IKP Centre for Technologies in Public Health

Final Proposal
Women's Health Intervention

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Abstract

The health needs of women vary depending on the stage of life in which they are. The services and care required by young girls, adolescents, pregnant women, women past their reproductive age, and elderly women are all vastly different. Health systems have tended to focus primarily on the needs of pregnant women, while ignoring the health demands of other women. As a result, some services such as antenatal care are much more likely to be in place at the primary care level than others, such as, say, cervical cancer screening and care. While this focus on maternal health is important to meet the Millennium Development Goals of reducing maternal and infant mortality, there are other important women's health issues where opportunities to make a difference have been missed. To address this imbalance, it is imperative that health systems provide more comprehensive healthcare services to women. Here, we outline the first steps taken towards the development of such a comprehensive "women's health package". In its current avatar, the women's health package will focus on screening and treatment of infections of the reproductive tract. Gradually, additional features will be introduced to specifically tailor the package to women of different age and developmental groups.

1. Introduction

In all societies, women play a pivotal role in providing healthcare. They do so through their role as mothers where they are the primary caregivers within a family, and more recognizably as health-care providers in the formal and informal health sectors. It is therefore paradoxical that the health needs of women have been largely overlooked by health systems. This discrepancy is much starker in poorer countries when compared to rich countries, and in poorer women compared to their richer counterparts within a country (**WHO 2009b**). A variety of factors contribute to this failure to meet and respond to the health needs of women, but they principally relate to the biases that women face in society. Cultural and social norms restrict women's access to education, thereby precluding awareness of their health needs, and preventing them from taking charge of their health. Furthermore, discrimination and violence against women also cause them to suffer poor health, and at the most extreme lead to death.

While men and women share many similar health challenges, the differences are such that the health of women deserves special attention. Biological and behavioural differences ensure that women, on average, have longer life expectancies than men. In India, for example, the life expectancy of women at birth is 66 years, compared to 63 years for men (**WHO 2009a**). However, the longer lives of women are not necessarily healthy lives. There are some conditions such as pregnancy and child birth that carry health risks, which are experienced only by women. Consequently, the negative impacts of these processes are also experienced only by women. There are other health conditions where both men and women are affected, but the impact is greater or different for women, so that responses also need to be specifically tailored for women. Finally, there are other health conditions where men and women are equally affected, but the outcomes for women are adverse because their access to healthcare is limited. Therefore, there is an urgent need for health systems to develop programmes that specifically cater to the needs of women and are also more accessible to them.

The health needs of women vary depending on the stage of life in which they are. The services and care required by young girls, adolescents, pregnant women, women past their reproductive age, and older women are all vastly different. In India, health systems have tended to focus primarily on the needs of pregnant women, while ignoring the health demands of other women. As a result, services such as antenatal care are more likely to be in place at the primary care level than others, such as, say, cervical cancer screening and care. While the focus on maternal health is important to meet the Millennium Development Goals (MDGs) of reducing maternal and infant mortality (**MDG 4 and MDG 5, http://www.un.org/millenniumgoals/**), there are other women's health issues where opportunities to make a difference have been missed (**WHO 2009b**). An unintended consequence of the spotlight on maternal health is that it has helped strengthen the erroneous notion that the reproductive role of women is their most important contribution to society. To address this imbalance, it is imperative that health systems provide more comprehensive healthcare services to women.

The ICTPH approach to health care provision is broad-based wherein a wide variety of services (both preventive and curative), including diagnostic tests, are provided to rural populations (**Johar, 2010**). The women's health program intends to incorporate both the preventive and curative aspects of health care. While the goal is to have a comprehensive health package for women, it will

initially focus on reproductive tract health. Since the reproductive health of women has important repercussions for women and their families, this aspect of women's health was chosen. In its current version, the women's health package will screen non-pregnant, premenopausal women of reproductive age for cervical cancer using VIA/VILI tests. Additionally, symptomatic women will also be treated for reproductive tract infections (RTIs) such as candidiasis, trichomoniasis, vaginosis, chlamydia, gonorrhoea, and syphilis. Treatment and management of these RTIs will follow guidelines laid down by WHO (**WHO 2007**), and adapted by National AIDS Control Organization (NACO) (**NACO 2007**).

Reproductive tract infections (RTIs) are now being recognized as a serious global problem, affecting not just individual women, but also their families and communities (**Population Council 1999**). There are three categories of RTIs-

- Endogenous Infections – These result from an overgrowth of microorganisms that are normally present in the vagina. They include bacterial vaginosis and candidiasis (or yeast infection in common parlance).
- Iatrogenic Infections – These occur when the cause of infection is introduced into the reproductive tract through a medical procedure such as menstrual regulation, induced abortion, insertion of an IUD, or during childbirth. This can happen when, for instance, instruments used during surgery are not properly sterilised.
- Sexually transmitted infections (STIs) – These are caused by viruses, bacteria, or other parasitic microorganisms that are transmitted through sexual contact with an infected partner. Some of the common STIs include syphilis, gonorrhoea, chlamydia, and trichomoniasis. These STIs can be easily cured with the appropriate antimicrobial agent. In contrast, infection with Human Papilloma Virus (HPV) can lead to cervical cancer in women following a prolonged progression. Screening and early detection of cervical cancer also saves lives. Besides adult men and women, STIs can also be transmitted from mother to child during pregnancy and childbirth.

The World Health Organisation (WHO) estimated in 1999 that 340 million new cases of STIs occur every year, of which around 151 million are in South and South-East Asia (**WHO, 2001**). However, the existing data on the prevalence of RTIs is not always reliable or complete. The quality and completeness of data is affected by the quality of care available, number of patients who seek care, intensity of case finding and diagnosis, and quality of reporting. The completeness of data is further affected by the natural history of the infections, which result in most patients being asymptomatic. For example, almost 70% of people suffering from chlamydia are asymptomatic. Furthermore, most data is collected from specific sources such as antenatal or STI clinics, and are therefore not indicative of the prevalence of infections in the general community. Therefore, it is important to keep in mind that most reports of prevalence of RTIs are likely to under report the disease burden.

Curable RTIs such as syphilis, gonorrhoea, chlamydia, and trichomoniasis have consequences far more severe than merely causing discomfort. When left untreated, these infections can have adverse outcomes for women and new-born children. Each of these RTIs can result in severe complications such as infertility, ectopic pregnancy, miscarriage, and chronic pelvic pain in women.

In children, consequences include pneumonia, blindness, low birth weight, prematurity, and stillbirth. The consequences of viral STIs such as HPV infection are also very severe for women and children. Persistent HPV infection in women leads to cervical cancer. HPV transmission to children during pregnancy and childbirth results in perinatal conjunctivitis and rarely, respiratory papillomatosis where warts are formed in the respiratory tracts of children. Apart from being serious diseases in their own right, STIs have also been shown to increase the risk of HIV transmission. The presence of an untreated STI can increase the risk of acquisition and transmission of HIV by a factor of 10 (**Population Council 1999**). Therefore, treatment and management of STIs is an important aspect of HIV prevention.

2. The Female Reproductive System

2.1 Anatomy and Physiology

The female reproductive system can be thought to consist of two parts- the upper and the lower reproductive tracts. The upper reproductive tract consists of the uterus, Fallopian tubes, and ovaries. The lower reproductive tract consists of the vulva, vagina, and cervix.

