = 2
 NA = 9, as per field width
 NK = 8

Date seen Interviewer: _____
 (DD / MM / YY)

1. CID Number
 RID Number
 Study Number
 2. Date of birth Religion : (Muslim-1 Hindu-2)
 3. Years of completed schooling
 4. (a) Occupation (CODE LATER)
 b) Has she ever worked outside her village in :
 Nearby town / thana Y / N
 Dhaka Y / N
 Outside Bangladesh Y / N
 Bazar Y / N
 Other rural area Y / N
 5. Is she currently employed outside her village ? Y / N
 6. (a) Age at first marriage
 (b) Number of marriages in lifetime
 (c) Current marital status :
 Married = 1
 Divorced / separated = 2
 Widowed = 3

If answer = 1, then ask the following, otherwise go to Q. 7

(d) Number of wives that husband currently has

(e) Length of current marriage (Years)

6. (a) Husband's occupation (CODE)

(b) Where does husband currently work ?

Village / rural area = 1

Town / city (e.g. in Dhaka) = 2

Out of Bangladesh = 3

Specify country _____

(c) In the past one month, how many nights has husband spent away from home ?

Most / all nights = 1

Spent occasional nights away from home = 2

He was always at home at night = 3

7. How many times has she been pregnant ?

How many children does she have that are currently living ?

Health Questions

8. Any fever in the past one week ?

Y / N

Has she taken any medication, in the past one week ?

Y / N

If she has taken any medication, list here the type (if she knows what it was) CODE LATER

9. Has she ever had a blood transfusion ? Y / N

If "yes", which year (s) ? (Code in most recent year)

10. Current method of contraception :

None = 0

Oral pill = 1

Injectable = 2

IUD = 3

Condoms = 4

Sterilisation / tubectomy = 5

Vasectomy = 6

Other barrier methods = 7

Other methods (specify) = 10

11. Age at first menstruation

12. Is she menstruating regularly? Y / N

If yes, how many days ago was the first day of her LMP?

13. If she is menstruating regularly ask the following :
(If she is not menstruating regularly Go To QUESTION 14)

(a) Length of menstrual cycle (days)

(b) Number of days she bleeds for

(c) Concerning her LMP, was it :

Same amount of bleeding as usual = 1

Heavier bleeding than usual = 2

Less bleeding than usual = 3

(d) Concerning her LMP, was it :

Same amount of pain as usual = 1

More painful than usual = 2

Less painful than usual = 3

No pain = 4

(e) Does she ever spend time in bed because of pain when
bleeding? *Y / N

* If "yes", how many days each period does she spend in bed?

< 1 = 1

1 - 2 = 2

> 2 = 3

(f) Does she ever pass any clots? Y / N

14. Ask these questions whether or not she is currently having regular menstruation :

(a) What dose she use as sanitary protection ? (choose one only)

- Nothing = 1
- Towels bought from shop = 2
- Tampons bought from shop = 3
- Cloths / towels / rags made at home* = 4
- Tampons made at home* = 5
- Petticoat = 6

* If she makes her own sanitary protection, what does she make it from

(specify & CODE) _____

(b) When she is menstruating, how many times in one day does she change her sanitary protection ?

(c) Does she ever wash INSIDE her vagina during menstruation ? Y / N

(d) *If "yes", what does she use to wash herself inside (choose one only) ?

- Water only = 1
- Soap and water = 2
- Savlon and water = 3
- Salt and water = 4
- Dry rags / cloths = 5
- Other (specify) = 6

THE FOLLOWING QUESTIONS ARE RATHER PERSONAL.
REMINDE THE WOMAN THAT EVERYTHING SHE TELLS YOU IS
IN COMPLETE CONFIDENCE.

15. (a) Age at which she first met with her husband

was this before or after her marriage ?

Before = 1

After = 2

(b) In her lifetime how many men has she met with ?

(c) In the past one year, how many men has she met with ?

16. (a) Does she ever wash INSIDE her vagina after sexual intercourse ?

*Y / N

(b) *If "Yes" to this question, what does she use to wash herself inside (choose one only) to wash ?

- Water only = 1
- Soap and water = 2
- Savlon and Water = 3
- Salt and water = 4
- Dry rags / cloths = 5
- Other (specify) = 6

17. Does she currently have any symptoms relating to her reproductive health ?

Y / N

(Explain to her what this means, then list the symptoms she complains of (CODE)

Now explain to the woman you are going to ask her about some symptoms that women often suffer from. You will need to know whether she currently has these symptoms, or whether she has ever suffered from them in the past.

18. Vaginal Discharge :

(a) Does she have an abnormal vaginal discharge at the present time ?

Y / N

If yes, how long has it been abnormal ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

(b) Has she suffered with an abnormal vaginal discharge in the past ? Y / N

(c) If she has a vaginal discharge, what is the colour today ?

White = 1
Yellow = 2
Brown = 3
Other colour = 4
Watery = 5
No discharge = 6

d) Does her vaginal discharge smell offensive ? *Y / N

*If yes, how long has it smelt offensive ?

< 7 days = 1
> 7 days < 1 month = 2
> 1 month = 3
> 1 year = 4

(e) If she has a discharge now, or has had one in the past, has she ever stopped meeting with her husband because of it ?

Y / N

(f) Has she ever sought treatment / advice for abnormal vaginal discharge (either now or in the past).

Y / N

19. Genital itching

(a) Does she suffer with any genital itching at the present time ?

Y / N

*If yes, how long has this been present ?

< 7 days = 1
> 7 days < 1 month = 2
> 1 month = 3
> 1 year = 4

(b) Has she suffered with genital itching in the past ? Y / N

(c) Has she ever sought treatment / advice for genital itching
(either now or past) ? Y / N

20. Lower abdominal pain.

(N.B. Make sure that she is not referring to menstrual pain)

(a) Does she have any lower abdominal pain at the present
time ? *Y / N

If 'yes', how long has the pain been present ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

Has she ever suffered with lower abdominal
pain in the past ?

Y / N

(b) Has she ever sought treatment / advice for her lower
abdominal pain ?

Y / N

21. Dyspareunia (pain during sex)

(a) How long ago did she last meet with her husband ?

- < 1 day = 1
- < 7 days = 2
- < 7 days < 1 month = 3
- > 1 month = 4
- > 1 year = 5

The last time she met with her husband, was it painful ? *Y / N

*If "yes", was the pain :
Superficial (external genitalia) Y / N
Deep (in the abdomen) Y / N

Has she ever in the past suffered with any pain whilst meeting with her husband ? Y / N

(b) Has she ever sought treatment / advice for her dyspareunia ? Y / N

22. Dysuria (pain passing urine)
(a) In the past one week, has she suffered with any pain whilst passing urine ? *Y / N

(b) In the past one week, has she been passing urine :
The same frequency as usual = 1
More often than usual = 2
Less often than usual = 3

(c) Has she ever suffered with pain passing urine in the past ? Y / N

(d) Has she ever sought treatment / advice for problems passing urine ? *Y / N

23. Genital Prolapse
(a) Does she suffer with any genital prolapse ? *Y / N

If "yes", how long has this been present ?
< 1 month = 1
> 1 month < 1 year = 2
> 1 year = 3

(b) If "yes", has she ever sought treatment / advice for genital prolapse ? *Y / N

(c) When she coughs / sneezes / laughs does she leak urine ? Y / N

24. Genital ulcer

(a) Does she have any genital ulcer at the present time ? *Y / N

"If 'yes", is it painful ? Y / N

Has she had a genital ulcer before ? Y / N

*If "yes", how long ago was the last time

< 7 days = 1

> 7 days < 1 month = 2

> 1 month = 3

> 1 year = 4

(b) Has she ever sought treatment / advice previously for any genital ulcer ? *Y / N

25. If she has ever sought treatment for any reproductive health problems, ask her the following :

Where did she go first for treatment / advice (Specify and code)

Did the treatment help her ? Y / N

*If "no" where did she go next for treatment / advice (specify & CODE)

Did the treatment help her ? Y / N

(c) If she has / had a reproductive health problem but has never before sought treatment / help for it, is it because :

- No time to go for advice / treatment = Y / N
- Treatment is too expensive = Y / N
- Symptoms not severe enough = Y / N
- She treats herself at home = Y / N
- Did not know where to go for treatment = Y / N
- Too shy to seek treatment = Y / N
- Other reason (specify) = Y / N

<input type="checkbox"/>

(d) Which symptoms did she not seek treatment for ? (specify)

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

26. (a) In the past one month, has her husband / sexual partner suffered from ;

- Pain on passing urine *Y / N
- Abnormal discharge from the penis *Y / N
- Genital ulcer *Y / N

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

*(b) If her husband / sexual partner has any of these symptoms :

- Did he stop meeting with her because of this problem (s) ? Y / N
- Did he seek treatment ? Y / N
- Did she have any treatment ? Y / N

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH,
 BANGLADESH.
 MATERNAL CHILD HEALTH AND FAMILY PLANNING PROJECT.
 Matlab, Chandpur.

CLINICAL EXAMINATION OF WOMEN

DATE SEEN
 (DD(MM/YY))

Note: Y = 1 NK = 8
 N = 2 NA = 9, as per field width

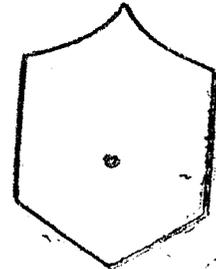
STUDY NO.

- Woman agrees to examination Y / N
1. Temp. — °C Pyrexial Y / N
2. Mucous membranes :
- Pale Y / N
- Mouth ulcer (s) Y / N
3. Lymphadenopathy (> 0.5cm) Y / N
- If "yes", site :
4. Blood pressure
- Is she : Normotensive = 1
- Hypotensive = 2
- Hypertensive = 3
5. Breasts / Axillae :
- Record on diagram any lumps/abnormalities (specify & CODE)



6. Examination of abdomen (mark abnormalities on diagram) :

- Splenomegaly Y / N
- Hepatomegaly Y / N
- Lower abdo. mass Y / N
- Guarding Y / N
- Rebound tenderness Y / N
- Lower abdo. tenderness Y / N
- Any other problem (specify) Y / N



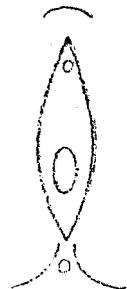
7. Skin :

- Scabies Y / N
- Fungal infection Y / N
- Acne Y / N
- Vitiligo Y / N
- Psoriasis Y / N
- Eczema Y / N
- Other abnormalities (Specify) Y / N

8. External genitalia :

- Genital ulcer present *Y / N
- Genital warts present *Y / N
- Inguinal lymphadenopathy *Y / N
- Tinea cruris Y / N
- Pubic lice Y / N
- Bartholin's cyst *Y / N
- Vulval candidiasis Y / N
- Other abnormality (specify) Y / N

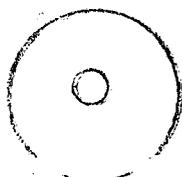
* If these are present, mark site on diagram



9. Speculum Examination

- Vaginal discharge normal Y / N
- Cervical mucopus present Y / N
- Cervical friability Y / N
- Cervical ectopy present *Y / N
- Cervical / vaginal ulcer *Y / N
- *Nabothian cyst present *Y / N
- Other cervical or vaginal abnormality (specify) Y / N

* If these are present, record site and size on diagram.



10. Colour of discharge :

- No discharge = 0
- Clear, mucoid = 1
- White = 2
- Yellow = 3
- Brown = 4
- Other (state) = 5

11. (a) Consistency of discharge :

- No discharge = 0
- Clumpy / curd like = 1
- Thin / watery = 2
- Thick = 3
- Other = 4

(b) Amount of discharge :

- Normal = 1
- Less than normal = 2
- More than normal = 3
- No discharge = 4

12. PH of discharge

- PH \leq 4.7 = 1
- PH $>$ 4.7 = 2

13. Whiff test : Pos = 1 Neg = 0

14. Bimanual examination

- Uterine size (weeks)
- Cervical motion tenderness Y / N
- Adnexal mass present *Y / N

If "yes", site : right Y / N tender Y / N

left Y / N tender Y / N

15. Genital prolapse :

- Uterine descent Y / N degree (1,2,3)
- Rectocele Y / N
- Cystocele Y / N degree (1,2,3)

16. Any other problems (specify)

AFTER TAKING SPECIMENS, LABEL THEM WITH THE PATIENT'S STUDY NUMBER. DO NOT WRITE THE PATIENT'S NAME ON ANY SPECIMENS.

17. WHAT IS YOUR DIAGNOSIS ? (CODE)

18. DOES SHE NEED ANY TREATMENT ? Y/N

19. Treatment given (Specify)

20. Treatment for partner needed ? *Y / N

* If "yes", choose one :

Medication given to client for distribution = 1

Partner to contact CHW = 2

CHW to contact partner = 3

Other (specify & CODE) = 4

21. Is Follow-up visit needed ? *Y / N

* If "Yes", at follow-up visit complete form B again, and ask additional questions :

(a) Is she symptomatic ? Y / N

(b) Is she: the same = 1

Better = 2

Worse = 3

Compared to last visit ?

(c) Did she take medication as prescribed Y / N

If "no", why not (specify & CODE)

--	--

(d) Did partner take treatment Y / N

If "no", why not (specify & CODE LATER)

Further action required (specify)

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH,
 BANGLADESH,
 MATERNAL CHILD HEALTH AND FAMILY PLANNING PROJECT.
 Matlab, Chandpur.

QUESTIONNAIRE FOR SYMPTOMATIC WOMEN

Y = 1
 N = 2
 NA = 9, as per field width
 NK = 8

Date seen : Interviewer :

1. CID Number
 RID Number
 Study Number

2. Date of birth Religion (Muslim-1, Hindu-2)

3. Years of completed schooling

4. (a) Occupation (CODE)

(b) Has she ever worked outside her village in :

Nearby town / thana	Y / N	<input type="checkbox"/>
Dhaka	Y / N	<input type="checkbox"/>
Outside Bangladesh	Y / N	<input type="checkbox"/>
Bazar	Y / N	<input type="checkbox"/>
Other rural area	Y / N	<input type="checkbox"/>

(c) Is she currently employed outside her village ? Y / N

5. (a) Age at first marriage

(b) Number of marriages in lifetime

(c) Current marital status :

Never married	= 1	<input type="checkbox"/>
Married	= 2	<input type="checkbox"/>
Divorced / separated	= 3	<input type="checkbox"/>
Widowed	= 4	<input type="checkbox"/>

If answer 2, ask the following, otherwise go to Q. 7

(d) Number of wives that husband currently has

(e) Length of current marriage (years)

6. ... (CODE):

Where ... currently work ?

- ... area = 1
- ... (e.g. in Dhaka) = 2
- ... Bangladesh = 3
- ... country ? _____

(c) In the ... one month, how many nights has husband spent away from home ?

- Most / all nights = 1
- Spent occasional nights = 2
- He was always at home at night = 3

7. How many times has she been pregnant in her life ?

How many children does she have that are currently living ?

Health Questions

8. Is she menstruating now ? Y / N

Any fever in the past one week ? Y / N

Has she taken any medication in the past one week ? Y / N

If she has taken any medication, list here the type (if she knows what it was) (CODE LATER):

9. Has she ever had a blood transfusion ? Y / N

If "yes", in which years ? (Code in most recent year)

10. Current method of contraception :

- None = 0
- Oral contraceptive pill = 1
- Injectable = 2
- IUD = 3
- Condom = 4
- Tubectomy = 5
- Vasectomy = 6
- Other barrier methods = 7
- Other methods (specify) = 10

11. Is she currently having regular periods? Y / N

If 'yes', how many days ago was the first day of her LMP?

