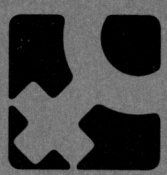
Special Challenges in Third World Women's Health

Presentations at the
1989 Annual Meeting of the
American Public Health
Association



IWHC

International Women's Health Coalition

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The International Women's Health Coalition is a private, non-profit organization dedicated to improving women's reproductive health in the Third World. By supporting innovative health care projects, policy-oriented field research, and public education, we serve as an advocate and catalyst for change in national and international policies and programs.

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Preface

In October 1989, the International Women's Health Coalition sponsored the panel, "Special Challenges in Third World Women's Health" at the Annual Meeting of the American Public Health Association. The panel focussed on several issues critical to women's health, which have received too little attention. Throughout the Third World, we have found women to be deeply concerned about reproductive tract infections, cervical cancer and contraceptive safety. It is their sense, and ours, that these issues need priority attention by their own governments and by international agencies. Since each presentation generated considerable discussion, we decided to publish them in March 1990. Demand for the report has been high, and since we continue to receive a steady number of requests for copies, we are issuing a reprint of our publication.

During the past twenty months, IWHC has undertaken a number of activities to increase knowledge of reproductive tract infections among those concerned with international health policy and programs. We published Dr. Judith Wasserheit's groundbreaking article, "The Significance and Scope of Reproductive Tract Infections Among Third World Women," in *The International Journal of Gynecology and Obstetrics*, a special supplement of the journal based on the proceedings of the Christopher Tietze International Symposium. Other activities have included the publication of a major report, *The Culture of Silence: Reproductive Tract Infections Among Women in the Third World* by Drs. Ruth Dixon-Mueller and Judith Wasserheit, in 1991. Copies of these publications may be obtained from IWHC.

We have also co-sponsored with the Rockefeller Foundation, an international conference, "Reproductive Tract Infections in the Third World: National and International Policy Implications," in Bellagio, Italy in May 1991. Thirteen papers were commissioned from leading experts to provide crucial data and to discuss program and policy implications. In 1992, Plenum Press will publish these papers as a book and IWHC will publish a report of the Conference. Most recently, we sponsored a panel on reproductive tract infections at the Annual Meeting of the National Council for International Health with panelists Dr. Rani Bang from India, Dr. Hind Abou Khattab from Egypt, Dr. Elizabeth Ngugi from Kenya, and Dr. Inne Susanti from Indonesia.

We hope these initiatives will encourage you to address these critical issues. We welcome your queries, requests for publications, and comments.

Joan B. Dunlop, President
Adrienne Germain, Vice President
International Women's Health Coalition
New York, NY, September 1991

Reproductive Tract Infections

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Each of us has been asked to examine an area of women's health which has, to date, received little attention among health policy makers, program planners, or donor agencies in the Third World. We have been asked to step back from our own individual interests in the issues of reproductive tract infections (RTIs), cervical cancer, and contraceptive safety to weigh their importance relative to other health care priorities for women in developing countries.

The decision to allocate scarce human and financial resources to a health problem hinges principally on three elements: the cost of the disease, its frequency, and the availability of interventions. A colleague for whom I have great respect and affection recently sat me down and patiently explained to me that the reasons given by the international health community for not addressing RTIs are largely that:

1) they are not fatal;

2) they are too expensive and too complicated to treat;

3) they are related to sexual behavior which is very difficult to study and to change; and

4) they are likely to stigmatize programs.

In essence, she was telling me that the biomedical cost of RTIs is felt to be too low when weighed against the perceived financial cost and technical difficulty of interventions. These arguments also reflect the perception that the individuals at risk for RTIs are primarily relatively small numbers of sexually promiscuous women such as prostitutes rather than significant numbers of the general population of sexually-active adolescents, wives, and mothers. During this session I would like to challenge each of these perceptions by reviewing with you what we know about RTIs with respect to each of these three areas: cost, prevalence, and potential interventions. I will conclude by discussing research needs and opportunities.

Definitions

Before we examine the *cost* of RTIs, a few definitions are necessary to make sure that we are all speaking the same language. Female reproductive tract infections are classified on the basis of where they occur and what causes them. In women, most RTIs originate in the lower tract as vaginitis, cervicitis, or genital ulcers. If untreated, some types of vaginitis and cervicitis may subsequently ascend into the upper tract to cause pelvic inflammatory disease or PID (endometritis, salpingitis, oophoritis, parametritis, or pelvic peritonitis). Some types of genital ulcer disease may spread to the blood stream to cause systemic infection.

The first column of Table A indicates that different organisms infect different parts of the lower tract. These differences in etiology are important because each type of infection requires different therapy.