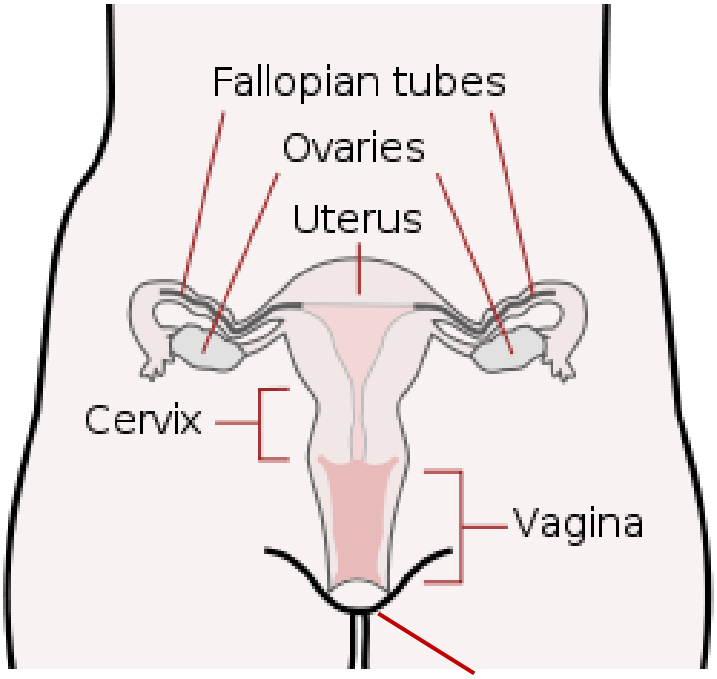

Figure 2.1. Pictorial depiction of the female Reproductive System. (Source – *http://en.wikipedia.org/wiki/Female_reproductive_system*)

The internal reproductive organs of a female are the vagina, cervix, uterus, Fallopian tubes, and ovaries.

Sources: http://en.wikibooks.org/wiki/Human_Physiology/The_female_reproductive_system

http://en.wikipedia.org/wiki/Female_reproductive_system

http://www.goldbamboo.com/topic-t8452-a1-6Cervix.html

Vagina - The vagina is a fibro muscular tubular tract that leads from the external female genitalia or vulva to the cervix (neck of the womb/uterus). The muscular walls allow the vagina to expand and contract. The vagina is the place where semen from the male is deposited during sexual intercourse, and it provides the path through the woman's body for a baby to take during childbirth.

Cervix - The cervix is the lower, narrow portion of the uterus where it joins the vagina. Approximately half the length of the cervix is visible with appropriate medical instruments, while the remaining half is hidden above the vagina.

- Ectocervix: The portion of the cervix projecting into the vagina is called *portio vaginalis* or ectocervix. It has a convex, elliptical surface and is divided into anterior and posterior lips.
- External os: The opening of the ectocervix is called the external os. The size and shape of the ectocervix and external os depends on age, hormonal state, and whether or not a woman has given birth vaginally.
- Endocervical canal: The passageway between the external os and the uterine cavity is referred to as the endocervical canal.
- Internal os: The endocervical canal terminates at the internal os, which is the opening of the cervix into the uterine wall.
- Cervical crypts: There are pockets in the lining of the cervix called cervical crypts. They function to produce cervical fluid.

Uterus – The uterus or womb is the major female reproductive organ. It is shaped like an upside-down pear and is located near the base of the pelvic cavity. The uterus is hollow to allow for implantation and growth of the fertilized egg or zygote. The muscles of the uterus are some of the strongest in the female body. These muscles expand and contract to accommodate the growing foetus, and also help to push the baby through during labour. Rhythmic contraction of these muscles during orgasm is thought to guide the sperm up from the uterus towards the fallopian tubes where fertilisation may be possible. The uterus is about three inches long and two inches wide, but during pregnancy its size change rapidly and dramatically.

Fallopian tubes – The fallopian tubes are at the upper corners of the uterus. They are also referred to as uterine tubes or oviducts. At the other end of the fallopian tubes are the ovaries, which lie close to but are not attached to the fallopian tubes. When an ovary ovulates, the egg or oocyte is swept into the lumen of the fallopian tube by the action of hair-like cilia on the inner lining of the tubes. The trip down the fallopian tubes takes the oocyte four to five days. If an oocyte encounters sperm during its journey down the fallopian tubes, fertilisation might occur. After fertilisation, the zygote will continue down to the uterus, where it will implant itself on the uterine wall, and continue to grow and develop.

Ovaries – The ovaries are small, paired organs that are located near the lateral walls of the pelvic cavity. They are responsible for the production of eggs, and secretion of the hormones progesterone and estrogen.

Reproductive Tract – The reproductive tract or genital tract is the space (lumen) that starts as a single pathway inside the vagina, splitting up into two lumens inside the uterus, both of which continue through the fallopian tubes and end eventually at the opening of the abdominal cavity. In the absence of fertilisation, the oocyte will travel the entire length of the reproductive tract from the fallopian tubes till its exit through the vagina during menstruation.

2.2 Pathophysiology of the Female Reproductive System

2.2.1 Reproductive System Disorders

Source:
http://en.wikipedia.org/wiki/Reproductive_system#Diseases_of_the_human_reproductive_system

The reproductive system is affected by many diseases like any other complex organ system. There are four main categories of diseases-

- Genetic or congenital disorders
- Cancers
- RTIs including STIs
- Functional problems and autoimmune disorders

Additionally, there are other reproductive disorders that are symptoms of other diseases or disorders, or have multiple, unknown causes making them difficult to classify.

Congenital Abnormalities – A congenital disease is a disorder that exists at birth and often before birth, or that develops during the first month after birth. While congenital disorders may be the result of genetic abnormalities, other factors such as the environment of the uterus may also contribute to development of the disease. An example of a congenital reproductive disorder is Kallmann Syndrome, a genetic disorder, characterised by reduced functioning of the glands that produce sex hormones. Females suffering from this disorder show delayed onset of puberty and lack of secondary sex characteristics, such as breast development.

Cancers – The cancers of the female reproductive tract (also called gynaecologic cancers) include cancer of the ovaries (ovarian cancer), cancer of the uterus (uterine cancer), and cancer of the cervix (cervical cancer).

- Ovarian Cancer – Ovarian cancer is cancer arising from the ovaries. Signs and symptoms are typically absent or very subtle early on. Most women with ovarian cancer exhibit one or more symptoms such as abdominal pain or discomfort, an abdominal mass, bloating, back pain, pelvic pain, abnormal vaginal bleeding, involuntary weight loss, constipation, and tiredness. Infertile women, women suffering from endometriosis, those who have never been pregnant, and women who use postmenopausal estrogen replacement therapy are at increased risk of ovarian cancer. Additionally, older women, and those with a family history of ovarian cancer are also an increased risk. Use of oral contraceptives acts as a protective factor.
- Uterine Cancer – There are several types of uterine cancer, the most common being endometrial cancer and uterine sarcoma. Symptoms include pelvic pain, pressure, unusual discharge, unusual or postmenopausal bleeding. A non-pregnant uterus that enlarges quickly

is also suspicious. Women who have not had children are at increased risk for uterine cancer. Additionally, women who had early menarche or late menopause, or have polyps, fibroids, and other growths in their uterus are also at increased risk for uterine cancer.

- Cervical Cancer – Cervical cancer is a malignant neoplasia of the cervical area. While it is largely asymptomatic in the early stages, symptoms of advanced cervical cancer include vaginal discharge, inter-menstrual bleeding, post-coital bleeding, pain during intercourse, vaginal bleeding, and pelvic pain. Infection with the high-risk types of Human Papilloma Virus (HPV) is a necessary risk factor in the development of most cases of cervical cancers. Other risk factors include a family history of cervical cancer, smoking, early age at first intercourse and first pregnancy, and parity.