Ask these questions whether or not she is currently having regular menstruation:

(a) What does she use as sanitary protection (choose one only)

- Nothing = 1
- Towels bought from shop = 2
- Tampons bought from shop = 3
- Cloths / towels made at home* = 4
- Tampons made at home* = 5
- Petticoat = 6

*If she makes her own sanitary protection, what does she make it from? (specify & CODE) _____

(b) When she is menstruating, how many times in one day does she change her sanitary protection?

(c) Does she ever wash INSIDE her vagina during menstruation? Y / N

*If 'yes', what does she use to wash herself inside (choose one)

- Water only = 1
- Soap and water = 2
- Savlon and water = 3
- Salt and water = 4
- Dry rags / cloth = 5
- Other (specify) _____ = 6

(d) Does she ever wash INSIDE her vagina after she has met with her husband? Y / N

*If 'yes', what does she use to wash herself inside (choose one)

- Water only = 1
- Soap and water = 2
- Savlon and water = 3
- Salt and water = 4
- Dry rags / cloth = 5
- Other (specify) _____ = 6

12. Which symptoms is the woman complaining of?

- | | |
|--|-------|
| Abnormal vaginal discharge | Y / N |
| Genital itching | Y / N |
| Genital ulceration | Y / N |
| Lower abdominal pain | Y / N |
| Lower back pain | Y / N |
| Pain during sexual intercourse | Y / N |
| Pain on passing urine | Y / N |
| Genital prolapse | Y / N |
| <u>Other (please specify & CODE)</u> | Y / N |

<input type="checkbox"/>

If a woman has any of the above symptoms then please ask the following questions. If she does not have the symptoms, do not ask the questions:

13. Vaginal Discharge :

(a) How long has she had an abnormal vaginal discharge ?

- | | |
|--------------------|-----|
| < 7 days | - 1 |
| > 7 days < 1 month | - 2 |
| > 1 month | - 3 |
| > 1 year | - 4 |

(b) What is the colour of her vaginal discharge today ?

- | | |
|--------------|-----|
| White | - 1 |
| Yellow | - 2 |
| Brown | - 3 |
| Other colour | - 4 |
| Watery | - 5 |

(c) Does her vaginal discharge smell offensive ?

Y / N

If "yes", how long has it smelt offensive ?

- | | |
|--------------------|-----|
| < 7 days | - 1 |
| > 7 days > 1 month | - 2 |
| > 1 month | - 3 |
| > 1 year | - 4 |

(d) Has she ever stopped having sexual intercourse because of her vaginal discharge ? Y / N

14. Genital itching

(a) How long has she been suffering from genital itching ?

- > 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

15. Genital ulcer

(a) How long has she had a genital ulcer ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

Is it painful ? Y / N

Has she had a genital ulcer before *Y / N

*If "yes", how long ago was the last time ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

16. Lower abdominal pain.

(a) If she has lower abdominal pain, how long has the pain been present ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

17. Pain during sexual intercourse

(a) If she is complaining of pain during sexual intercourse, is the pain,

Superficial (external genitalia) ? Y / N

Deep (in the abdomen)? Y / N

(b) How long has she been suffering from pain during Sexual intercourse

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

18. Pain Passing urine

(a) How long has she had pain on passing urine ?

- < 7 days = 1
- < 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

(b) Is she passing urine more frequently than usual ?

Y / N

19. Genital prolapse

If she suffers with genital prolapse, how long has this been present ?

- < 7 days = 1
- > 7 days = 2
- > 1 month = 3
- > 1 year = 4

20. Ask every woman :

Has she had any other treatment/advice before coming here to ICDDR,B ? Y / N

If "yes", where did she go for treatment/advice (specify & CODE) _____

Did the treatment help her ? Y / N*

*If "no" where did she go next for treatment/advice (specify & CODE) _____

Did the treatment help her ? Y / N

If she has a problem but has never sought treatment/help for it, is it because :

- No time to go for advice/treatment = Y / N
- Treatment is too expensive = Y / N
- Symptoms not severe enough = Y / N
- She treats herself at home = Y / N
- Did not know where to go for treatment = Y / N
- Too shy to seek treatment = Y / N
- Other reason (specify) _____ = Y / N

THE FOLLOWING QUESTIONS ARE RATHER PERSONAL: REMIND THE WOMAN THAT EVERYTHING SHE TELLS YOU IS IN COMPLETE CONFIDENCE.

21. (a) How old was she when she first had sexual intercourse ?

Was this before or after her marriage ?

Before - 1

After - 2

Not yet married - 3

(b) In her lifetime, how many men has she met with ?

(c) In the past year how many men has she met with ?

22. How long ago did she last meet with her husband/sexual partner ?

< 1 day - 1

< 7 days - 2

> 7 days < 1 month - 3

> 1 month - 4

> 1 year - 5

23. (a) In the past one month, has her husband/sexual partner suffered from :

Pain on passing urine *Y/N

Abnormal discharge from the penis *Y/N

Genital ulcer *Y/N

(b) If her husband/sexual partner has any of these symptoms :

Did he stop having sex with her because of

This problem ? Y/N

Did he seek treatment ? Y/N

Did she have any treatment ? Y/N

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH.
 MATERNAL CHILD HEALTH AND FAMILY PLANNING PROJECT.
 Matlab, Chandpur.

REPRODUCTIVE TRACT INFECTION STUDY

POPULATION BASED QUESTION FOR MEN

NOTE : Y = 1
 N = 2
 NA = 9 as per field width.
 NK = 8

Interviewer

1. Study Number

Date seen
 DD / MM / YY

CID Number

RID Number

2. Date of birth

Religion (Muslim — 1, Hindu — 2)

3. Years of completed schooling :

4. Occupation (specify & CODE)

5. Has he ever worked outside the village in :

Other rural area = Y / N

Nearby town / urban area = Y / N

Dhaka = Y / N

Other major town/city in Bangladesh = Y / N

Outside Bangladesh = *Y / N

* If "Yes", which country ? (specify CODE)

Is he currently mainly employed outside his village in ;

Other rural area = Y / N

Nearby town = Y / N

Dhaka = Y / N

Other major town/city in Bangladesh = Y / N

Outside Bangladesh = *Y / N

* If "Yes", which country (specify & CODE)

In the past one month, how many nights has he spent away from home :

- Most nights = 1
- Spent occasional nights away from home = 2
- He was always at home at night = 3

6. Current marital status :
- Single (never married) = 1
 - Married = 2
 - Divorced / separated) = 3
 - Widowed = 4

If answer = 1, then go to Question 12, otherwise ask the following :

- 7. Age at first marriage

- 8. Number of wives that he has

- 9. Number of living children that he has

- 10. Wives' occupation (s) (specify & CODE)

- 11. What method of family planning does he use
(Specify for each wife and code)

- 12. Has he ever used condoms ? Y / N

If he is not using condoms WHY NOT ? (specify & CODE)
(Open question)

13, (a) Does he have any problems relating to his genital area ? Y / N

(b) Does he have any problems relating to sexual health ? Y / N

(Explain to him what these questions mean, then list the symptoms
he complains of (CODE LATER)

14. (a) Does he have any pain passing urine ? Y / N

If yes, how long has this been present ?

- < 7 days = 1
- > 7 days < 1 month = 2
- > 1 month = 3
- > 1 year = 4

(b) Has he ever suffered with pain passing urine in the past ? Y / N

If he has pain passing urine now, or has suffered from it in the past, ask the following questions, otherwise Go To QUESTION 15.

(c) Has he ever sought treatment / advice for this problem ? Y / N

If "Yes" where did he first go for treatment / advice (specify & CODE)

Did the treatment help him ? Y / N*

*If "no", where did he go next for treatment / advice (specify & CODE)

Did the treatment help him ? Y / N

(d) If he has a problem with dysuria but has never sought treatment / help for it, is it because :

- No time to go for advice / treatment - Y / N
- Treatment is too expensive - Y / N
- Symptoms not severe enough = Y / N
- He treats himself at home = Y / N
- Did not know where to go for treatment = Y / N
- Too shy to seek treatment = Y / N
- Other reason (specify & CODE) = Y / N

15. (a) Does he have any urethral discharge ? =Y / N

If yes, how long has this been present

< 7 days = 1

> 7 days < 1 month = 2

> 1 month = 3

> 1 year = 4

(b) Has he ever suffered with urethral discharge in the past ? Y / N

If he has urethral discharge now, or has suffered form it in the past, ask the following questions, otherwise GO TO QUESTION 16.

(c) Has he ever sought treatment/advice for this problem ? Y / N*

*If "Yes", where did he go for treatment/advice (specify)

Did the treatment help him ? Y / N*

*If "no", where did he go next for treatment/advice (specify & CODE)

Did the treatment help him ? Y/N

(d) If he has a problem with urethral discharge but has never sought treatment/help for it, is it because :

No time to go for advice/treatment = Y / N

Treatment is too expensive = Y / N

Symptoms not severe enough = Y / N

He treats himself at home = Y / N

Did not know where to go for treatment = Y / N

Too shy to seek treatment = Y / N

Other reason (specify & code) = Y / N

16. (a) Does he have any genital ulcer ? =Y / N

If yes, how long has this been present

< 7 days = 1

> 7 days < 1 month = 2

> 1 month = 3

> 1 Year = 4

(d) If his wife / partner has recently received treatment for a problem of the genital tract, was he treated as well? Y / N

18. Has he ever had a blood transfusion? Y / N

If "Yes," which year (s) (code in most recent year)

The following questions are personal. Reassure him that all answers will be treated in the strictest confidence.

19. Age at first sexual intercourse.

Was this before or after his marriage?

Before = 1

After = 2

Not yet married = 3

20. (a) During his lifetime, how many women has he had sexual intercourse with (including his wife)

(b) Has he ever given gifts/money/food in exchange for sex? Y / N

(c) How many women has he had sexual intercourse with in the past one year (including his wife/wives)

21. (a) Has he ever had sexual relationships with another man/boy Y/N

(b) If "Yes" how old was he the first time he had sexual relations with another man, boy?

(c) If "Yes", how old was he the most recent time he had sexual relations with another man / boy?

22. (a) After sexual intercourse, does he usually wash himself in the genital area? Y / N

(b) If "Yes", what does he usually wash/clean with? (choose one)

Water only = 1

Soap and water = 2

Savlon and water = 3

Dry rags/tissue/cloth = 4

Other (specify) = 5

23. Now explain to client that you require a urine sample which you will test for the presence of infection.

(a) Man agrees to give urine sample

Y / N

(b) If man gives urine sample, record here the amount of time since he last passed urine

< 1 hour	= 1
> 1 hour < 2 hours	= 2
> 2 hours < 4 hours	= 3
> 4 hours	= 4

(c) What is LED result ?

0	= 0
1+	= 1
2++	= 2

NOW LABEL URINE SPECIMEN WITH STUDY NUMBER AND RETURN IT TO LABORATORY.

24. (a) Man agrees to give blood sample.

Y / N

Now take finger-prick blood sample.

(b) LABEL BLOOD SAMPLE WITH STUDY NUMBER AND RETURN IT TO LABORATORY

NOTE : If man is symptomatic and/or his LED result is positive (result = 1 or 2), then he should be referred for treatment at the SUBCENTRE clinic.

**INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH
BANGLADESH
MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME
MATLAB, CHANDPUR**

REPRODUCTIVE HEALTH PROJECT

QUESTIONNAIRE FOR PREGNANT MOTHERS

Yes - 1
No - 2
Don't know - 8
Not applicable - 9

Date of Interview :

Interviewer :

1. CID Number
RID Number :
Study Number :

2. Date of birth: Religion : Muslim - 1
Hindu - 2

3. Education : Highest class passed

4. (a) Occupation : (Specify) _____

(b) Have you ever worked outside the village ?

- market yes / no
- town nearby (thana / district) yes/ no
- Dhaka yes / no
- outside Bangladesh yes / no
- any other village yes / no

(c) At present, do you work outside the village ? yes / no

5. (a) How many times you were married in your life ?

(b) How old were you when you got married (first) ?

(c) Current marital status:

single : 1
 married : 2
 divorcee/separated : 3
 widow : 4

(Answer = if 2, then ask next question and Q. No.6, if answer is not 2, then go to Q. No.7)

(d) How many wives does your husband has at present ?

(e) How long ago present marriage has taken place ? (years)

6. What is your husband's main profession ?
Specify _____

At present, where does your husband work ?

in own village / other village = 1
 in town / city = 2
 outside Bangladesh = 3 (write in which country : _____)

does your husband stay at home ? yes / no
 if 'yes', does he spend night outside home for his work or to visit relatives -
 yes / no
 if 'no', for how long is he staying outside home ?

for few days = 1
 for more than one month = 2
 for more than one year = 3

7. Have you taken blood of other people in your body ? yes / no
if 'yes', in which year - (last taken)

8. At present, do you have any infection in your reproductive organ? yes / no
if there is, for how long the reproductive organ has infection (week)

less than one week = 1
more than one week = 2
more than one month = 3
over one year = 4

■ does it make any pain? = yes / no

9. Did you ever had any infection in your reproductive organ in the past? yes / no

if 'yes', how long ago was it? yes / no

less than one week = 1
more than one week = 2
more than one month = 3
over one year = 4

**COLLECT BLOOD SAMPLE FROM THE WOMAN
LABEL IT WITH STUDY NUMBER AND DATE.**

DO NOT USE THE NAME OF THE WOMAN.

■ Did the woman allow to take the interview? yes / no
if not, why? (write down the reasons)

■ Did the woman give blood sample? yes / no
if not, why? (write down the reasons)

FORM-H

**INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH
BANGLADESH
MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME
MATLAB, CHANDPUR**

REPRODUCTIVE HEALTH PROJECT

QUESTIONNAIRE FOR POST-DELIVERY MOTHERS

Date of Interview :

--	--	--	--	--	--

day / month / year

Interviewer :

--

Date of birth

--	--	--	--	--	--

day month year

Yes = 1
No = 2
Do not know = 8
Not applicable = 9

Religion :

--

Study number : (mother)

--	--	--	--

Study number : (child)

--	--	--	--

MCID

--	--	--	--	--	--	--	--	--	--

MRID

--	--	--	--	--	--	--	--	--	--

CCID

--	--	--	--	--	--	--	--	--	--

1. Date of delivery :

--	--	--	--	--	--

day / month / year

2. Place of delivery :

- house = 1
- Matlab Clinic = 2
- Sub-centre Clinic = 3
- Chandpur Govt. Hospital = 4
- Others (write _____) = 5

--

3. During delivery who held the baby ?

- family member = 1
- village dai = 2
- health assistant (LFPV/midwife) = 3
- doctor = 4
- community health worker (CHW) = 5
- other (write _____) = 6

--

GROUP - A

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH BANGLADESH MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME MATLAB, CHANDPUR

RESEARCH ON "REPRODUCTIVE HEALTH" POPULATION-BASED SURVEY OF WOMEN

CONSENT FORM

We are asking you to participate in a reproductive health research project conducted by ICDDR,B. The objective of this research is to collect information about the 'Reproductive Health' of men and women of Bangladesh. 'Reproductive Health' refers to the problems of health related to reproductive tract and the health of the new-born after delivery. We are concerned about these problems because we know that these problems can create health hazards for people. Especially in case of women, and if these problems are not treated then it can create lower abdominal pain (child producing parts), sterility and can cause eye problem for children after birth. Adults can have reproductive tract infection without any symptoms of disease. Treatment for those women are most urgent, because they may have long-term complications of health due to this hidden infection.

Those, whom we have selected to participate in this study is strictly based on where do they live, and not for this reason that they have more or less the possibility of having reproductive health problem. We are asking you to participate in this research even if you do not have symptoms of this disease.

If you are willing to participate in this research then we will ask you to give your consent to the work-schedule described below.