Although RTIs are often equated with sexually-transmitted diseases (STDs), such as trichomonal vaginitis, chlamydial or gonococcal cervicitis, and syphilis or herpes, I want to emphasize that I am *not* using the term "RTI" as a euphemism. When I talk about RTIs in women, I am also talking about endogenous infections due to overgrowth of organisms which are normally present in the reproductive tract (e.g., bacterial vaginosis (BV) and vulvovaginal candidiasis).

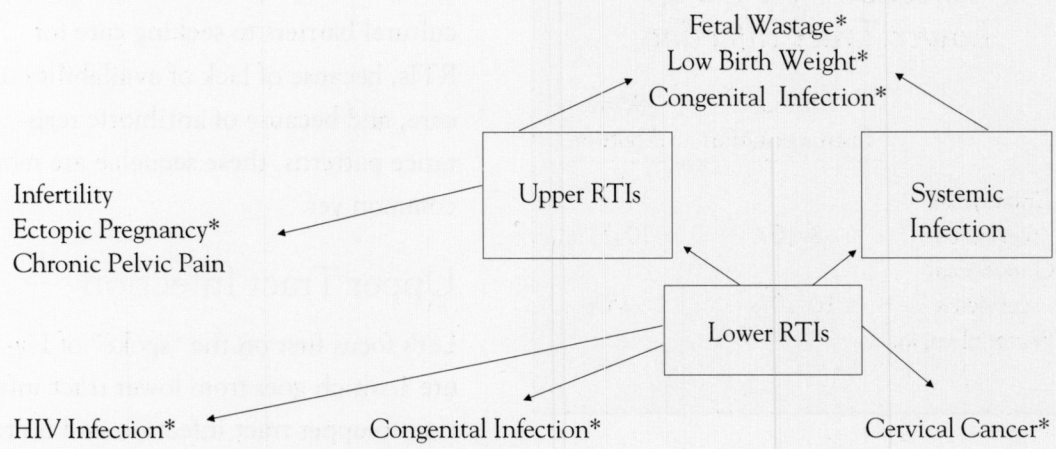
It is also essential to remember that of these lower tract syndromes, BV, and chlamydial and gonococcal cervicitis are particularly important because they are the ones which most often result in upper tract infection and its sequelae. Syphilis and herpes are noteworthy because in both cases primary infection is associated with a blood-borne, systemic phase which may have particularly serious consequences if it occurs during pregnancy.

Table A

Reproductive Tract Infections

Lower RTIs	Upper RTIs	Systemic Infection
Vaginitis		
BV (anaerobes)	X	
Trichomoniasis		
Candidiasis		
Cervicitis		
Chlamydia	X	
Gonorrhea	X	
HPV		
Genital ulcers		
Syphilis		X
Herpes		X

Figure 1. Overview of Biomedical Costs of Female Reproductive Tract Infections



* Potentially fatal

Costs

Let's look now at the biomedical, psychosocial, and economic "costs" of female RTIs. The diagram above provides an overview of the biomedical costs of RTIs.

Either directly or through the development of upper tract or systemic infection, lower RTIs cause numerous, potentially devastating sequelae. In view of the impression that RTIs are not fatal, I want to emphasize that six of the eight complications of RTIs shown in Figure 1 frequently result in death, particularly in the developing world.

Furthermore, I would argue that our focus on mortality rather than morbidity in formulating health policy is largely an unfortunate function of the fact that it is easier to standardize definitions and maintain surveillance of deaths than of outcomes such as infertility or chronic pelvic pain. If we are concerned about the quality of life and productivity of Third World women, then certainly the impact of non-fatal outcomes such as infertility (which may result in divorce and social ostracism) must be considered side-by-side with the impact of cervical cancer, fetal wastage, or HIV infection.

Table B

Proportion of Women Developing Upper Tract Infection by Type of Lower Tract Infection

	Without Instrumentation	With Abortion
Chlamydial cervicitis	8–10%	10–23%
Gonococcal cervicitis	10–20%	~15%
Bacterial vaginosis	?	?

The other important point here is that the outcomes that you see in Figure 1 are frequent sequelae of lower RTIs even in industrialized countries. In many developing countries, because of cultural barriers to seeking care for RTIs, because of lack of availability of care, and because of antibiotic resistance patterns, these sequelae are more common yet.

Upper Tract Infection

Let's focus first on the "spoke" of Figure 1 which goes from lower tract infection to upper tract infection and on to infertility, ectopic pregnancy, and chronic pelvic pain. In industrialized countries, upper tract infection occurs in 8 to 10 percent of women with untreated chlamydial cervicitis, and in 10 to 20 percent of women with untreated gonococcal cervicitis. If abortion is performed in women with untreated cervicitis, roughly 15 to 20 percent develop PID.

The proportion of women with untreated bacterial vaginosis who develop PID is still ill-defined, but the polymicrobial flora frequently recovered from peritoneal fluid and tubal specimens of women with PID often includes the same anaerobes that are characteristic of BV.