Reproductive Tract Infections – These include both endogenous and sexually transmitted infections (**Refer Introduction**). RTIs and STIs will be used interchangeably henceforth. The most common endogenous infections is-

- Candidiasis – This encompasses infections of the vagina caused by all fungi of the genus *Candida*. *Candida* is normally present in all human beings, and their growth is limited by the human immune system and other microorganisms such as bacteria that occupy the same niches. A weakened or undeveloped immune system and metabolic conditions such as Diabetes mellitus are factors that predispose towards development of candidiasis. Furthermore, treatment with antibiotics can result in elimination of bacteria that normally keep *Candida* in check, thereby resulting in their uncontrolled growth. Candidiasis is a very common cause of vaginal irritation or vaginitis, and symptoms include redness, itching, and discomfort. Most candidial infections are easily treatable with antimycotics (antifungal drugs).
- Bacterial Vaginosis (BV) – Bacterial vaginosis is less commonly known as vaginal bacteriosis, and is a vaginal disease caused by bacteria. Diverse bacteria are involved in vaginosis, with the most common being *Gardnerella vaginalis*, *Mobiluncus*, *Bacteroides*, and *Mycoplasma*. Similar to candidiasis, BV is also a result of elimination of normal bacterial flora such as Lactobacillus, which keeps the above mentioned bacteria in check, and prevents them from multiplying. Pregnant women and those with STIs are at increased risk of BV, and there is no clear evidence of sexual transmission of the bacteria. The most common symptom of BV is a homogenous, off-white vaginal discharge with a "fish-like" odour, especially after sexual intercourse. Other symptoms include burning during urination and itching around the outside of the vagina.

The most common sexually transmitted infections (STIs) are-

- Trichomonas vaginalis (TV) – TV or trichomoniasis is a sexually transmitted infection caused by a protozoan parasite called *Trichomonas vaginalis*, where typically only women experience symptoms. Symptoms usually appear within 5 to 28 days of exposure. The infection does not cause symptoms in men, and typically goes away on its own in a few days. The most common symptom is a greenish, frothy vaginal discharge. Other symptoms include vaginal itching, vulvar itching, vaginal odour, discomfort during sexual intercourse, and itching of the inner thighs. A pelvic examination will reveal red blotches on the walls of the vagina or cervix.

- Chlamydia – Chlamydia is an STI caused by the bacteria *Chlamydia trachomatis*. The incubation period for the infection, after which symptoms appear, is between one and three weeks. Only about 30% of women with chlamydia are symptomatic. Symptoms include vaginal discharge, bleeding after intercourse, burning sensation during urination, and abdominal pain. Sexually active individuals and individuals with multiple sexual partners are at highest risk for chlamydia.
- Gonorrhoea – Gonorrhoea is a common STI caused by the bacterium *Neisseria gonorrhoeae*. While gonorrhoea is asymptomatic in almost 50% of women, symptoms may appear as early as two days after infection, or take as long as one month. Symptoms include vaginal discharge, pelvic pain, lower abdominal pain, and pain during intercourse. All sexually active women are at increased risk for gonorrhoea. Gonorrhoea can be transmitted from mother to child during childbirth; when the infant's eyes are affected, it is referred to as ophthalmia neonatorum. If left untreated, gonococcal ophthalmia neonatorum will develop in 28% of infants born to women with gonorrhoea (**Goldbloom, Public Health Agency of Canada**). Thus, there is a strong case to be made for screening pregnant women for gonorrhoea.
- Syphilis – Syphilis is caused by the spirochete bacterium *Treponema pallidum*. Symptoms can appear anywhere between 10 and 90 days after infection with the bacteria. Syphilis can present in any of four stages- primary, secondary, latent, or tertiary. The symptoms exhibited during each of these four stages are unique. Congenital syphilis may occur during pregnancy or during birth. Untreated babies can develop deformities, delays in development, or seizures along with other conditions such as rash, fever, jaundice, anaemia, and hepatosplenomegaly. When left untreated in adults for long periods of time, neurosyphilis (involving the central nervous system), or cardiovascular syphilis may occur.
- Chancroid – Chancroid is a bacterial infection caused by the streptobacillus *Haemophilus ducreyi*. Symptoms may appear any time from one day to several weeks post-infection. Chancroid begins with a small bump that becomes an ulcer within a day of its appearance. Chancroid is easily treatable with antibiotics such as azithromycin.

Functional Problems – Functional problems are caused by environmental factors, physical damage, psychological issues, autoimmune disorders, and other causes. The best known types of functional problems are sexual dysfunction and infertility.

2.2.2 Prevalence and Incidence of Reproductive System Disorders

Data on prevalence and incidence of diseases give us an idea of the disease burden of individual disorders and are very useful in prioritising diseases that require immediate attention. Because of their rarity, there is no information on the prevalence or incidence of congenital reproductive disorders. However, there is some data available on the prevalence and incidence of cancers of the reproductive system, and RTIs. In some cases, data is available for South Asia as a whole, whereas in others, data is specifically available for India.

While data is not available for uterine cancer, WHO estimates that in 2008 ovarian cancer was responsible for a death rate of 2.3/100,000 deaths among Indian women (**WHO 2011**). In India, cervical cancer is the most common form of cancer, closely followed by breast cancer (**National Cancer Registry**). In fact, cervical cancer is the most prevalent form of cancer among women in the

Thanjavur district (**Nandakumar *et al.*, 2004**). 80% of all newly diagnosed cervical cancers occur in developing countries, with India bearing a significant burden of the diseases. The death rate among women due to cervical cancer was 8.1/100,000 deaths in 2008.

Due to reasons described above, unambiguous data on prevalence of RTIs are not available. Furthermore, data, when available, is not current. WHO estimated in 1999 that there are 340 million new cases of STIs worldwide, with 151 million of these in South and South-east Asia (**WHO 2001**). Prevalence (per 1000 people) of all curable STIs in South-east Asia was estimated at 50. The estimated incidence in South-East Asia of different curable STI was as follows-

Chlamydia – 43 million

Gonorrhoea – 27 million

Syphilis – 4 million

2.2.3 Screening Recommendations for Reproductive System Disorders

This section details the screening recommendations laid down by the United States Preventive Services Task Force (USPSTF) for various reproductive system disorders.

Source: http://www.uspreventiveservicestaskforce.org/uspstopics.htm#AZ

- Cervical Cancer – The USPSTF ***strongly recommends*** screening all sexually active women over the age of 26 years, and who have a cervix.
- Ovarian Cancer – The USPSTF ***recommends against*** routine screening for ovarian cancer.
- Chlamydia – The USPSTF ***strongly recommends*** screening for all sexually active non-pregnant women below the age of 24 years, and for older non-pregnant women who are at increased risk. USPSTF ***recommends*** screening all pregnant women aged 24 and younger, and for older pregnant women who are at increased risk.
- Gonorrhoea – The USPSTF ***recommends*** that clinicians screen all sexually active women, including those who are pregnant, for gonorrhoea infection if they are at increased risk for infection (i.e. if they are young or have other population or individual risk factors).
- Syphilis – The USPSTF ***strongly recommends*** that clinicians screen persons at increased risk for syphilis infection. USPSTF ***strongly recommends*** that clinicians screen all pregnant women for syphilis infection. The USPSTF ***recommends against*** routine screening of asymptomatic persons who are not at increased risk for syphilis infection.

2.2.4 Diagnosis and Treatment of Selected Reproductive System Disorders

Based on the disease burden and screening recommendations of various reproductive system disorders, specific conditions were chosen to be part of the women's health package. The processes involved in the diagnosis and treatment of these conditions is discussed in this section.

Cervical Cancer – The disease burden of cervical cancer is very small in developed countries, primarily as a result of effective screening resulting in early diagnosis and treatment.