1. One female health worker will ask you a few questions about your reproductive health and if you have any problem of reproductive tract, she will tell you how to manage it.
2. One female physician will ask you a few questions about your general health and will ask questions in detail about your reproductive health.
3. Besides examining your reproductive health, a female physician will also examine your general health. If you have any worries about your health, then you can discuss about those with the physician. The physician will then specially come to know about your reproductive health and will examine the internal part of your reproductive tract. This check up will include seeing the inside of reproductive tract. The physician will collect some sample from your reproductive tract and will send it to laboratory, from where it will be known whether there is any infection in your reproductive tract. However, she will not do any such thing which will effect your fertility at present or in future. Undoubtedly, she will neither insert IUD in your uterus or take out from inside and also she will not perform sterilization.

4. Health Worker will collect blood sample from your finger tip. From this blood sample it will be known whether you have any reproductive tract infection which may be harmful for your health and the health of your future children.

Results of all your tests will be completely kept secret. These will only be known to the female physician who examined you and to the physician in charge of the ICDDR,B Project. If any infectious disease is detected in you which needs treatment, we will inform your regular Health Worker who will give you the necessary medicine. However, if you do not want that your Health Worker should know the results of your test, then you can consult the physician of ICDDR,B Hospital and avail the proper treatment (if needed) in accordance with the results of your tests.

We want to say this with emphasis that your participation in this study is completely on your own wish. Even if you do not take part in this study, still the regular health services that you are getting at present from ICDDR,B will not be affected in any way. You will get the regular health services.

If you have any problem or question regarding this study, then kindly ask your regular Health Worker or her supervisor about it.

Thank you for your help.

After hearing in details about this study, I give my consent to participate willingly in this programme.

Signature of the woman/impression of left-thumb

Date: _____

Witness _____

Date: _____

GROUP - C

**INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH
BANGLADESH
MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME
MATLAB, CHANDPUR**

**RESEARCH ON "REPRODUCTIVE HEALTH"
REPRODUCTIVE TRACT INFECTION SYMPTOMS / INFORMATION ABOUT
PROBLEMS OF REPRODUCTIVE TRACT PARTS DURING POST-DELIVERY**

CONSENT FORM

We are informing you to participate in a 'Reproductive Health' research project conducted by ICDDR,B. The objective of this research project is to collect information about the 'Reproductive Health' of men and women of Bangladesh.. 'Reproductive Health' refers to the problems of reproductive tract, during pregnancy and after delivery and health problems of new-born babies.

During my discussion with you, you have told me or given me hint about some symptoms of your reproductive tract infection. We want to examine you carefully to find out whether you have any infection. We want to collect some information about the symptoms of your disease and also about yourself.

If you decide to take part in our study, then we will ask you to give your consent to the following activities:

1. One female health worker will ask you a number of questions about your 'Reproductive Health' and how do you treat yourself if you have any problem in your reproductive tract.
2. One female health worker will have your general physical check-up and will examine the inside of your reproductive tract. This will include examining the internal part of your reproductive tract. That worker will collect some sample from your reproductive tract which will be sent to the laboratory to examine whether or not you have any infectious disease. However, she will not do any such thing which will effect your fertility at present or in future. To be specific, she will neither insert IUD in your uterus or take out from inside and also she will not perform sterilization.
3. Health Worker will collect blood sample from your finger tip. From this blood sample it will be known whether you have any reproductive tract infection which may be harmful for your health and the health of your future child.

If it is known from those examinations that there is infection in your reproductive tract, then we will arrange for your treatment. If we detect from our laboratory test that you also have some other infectious disease, then we will inform you that. All the treatment that we will do for you , will be free of cost. It is not known to us that this treatment has any harmful side.

Your participation in this study is completely on your own willingness. Even if you do not take part in this study, still the regular health services that you are getting at present from ICDDR,B will not be affected in any way.

All the information that you will provide us and results of all your tests will be completely kept secret.

If you have any question regarding all these tests, then kindly ask the physician or the health worker.

Thank you for your help.

After hearing in details about this study, I give my consent to participate willingly in this programme.

Signature of the woman/impression of left-thumb

Date: _____

Witness _____

Date: _____

GROUP - E

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH BANGLADESH MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME MATLAB, CHANDPUR

RESEARCH ON "REPRODUCTIVE HEALTH" POPULATION-BASED SURVEY OF MEN

CONSENT FORM

We are informing you to participate in a 'Reproductive Health' research project conducted by ICDDR,B. The objective of this research is to collect information about the 'Reproductive Health' of men and women of Bangladesh. In case of men, problems of reproductive health refer to pain and burning sensation while urinating, or any urethral discharge. We know that in case of some men these problems can occur due to some infection and we want to examine you to find out the cause of these infections. We have also seen that some men carry germs of these infections without any symptom, and they can spread those germs to their wives. As a result, their wives may have various problems such as sterility or newborns may have health problems.

Those men whom we have selected to participate in this study is strictly based on where do they live. It is not for this reason that we think, they have more or less the possibility of having reproductive health problem. We are asking you to participate in this research even if you do not have or have symptoms of this disease.

If you decide to take part in our study, we will ask you to give your consent to the following activities:

1. One male health worker will ask you some questions about your general health, reproductive health and how you will treat yourself when you are affected, specially, if you have any problems of reproductive or sexual organs. He will also ask you few more questions to know that how you can be infected by some infections of reproductive tract.
2. One male health worker will examine you physically to check whether or not there is any health problem in your reproductive tract.
3. To check if you have any infection, male health worker will collect urine sample from you and will examine it instantly. If any urine problem is detected, then-he will ask you to provide sample of your urethral discharge and will sent it to the laboratory for test.

4. Health worker will collect blood sample from your finger tip. This blood sample will be examined to check whether you have any type of infectious disease which may be harmful for your health and the health of your future child.

The tests that we will perform, none of them will ever be the cause of any health problem for any men, their wives or any of their future children.

Your interview and the results of all your tests will completely remain secret. These will only be known to the health worker with whom you meet and to the physician in-charge of the ICDDR,B Project. If it is detected from the test that you have some infection for which treatment is necessary, then we will treat you.

We want to say this with emphasis that your participation in this study depends completely on your willingness. If you decide that you will not participate in this study, then it will not in any way restrict any health services that you want to have from ICDDR,B.

If you have any problem or question regarding this study, then you can kindly ask the health worker or his supervisor.

Thank you for your help.

After hearing in details about this study, I give my consent to participate willingly.

Signature of the man/impression of left-thumb Date: _____

Witness _____ Date: _____

GROUP F

**INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH BANGLADESH
MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME
MATLAB, CHANDPUR**

**RESEARCH ON "REPRODUCTIVE HEALTH"
COLLECTION OF INFORMATION ABOUT REPRODUCTIVE HEALTH OF
PREGNANT WOMEN**

We are asking you to take part in a 'Reproductive Health' project being carried out by ICDDR,B. The aim of this study is to do more research about the reproductive health of men and women in Bangladesh. Reproductive health means looking at problems concerning the reproductive tract, and the health of pregnant women, women post-partum and their new-born infants.

You are being asked to participate in this research as you are pregnant. We know that some women can have infections in their blood without any symptoms but which can lead to severe illnesses in their babies or even to the loss of the pregnancy. We are asking all pregnant women who live in this area to take part in the study.

If you participate, we will take a sample of your blood from your finger-tip and test it to see whether you have any infection. If you do have an infection present then we will give you treatment with antibiotics. This treatment will in no way harm the health of you or your baby, and will possibly prevent your baby suffering from some illnesses at birth.

If you decide to participate in this study then we will test your blood and the results of your test will be entirely confidential and will only be known to the health worker of your area and to the physician of ICDDR,B.

If you decide not to take part in this study then this will in no way affect the future care that you receive from ICDDR,B.

Thank you for your participation.

After hearing this explanation I agree to take part in this study and to have a finger-tip blood sample taken.

Signature of pregnant woman
/ let-thumb impression

Date

Witness (signature and name)

Date

GROUP H

**INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH BANGLADESH
MOTHER AND CHILD HEALTH AND FAMILY PLANNING PROGRAMME
MATLAB, CHANDPUR**

**RESEARCH ON "REPRODUCTIVE HEALTH"
COLLECTION OF INFORMATION ABOUT POSSIBLE EYE INFECTION
OF
NEW-BORN INFANT**

We are asking you to take part in a reproductive health project being carried out by ICDDR,B. The aim of this study is to understand more about the reproductive health of men and women in Bangladesh. Reproductive health means looking at problems concerning the reproductive tract, and the health of pregnant women, women post-partum and their new-born infants.

We are asking you to take part in this study as your baby has an infection in its eye. We would like to take a small sample from the baby's eye to see what type of infection this is so that we can give the baby the correct treatment. We have previously seen that if a baby has an eye infection after birth this can cause damage to the baby's eyesight if it is left without treatment. The sample that we are going to take from the baby's eye will in no way harm the baby, and will not cause him/her any problems in the future. The treatment of this is also not known to cause any other problem for the baby.

We want to ask you some questions about your health as we know that in some cases the baby gets this infection from the mother's birth canal during its birth and if this is the case, then the mother also needs treatment as well. Then we will also be sure about your treatment.

If either you or the baby need treatment this will be given free of charge.

Your participation in this study is completely on your willingness and all the information that you give us will be entirely confidential.

Thank you for your help.

After hearing this explanation I give my consent to take a sample from my baby's eye.

Signature of mother / Left-thumb impression

Date _____

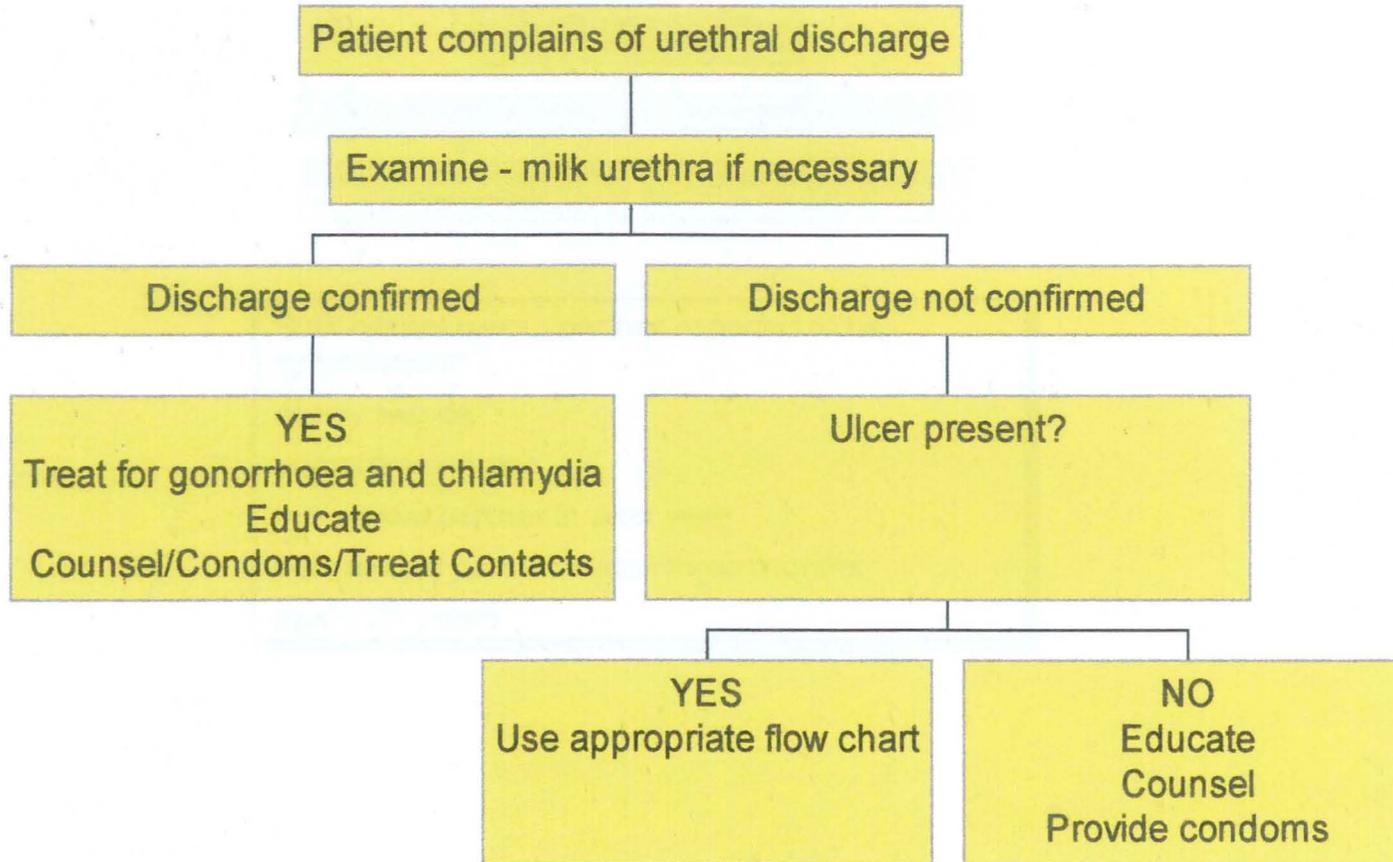
Witness (Signature and name)

Date _____

Sarah/consent2.doc

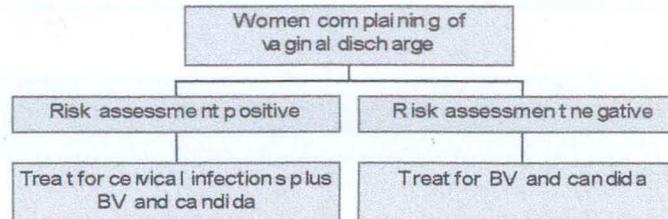
APPENDIX THREE: FLOW CHARTS

URETHRAL DISCHARGE



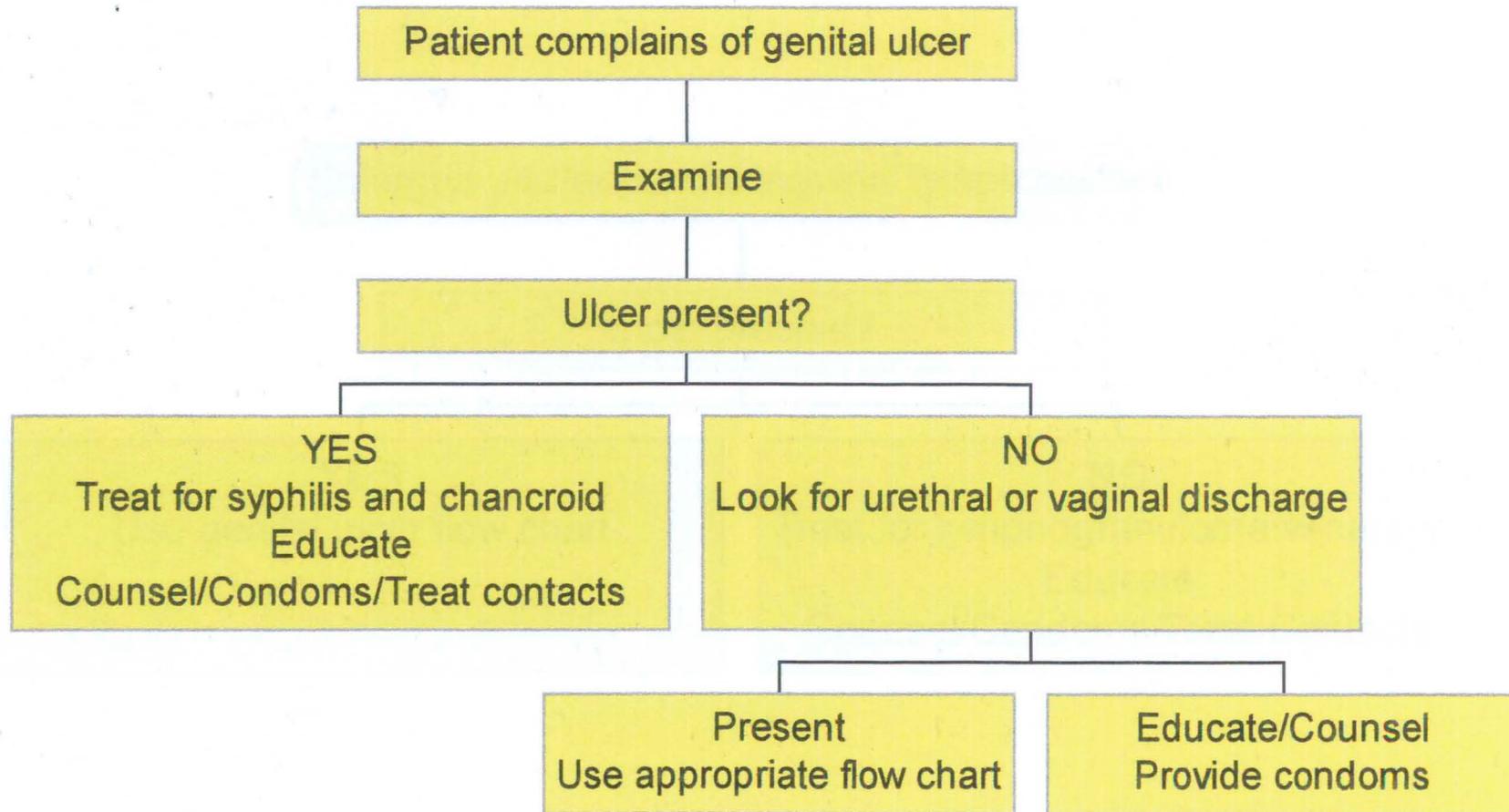
GENITAL ULCERS

WHO algorithm for Primary Health Care level workers (not used in this study)