Sequelae of Upper Tract Infection

In nonpregnant women, the complications of PID are frequent and usually irreversible. In Western countries infertility occurs in 17 to 25 percent of women following PID, and a potentially lethal ectopic pregnancy is 6 to 10 times as common in this group as among women who have never had upper tract infection. Chronic pelvic pain and recurrent infection each develop in roughly 20 percent of women who have had pelvic infection.

Table C

Sequelae of Upper Tract Infection

Infertility	17–25%
Ectopic pregnancy	6–10-fold risk
Chronic pelvic pain	15–18%
Recurrent infection	20–25%

Table D

Rates of Adverse Outcomes of Pregnancy Associated with Reproductive Tract Infections

Maternal Diagnosis	Fetal Wastage	LBW or Prematurity	Congenital Infection
Chlamydial infection	10–33%	20–30%	45–67%
Gonococcal infection	5–40%	15–67%	30–45%
Early syphilis	0–25%	15–50%	40–50%
Genital herpes			
Primary	54%	35%	>50%
Recurrent	25%	14%	4%
Bacterial vaginosis	—	20–25%	rare

Adverse Outcomes of Pregnancy

In pregnant women, both sexually transmitted and endogenous pathogens may play a role in fetal wastage, low birth weight, and congenital infection. These complications occur via intra-uterine exposure due to upper tract or systemic infection or, in the case of congenital infection, via exposure to lower tract pathogens during delivery.

This table summarizes the rates of adverse outcomes of pregnancy associated with RTIs. The impact of infection on pregnancy depends upon the organism involved, the stage of gestation during which infection occurs, and the chronicity of the infection. As you can see here, existing data suggest that fetal wastage occurs in as many as 25 to 50 percent of pregnancies in acutely infected women.

Low birth weight or prematurity complicates roughly up to one quarter to two thirds of acutely infected pregnancies. This means, for example, that women with acute chlamydial or gonococcal infection are 3 to 5 times as likely to deliver a low birth weight or premature infant as are uninfected women.

Congenital or peripartum infection, the third of the potential adverse outcomes of pregnancy, may result in transient illness, permanent disability or neonatal death. Vertical transmission occurs in approximately one- to two-thirds of infants of mothers infected with common reproductive tract pathogens.

Cervical Cancer

Current evidence also suggests that human papillomavirus (HPV) infection of the cervix (particularly subtypes 16, 18 & 31) is associated with an increased risk of cervical neoplasia on the order of at least 3- to 10-fold. An enormous range of risk estimates have resulted from methodologic issues in the design and analysis of these studies and, with the advent of new technologies such as polymerase chain reaction (PCR), many of these data are being re-evaluated. But I have little doubt that this association will persist.

Human Immuno

Finally, data continue to demonstrate an association between those RTIs which result in breaks in epithelial barriers or which elicit strong inflammatory responses and an increased risk of transmission of the human immunodeficiency virus (HIV).

Table E summarizes the associations between various STDs and HIV infection. Several fairly good studies which control for potential confounding by behavioral risk factors clearly link genital ulcers such as syphilis, chancroid, and herpes with HIV transmission. The data linking chlamydial cervicitis, trichomoniasis, and genital warts with HIV transmission must still be considered preliminary, but are biologically plausible and cannot be discounted. Furthermore, because of the prevalence of trichomoniasis in many parts of the developing world, if these associations do hold up, the attributable risk of trichomoniasis may far outweigh that of genital ulcer disease.

Psychological, S and Economic C

In addition to the biomedical "costs" of RTIs, I want to re-emphasize the psychological, societal, and economic costs of these diseases. These costs are more difficult to quantitate and we currently have little data in these areas. But they are an important part of the equation if we are trying to set priorities.

It is clear, for example, that in much of the developing world a woman's status within both her family and her commu-

Table E

Associations Between STDs and Risk of HIV Transmission

Syndrome	Risk Estimate
Genital ulcers	2–18*
Syphilis	3–10
Herpes	2–4
Chancroid	2–18*
Chlamydial cervicitis	3
Trichomonal vaginitis	3
Genital warts	4

* The upper figure refers to circumcised males.

nity remains tied to her role as a wife and a mother. In such a context the impact of RTIs or infertility goes far beyond the physical discomfort associated with gonorrhea or PID. A sad, vicious cycle may even occur in which STDs introduced by the husband's extramarital contacts result in post-infectious infertility, and subsequent abandonment or divorce of the barren wife. Prostitution may then become one of the few income-generating options available, further facilitating spread of STDs.

Table F

Impact of RTIs on Famly Planning Programs

Direct:	RTIs, when perceived as "side-effects" of contraceptive methods may result in discontinuation of methods.
Indirect:	RTIs, by compromising healthy childbearing in a community, may decrease acceptance of of contraceptive methods.