- Diagnosis - The most common diagnostic tool used for screening of cervical cancer is the Pap Smear. The Pap smear is a cytological test that can detect premalignant and malignant processes is the endocervical canal (transformation zone). In doing a pap smear, a speculum

is used to dilate the cervix for thorough examination. Cells are gathered from the outer opening of the cervix and the endocervix. The cells are then observed under a microscope to look for abnormalities. While the Pap smear has helped to significantly reduce the burden of cervical cancer in developed countries, it requires resources such as a microscope and trained cytologists to observe and interpret the results. Therefore, the use of pap smears is not an ideal option in low-resource settings. It has been shown that visual inspection tests such as Visual Inspection by Acetic Acid (VIA) and Visual inspection by Lugol's Iodine (VILI), when used in concert, are as effective as Pap smears in detecting cervical cancer (**Sankaranarayanan *et al*., 2005; Sankaranarayanan *et al*., 2007**). VIA/VILI can be performed by trained, non-medical personnel and require only cheap, easily available reagents such as acetic acid (vinegar) and iodine solution. Another recently developed diagnostic tool that has been used for cervical cancer screening is HPV DNA testing. Since the high-risk types HPV 16 and 18 are the cause of almost all cervical cancers, the presence of HPV DNA in cervical swabs is an indicator of infection. However, this option is also resource-intensive and cannot be applied to a primary care setting. The results of the screening are then confirmed by colposcopy and biopsy.

- Treatment - Colposcopy/biopsy can detect cervical intraepithelial neoplasias (CIN), the potential precursor to invasive cervical cancer. For premalignant changes, the CIN grading is used. Mild dysplasia is classified as CIN1, moderate dysplasia as CIN2, and severe dysplasia or carcinoma *in situ* (CIS) as CIN3. More recently, CIN2 and CIN3 have been combined into CIN2/3. Precancers are treated using a variety of techniques. Cryotherapy is used to freeze premalignant cells in a localised area, eventually leading to their sloughing off. Loop electrical excision procedure (LEEP) and conisation, in which the inner lining of the cervix is removed, are used when the biopsy confirms severe CIN. Cervical cancer is staged by the International Federation of Gynaecology and Obstetrics (FIGO) staging system. Detailed treatment is listed depending on the stage of cervical cancer. With treatment, the 5-year survival rate for the earliest stage of invasive cancer is 92% and the overall (all stages combined) 5-year survival rate is 72%.

Reproductive Tract Infections – The RTIs we will primarily focus on include chlamydia, gonorrhoea, and syphilis. Treatment will also be provided for chancroid, lymphogranuloma venereum, and endogenous vaginal infections such as candidiasis, and bacterial vaginosis.

- Diagnosis – There are three methods used for diagnosis of RTIs. These are-

  Etiological diagnosis - It involves laboratory tests to detect microorganisms that cause various RTIs, and is therefore the most resource-intensive method. The gold standard for chlamydia was culturing the bacteria responsible for the STI. It is fast being replaced by nucleic acid amplification tests (NAAT) that detect the bacterial DNA in cervical swabs, self-collected vaginal swabs, and voided urine samples. Gonorrhoea is traditionally diagnosed used microbiological techniques such as gram staining and culture, though NAAT based tests are fast gaining traction. Syphilis is diagnosed using two tests- Rapid Plasma Reagin (RPR) and Treponema pallidum particle agglutination (TPHA). RPR looks for non-specific antibodies in the blood of patients that may indicate that the microorganism that causes syphilis is

present. TPHA is more specific since it looks especially for antibodies produced against the causative agent of syphilis, *Treponema pallidum.*

Clinical Diagnosis – Clinical diagnosis is made based on the medical history and physical examination of the patient by an experienced clinician.

Syndromic Case Management – This approach was developed by WHO for the treatment and management of RTIs in low-resource settings. This approach does not require laboratory tests and has been tested in many countries. RTIs are grouped into seven categories, depending on the signs and symptoms. Each category is referred to as a syndrome. Four of these seven syndromes are specific to women, whereas two are male-specific, and the remaining one is a congenital defect in children. Each syndrome is easily recognised by the symptoms and physical examination, and sexual history is recorded to look for specific risk factors. WHO has designed easy-to-use flowcharts for the case management of each syndrome (**Refer Appendix 1 - 4**). Treatment covers the most common organisms potentially responsible for the syndrome.

- Treatment – Chlamydia, gonorrhoea, and syphilis are treatable with antibiotics. Chlamydia is treatable with a variety of different antibiotics including azithromycin, erythromycin, doxycycline, and tetracycline. Erythromycin and amoxicillin are recommended for pregnant women. Because of increasing antibiotic resistance, only a few antibiotics are still effective against gonorrhoea. This is true of parts of north India as well, where there is an increasing trend of tetracycline and ciproflaxin resistance (**Ray et al., 2000**). As of 2010, injectable ceftriaxone appears to be one of the few effective antibiotics. Syphilis is treatable with a single dose of intramuscular penicillin G or a single dose of oral azithromycin. The syndromic case management approach proposed by WHO lists the treatment for each syndrome, which may include combinations of antibiotics depending on the organism(s) responsible for the syndrome.

3. ICTPH Health Systems Approach

IKP Centre for Technologies in Public Health (ICTPH) is a not-for-profit research organization whose mission is to innovate health care systems for remote rural populations (**ICTPH Health Systems Approach, Johar 2010**). The core elements of the ICTPH health systems approach are human resources, technology and infrastructure, interventions, and financing (**ICTPH Health Systems Approach, Johar 2010**). The ICTPH approach to health care provision is broad-based wherein a wide variety of services, including diagnostic tests, are provided to rural populations. These services are provided at the village-based rural micro health centre (RMHC), which serves a population of 10,000 people and is manned by a village-based physician and health extension worker (HEW). The overarching goal of each RMHC is to ensure the 'wellness' of the community it serves. This is achieved not only through the provision of curative care, but also through preventive care (**ICTPH Health Systems Approach, Johar 2010**). Preventive care involves the identification of groups of individuals who are high risk for specific conditions, such as cardiovascular diseases (CVD) or nutritional deficiencies, and providing each cohort with the required intervention (**Johar and Swetha in preparation; ICTPH Nutrition Intervention – Phase I, Peugh 2010**).

3.1 Women's Health Examination Protocol

Initially, the protocol listed below will be administered by a trained physician and nurse. Eventually, the goal is to train the Health Extension Worker (HEW) on the field, so that she can carry out the entire examination herself. The patient will speak with the physician and receive medication, if advised, after completion of the entire examination (**Refer Appendix 5 for flowchart detailing entire examination**).

- PISP – All women walking into the clinic will be administered the Population-level Individual Screening Protocol (PISP) by the HEW. If the PISP had been administered during a previous visit, vitals will be recorded for the current visit. Women who are pregnant will be offered the pregnancy package (under development), and will not enter the pathway for the women's health examination.
- Signed Consent – Eligible women (Selection Criteria: 18 < Age < 55 years, Premenopausal, Non-pregnant, Sexually active) will be read the contents of the consent form (**Refer Appendix 6 for sample consent form**). Only women who consent to the examination will enter the pathway.
- Sexual History – Detailed sexual health history will be recorded for those who consent to the women's health examination (**Refer Appendix 7 for sample sexual history form**). The sexual history will be used to perform risk assessment for both cervical cancer and RTIs.
- Syndromic Management of RTIs – Women will be asked about any gynaecological symptoms they might currently be experiencing. Physical examination will be done to confirm symptoms, when possible. The genitourinary (Gu) tree of the physical examination will contain the relevant information. Syndromic case management protocol will be followed and patient will be offered treatment. Women will be provided medication for their partners to encourage patient-delivered partner treatment (PDPT).
- Cervical Screening - After a pelvic examination, women will be screened using VIA/VILI (**Refer Appendix 8**). Further steps will be based on results of VIA/VILI tests (**Refer Appendix 9**).