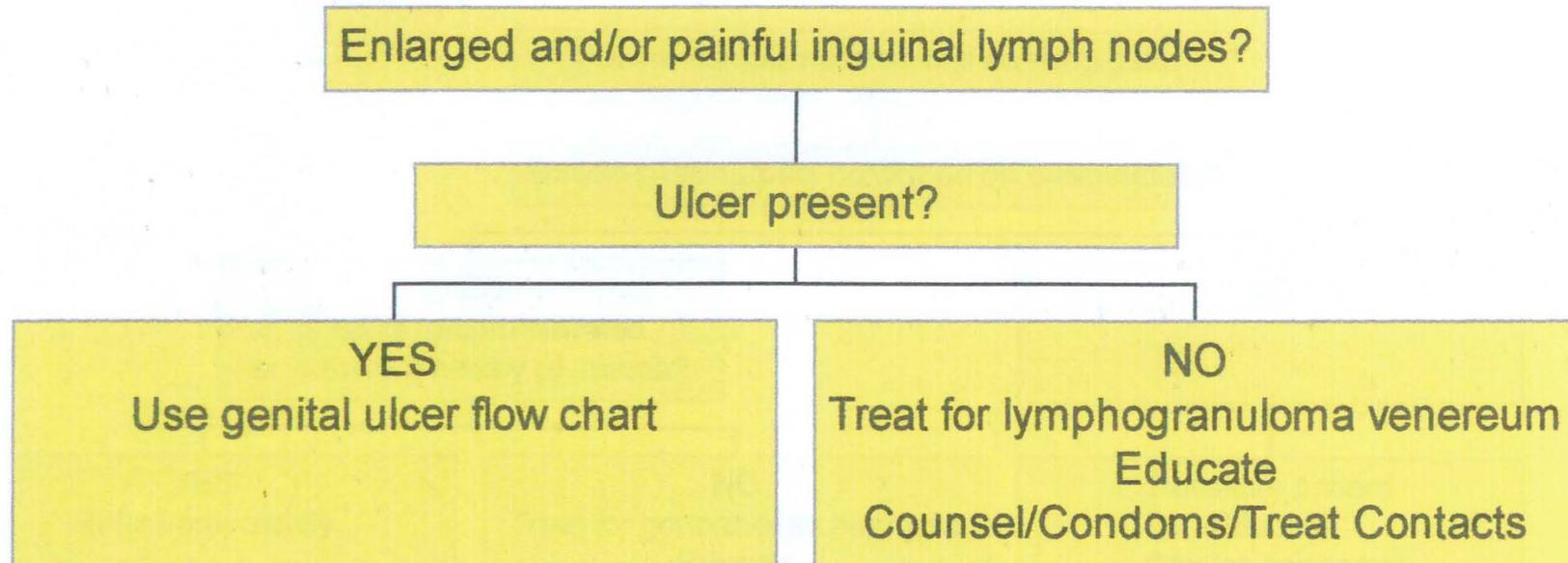


Risk assessment : partner reported to be symptomatic
or any two of:
unmarried woman
> 1 sexual partner in past year
new sexual partner in last three months
age < 21 years