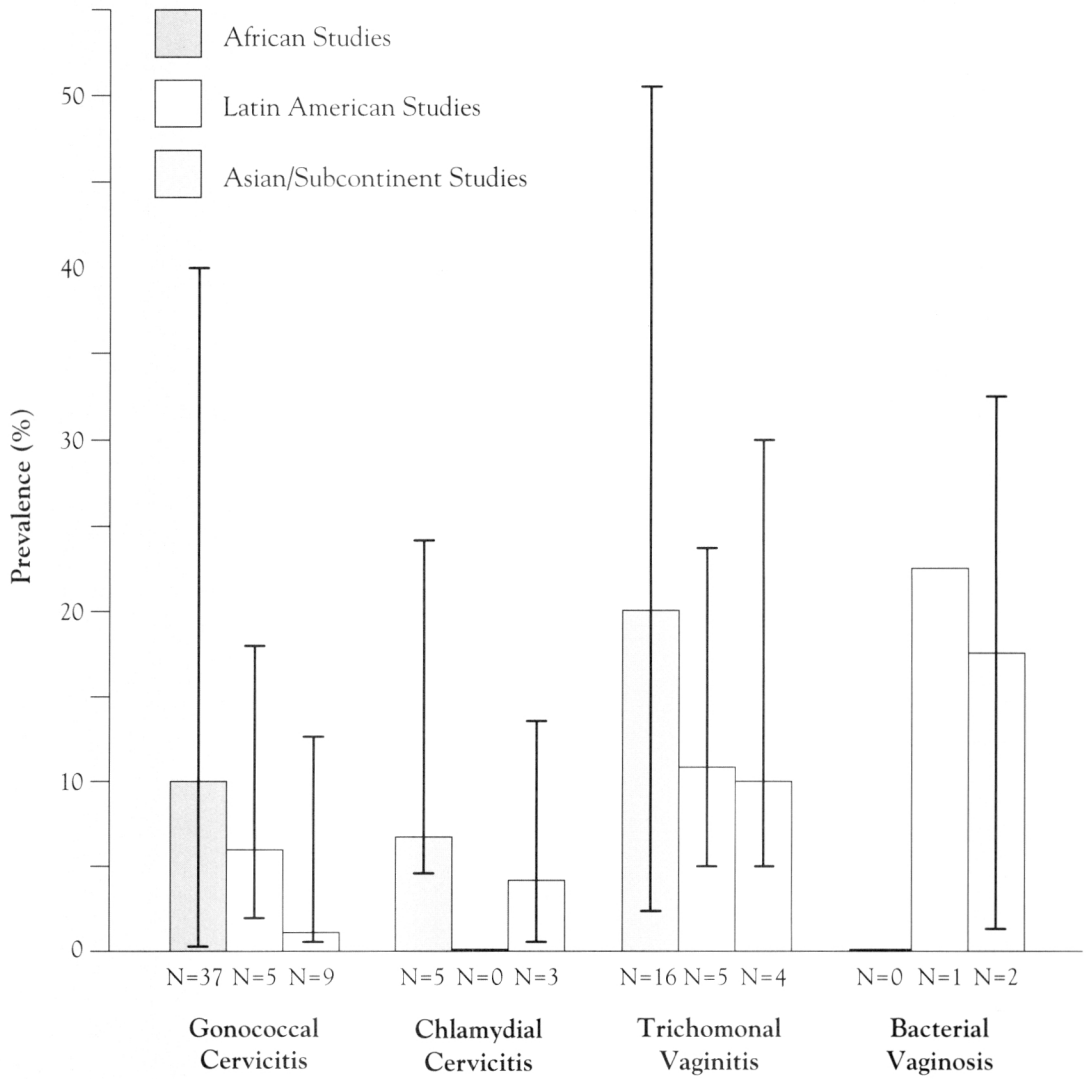
The societal costs of RTIs must also include their impact on the effectiveness of family planning services. RTIs may decrease acceptance and continuation of family planning methods in two ways: directly by creating the perception of a contraceptive side-effect and indirectly by creating a fear of limiting fertility in the face of frequent complications of RTIs which prevent healthy childbearing. In either case, one might argue that rather than stigmatizing family planning programs, care for RTIs may well be an essential component for their success.

Loss of productivity and rapid population growth translate to the economic costs of RTIs. Unfortunately, few data are currently available estimating days lost from work, potential years of reproductive life lost, or annual comprehensive costs for these diseases in the Third World. However, there is, finally, an awareness of the need for such estimates and some investigators are currently attempting these types of calculations.

Prevalence

Having reviewed the "costs" of RTIs, let's turn now to what we know about the prevalence of lower tract infection. Figure 2 (page 8) shows the median prevalence (and range) of vaginitis and cervicitis among Third World women who are neither prostitutes nor STD clinic attendees. The data are from populations which are somewhat representative of the general population of sexually active women in that they come from studies in antenatal, family planning, and gynecology clinics or from women surveyed in Pap smear screening campaigns or in population-based studies. The data are grouped geographically.