3.2 Infrastructure and Technology Requirements

One of the most important requirements for the women's health examination from the infrastructure point-of-view is that privacy of women be ensured during the examination. While devoting an entire room to the women's health examination might not be practical, adequate measures must be taken to ensure that the women feel secure. In terms of instruments and equipment, an examination table with stirrups will enable women to be comfortable during the pelvic examination, and allow for better visualisation of the cervix. Vaginal speculums (Cusco) of three different sizes (small, medium, large) will also be required for the pelvic examination. A strong light source is also a necessity to enable adequate visualisation of the cervix and the VIA/VILI results. Additionally, a digital camera will be required to take pictures of the VIA/VILI test results for quality assessment. These arrangements will also cover requirements for syndromic case management. No fee will be charged for the screening. Patients will be charged for any medication that is prescribed.

The findings of the pelvic examination, speculum examination, and VIA/VILI tests will be recorded in the Gu tree of the physical examination. This page is currently accessible only by the

physician. Since the examination will initially be administered by the physician, this will not pose a problem. In upcoming releases of the HMIS, this page will become accessible to the HEW. The sexual history of the patient will also be recorded as a survey in the HEW's page.

3.3 Human Resources Training

Training manuals have been prepared for cervical screening and syndromic case management. Two nursing officers, Viji and Menaka, and one physician, Dr. Priya, attended a two-week long training session for cervical screening by VIA/VILI at the Adyar Cancer Institute in Chennai. Menaka and Dr. Priya will initially perform cervical screening, with other physicians receiving training subsequently. Eventually, the goal is to have HEWs trained in theory and receive practical training in the clinic.

3.4 Impact Evaluation

Since our objective is to improve the quality of women's health, it is important that we assess the impact of the women's health package to ensure that this objective is met. Therefore, a list of parameters which will be used to measure the impact of the programme have been generated (**Refer Appendix 12**). These parameters will be used to measure both the short-term and long-term impacts of the programme.

4. Future Directions

The proposal for the women's health package outlined here is the first step in the journey to bring women's health into focus. We are also in the process of developing a "pregnancy package", which will designed along the antenatal care provided by government-run primary health centres (PHCs). Pregnant women will be provided with Iron Folic Acid (IFA) supplementation to treat anaemia. Additionally, pregnant women will also be tested for gestational diabetes and pre-eclampsia. They will also be tested for STIs and provided treatment, thereby preventing congenital disorders such as gonococcal ophthalmia neonatorum. Another group that we intend to target is young women who are likely to get married soon. The so-called "marriage package" will essentially be a nutritional intervention, where young women will be provided nutritional supplements to make up for any deficiencies before marriage and conception of a child. Also included in this package will be literature on healthy sexual practices, and awareness of contraception.

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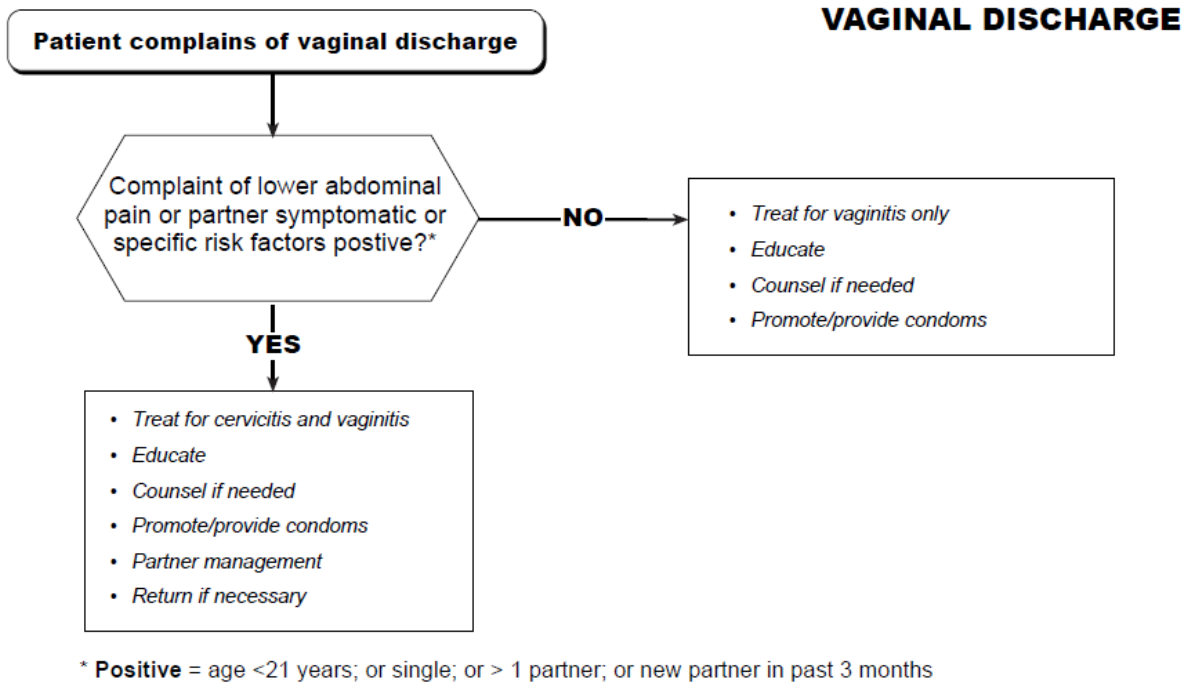
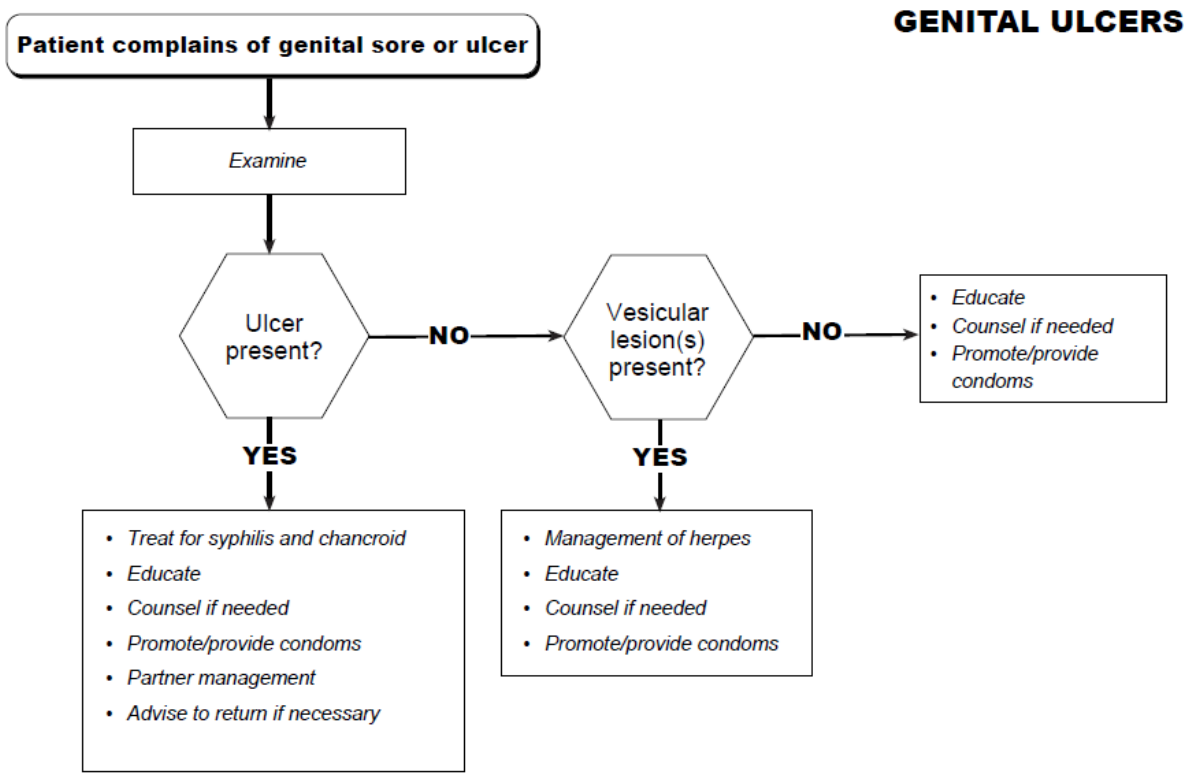
Appendix