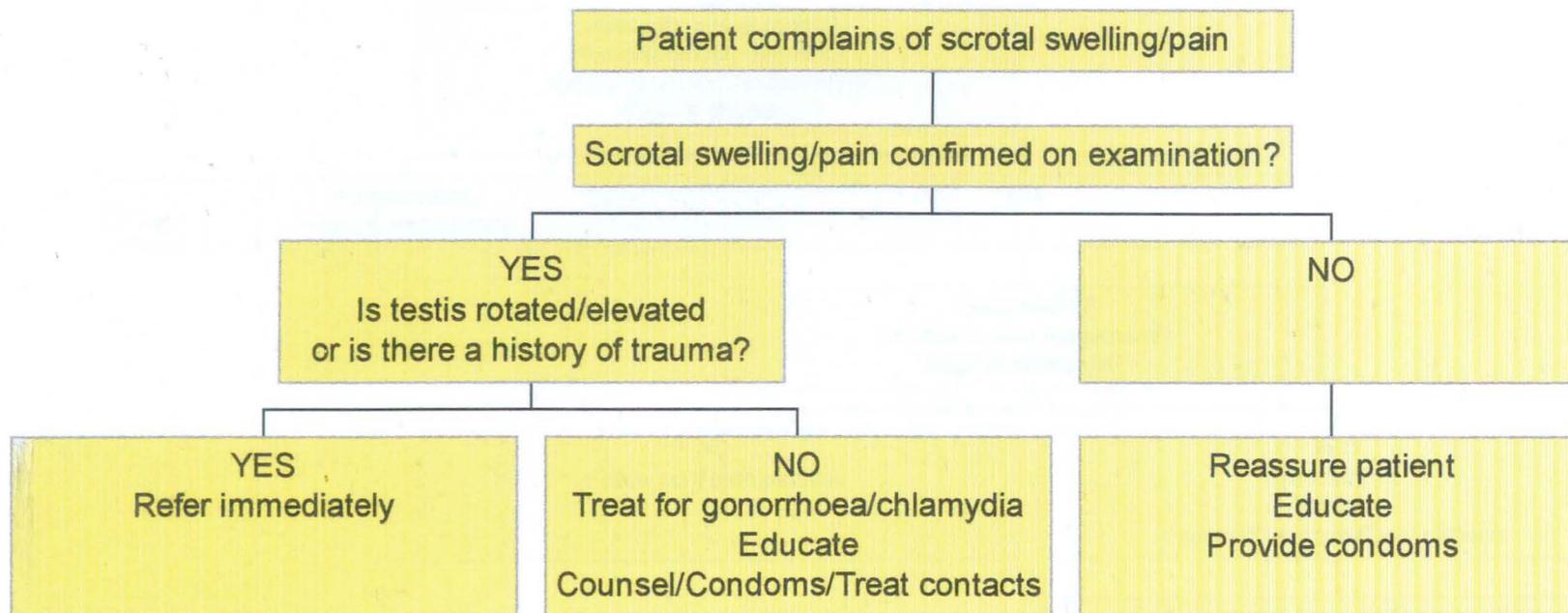
GENITAL ULCERS



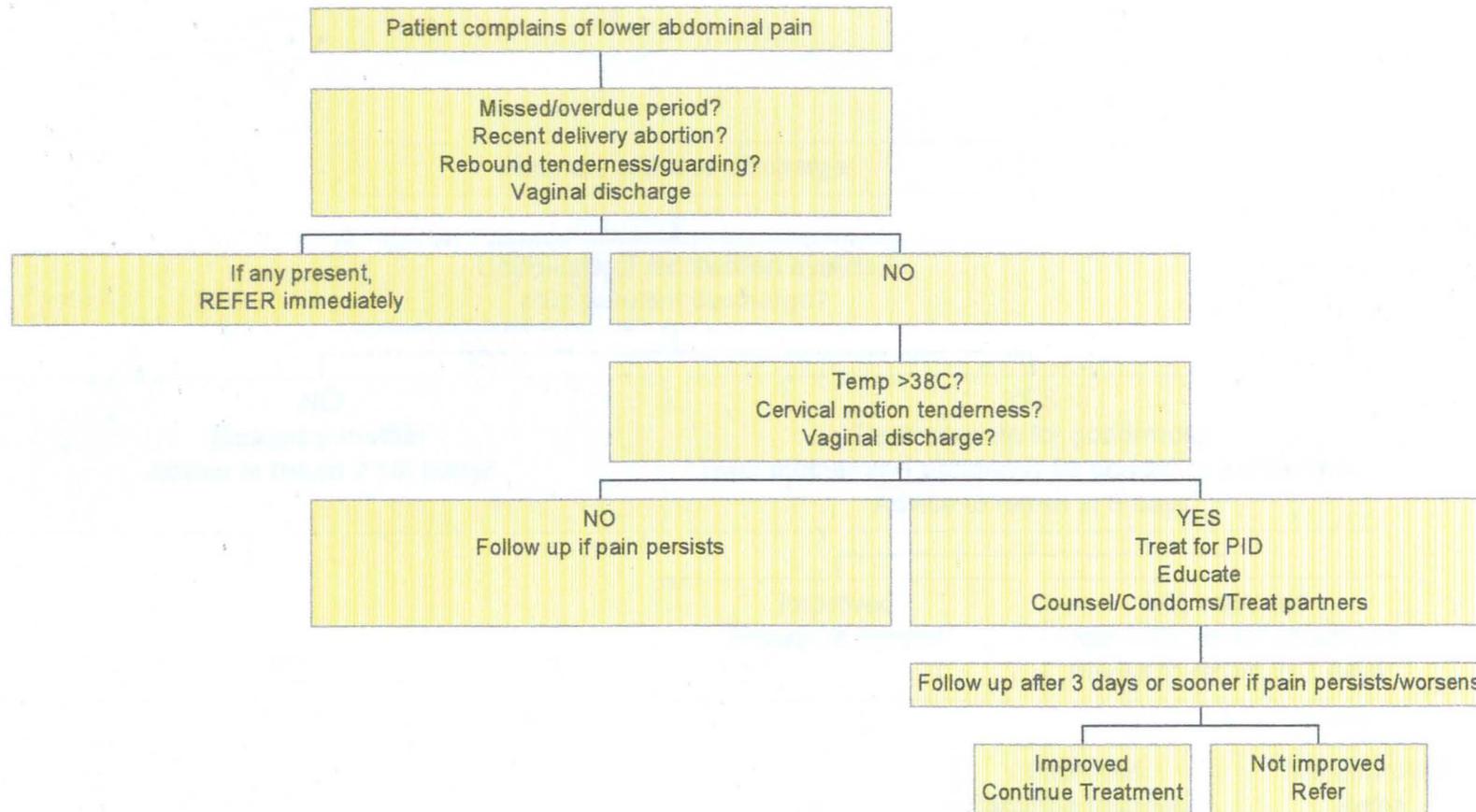
INGUINAL BUBO



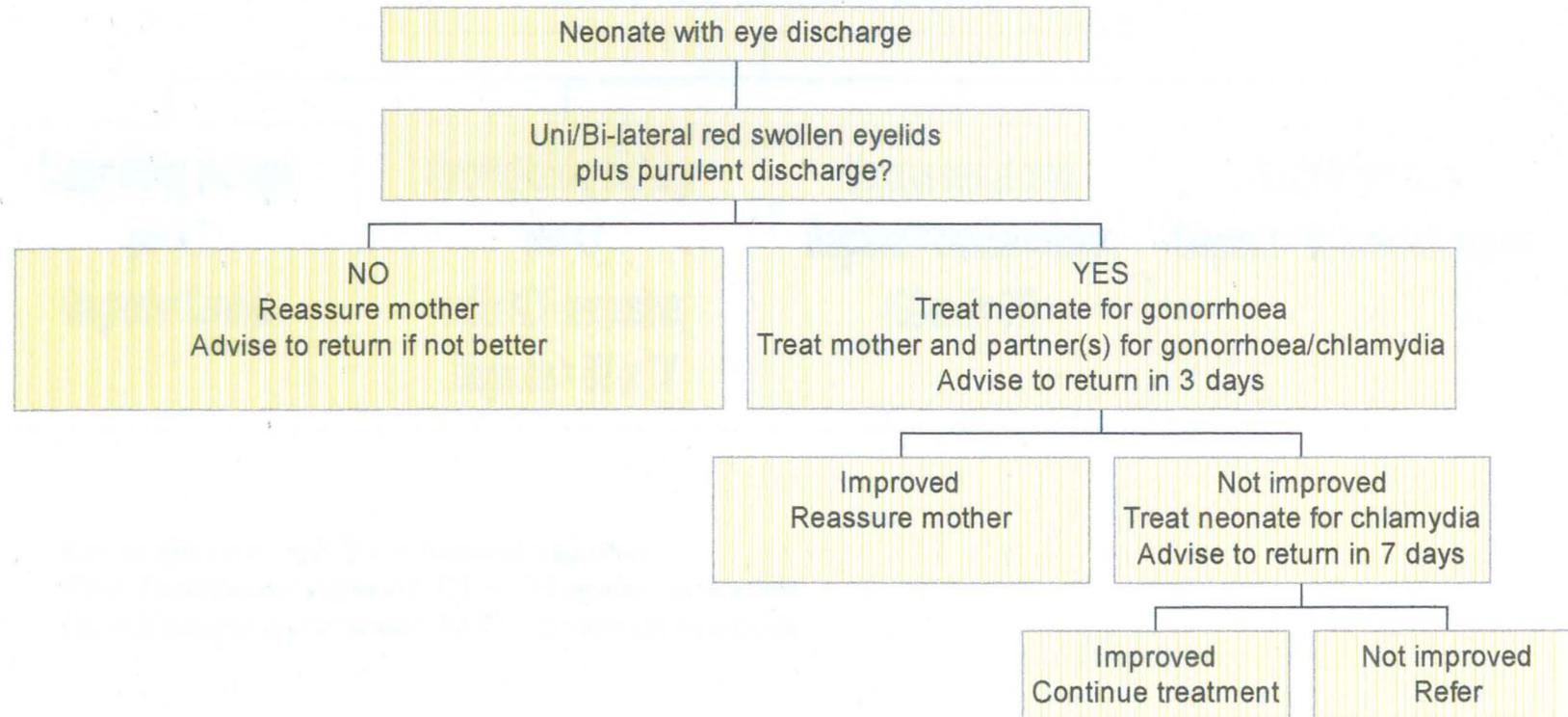
SCROTAL SWELLING



LOWER ABDOMINAL PAIN

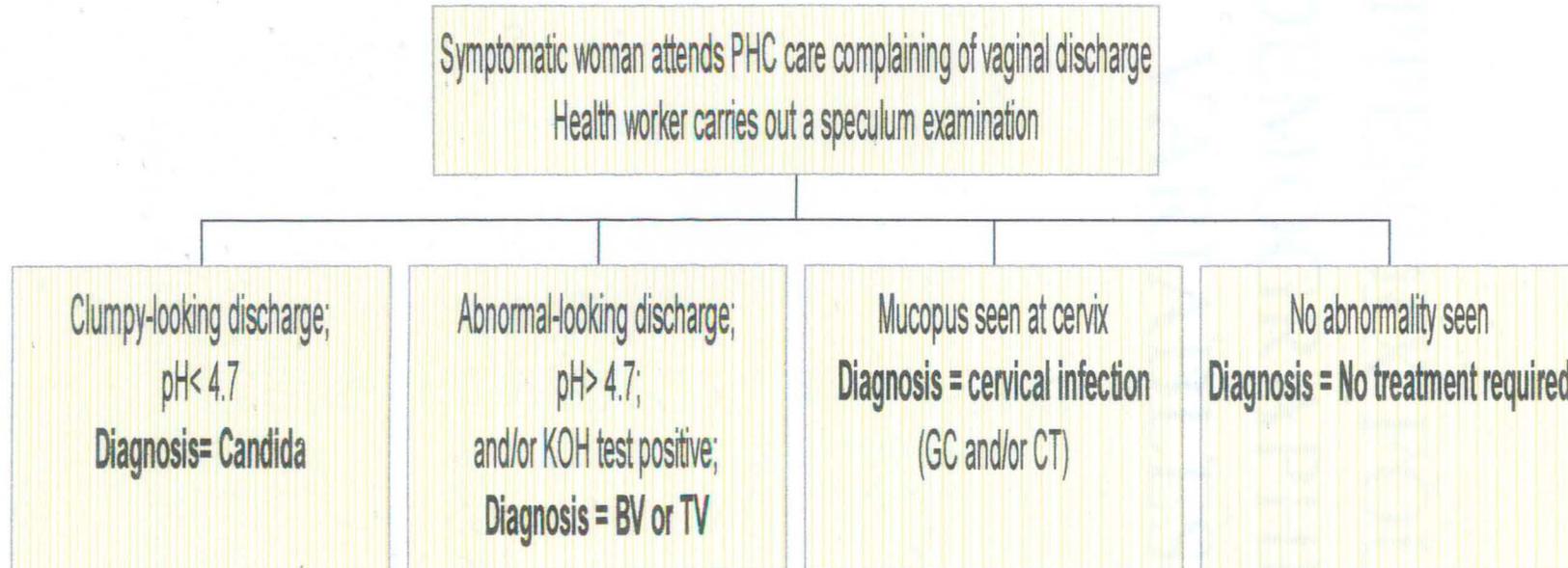


NEONATAL CONJUNCTIVITIS



VAGINAL DISCHARGE

Flow chart modified for use in Matlab



Key to abbreviations: BV = bacterial vaginosis;
TV = *Trichomonas vaginalis*; CT = *Chlamydia trachomatis*;
GC = *Neisseria gonorrhoeae*; KOH = potassium hydroxide

APPENDIX FOUR: DEMOGRAPHIC VARIABLES

Data on 17,820 RKS eligible women and their husbands, August 1995

	Education (mean yrs. (S.D.))	Most common occupations	Contraception in use	Mean no. of pregnancies	Mean no. of living children
Wife	2.71 (3.41)	housewife = 97.7%	OCP = 15.5% IUD = 1.8% DMPA = 34.4% condom = 2.3% tubectomy = 7.6% none = 29.9%	3.58 (2.31)	2.74 (1.77)
Husband	3.7 (4.2)	farmer = 27.4% service = 13.3% skilled labour = 10.9%			

Data on all eligible women and entire RKS list, August 1995

	Interviewed (N = 804)	Absent (N = 77)	Declined (N = 224)	Other (N = 65)	Out-migration (N = 46)	Entire POPW.DBF (N = 1216)	RKSELW.DBF (N = 17,820)
Age	32.68 (7.67)	31.44 (8.28)	32.03 (8.75)	30.31 (8.34)	32.97 (8.57)	32.38 (7.98)	31.51 (7.81)
Women's level of education	2.66 (3.14)	2.48 (3.67)	2.46 (3.19)	2.70 (3.39)	2.89 (3.63)	2.60 (3.21)	2.71 (3.41)
Total no. of pregnancies	3.59 (2.18)	3.14 (2.71)	3.34 (2.43)	2.53 (2.39)	2.96 (2.80)	3.44 (2.31)	3.58 (2.33)

popw.dbf = 1216 eligible women drawn from RKS list
 RKSelgw.dbf = all women on RKS list, August 1995

CONTRACEPTIVE USE BY WOMEN IN THE POPULATION AND IN THE STUDY

Contraceptive use (%)	Interviewed (N= 804)	Absent (N = 77)	Declined (N = 224)	Other (N = 65)	Out-migration (N = 46)	Entire POPW.DBF (N = 1216)	RKSELW.DBF (N= 17,820)
None	21.4	40.3	37.5	46.1	47.8	27.9	29.9
OCP	16.2	14.3	15.2	12.3	13	15.5	15.5
DMPA	43.3	22.1	29	30.8	23.9	37.9	34.4
IUD	2.7	3.9	0.4	0	0	2.1	1.8
Condom	4.1	6.5	3.1	1.5	0	3.8	2.3
Tubectomy	11.1	6.5	6.5	1.5	10.9	9.4	7.6
Other barrier methods	0	0	2.7	1.5	2.2	0.7	
Other methods	1.1	0	0	0	0	0.7	<2.2

Popw.dbf = all eligible women drawn from RKS list
 rkseiw.dbf = data on women in RKS list, August 1995

Data on eligible men drawn from census list, August 1995 (N=1618)

		Interviewed (N=969)	Absent (N=383)	Declined (N=37)	Other (N=76)	Out-migration (N=153)	Total POM.DBF (N=1618)	Total DSS.DBF (N=25650)
AGE		30.80 (9.54)	32.37 (9.28)	35.10 (9.16)	42.64 (9.98)	26.40 (8.10)	31.45 (9.70)	29.2
Marital status								
%	never married	42	41.3	29.7	52.6	90.2	40.1	46.8
	married	57.5	58.5	70.3	46.1	9.8	59.8	52.8
	divorced	0.4	0	0	1.3	0	0.1	0.1
	widower	0.1	0.3	0	0	0	0.1	0.4
Education level		5.11 (4.26)	2.57 (3.97)	3.03 (4.36)	0.83 (1.88)	0.89 (2.58)	3.86 (4.29)	?

popm.dbf = random selection of men drawn from census list in August 1995;
dss.dbf = census list (1993 dataset)

DATA ON PARENTS OF NEONATES showing mean values and standard deviation

	Interviewed (N=1008)	Overage before seen (N=446)	Pregnancy loss before seen (N=17)	Migration out (N=16)	Absent (N=130)	Died (N=5)	No remarks (N=46)	Total number of eligible women with newborns (N=1670)	RKSELGW.DBF (N=17820)
AGE	27.01 (5.58)	25.97 (5.60)	29.19 (6.84)	22.44 (3.65)	23.47 (4.60)	25.12 (3.46)	25.06 (5.84)	26.38 (5.66)	31.51 (7.81)
Women's level of education	3.57 (3.73)	3.11 (3.50)	1.47 (2.90)	4.50 (2.78)	4.62 (3.83)	8.33 (4.04)	3.71 (3.60)	3.53 (3.68)	2.71 (3.41)
Husband's level of education	3.93 (4.50)	3.53 (4.11)	1.33 (3.33)	4.25 (4.68)	4.25 (4.19)	7.2 (3.83)	2.30 (2.80)	3.79 (4.34)	3.70 (4.20)

Data on eligible pregnant women (showing mean values and standard deviation)

	Interviewed (N=1021)	Already given birth (N=323)	Absent (N=177)	Not visited (N=51)	No remark (N=24)	Declined (N=16)	Total no. of eligible preg. women (N= 1626)	All women in RKS list, August 1995 (N=17820)
AGE	26.82 (5.52)	26.43 (5.70)	24.27 (4.73)	26.36 (5.49)	26.24 (5.96)	27.71 (4.37)	26.49 (5.52)	31.51 (7.81)
Women's level of education	3.09 (3.4)	2.39 (3.27)	2.77 (3.38)	1.64 (2.67)	1.71 (2.97)	1.4 (2.23)	2.84 (3.36)	2.71 (3.41)
Total number of pregnancies	2.32 (1.97)	2.56 (2.04)	1.46 (1.59)	1.63 (1.87)	1.96 (1.9)	3.13 (2.87)	2.25 (1.98)	3.58 (2.33)

APPENDIX FIVE:
COST-
EFFECTIVENESS OF
SYNDROMIC
MANAGEMENT

Managing reproductive tract infections in women in low-income, low-prevalence situations: an evaluation of syndromic management in Matlab, Bangladesh

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Rosanna W. Peeling†, Andres de Francisco* David Mabey**,

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† Laboratory Centre for Disease Control, Winnipeg, Canada

Introduction

In many low-income countries there is currently a concerted effort to establish programmes for the control of reproductive tract infections (RTIs), including the sexually transmitted infections (STIs). Antecedents for such a policy have arisen from several quarters: recent findings which have linked STI control with a reduction in HIV incidence;^{1,2} a 1993 World Bank report which showed that the burden of STIs in many urban populations in the developing world, as measured by disability-adjusted healthy life years lost, is a substantial fraction of the entire disease burden of those populations;³ and recommendations from the 1994 United Nations International Conference on Population and Development (ICPD).⁴ ICPD stated: "All countries should strive to make accessible through the PHC [primary health care] system, reproductive health to all individuals of appropriate ages... [this] should include ...treatment of reproductive tract infections; sexually transmitted diseases and other reproductive health conditions".

Despite global acknowledgement that control of STIs is a worthwhile target,^{3,4,5,6,7} the tools available for achieving this goal in low-income countries are limited. However, accurate management of infected persons remains a cornerstone of most STI control programmes. In the absence of either cheap, simple and accurate diagnostics or comprehensive laboratory services for microbiological diagnosis, the World Health Organisation has developed a set of syndromic management guidelines for the treatment of symptomatic men and women presenting to basic levels of health care services in developing countries.⁸ These clinical algorithms recognise that there are several possible aetiologies for common clinical syndromes, and recommend treatment for the most common causative organisms.⁹

Vaginal discharge is recognised as one of the most common clinical complaints among women of reproductive age in many parts of the world,¹⁰ and current campaigns to broaden reproductive health care services may result in more women accessing care. The effectiveness of treatment therefore carries both clinical and economic implications for many developing countries. We have studied the prevalence of reproductive tract infections (RTIs) in women complaining of abnormal vaginal discharge who reported to primary health care centres in one area of rural Bangladesh, using 'gold standard' laboratory diagnostic tests, and estimated the costs associated with two management algorithms: the currently recommended WHO clinical algorithm for PHC workers (Figure 1) and the diagnoses made by trained health workers using a speculum and simple bedside diagnostic tests (Figure 2), on symptomatic women reporting for care. Recommendations are advanced for national programmes in low- STI prevalence, low-income countries, similar to Bangladesh.

Methods

The International Centre for Diarrhoeal Disease, Bangladesh (ICDDR,B) operates a system of clinical service provision and demographic surveillance in Matlab, a rural area of Bangladesh, covering a population of approximately 105,000 people. Free clinical and contraceptive services are provided through a series of 80 village-based (female) community health workers, four PHC centres (predominantly for maternal and child health care) and one central referral hospital with a laboratory.

Clinic-based assessment of syndromic management

In 1995, 32 regular PHC-level staff in the Matlab programme participated in a five-day training course in the syndromic management of RTIs/STIs in men and women, based on published WHO training modules.¹¹ The staff were all either qualified family planning practitioners or nurse/midwives. Some members of staff had previously been trained in a prototype of syndromic management during the 1980s.¹² This previous training programme had included the use of a speculum and pH paper for diagnosing vaginal infections. Therefore, to continue existing practices in the PHCs we adapted the recommended WHO clinical algorithms (incorporating use of a speculum) slightly to include the use of pH paper and KOH - Figure 2. The use of these two diagnostic tests as part of the algorithm may act to increase sensitivity and specificity in the diagnosis of vaginal infections.¹³

The WHO recommends the use of 'risk assessment' requiring a sexual history (Figure 1) in order to identify those women most likely to be suffering from an STI. This has been shown to increase the sensitivity and specificity of the algorithms in some settings^{14,15}. Clinical staff in Matlab thought that only asking questions about sexual behaviour would be culturally inappropriate. Therefore, sexual behavioural information was collected as part of a more detailed questionnaire on social and demographic factors, and all possible risks were subsequently assessed as possible predictors of infection. With the woman's recorded consent, structured interviews documenting demographic factors, reproductive history, sexual behaviour history, and health care seeking behaviour were administered by trained female interviewers in private. Current and past clinical symptoms in the reproductive tract were assessed by both open (unprompted) and closed (prompted) questions. Subsequently each woman underwent a general clinical examination and detailed gynaecological examination by the PHC staff under supervision of one of the project physicians.

Clinical examination

Clinical samples were collected from each woman as follows: (1) the ectocervix was cleaned using sterile cotton wool, and a dacron-coated swab was taken from the endocervix, immediately plated onto Modified Thayer Martin Medium and placed in a candle extinction jar for *Neisseria gonorrhoeae* culture. (2) A high vaginal swab was taken for Gram-staining, then placed in a drop of saline for immediate wet mount examination. (3) A further swab from the posterior vaginal fornix was placed in *Trichomonas vaginalis* culture medium. (4) On removal of the speculum, the vaginal fluid was tested with both pH paper and potassium hydroxide (KOH), when these were available to the project. (5) A

bimanual examination was carried out, and if the woman had cervical motion tenderness, or adnexal tenderness, and an abnormal discharge, she was diagnosed as having pelvic inflammatory disease.¹⁶

(6) A sample of blood for syphilis serology was obtained by finger prick, and a first-void urine sample for *Chlamydia trachomatis* detection, was collected.

Diagnoses were recorded by PHC-workers based on the use of Figure 2. If the supervising physician felt that the PHC-worker had overlooked a clinical diagnosis, this was rectified by giving treatment to the woman, but leaving the diagnosis of the PHC worker unchanged. Subsequently, the PHC worker's diagnosis was compared to the laboratory-based aetiological diagnosis for each woman.

Laboratory analyses

Immediate wet mounts were read by light microscopy looking for motile trichomonads. Candida was diagnosed when fungal hyphae and/or budding yeasts were seen on wet mount. In addition, *T.vaginalis* culture specimens were incubated at 37°C and read every 24 hours for a maximum of five days. The presence of bacterial vaginosis (BV) was defined according to Nugent's criteria¹⁷, slides were read at the Department of Internal Medicine, Louisiana State University, New Orleans, USA. Gonococcal cultures were incubated at 36-37°C in CO₂ for a maximum of 48 hours. *N. gonorrhoeae* were identified on the basis of colonial morphology, Gram stain, oxidase tests and carbohydrate fermentation reactions. Urine specimens were used to detect *C. trachomatis* infection using the Amplicor *C. trachomatis* PCR assay (Roche Diagnostic Systems, Branchburg, New Jersey, USA). All positive specimens were confirmed by another PCR assay targeting a different chlamydial gene, the *C. trachomatis* major outer membrane protein¹⁸. Blood samples were tested by RPR (Human, Germany) and TPHA (Murex Diagnostics, England). All syphilis positive test results (either RPR and/or TPHA) were confirmed with a repeat blood sample. RPR+/TPHA+ samples were defined as active syphilis; TPHA + only was defined as evidence of past syphilis. Results are not available for all infections in all women as we experienced occasional shortages of reagents during the course of the study.

Statistical methods

Data were entered into FoxPro (Version 3.0, Microsoft) databases and validated using double data entry. The sensitivity, specificity and positive predictive values for diagnosis of cervical and endogenous infections of each algorithm were calculated using cross-tabulations in Epi-Info (Version 6, Stone Mountain, GA). Risk factors for endogenous and sexually transmitted infections were first examined individually using cross-tabulations and χ^2 tests (or Fishers exact test if the assumptions for the χ^2 test were violated). Independent risk factors for endogenous infections were determined using a logistic regression model (Stata, Version 5 Austin, TX) to control for confounders, and described using odds ratios (OR) and 95% confidence intervals (CI). The number of cases of sexually transmitted infections was too small for more detailed analyses.