Figure 2. Median Prevalence of Lower RTIs Among Non-Prostitute, Non-STD Populations of Third World Women by Continent



There are four important points here:

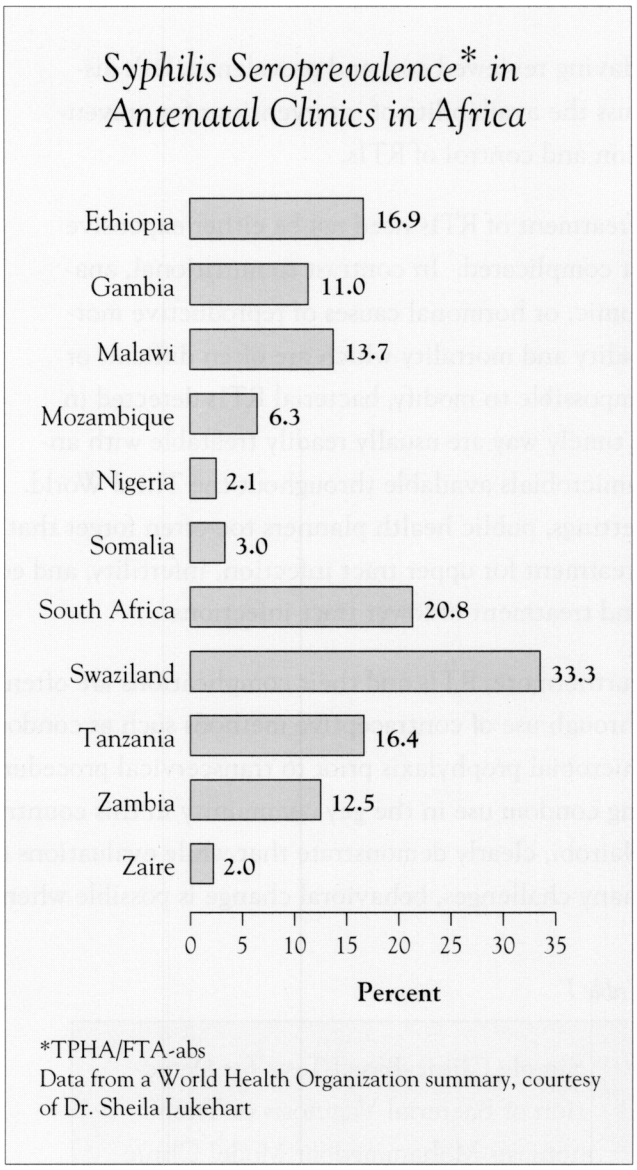
1) These infections are common in most of the developing countries in which they have been investigated.

2) Although data are much more limited for Asia and for Latin America than for Africa, in general the prevalence of each infection is greater in the African than in the Latin American or Asian studies.

3) Please look at the small numbers below each bar of the figure! They indicate the number of published studies available for each organism in each region. Despite the importance of chlamydial infection and BV in upper tract infection and its sequelae, we know very little about the prevalence of these syndromes in the developing world.

4) As mentioned previously, if trichomoniasis does, in fact, facilitate transmission of HIV infection, the attributable risk of this infection may be substantial.

Table G



Genital ulcers are also common in non-STD clinic populations in much of the developing world. The table above, for example, shows the prevalence of FTA-confirmed serologic evidence of syphilis in antenatal populations in Africa. The median prevalence is 12.5 percent (range 2 to 33 percent). To put these figures in perspective, at a prevalence of 10 percent, it is estimated that between one in 20 and one in 12 pregnancies surviving beyond 12 weeks will result in fetal death or the birth of a syphilitic infant.

Interventions

Table H

Treatment
■ Antimicrobial therapy
Prevention
■ Education
■ Use of condoms/spermicides
■ Antimicrobial prophylaxis

Having reviewed cost and prevalence, let's discuss the availability of interventions for prevention and control of RTIs.

Treatment of RTIs need *not* be either expensive or complicated. In contrast to nutritional, anatomic, or hormonal causes of reproductive morbidity and mortality which are often difficult or impossible to modify, bacterial RTIs detected in a timely way are usually readily treatable with antimicrobials available throughout the Third World. In fact, particularly in resource-poor settings, public health planners too often forget that the most efficacious, *least* expensive treatment for upper tract infection, infertility, and ectopic pregnancy is timely diagnosis and treatment of lower tract infections.

Furthermore, RTIs and their complications are often preventable through education, through use of contraceptive methods such as condoms and spermicides, and through antimicrobial prophylaxis prior to transcervical procedures. Trends in sexual behaviors, including condom use in the gay community in this country and in a prostitute cohort followed in Nairobi, clearly demonstrate that while evaluations of behavioral interventions present many challenges, behavioral change is possible when individuals understand the links between their behaviors (or their partners' behaviors) and devastating health outcomes.