Appendix 1 – Syndromic Case Management of Vaginal Discharge



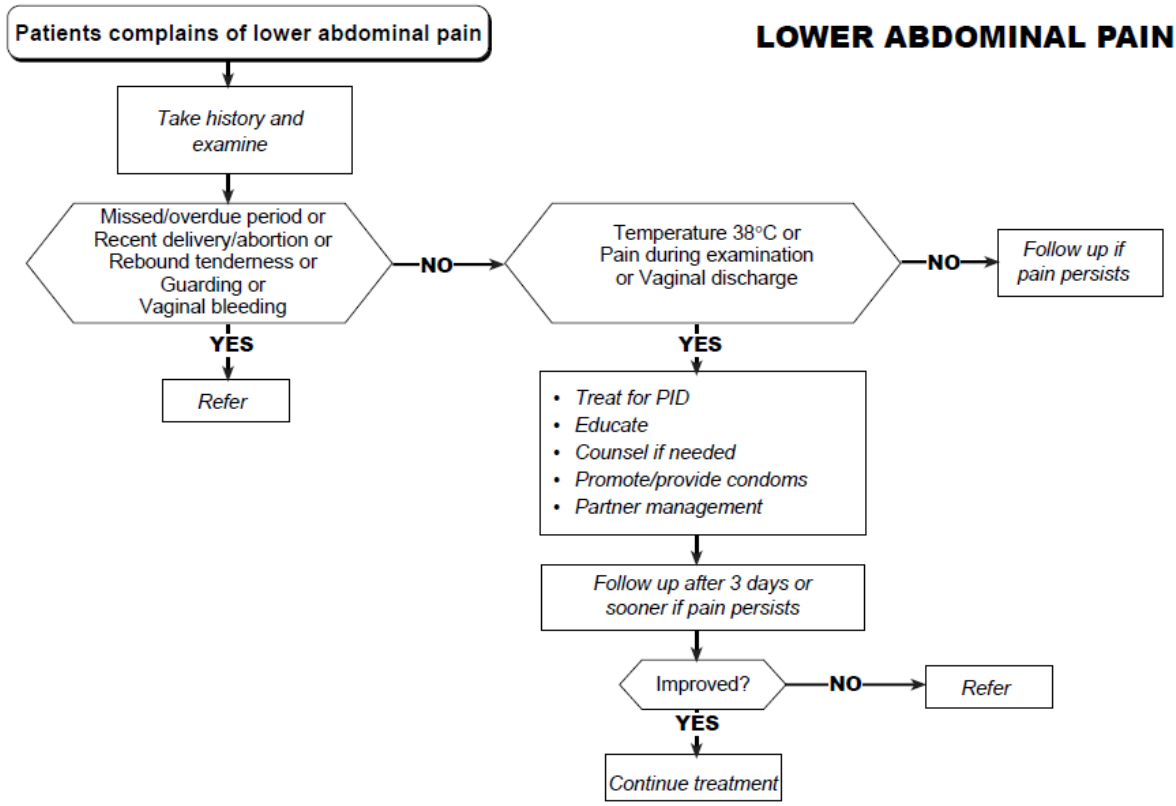
Source: Flow-charts for syndromic case management of STD. World Health Organization, 1995.

Appendix 2 – Syndromic Case Management of Genital Ulcers



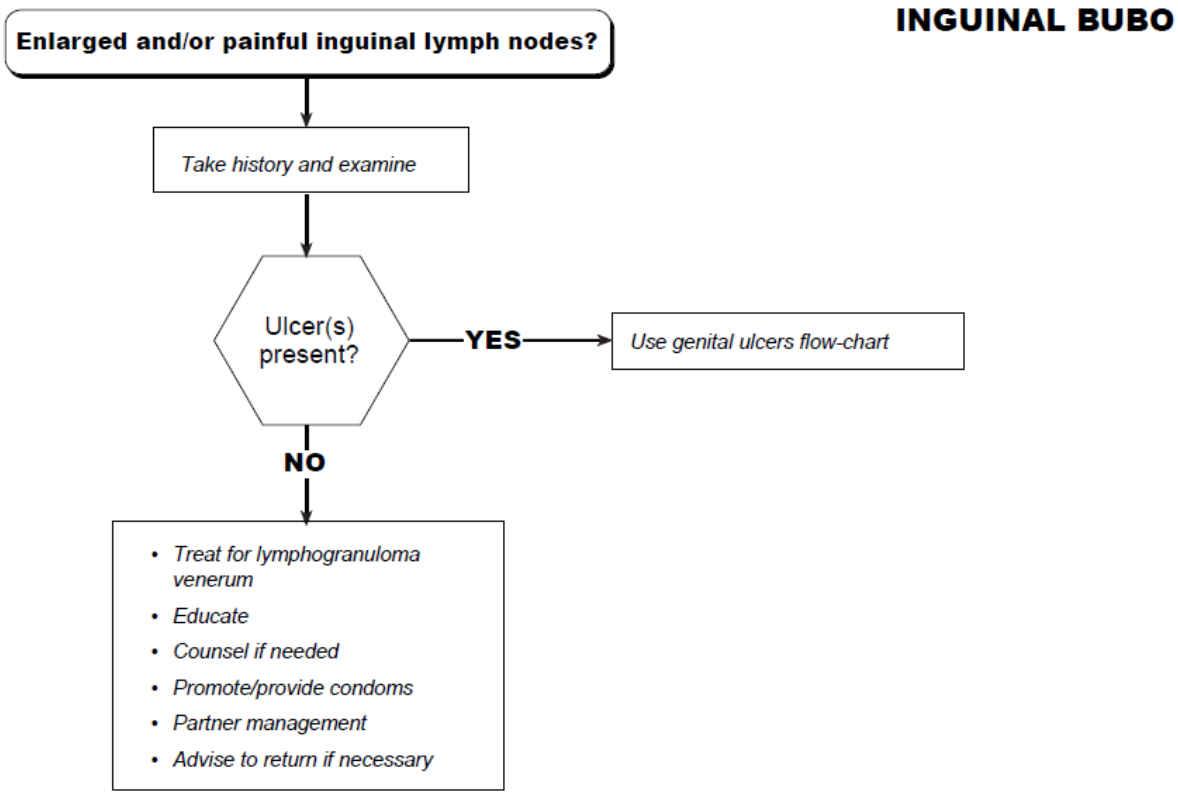
Source: Flow-charts for syndromic case management of STD. World Health Organization, 1995.