Cost-benefit analysis of different approaches to management

We have compared the costs of treating symptomatic women at PHC level complaining of vaginal discharge, using both the WHO risk assessment algorithm (Figure 1, no speculum necessary, all women are treated for endogenous infections, plus some are treated for STIs), and our modified algorithm (Figure 2) which was in routine use by trained health workers in the study. The algorithms are described in more detail above. The marginal costs of treatment using the two algorithms were obtained using the costs of drugs purchased locally, Bangladesh drug prices being comparable to international bulk generic drug prices. The costs of staff time and training of health care workers are excluded, because these were assumed to be similar for both approaches. The local currency costs were converted to US Dollars at the August 1997 exchange rate of 43 Taka:1 US dollar.

Results

All 465 symptomatic women attending PHCs during the study period agreed to take part in the survey. Their median age was 30.2 years (range = 15.9-62.3). Ninety seven percent were currently married, 3 girls (0.6%) had never been married, the remaining 2.4% were widowed or divorced. The majority of women reported an abnormal vaginal discharge (439/465, 94%). Other common symptoms were genital itching (254/465, 55%); and/or lower abdominal pain (186/465, 40%). A smaller number of women complained of dyspareunia (31/465, 7%) and/or genital ulceration (5/465, 1%). On direct questioning, 31% (135/439) of women complaining of an abnormal discharge also reported an offensive smell. Table 1 details the laboratory findings for all women, and shows that there were no significant differences in prevalence between the overall group and the 320 women on whom cost analyses were undertaken.

Prevalence of infection

Cervical sexually transmitted infections (*Neisseria gonorrhoeae*, *Chlamydia trachomatis*) were identified in 5 of 449 women (1.1%). A further 6/399 (1.5%) had *Trichomonas vaginalis*. Examination of risk factors for the 385 women for whom results of all STIs were available found that the main risk factor for any STI was working 'in service' (e.g. teacher, cook) as opposed to being a housewife or having any other occupation ($p=0.005$, OR= 13.5). There was some suggestion that working outside the village ($p=0.07$, OR = 28.5) was also associated with an increased risk of STI – see Table 2. No other demographic or social variables were associated with STIs.

Endogenous infections (candida and/or bacterial vaginosis) were diagnosed by the laboratory in 133 of 418 (32%) of symptomatic women for whom results of BV and candida are available. After controlling for possible confounders, IUD use was associated with an increased risk of endogenous infection ($p=0.018$, OR 4.04), and women with a tubectomy were more likely to have an endogenous infection when compared to those not using contraception ($p=0.047$, OR 2.46). Hindu women were more likely to have an endogenous infection compared to Muslim women ($p=0.02$, OR 2.53). Women who did not report possible symptoms in their husbands were more likely to have an endogenous infection than

those women who said that their husbands were suffering from urethral discharge, dysuria or genital ulcer ($p=0.046$, OR 1.74). There was no observed relationship between age, education level, regularity of menstruation or menstrual hygiene practices (washing after sex or menstruation, type of sanitary protection used, and frequency of changing protection) and the risk of having an endogenous infection – see Table 3.

Comparison of algorithms

Data presented here refer only to the 320 women complaining of vaginal discharge for whom all laboratory results were available (these 320 include 3 women with cervical infections). Figure 1 shows that the WHO 'risk assessment' algorithm results in all women being treated for an infection: 178 are treated for endogenous infections only, and 142 are treated for cervical and endogenous infections together. The large number receiving treatment for cervical infections arises from the finding that although WHO criteria risk assessment yielded only one at-risk woman – 1 unmarried girl aged less than 21 years - a further 83 women reported that their husbands were currently suffering from urethral discharge, dysuria and/or a genital ulcer. Laboratory results showed that 2 of the 3 women with a cervical infection were in this latter group. The third woman with a cervical infection was among the 58 women who did not know the symptom-status of their spouse; therefore this group has been included in the STI-treatment arm of the algorithm although in reality it would currently be for the individual health-worker to decide whether or not to treat a woman who does not or cannot answer risk assessment questions.

Algorithm 2. All women were examined by a PHC-level worker, using a speculum, and a diagnosis was made according to the use of algorithm 2. The comparison of trained health workers' diagnoses against laboratory findings is shown in Table 4. Diagnosis of endogenous infections was more accurate than diagnosis of either the vaginal *T. vaginalis* or the cervical sexually transmitted infections (*N.gonorrhoeae* and *C.trachomatis*). None of the 3 women with a cervical infection were correctly identified by the health workers, and the 8 women treated for a cervical infection were subsequently proven to be uninfected on laboratory analysis.

Table 5 presents the results of the cost analysis in several ways. The cost per woman is the overall cost of treatment prescribed per symptomatic woman presenting to the health centres. The cost per true case treated is the cost of treating women with any laboratory proven infection. The cost per cervical infection treated is the cost of treating women with confirmed chlamydia or gonorrhoea; and the cost per STI treated is that of treating chlamydia, gonorrhoea, or trichomoniasis. (In this study the cost of treating cervical infections under algorithm 2 is infinite because no true cases were treated.)

As table 5 shows, the two approaches differed greatly in their overall impact. Under Algorithm 1, all cases of STIs, cervical infections and endogenous infections were treated, at a cost of US \$3.56 per true case treated or US \$0.83 per symptomatic woman seen. However 92% of the expenditure was 'wasted'

on overtreatment. Algorithm 2, by contrast, treated only 22% of the women with STIs (trichomoniasis only), no women with cervical infections were treated and only 42% of those with endogenous infections, at a lower overall cost per case of US \$1.32, and only US \$0.12 per symptomatic woman. Even so, 75% of expenditure on algorithm 2 was 'wasted' on overtreatment, despite the fact that the majority of 'serious' cases (STIs and cervical infections) were not detected or treated.

Discussion

In this study of symptomatic women attending PHC centres in rural Bangladesh, we have found a low STI prevalence and a moderate prevalence of endogenous infections. These findings are consistent with other studies from the South Asian region,^{10,12} although some researchers have found higher levels of individual STIs or of vaginal infections in the populations studied.¹⁹ Such differences in prevalence may be true differences, alternatively they may reflect sample selection bias, or differences in the laboratory definitions used.²⁰ The prevalence of STIs in this Bangladeshi population is in marked contrast to the figures reported from many studies in the African region¹⁰.

A factor which may have resulted in a lower STI prevalence in this population is that in general, maternal and child health – family planning (MCH-FP) clinics in this area of the world only see married women of reproductive age. It is known that in many societies, younger (unmarried) adolescents are at higher risk of infection with STIs.²¹ Unmarried girls rarely attend for MCH-FP services in countries such as Bangladesh. Exclusion, usually through societal sanctioning, of these girls from service provision may have resulted in the low prevalence of STI infections found in the population studied.

Identification of the risk factors predicting an STI was limited to looking at sociodemographic characteristics since very little information was obtained on sexual behaviour from any women in the study – 3 women reported sex before marriage (including one unmarried girl), and one woman reported an extra-marital partner. Women working 'in service' or outside their own village were more likely to have a laboratory diagnosed STI. However, given the low prevalence of STIs, this association should be interpreted with caution. Risk of endogenous infections was higher in women using IUDs or those with a tubectomy, consistent with previous reports.^{15,22,23} Hindu women were more likely to have an endogenous infection. In Bangladeshi society, Hindu men are unlikely to have been circumcised, whilst most Muslim men are circumcised whilst young. Previous studies have shown increased risk of sexually transmitted infections, especially HIV,^{24,25} among uncircumcised men and their partners, but it is not known if the same is true for the endogenous infections. The finding that women who did not report a possible RTI/STI symptom in their husband were more likely to be suffering from an endogenous infection may simply be a reflection of the difficulty of asking such questions. This carries implications for the currently recommended risk assessment.

Our analysis of the two algorithms in current use (algorithms 1 and 2), has shown that neither deals adequately with the management of symptomatic women complaining predominantly of abnormal vaginal discharge, the most common presenting complaint. Use of the WHO recommended 'risk assessment' algorithm (Figure 1), based on questions of sexual behaviour to identify women with a possible STI, was unworkable in a population where the social sanctions administered to women who have sex outside of marriage are high, and very few women report extra- or pre-marital sexual activity. Furthermore, a large number (24% in this study) report symptoms in their husbands. These women were not more likely to have an STI than those who did not report such symptoms. However, we did identify site and type of work as factors associated with an increased risk of having an STI, and it may be more helpful to include questions on other demographic variables in the risk assessment.

Results from diagnosis based on clinical signs and low-cost diagnostics (Figure 2) has demonstrated that trained health workers given access to a speculum and simple, cheap screening tools such as pH paper and KOH, may be able to diagnose and manage endogenous infections – especially candida. The sensitivity and positive predictive value of using pH paper alone to diagnose BV, were higher than asking the health workers to make a diagnosis based on pH paper, whiff test and diagnosing an 'abnormal-looking' discharge. The ability of health workers to diagnose and manage the more serious cervical sexually transmitted infections was compromised by a lack of diagnostic tools and by the low specificity or absence of clinical signs of infection.^{26,27} Consequently, in this low prevalence population, the sensitivity and positive predictive values for the diagnoses of cervical STIs were zero.

Given this picture, it is clear that improved diagnostics would change the situation dramatically, and would be worth paying for – a situation similar to that described for malaria.²⁸ Taking the example of cervical infections, under algorithm 1, 142 women were treated for cervical infection, of whom only 3 (2.1%) had laboratory confirmed infections, under algorithm 2, none of the infected women were treated. In the WHO algorithm, total expenditure on treatment of cervical infections was US \$128, of which only US \$3.56 was spent on treatment of true infections. Nearly US \$124 was spent on overtreatment, and could be reallocated to diagnostics without a loss of care. Assuming 100% sensitivity and specificity for diagnostics, an expenditure of up to \$0.76 per test to detect cervical infections reliably would still result in savings. Furthermore, overdiagnosis of STIs also carries possible social consequences since the social status of many women is precarious and the risk of domestic violence is thought to be high.

The problem still remains, however, that PHC centres in the developing world see many women complaining of an abnormal vaginal discharge, and there are no cheap and effective diagnostics yet available. When the prevalence of STIs is low and endogenous infections are found in less than one third of women (as in this study), then other causes for such symptoms need to be explored, for example, as a side effect of contraceptive use,^{29,30} or a misconception about normal physiological discharge. This under-researched area needs further exploration. Understanding and changing women's treatment seeking behaviour with regard to self-perceived vaginal discharge may result in considerable

improvements in management at the PHC level. Reducing overtreatment through the use of improved algorithms or diagnostic tests would only result in savings of staff time and other resources if the uninfected women did not present in the first place.

Countries such as Bangladesh clearly recognise the importance of controlling STIs in order to reduce the associated morbidity and mortality and hopefully to curb the incidence of HIV infection.³¹ Such policies are in line with the well-recognised cost-effectiveness of STI management,^{5,6,32} and conform to international guidelines on development of reproductive health programmes.⁴ However, this study has called into question both the clinical- and cost-effectiveness of siting STI control primarily at the PHC level in a low prevalence environment. This approach is unlikely to be as cost-effective as one which recognises that some people may be in situations which place them at higher risk of infection (for example, those living in urban areas, male and female adolescents, or among persons with an occupational or recreational risk – sex workers and their clients) and consequently targets them first for service provision.³

A targeted approach should not be used to deny services to those symptomatic women at PHC level, but recognises that, in generally low STI prevalence areas, the cause of their symptoms is unlikely to be an STI, and that other interventions may be more appropriate. A programme of action for symptomatic women should certainly include the following: training PHC workers in the management of endogenous infections in women (using simple diagnostic methods), and in use of the other syndromic algorithms, which are known to work better, such as the one for treatment of genital ulcer disease; primary prevention and information campaigns for both (for example, exploring the issue of menstrual hygiene, and normal discharge); and encouraging appropriate health-care seeking behaviour to trained health care providers. Furthermore, evidence suggests that syndromic algorithms work better in men with clinically observable discharge than in women.³³ The policy of many countries to link STI control predominantly with the family planning programme^{34,35,36,37} may effectively exclude that population with at least equal and possibly higher risk of STIs, who are clinically easier to manage: namely, men. Treating symptomatic men and encouraging them to ensure treatment of their female partners may prove to be a successful strategy in bringing 'hard to reach' and asymptomatic but infected women into the treatment framework.³⁸

A low prevalence of STIs in a population does not obviate the need for interventions which are proven to be cost-effective even in such situations: for example, screening all pregnant women for syphilis.³⁹ Finally, the development of simple to use, cheap and effective diagnostic tests in the near future will potentially allow correct identification of those men and women suffering from STI, even at the most basic health care facilities. In the interim, however, STI control and management policies in countries with a generally low prevalence, need to explicitly include those groups in the population with presumed or known higher levels of STIs. This approach requires willingness on the behalf of policy-makers, programme managers and public health specialists to publicly recognise the existence of persons at higher risk in their society and to ensure adequate service provision for them.

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Table 1 - prevalence of reproductive tract infections in symptomatic women in Matlab

(n/denominator) % +ve	Prevalence in 465 symptomatic women presenting to PHC care	Prevalence in 320 symptomatic women for whom all laboratory results are available*
<i>N. gonorrhoeae</i>	(1/465) 0.2%	(1/320) 0.3%
<i>C. trachomatis</i>	(4/449) 0.9%	(2/320) 0.6%
RPR+/TPHA+ (active syphilis)	(4/465) 0.9%	(3/320) 0.9%
<i>Trichomonas vaginalis</i>	(6/395) 1.5%	(6/320) 1.9%
Bacterial vaginosis	(79/418) 18.8%	(60/320) 18.8%
Candidiasis	(58/460) 12.6%	(39/320) 12.2%
Any cervical or vaginal STI (<i>N. gonorrhoeae</i> , <i>C. trachomatis</i> , <i>T. vaginalis</i>)	(11/395) 2.8%	(9/320) 2.8%
Any endogenous infection	(133/418) 31.8%	(92/320) 28.8%

* pH paper, KOH and *T. vaginalis* culture kits were not always available. The cost analysis includes only those cases where all tests could be fully carried out.