Table I

Simple Clinic-Based Tests for Detection of Bacterial Vaginosis or Trichomoniasis Mohammedpur Model Clinic Bangladesh 1986

	Sensitivity	Specificity
Vaginal pH*	80%	63%
KOH odor	74%	85%

*pH < 5.0 vs. pH ≥ 5.0

One of the most critical determinants of the complexity and expense of treatment of RTIs is the diagnostic approach which is used. Two inexpensive, clinic-based techniques which are available for diagnosis of vaginal infections are pH dipsticks which cost 6 cents a piece (3 cents if you cut them in half as we did in Bangladesh), and potassium hydroxide (KOH) and normal saline. The amount of potassium hydroxide and saline needed to evalu-

ate a patient costs about one cent. Together, pH dipsticks and KOH provide an inexpensive set of tools with which community health-workers can diagnose vaginal infections by simply looking for a color change on a strip of paper and smelling for a fishy odor in vaginal secretions. If microscopes are available, a saline wet mount reading can easily be taught to paramedically trained personnel.

In a study performed by Dr. Sabera Rahman and her colleagues at the Mohammedpur Fertility Services and Training Centre (MFSTC) in Bangladesh, pH dipsticks were 80 percent sensitive and 63 percent specific for the diagnosis of BV or trichomoniasis compared with vaginal Gram stain for BV and culture for trichomoniasis. KOH odor was 74 percent sensitive and 85 percent specific.

While relatively good, appropriate technologies are already available for detection of vaginal infections, the diagnosis of cervicitis still presents problems. Currently, the cervical Gram stain is the standard rapid, inexpensive "surrogate" test for gonococcal and chlamydial infections. Unfortunately, cervical Gram stains require not only the availability of a microscope, but also a moderate amount of skill in interpretation. In part because of this, their sensitivity and specificity have been questioned. We still lack accurate, inexpensive, simple tests for cervicitis ... which leads naturally into my final topic ... research needs and opportunities.

Research Needs and Opportunities

Where do we go from here? There is a terrific amount of work to be done and, rather than attempt to be comprehensive, I will only hit the highlights in four areas: biomedical research, clinical/epidemiologic research, behavioral research, and operations research.

There are two very important research priorities in the biomedical arena:

- the development and evaluation of simple, inexpensive, rapid diagnostic tests; and
- the development and evaluation of female-driven prevention technologies.

Recent advances such as solid phase ELISAs and creative application of older approaches such as leukocyte esterase dipsticks could greatly improve the ease with which RTIs are detected in resource-poor settings. Efforts should be focused on tests for detection of cervicitis and genital ulcer disease pathogens.

The social context in which STDs occur mandates that we actively explore bactericidal and virucidal products, as well as barrier methods (such as the female condom) which are fully controllable by women.

In the clinical/epidemiologic realm, I want to mention four priorities:

- determination of the prevalence and microbial spectrum of RTIs;
- evaluation of syndrome-oriented algorithms with and without simple diagnostic tests;
- definition of the primary risk factors for RTIs and their complications; and
- assessment of the attributable risk of specific RTIs in infertility, ectopic pregnancy, cervical cancer, adverse outcomes of pregnancy and HIV transmission.

First of all, as is clearly demonstrated by the data I presented earlier, we need more information on the prevalence of RTIs and their microbial spectrum in various populations. Surveillance should be conducted both in high risk sentinel populations and in accessible samples representative of the general population of sexually active women (such as family planning or antenatal clinic attendees). The latter data will also be useful in monitoring the effectiveness of program interventions. Surveillance for antibiotic resistance, particularly in cases of gonorrhea and chancroid, is also important.

Secondly, we must compare the efficacy and cost-benefit of syndromic diagnosis using algorithms for management of RTIs which incorporate simple tests such as vaginal pH or endocervical Gram stain with etiologic diagnosis using gold-standard diagnostics.

In addition, in different countries and cultures we must define the primary risk factors for acquisition of RTIs and development of their sequelae. What, for example, is the influence of culture-specific practices such as circumcision, douching, and vaginal mucosal desiccation, on transmission of STDs? In one such important study, Dr. Subhash Hira has demonstrated that the risk of HIV seroconversion is increased 28-fold among Zambian women in couples practicing "dry sex," i.e.: couples who wipe out the vagina with a rag if the women becomes very lubricated during intercourse.

We must also examine the attributable risk of specific RTIs in the development of infertility, ectopic pregnancy, cervical cancer, fetal wastage, low birth weight, congenital infection, and HIV transmission in Third World populations. One approach to this is the design of clinical trials or demonstration projects to evaluate the impact of STD control on specific outcomes such as low birth weight or HIV infection.