Appendix 3 – Syndromic Case Management of Lower Abdominal Pain



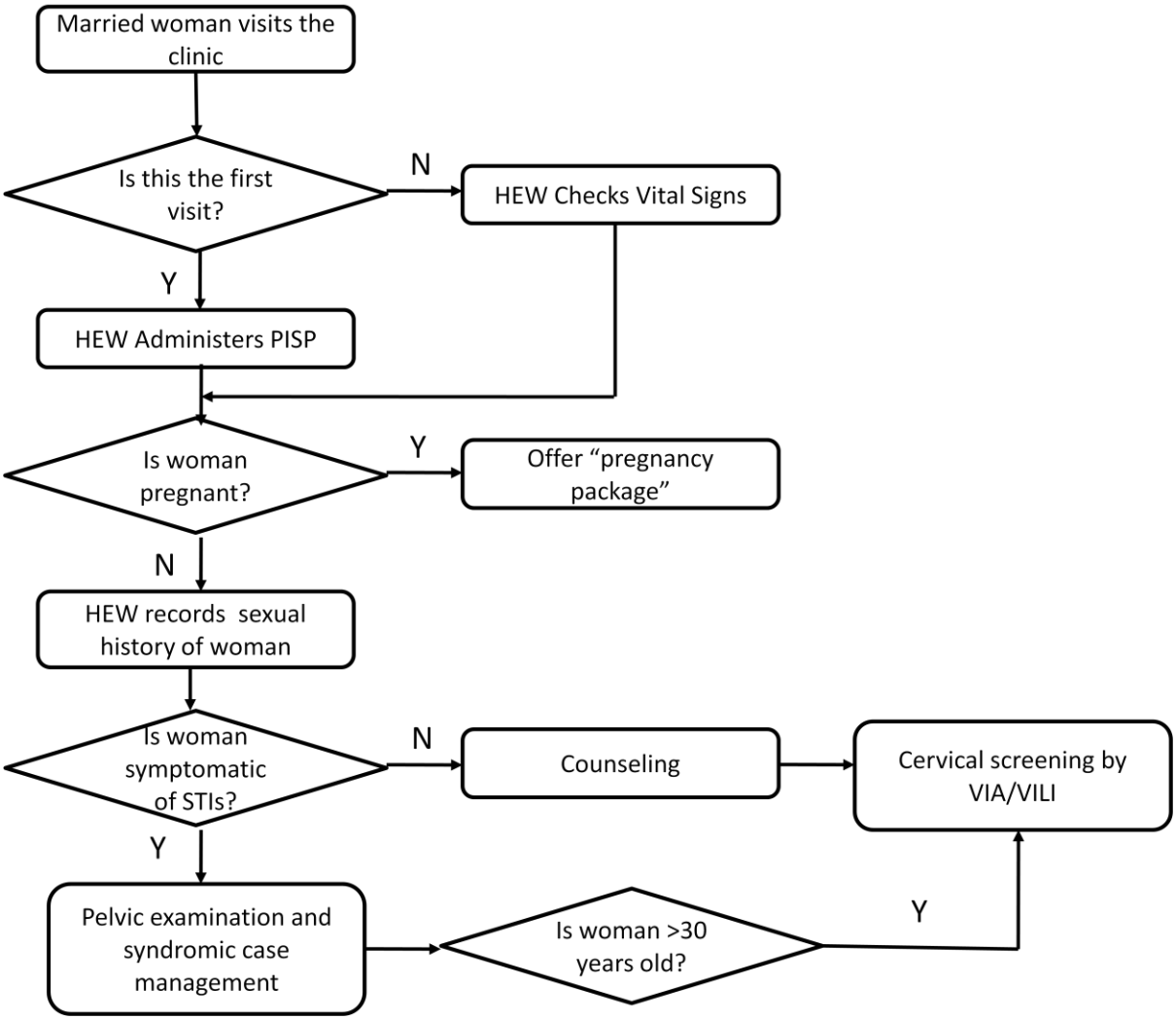
Source: Flow-charts for syndromic case management of STD. World Health Organization, 1995.

Appendix 4 – Syndromic Case Management of Inguinal Bubo



Source: Flow-charts for syndromic case management of STD. World Health Organization, 1995.

Appendix 5 – Flowchart Outlining Women's Health Examination



Appendix 6 – Informed Consent Form

The physician/ health extension worker (HEW) has explained to me in detail about the women's health examination. I understand that I will be asked questions of a very personal nature to better assess the state of my reproductive health. I understand that there will be no laboratory tests to confirm diagnosis of sexually transmitted infections. I understand that treatment for these infections will be based only on my symptoms and a physical examination by the HEW. I understand that, if diagnosed with any of the infections, I will be provided antibiotics for myself and for treatment of my partner. I understand that I must refrain from any kind of sexual activity during the entire course of the antibiotic treatment.

The physician/health worker explained to me in detail about the vinegar (VIA)/iodine (VILI) test(s)* for the early detection and prevention of abnormalities in the neck of my womb (uterine cervix). I understand that the surface of my cervix will be visually inspected after application of 5% acetic acid/dilute iodine solution to detect or to exclude any abnormalities. I understand that these procedures are generally harmless, but may occasionally cause some irritation or mild bleeding, which can be easily controlled. I understand that a photograph will be taken to record the VIA/VILI test results, and that this photograph will not contain anything that will identify me. I understand that, if the test is positive, I will be referred to a higher care centre for biopsy, other investigations, and further treatment.

I hereby express my willingness to undergo the above tests and treatment, if advised.* / I am not willing to undergo the above procedures. *

Signature:

Date:

Name:

Address:

* Delete as appropriate

Appendix 7 – Sexual History Form

1. Partners

Does your partner work in another place or travel a lot for work?

_____ Yes _____ No

Have you had more than one partner in the last three months?

_____ Yes _____ No, I've had one partner _____ No, I've not had sex in that time

Did you use barriers such as condoms during sexual encounters with any of your partners?

_____ Always _____ Never _____ Sometimes

Have any of your partners experienced symptoms such as penile discharge, genital sores/ ulcers, and scrotal swelling?

_____ Yes _____ No _____ Other (*please specify*)

2. Prevention of pregnancy

Are you aware that some contraceptives such as condoms can prevent transmission of infections?

_____ Yes _____ No

Are you aware that contraceptives can be used to prevent pregnancy?

_____ Yes _____ No

(If no, skip to 3)

Are you currently using contraception?

_____ Yes _____ No _____ No, I've had a hysterectomy

(If no, skip to 3)

Which contraceptive method do you use to prevent pregnancy?

_____ Condoms _____ Oral contraceptives (birth control pills)

_____ I am trying to get pregnant _____ Intrauterine Device (IUD)

_____ Other (*please specify*)

How many times have you been pregnant?

How many children (live/stillborn) have you given birth to?

3. Past History of Sexually Transmitted Infections

Have you ever been told by a doctor/health worker that you have a sexually transmitted infection (STI)?

_____ Yes _____ No

(If no, skip to 4)

What STI(s) were you diagnosed with?

_____ Chlamydia _____ Gonorrhoea _____ Syphilis

_____ Chancroid _____ Genital warts _____ Genital herpes

_____ HIV/AIDS _____ Pelvic Inflammatory Disease

_____ Other (*please specify*) _____ Don't know

Did you receive treatment for the STI(s)?

_____ Yes _____ No

Did you complete treatment for the STI(s)?

_____ Yes _____ No

Did your partner receive treatment for the STI(s)?

_____ Yes _____ No

Did your partner complete treatment for the STI(s)?