Table 2 – Risk factors for sexually transmitted infections (N= 385)

Possible risk factor		r/n	Unadjusted OR	P
Religion	<i>Muslim</i>	12/351	1	0.35
	<i>Hindu</i>	2/34	1.77	
Contraception	<i>None</i>	4/116	1	0.14
	<i>DMPA</i>	3/121	0.71	
	<i>IUD</i>	2/13	5.09	
	<i>Condom</i>	0/27	-	
	<i>Tubectomy</i>	1/38	0.76	
	<i>OCP</i>	3/64	1.38	
Age group	<i>< 25 years</i>	4/78	1	0.58
	<i>25-34 years</i>	6/207	0.55	
	<i>35+ years</i>	4/100	0.77	
Schooling	<i>0 years</i>	5/169	1	0.72
	<i>01-05 years</i>	7/145	1.66	
	<i>06+ years</i>	2/70	0.96	
Occupation	<i>Housewife</i>	11/358	1	0.008
	<i>In service</i>	3/10	13.5	
	<i>Other</i>	0/14	-	
Working outside her village	<i>Yes</i>	1/2	28.46	0.07
	<i>No</i>	13/383	1	
Marital status	<i>Single</i>	0/1	-	1.0
	<i>Married</i>	14/379	-	
	<i>Divorced/</i>	0/5	-	
	<i>Widowed</i>			
Number of marriages in lifetime	<i>1</i>	13/352	1	0.89
	<i>2+</i>	1/31	1.15	
Husband's occupation	<i>Manual labour</i>	7/201	1	0.80
	<i>Skilled labour</i>	2/68	0.84	
	<i>Business</i>	5/104	1.4	
	<i>Irregular</i>	0/4	-	
Husband spent nights away in the past month	<i>Most/all</i>	4/139	1	0.84
	<i>Occasional</i>	1/32	1.1	
	<i>None</i>	9/208	1.53	
Husband symptomatic	<i>Yes</i>	6/98	2.34	0.14
	<i>No</i>	6/221	1	

Table 3– Risk factors for endogenous infections (N=418)

Possible risk factor		r/n	Unadjusted OR	Adjusted OR	P
Religion	<i>Muslim</i>	115/378	1	1	0.02
	<i>Hindu</i>	18/40	1.87	2.32	
Contraception	<i>None</i>	40/125	1	1	0.39
	<i>DMPA</i>	38/132	0.86	1.33	0.018
	<i>IUD</i>	8/15	2.43	4.05	0.047
	<i>Condom</i>	3/26	0.28	2.47	0.19
	<i>Tubectomy</i>	17/38	1.72	1.62	
	<i>OCP</i>	27/76	1.17		
Age group	<i>< 25 years</i>	30/97	1		0.84
	<i>25-34 years</i>	69/215	1.06		0.86
	<i>35+ years</i>	34/106	1.05		
Schooling	<i>0 years</i>	65/177	1		0.07
	<i>01-05 years</i>	42/154	0.65		0.22
	<i>06+ years</i>	25/86	0.71		
Season when seen	<i>Cold, dry</i>	56/167	1		0.11
	<i>Hot, dry</i>	16/70	0.59		0.97
	<i>Hot, wet</i>	61/181	1.01		
Sanitary protection	<i>Cloth/towel made at home</i>	100/321	1		0.51
	<i>Other</i>	33/95	1.18		
Number of times per day that she changes sanitary protection	<i>1</i>	12/30	1		0.62
	<i>2</i>	62/176	0.82		0.15
	<i>3+</i>	56/206	0.56		
Days since LMP	<i><11</i>	14/45	1		0.89
	<i>11-20</i>	50/155	1.05		0.12
	<i>21+</i>	19/40	2.00		
Having regular menstruation	<i>Yes</i>	81/232	1		0.13
	<i>No</i>	52/186	0.73		
Male partner symptomatic	<i>Yes</i>	25/103	1	1	0.046
	<i>No</i>	82/243	1.59	1.74	
Last sexual intercourse	<i>(1) 1 day – 1 week</i>	27/88	1		0.54
	<i>(2) >1 week < 1 month</i>	51/188	0.84		0.14
	<i>(3) > 1 month < 1 year</i>	31/74	1.63		0.63
	<i>(4) > 1 year</i>	22/64	1.18		

Table 4 - accuracy of PHC workers' syndromic diagnoses, compared to microbiological findings (n = 320 symptomatic women)

Diagnosis	Sensitivity of diagnosis	Specificity of diagnosis	PVP of diagnosis
Bacterial vaginosis	(19/60) 32%	(213/260) 82%	(19/66) 29%
Candida	(23/39) 59%	(221/281) 79%	(23/83) 28%
Trichomonas infection	(2/6) 33%	(250/314) 80%	(2/66) 3%
Cervical Infection*	(0/3) 0%	(309/317) 97%	(0/8) 0%

* cervical infection with either *N.gonorrhoeae* or *C.trachomatis*
PVP = predictive value of a positive diagnosis

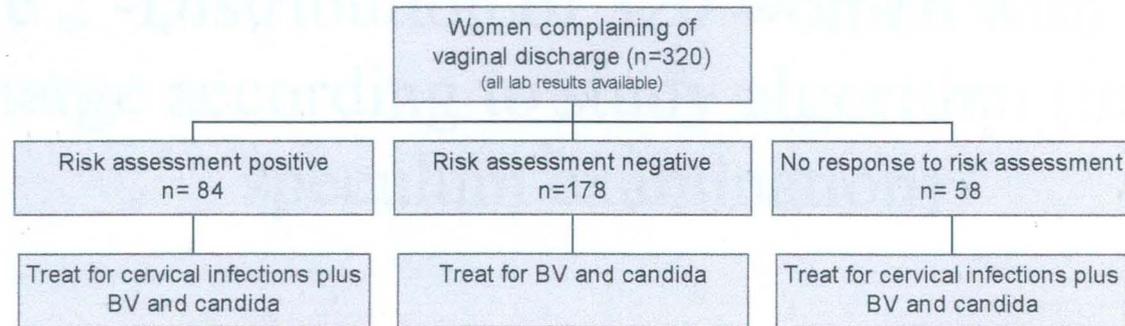
TABLE 5 - COSTS OF TREATING VAGINAL DISCHARGE USING DIFFERENT FLOW CHARTS

	No. of women	WHO - Figure 1	Clinical diagnosis - Figure 2
total cost	320	\$384.95	\$57.86
overspend per woman		\$0.76	\$0.09
cost /true case	101	\$3.56	\$1.32
total cost/cervical infection (GC,CT) treated	3	\$128.32	inf.*
cost/std treated (GC,CT,TV)	9	\$42.77	\$28.93
% of total cost on true cases		8.1%	25.0%
% of total cost on overtreatment		91.9%	75.0%
% of STIs treated		100.0%	22.2%
% of cervical infections treated		100.0%	0.0%
% endogenous infections treated		100.0%	42.4%

Abbreviations: GC = *Neisseria gonorrhoeae*; CT = *Chlamydia trachomatis*; TV = *Trichomonas vaginalis*

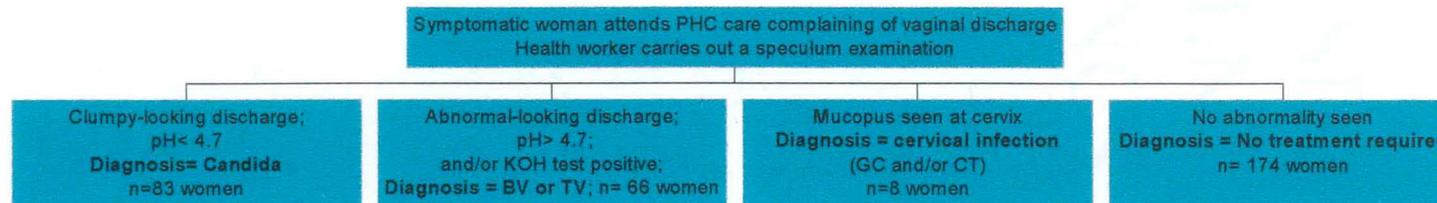
* = infinity (no women with cervical infections were correctly identified and treated by the health workers)

Figure 1 - Distribution of 320 women with vaginal discharge according to WHO algorithm for Primary Health Care level workers (no speculum)



Risk assessment : partner reported to be symptomatic
or any two of:
unmarried woman
> 1 sexual partner in past year
new sexual partner in last three months
age < 21 years

Figure 2 -Distribution of 320 women with vaginal discharge according to study algorithm (includes speculum examination)



Key to abbreviations: BV = bacterial vaginosis; TV = *Trichomonas vaginalis*; CT = *Chlamydia trachomatis*; GC = *Neisseria gonorrhoeae*; KOH = potassium hydroxide

Appendix 5 - review of cost-effectiveness

APPENDIX SIX:
ESTABLISHMENT OF
MALE CLINCS

WHY INCLUDE MEN?

Establishing sexual health clinics for men in rural Bangladesh

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Summary:

Subsequent to recommendations from the 1994 United Nations International Conference on Population and Development, and given recent findings outlining the links between control of sexually transmitted infections (STIs) and a reduction in HIV incidence, many countries are now seeking to establish STI control programmes. In many cases this is through a policy of providing comprehensive reproductive health care through the maternal and child health/family planning (MCH-FP) system. This involves management of all reproductive tract infections including STIs. This paper demonstrates how such an approach may miss one of the largest target groups – men. In general, men are at higher risk of initially contracting STIs, but, once infected, their clinical management is usually simpler than treating equivalent infections in women. It is argued that these two factors alone make the inclusion of men in STI control programmes critical. The paper outlines the experiences of one programme in rural Bangladesh in establishing sexual health clinics for men within the existing service structure. In response to client demand, the clinics moved beyond simple STI care towards provision of comprehensive sexual health services. Finally, the paper argues that whilst including men in sexual health programmes should never be at the expense of providing services for women, excluding them from service provision may make the objectives of STI control programmes unattainable.

Introduction

Throughout many low income countries there is currently a concerted effort to establish sexually transmitted infection (STI) control programmes where few or none have previously existed. In general, such programmes are being promoted through the strategy of providing integrated, comprehensive reproductive health care. This is a direction which is mostly supported by health advocates, health professionals, international agencies, the donor community and respective national Ministries of Health (United Nations, 1994; Hardee and Yount, 1995; Elias, 1994; Fox *et al.* 1995; Ashford, 1995; Cates, 1993; Van Dam, 1995; Temmerman, 1994; Garcia-Moreno and Turmen, 1995; Luthra *et al.* 1992; Pachauri, 1994). Whilst the content of these programmes is usually agreed on by most actors involved, the strategies for organising services to achieve optimal coverage and benefit are less clear. This paper addresses one issue in integrated reproductive health care: management and control STIs in one rural area of Bangladesh.

The impetus for STI control programmes has arisen from different yet complementary directions. First, recent epidemiological evidence linking STI control with a reduction in HIV incidence (Grosskurth *et al.* 1995) has given many policy makers an added incentive to push for the provision of STI services. In countries such as Bangladesh, which are at the perceived early or middle stages of an HIV epidemic, the contribution of STI control to curbing the spread of HIV may be significant.

Second is the increased recognition of the burden of morbidity and mortality associated with STIs and the consequences for health care systems seeking to provide effective management for the clinical manifestations and complications of these (preventable) infections. A report by Over and Piot (1993) showed that the burden of STIs in many urban (high prevalence) populations in the developing world, as measured by age-adjusted healthy life years lost, is a substantial fraction of the entire disease burden of those populations. The contribution of STIs to the problems of foetal wastage, premature births, congenital infections, blindness, ectopic pregnancies, infertility, and genital

cancers is now widely accepted (Wasserheit and Holmes, 1992; Meheus, 1992). It is estimated that up to 80% of female infertility in low income countries is a consequence of reproductive tract infections (RTIs) including STIs (Wasserheit and Holmes, 1992).

Finally, the recommendations from the 1994 International Conference on Population and Development (ICPD, Cairo) encouraged all countries to "...strive to make accessible through the PHC system, reproductive health to all individuals of appropriate ages... [this] should include ...treatment of reproductive tract infections; sexually transmitted diseases and other reproductive health conditions" (United Nations, 1994). Following the ICPD Programme of Action, many countries are now attempting to provide comprehensive, integrated reproductive health services at the primary health care (PHC) level.

Health planners now face the question of where STI services should be located in order to achieve the highest impact, whilst taking into consideration fundamental issues such as cost and coverage rates. As with many other health programme debates, planners are faced with what combination of 'vertical' and 'horizontal' STI control programmes should be adopted (Mills, 1983). Many are favouring a 'horizontal' approach with the integration of STI control into the pre-existing clinical services, usually, but not limited to, the PHC system. It should be recognised, however, that if STI control is to achieve its optimal potential, then a targeted approach is often appropriate (Over and Piot, 1993) - thus ensuring clinical services and prevention campaigns reach those at higher risk of infection.

Recognising that in many countries the PHC system is predominantly a source of mother and child health care (often linked with family planning provision, MCH-FP), it is pertinent to ask whether in its current format this is the most effective site to place the majority of public sector clinical services aimed at achieving STI control, or whether other sections of society should be at least equally targeted for the provision of such services.

Given that in many societies it is men who are more at risk of initially contracting STIs (Mundigo, 1995) - and who may then transmit them to their wives/sexual partners - public sector STI services which are predominantly MCH-FP based, and consequently targeted mainly at women, may be unavailable to men at risk. Such was the case within our own project (see below). Whilst women who were identified as suffering from an RTI or STI were offered clinical management at PHC clinics, similar on-site management possibilities were not available to men within the existing service structure as PHC is female-focused. Given that cultural considerations and taboos precluded the suggestion that female staff could treat any men presenting with sexual or reproductive health problems, the male medical assistants in our programme proposed that they should be adequately trained to manage reproductive health-care problems in men, if male clinics were established.

The remainder of this paper looks at our experience in aiming to establish whether the MCH-FP infrastructure could be used as a conduit for providing STI services to both men and women. This was the first time that such an approach had been undertaken in Bangladesh.

Background to the clinics

The Centre for Health and Population Research (CHPR, also and formerly known as the International Centre for Diarrhoeal Disease Research, Bangladesh) is a large UN-affiliated research organisation which has been working in Bangladesh for the past thirty years. Although originally established as the Cholera Research Laboratories, the Centre was expanded in the 1970s to include family planning and MCH services, and much of its research has been carried out in Matlab, a rural area some 50 kms south-east of Dhaka (the capital), working with a population of approximately 105,000 people.

The PHC system operated by the CHPR has several components including community health workers (CHWs) who visit households on a fortnightly basis and provide contraceptives, vaccines (within the EPI programme) and basic medicine; collect

demographic and morbidity data; and refer women and their children to PHC centres known as subcentres. Complicated cases are sent to a central CHPR hospital in Matlab. Each subcentre serves a population of about 25,000 people, but basic health care (including reproductive health care) is currently predominantly available only for married women and their children under the age of five years. The majority of staff at the subcentres are female, but each subcentre also has one male medical assistant (who has received at least three years of general medical training).

With its comprehensive and ongoing system of demographic surveillance, Matlab provides a unique opportunity to measure disease burden at a population-based level. At the end of 1994, CHPR established a large project to determine the population-based prevalence of RTIs/STIs in men and women in the Matlab area. The objectives of this ongoing study are to determine the epidemiology and aetiology of these infections, derive possible risk factors for infection, and outline current health care seeking practices. The training of staff in syndromic management of these infections, as recommended by WHO training modules (WHO, 1995), is also being evaluated, along with the efficacy of the clinical algorithms in women only.

Men in the population-based survey were randomly selected from demographic surveillance lists and interviewed in private at home by trained male interviewers. Samples of blood and urine were collected and analysed for the presence of syphilis (study completed), *Neisseria gonorrhoeae* and *Chlamydia trachomatis* (ongoing). Questionnaires were administered to determine demographic variables, reported symptomatology, health-care seeking patterns, and lifetime sexual behaviour histories. Nine hundred and sixty-nine men aged 15-50 years have been recruited.

Seeking health-care prior to the opening of the clinics

Men in the population-based study were asked about their previous patterns of treatment-seeking behaviour for three symptoms indicative of possible STIs: urethral discharge, pain passing urine and genital ulcer disease. Table 1 presents treatment-seeking histories from the men who had suffered from these symptoms in the past or were currently

suffering from them. The majority of men experiencing such symptoms had sought care. Given that at the time the survey was conducted there were no public sector services for STI care (aside from our own new clinics), most had gone to the private sector (formal and non-formal, trained and untrained) with previous problems. Table 2 addresses the reasons why men with symptoms had not sought care. Each man could give more than one reason, and the most frequent were: symptoms not perceived as severe enough; and too embarrassed to seek treatment.

Researching and marketing the clinics

The male sexual health clinics were opened only after the community had been consulted both formally and informally, and acceptability, nomenclature and need had been discussed. This was carried out at several levels: by the male medical assistants going out into their local communities and holding focus group discussions with various sections of the male population; by the male interviewers from the project talking about service provision with the men being interviewed for the population-based STI prevalence survey; and by the female community health workers informing their regular (female) clients that a new service for men would be opening, and to encourage their partners/husbands to attend if they had any symptoms. By the time the clinics opened, the communities they served had been made aware of the existence of this new service through the use of word-of-mouth and person-to-person communication networks. This, rather than a written poster or leaflet campaign, was felt to be an appropriate method of communication in a situation where only 43% of men and 22% of women are literate (Government of Bangladesh, 1993), and access to any form of mass media is low.