There are three behavioral research priorities on which I would like to focus:

- definition of the prevalence of risk behaviors in population subgroups (both sexual and health-seeking behaviors);
- development of improved culture-specific methodologies for measuring and validating sexual behaviors; and
- design and evaluation of culture-specific health education and behavioral interventions.

One important issue is definition of the prevalence of specific risk behaviors in population subgroups, both with respect to sexual and health-seeking behaviors. Such studies are complicated by our need to develop improved, culture-specific methods for measuring and validating sexual behaviors. In a given community, for example, are same-sex interviewers more effective than opposite-sex interviewers in obtaining accurate data on sexual behaviors? How do we validate the answers we get?

We must also design and evaluate educational projects and behavioral interventions that reflect an understanding of the norms and potent "motivating" factors in the subgroups of each society. What, for example, is the impact of various counselling formats on the control of RTIs? In Zambia, Dr. Hira has found that counselling couples about condom usage is much more effective than counselling individuals. Is this true in Uganda, Brazil, or Thailand?

Finally, operations research priorities include:

- documentation of existing sources of clinical services for RTIs;
- evaluation of the impact and cost-effectiveness of integrated vs. categorical services for RTIs;
- determination of the effectiveness and acceptability of partner notification in identification of target populations for STD control; and
- estimation of the comprehensive costs of RTIs.

Where do women currently go when they have symptoms such as vaginal discharge, genital ulcers, or lower abdominal pain? In light of existing infra-structures and programmatic goals, what are the additional benefits of integrated services in family planning clinics both for control of STDs and for achieving family planning objectives? What about integrated services in MCH, antenatal or adolescent health care settings? In various countries, how

effective (and acceptable) is partner notification in identifying the target population for STD control efforts? Are the benefits of case detection offset by risks to the psychological, social, or physical well-being of the women who are index cases? These questions might be approached initially through focus groups.

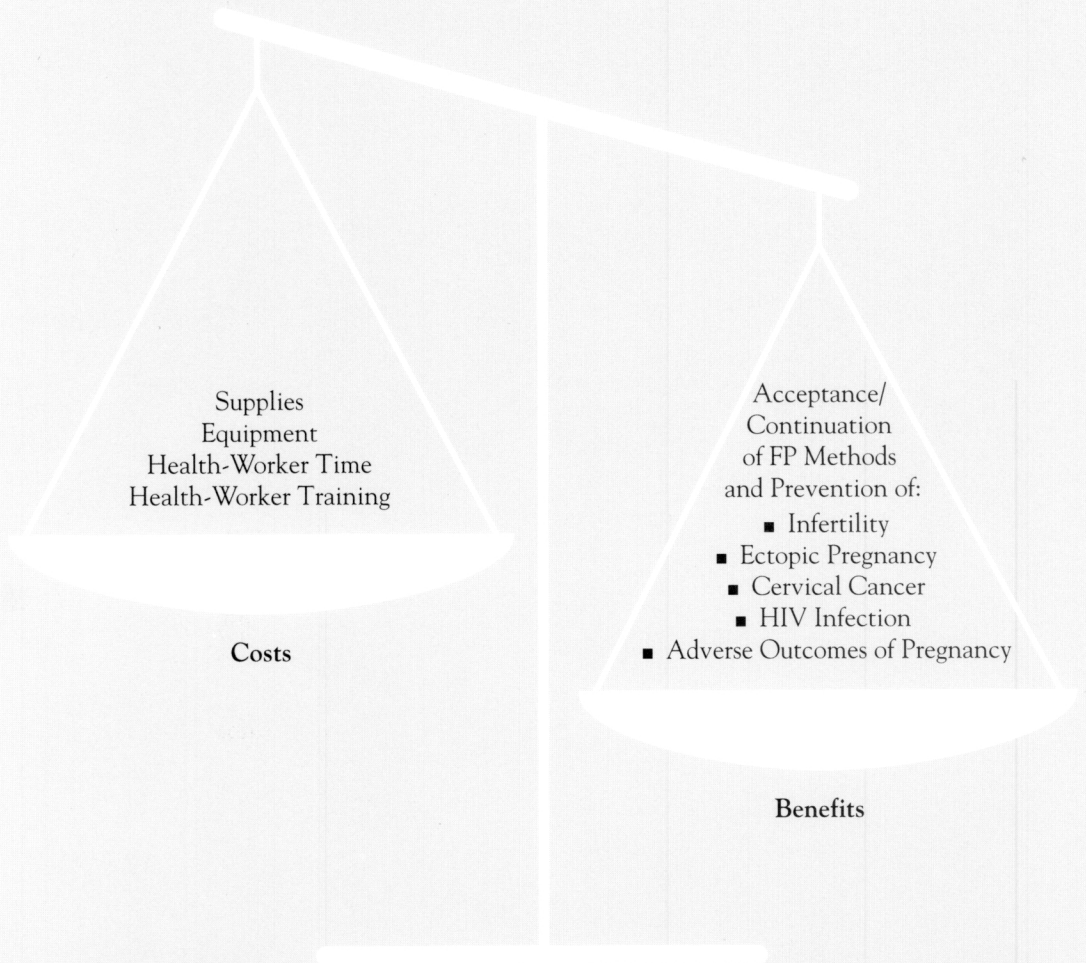
And finally, what *are* the annual comprehensive costs of RTIs for women and for men in the Third World? These estimates are essential for rational planning of program priorities and policy.