_____ Yes _____ No

4. Past Medical History

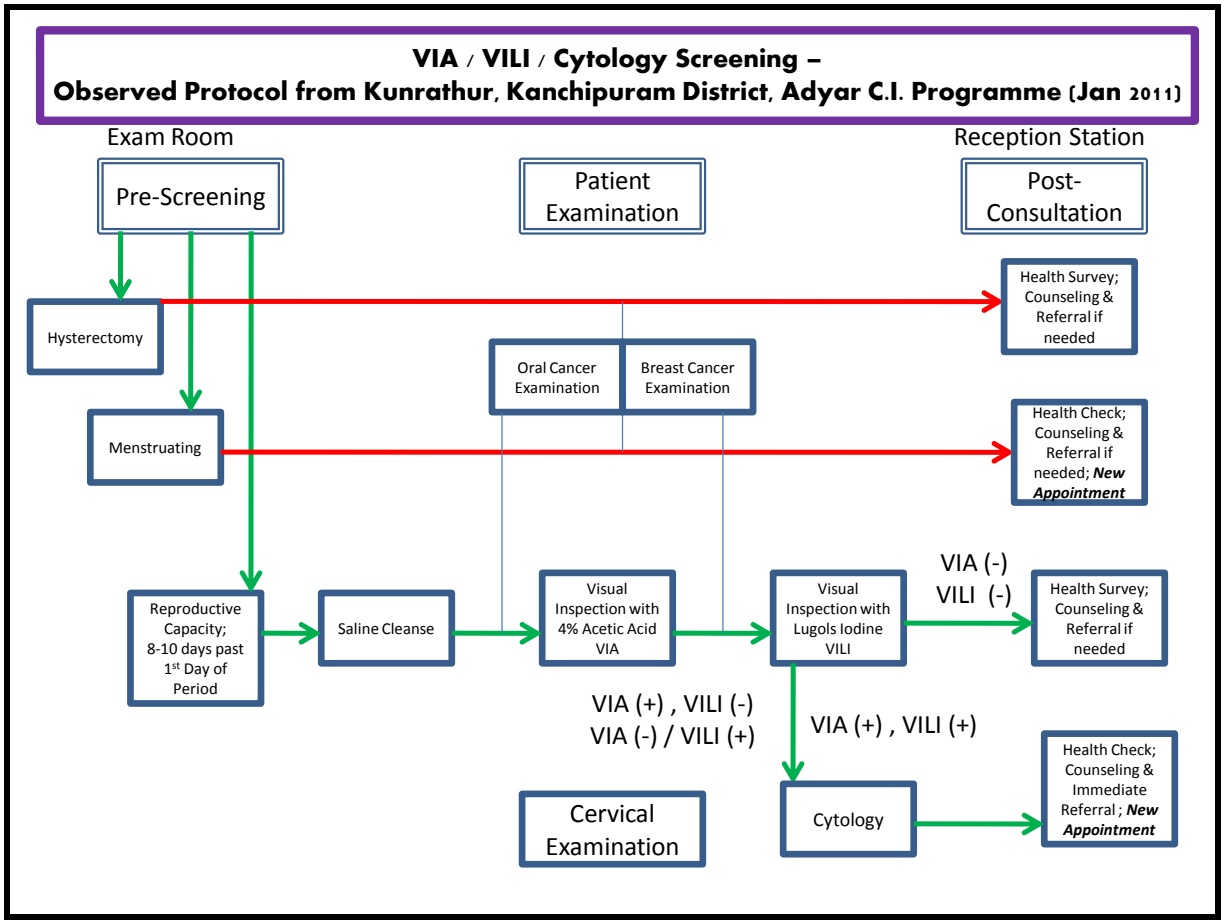
Have you ever had a surgical procedure requiring blood transfusion?

_____ Yes _____ No

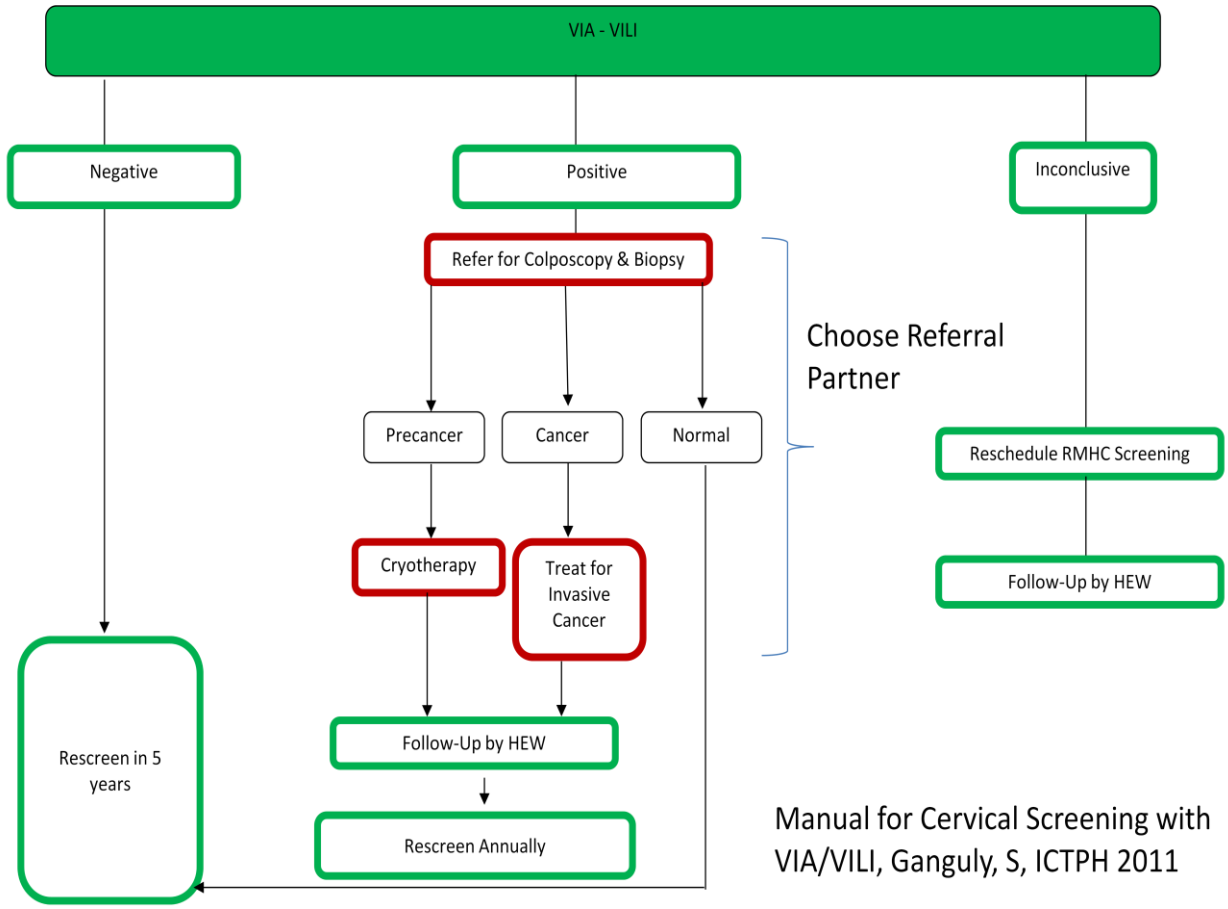
(If no, skip to end)

When did you have this procedure?

Appendix 8 – VIA/VILI Screening Protocol for Cervical Abnormalities



Appendix 9 – Treatment of Cervical Cancer Detected by VIA/VILI Tests



Appendix 10 – Impact Assessment Parameters

Impact Assessment Parameter	Performance Indicator (Measure)
Coverage – Uptake of women's health package by desired demographic	# and % of women in target population who underwent women's health examination
Follow-up and screening of women who could not undergo examination in first visit	# and % of women scheduled for new appointment who actually returned for screening on date of new appointment
Quality of VIA/VILI tests	% of cases where VIA/VILI results agree with colposcopy ("agreement" must be defined)
Effectiveness of VIA/VILI in detecting early precancers	% of cases where CIN1 precancers detected by VIA/VILI agree with colposcopy/biopsy ("agreement" must be defined)
Follow-up of women testing VIA/VILI positive	# and % of women referred for colposcopy/biopsy who actually went to referral centre and had tests done # and % of women who tested positive by colposcopy/biopsy who received further treatment
Quality of colposcopy	% of cases where colposcopy results agree with biopsy ("agreement" must be defined)
Quality of treatment	% cone/LEEPs with clear margins % cryotherapy with no lesions at 1 year follow-up
Retention of women for follow-up and re-screening	# and % of women who tested positive who returned for re-screening after 1 year # and % of women who tested negative who returned for re-screening after 5 years
Follow-up of women diagnosed with RTIs	# and % of women diagnosed with RTIs who completed the antibiotic regimen
Patient-delivered partner treatment	# and % of women diagnosed with STIs whose partner(s) completed antibiotic regimen
Effectiveness of RTI treatment and counselling	% of women with repeat diagnosis of STIs