Four clinics were opened between August 1995 and January 1996. It was agreed that the clinics would initially open for one afternoon per week, although this was later expanded to a full day per week. They were located within the existing MCH-FP subcentre buildings as these were equipped with basic facilities for examination, and were also well recognised as sites of health-care provision. Given the lack of laboratory facilities at subcentre level, and the fact that these clinics were designed to be a replicable model for

the public sector, men are treated according to WHO syndromic management flow-charts for STIs (WHO, 1995).

Attendance at the clinics

The clinics are open to all men in the local community, both married and unmarried, and are currently free of charge. Each clinic has seen on average 4 men per session - a similar figure to the number of women with RTI/STI symptoms presenting weekly to each subcentre. Most of the men (>80%) are self-referred, and smaller numbers were either identified through the population-based prevalence survey or are the partners of infected women. Attendance rates of women seeking MCH-FP services during the period that the male clinics have been open do not appear to have been affected in any significant way.

Table 3 presents data from the first year of running the clinics. A total of 622 men attended the clinics during this time, and their presenting complaints/symptoms are shown along with the syndromic (and other) diagnoses made by the medical assistants. Each man could be recorded as having more than one symptom and/or diagnosis. The most frequent treatment categories relate to possible STIs: 19.7% of men received treatment for urethral discharge, genital ulcer disease, scrotal swelling, inguinal bubo. A further 8.5% were treated for pain passing urine. Whilst symptoms of urethritis (urethral discharge or pain passing urine) may be due to non-sexually transmitted causes, the majority are probably due to STIs (Bowie, 1990). Over two fifths of men presented with problems which fall into the psychosexual category: impotence, premature ejaculation, 'sexual dissatisfaction', difficulty in maintaining an erection, and "night pollution" (nocturnal emissions). However, the number of men who were eventually diagnosed as having a predominantly psychosexual condition was much smaller (8.5%), and all of but one of these men were diagnosed in only one of the four subcentre clinics by one of the medical assistants.

Results from the population-based survey of 969 men in the same community are presented in Table 4. Men in this survey were asked an open (unprompted) question to

report any *current* symptoms or sexual health problems – each man could report more than one problem. The largest self-reported category was of psychosexual problems. Symptoms relating to a possible STI were reported by the second largest number of men. More detailed prompted questions on three specific symptoms (dysuria, urethral discharge and genital ulcer) resulted in double the number of men reporting these symptoms.

Discussion

It is generally recognised that the public health control of sexually transmitted infections (STIs) should be multisectoral and multidisciplinary in its approach. Epidemics of STIs are dependent upon a number of parameters, some fixed and some open to modification: the infectivity of the pathogen; the rate of partner change (interaction between infected persons and susceptible individuals); and the duration of infectiousness (Holmes, 1994; Brunham and Plummer, 1990; Anderson and May, 1988).

Whilst the biological infectivity of the pathogen is generally not open to change (although condom use can make transmission less likely), both the rate of partner change and the duration of infectiousness can be amenable to programmes of intervention. The latter through encouraging appropriate health-care seeking behaviour and providing effective clinical management. Such approaches are the cornerstones of programmes of STI control, and along with other factors (such as the general availability of high quality general health care, and the impact of education and primary prevention campaigns) they are thought to have played a significant role in bringing down the rates of (bacterial) STIs in many industrialised nations (Renton *et al.* 1994). However, provision of comprehensive, widespread and accessible STI services is an option affordable in only a few industrialised nations. In situations of cost constraint, for control programmes to be effective it is important that they are targeted to populations where the presumed and actual risk of infection is greatest (Over and Piot, 1993).

Decisions concerning the most appropriate group or section of a society to target are usually based on epidemiological evidence of disease burden and distribution. In countries such as Bangladesh, where basic epidemiological evidence of STI prevalence and incidence is lacking, the decision on where and how to target STI services has to be based on other assessments such as deciding who is most likely to be at risk (based on knowledge and assumptions about cultural norms, socioeconomic conditions and prevailing patterns of risk behaviour) and the capability of existing clinical services to provide effective management for these target groups.

In this society, as in many others, it is probably men who have a greater likelihood of being involved in extra- or pre-marital sexual relationships, have higher rates of partner change and hence a greater risk of exposure to STIs (Mundigo, 1995). The results from our current population-based study highlight the large discrepancies in reported sexual behaviour patterns: whilst 58% of men reported pre-marital sex, only three women (out of more than 1200 interviewed) have reported any lifetime sexual partners apart from husbands. The reasons for this discrepancy are undoubtedly, in part, due to the reluctance of women to report accurately on socially sanctioned behaviours, and in large measure a reflection of the insensitivity of methodologies used in asking sensitive questions (Dare and Cleland, 1994), but it may also reflect a true difference in the sexual behaviour patterns of men and women. Results from other countries show that it is primarily the sexual behaviour of married men which puts their wives at risk of sexually transmitted infections (Hunter *et al.* 1994; Moses *et al.* 1994; Thomas *et al.* 1996). The reasons for this are multiple: men may be more likely to be involved in sexual networks that include more than one partner; they are, generally, more mobile and more often involved in inter- or intra-country patterns of migration pursuing employment opportunities - from Bangladesh, for example, more than 165,500 men go abroad each year to work (Government of Bangladesh, 1996); and finally, men are more likely to be the purchasers of commercial sex.

In our own population-based survey of 969 men (aged 15-50 years) in the Matlab area, self-reported lifetime sexual behaviour has been obtained from 716 men who reported that they had ever had sexual intercourse at any time. Of this group, 18% (129) stated that they had paid for sex at some point in their life. This figure contrasts with 6.8% in the population-based British National Survey of Sexual Attitudes and Lifestyles (Johnson *et al.* 1994), and 64% amongst Thai military recruits (Nelson *et al.* 1996). Given that this is a socially stigmatizing behaviour and our interviews were conducted in the household without any guarantee of confidentiality or privacy, it can be expected that our results are low estimates.

A recent survey of condom use at last sexual episode in a brothel in a metropolitan area in Bangladesh found less than 6% of such episodes were protected (Ahmed and Hawkes, 1996). Given that there are an estimated one hundred thousand women and girls engaged in the commercial sex trade in this country, each with an average three male customers per night (Ahmed and Hawkes, 1996), high levels of STIs (20% of girls and women infected with gonorrhoea and 20% infected with chlamydia in one brothel-based study reported by Sarkar *et al.* in 1997) and reports of large numbers of male sex workers (Khan, 1996), there is a potentially high burden of STI risk through unprotected commercial sex.

Biomedical factors add further weight to any decision to also include men in STI service provision. From both clinical management and public health perspectives, one of the central problems of STI control in women is that in up to 50% of cases the infections are asymptomatic (Hook and Handsfield, 1990, Stamm and Holmes, 1990). Leaving aside the critical issues of where and whether an infected woman can seek treatment, or if she will receive adequate and appropriate management, there still resides the fundamental problem that almost one half of women suffering from cervical infections due to *N. gonorrhoeae* or *Chlamydia trachomatis* will not know they have a problem. Many women only present for care when they are suffering from the secondary complications of the infection - such as pelvic inflammatory disease, ectopic pregnancy or infertility. The same is not thought to be true of men who are infected with these organisms: many infected with either gonorrhoea (Handsfield *et al.* 1974) or chlamydia (Stamm and Holmes, 1990) will be symptomatic, and the symptoms and signs of infection are more specific than the equivalent syndromes in women, thus making the validity of syndromic management flow charts higher.

As a tool for STI/RTI management at the PHC level, most programmes rely on WHO syndromic management flow charts to manage symptomatic patients (Adler, 1996). These charts are clinical algorithms that recognise that a number of organisms may be responsible for commonly presenting symptoms and signs. In the absence of diagnostic laboratory support or simple, cheap and effective on-site diagnostics, and acknowledging

the difficulties inherent in accurate clinical diagnosis, the syndromic flow charts recommend treatment for a group of possible aetiologies (WHO, 1991). Results from surveys in some areas evaluating the sensitivity and specificity of these clinical algorithms in women presenting with vaginal discharge (usually the most common presenting symptom) are not encouraging. Recent results from Bangladesh (Sarkar *et al.* 1997) and Kenya (Thomas *et al.* 1996) suggest that even in high prevalence situations the usefulness of the flow charts in women may be limited.

The flow charts are known to work well in treating symptomatic men, however, and the training of health-care providers (in both the public and private sectors) in the use of clinical algorithms will have a number of potentially beneficial outcomes: firstly more men will receive appropriate and effective clinical management of STIs; secondly correct antibiotic prescribing practices will lower the possibility of drug resistance; thirdly, the flow charts afford the health worker an opportunity to disseminate messages focusing on primary prevention; finally, the flow charts recommend treatment of sexual partners. This last point may bring more 'hard-to-reach' and asymptomatic but infected women (partners) into the treatment framework. These benefits can only be accrued, however, if men seek health care from trained providers. Our survey of 969 population-based men found that a majority of men with symptoms sought care (Table 1). Sites of care, however, were generally in the non-formal sector, and it can be presumed that the majority of private providers in both the formal and non-formal sectors have not received dedicated training in STI management. Amongst those men who did not seek care (Table 2), the most common reason was that men did not think the symptoms were severe enough – this finding carries implications for intervention programmes aiming to modify health-care seeking behaviour.

Of note, results from both the clinic-based and population-based surveys have highlighted the large number of men complaining of, and seeking care for, psychosexual problems. This was an unexpected finding for our survey, and has resulted in new training programmes for the medical assistants in order to address the special needs of clients with these problems – especially given the discrepant inter-clinic diagnosis rates found in the

course of the study. Clearly such training carries both financial and other resource implications. Suitable training programmes in psychosexual health are uncommon in this Region, but are required if personnel are to adequately address the needs of the clients they serve. Further research into this area will shortly begin in Matlab with a programme of work aiming to address in detail issues of male sexual health beliefs, concerns, and attitudes to various aspects of sexual and reproductive health (including contraception and primary prevention).

Conclusions

This paper has outlined the reasons why including men in the provision of services to control STIs is important from social, public health and biomedical viewpoints. In rural Bangladesh we have shown how even in a relatively conservative society it is possible to establish STI clinics for men within an existing MCH-FP system, and these clinics have continued beyond the life of the primary study. The clinics have so far shown that not only is there an unmet need for STI services for men, but that the male clients themselves are asking for other reproductive and sexual health services. Such services include more psychosexual health-care and contraceptive services (including male sterilisation). Given that the second largest diagnostic category in our clinics is psychosexual problems, the time has perhaps come to address the *comprehensive* reproductive and sexual health care needs of men as well as those of women. It may even prove to be an effective strategy in controlling the spread of STIs, and hence reducing the disproportionate burden of their complications suffered by women.

Such policies to include men are not, however, without their obvious financial and programme costs. Firstly, male sexual health services can only currently be provided by trained male health workers - which influences personnel allocation time. Secondly, the expansion of such clinics to incorporate more general sexual health services (including psychosexual and counselling services) requires extra staff training and the identification of adequate referral mechanisms to secondary and tertiary level care (which may not be available). Thirdly, male clients and health workers alike have begun to question the absence of comprehensive public sector health care for men. Programme expansion to provide basic essential health care for men at PHC level carries clear financial implications. Finally, it is clear that most men currently seek care in the private (formal and non-formal) sector; possibilities for provider training in this sector need

to be evaluated. Other sites of health care for men (such as occupational health services) may also prove to be valuable intervention sites for provider training.

Targeting men in STI control programmes should never be at the expense of providing high quality, comprehensive reproductive health care for women (Berer, 1996), which includes RTI/STI management. It should be recognised, however, that targeting women as the primary focus of STI control programmes may make achieving the objectives of such programmes more difficult. It may also contribute to the prolongation of the common stereotype that STIs are 'women's diseases', with a concomitant attribution of blame to women (Mbvizo and Bassett, 1996; Campbell, 1995). Incorporating men into these programmes and encouraging and helping them to change their risk behaviour may have greater impact on STI control in a country such as Bangladesh than activities focused solely on women.

In conclusion, we would recommend the following steps be taken by programmes wishing to establish sexual health clinics for men in situations similar to those found in Bangladesh:

- community consultation prior to the opening of the clinics: evaluating acceptability and need for the clinics
- understanding current health care seeking practices within the community and client reasons for choice of provider
- ensuring the availability of male health workers to run the clinical services
- understanding men's beliefs and attitudes towards all aspects of their sexual health (psychosexual problems, contraception, etc.)
- adequate training of the health workers in all aspects of male sexual health - not only clinical management, but also dealing with psychosexual issues and sexual health counseling
- adequate 'marketing' of the clinics through formal and informal mechanisms
- ensuring that female attendance in concomitant MCH services is not adversely affected
- occasional evaluations (at local and national level) of recommended syndromic management flow charts for dealing with STIs in men - evaluating both clinical and laboratory features

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TABLE 1: TREATMENT-SEEKING HISTORIES FOR PAST AND PRESENT SYMPTOMS, POPULATION-BASED MEN

	Urethral discharge (n = 146)	Pain passing urine (n = 273)	Genital ulcer disease (n = 82)
% with symptom who have sought health care	60.3% (88/146)	56.8% (155/273)	84% (69/82)
SITE WHERE HEALTH CARE WAS SOUGHT	<i>n=88</i>	<i>n=155</i>	<i>n=69</i>
Indigenous systems of medicine practitioner	53.4%	43.8%	27.6%
Village 'quack'	15.9%	16.8%	13.0%
Pharmacy	5.7%	11.6%	15.9%
Private allopathic doctor	23.9%	27.1%	27.5%
Self-treatment		0.6%	2.9%

TABLE 2: REASONS FOR NOT SEEKING TREATMENT, POPULATION-BASED MEN

	Urethral discharge (n = 146)	Pain passing urine (n = 273)	Genital ulcer disease (n = 82)
% with symptom who have NOT sought treatment	39.7% (58/146)	43.2% (118/273)	15.9% (13/82)
REASON FOR NOT SEEKING TREATMENT	<i>n=58</i>	<i>n=118</i>	<i>n=13</i>
No time to seek treatment	8.6%	6.8%	7.7%
Treatment too expensive	31.0%	25.4%	15.4%
Symptoms not severe enough	56.9%	72.9%	76.9%
Self-treatment	17.2%	24.6%	23.1%
Did not know where to go	22.4%	17.8%	7.7%
Too embarrassed to seek treatment	43.1%	29.7%	38.4%

**Table 3 - SYNDROMIC DIAGNOSES AT MALE CLINICS IN
MATLAB, 1995-6**

Morbidity	% of 622 men who complain of this symptom	% of 622 men who receive this diagnosis after clinical exam.
Pain passing urine	41.8%	8.5% ^a
Psychosexual problem ^b	41.5%	5.9%
Urethral discharge	37.8%	10.8%
Skin problem	9%	18.2%
Partner management ^c	7.1%	7.1%
Genital ulcer disease	3.9%	3.9%
Urethral pain	3.9%	0%
Scrotal swelling	1.4%	2.3%
Blood in urine	1.3%	0%
Inguinal bubo	0%	2.7%
Other, non-reproductive health morbidity ^d	18.3%	3.5%
No abnormality detected		37%

(a) diagnosis = urinary tract infection; (b) psychosexual problems - see text; (c) female partner has received initial diagnosis of STI; (d) other morbidity such as cough, weakness, etc.

Table 4 - CURRENT SYMPTOMS REPORTED BY MEN IN POPULATION-BASED SURVEY

Reported symptom(s)*	% of men reporting symptom (n =969)
No problem	74.2%
Psychosexual problem**	16.7%
Pain passing urine	7.9%
Urethral discharge	3.1%
Urethral discharge plus dysuria	1%
Painful coitus	1.7%
Genital ulcer	0.6%

*Men could report more than one symptom **Psychosexual problems include the following: premature ejaculation; impotence; dissatisfaction with sexual intercourse; difficulty in maintaining an erection; and "night pollution"