Summary: Balancing the Scales

In summary, then, RTIs are common diseases with severe, multidimensional costs to the health of Third World women. These costs include potentially fatal outcomes such as ectopic pregnancy, cervical cancer, adverse outcomes of pregnancy, and HIV infection, as well as outcomes with severe social consequences, such as infertility and decreased acceptance and continuation of family planning methods.

On the other side of the scales, as depicted in Figure 3, if we are prepared to commit supplies, equipment, health-worker time, and health-worker training, both prevention and treatment of RTIs are possible in Third World settings. Inexpensive, simple approaches are already available for many RTIs. And, because of recent biomedical advances, technologies exist which could easily be translated to additional diagnostic tools. In my view, RTIs are one challenge in the health of Third World women that can no longer be ignored.

Figure 3. Balancing the Scales: The Costs and Benefits of Addressing RTI's



Cervical Cancer in Developing Countries

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Squamous cell cancer of the cervix is frequently the leading cause of death from cancer among women in the less developed countries.[1] There are about half a million new cases of cancer of the cervix per year and 77 percent of these are in less developed countries. In many areas of the world, at least 3 to 5 percent of adult female deaths are due to this cancer. Unlike the West where cervical cancers peak in the 50 and 60 year age groups, in LDCs the peak seems to be in the 30 and 40 year age groups.

Virtually all of the epithelial neoplasms of the male and female lower anogenital tract are causally related to infection with human papillomaviruses (HPV).[2] Approximately 60 HPV types have been identified, of which approximately 22 produce lesions of the genital tract. These viruses are generally divided into three groups – those of low oncogenic risk, medium oncogenic risk, and high oncogenic risk. The principal viral types of low oncogenic risk are types 6 and 11, those of high oncogenic type principally 16 and 18, and those of intermediate oncogenic risk principally HPV types 31, 33, 35, 51, 52, and 56.[3] Although genital tract HPVs are sometimes transmitted by non-sexual means,[4] the overwhelming majority of these infections appears to be sexually related.

The epidemiology of lower tract epithelial neoplasia parallels that of other sexually transmitted diseases. Cervical cancers are extremely rare in virginal women or in women who are in mutually monogamous relationships. In contrast, the principal co-variable which identifies a woman or group of women as being at high risk is the history of multiple male sexual partners or a male partner or partners who have had multiple partners. Relative risk of six-fold and greater are associated with having had partners in excess of six, and data suggest that a woman who smokes will suffer from an independently increased relative risk of lower genital tract cancer on the basis of her smoking behavior.[5]

In those countries in which early sexual intercourse, multiple sexual partners, either in women or their male sexual partners, and prevalent cigarette smoking are the rule, lower genital tract cancers – particularly cervical cancers – would be expected to be, and in fact are, highly prevalent. It has been reported that in much of the developing world cervical

cancer is either the leading cause or the second leading cause of death from cancer among women, and in some parts of the world penile cancer has been reported to be a leading cause of death from cancer among men.[6]

Virtually all of the cancers of the epithelia of the lower genital tract have well studied and well defined precursor stages. It has been reported by a number of authors and convincingly substantiated in a number of statistical studies that the detection and eradication of precursor stages will lead to a substantial fall in the risk of developing lower genital tract cancers – particularly cervical cancer – and to a substantial decline in deaths from cervical cancer as well.[7] Most of the precursor lesions in women are detected using the Papanicolaou smear which, in much of North America and Europe, is available as a routine procedure to virtually the entire population. In these highly developed and industrialized areas of the world, it is principally the poor, the elderly, and the uneducated who fail to avail themselves of Papanicolaou smear screening, and it is these populations in which invasive cervical cancer still persists at a high rate. In the remainder of the population, cervical cancer has fallen to an extremely low level which has been sustained for a number of years. Even those invasive cancers which are discovered tend to be low-stage cancers with higher survival rates than in the pre-Papanicolaou era when late-stage cancers were the rule and survival was relatively uncommon.

One of the principal advantages of Papanicolaou smears for screening is the cost effectiveness of this approach. Even a single smear in the patient's lifetime will reduce the death rate from cervical cancer by about 50 percent, with each additional smear reducing the death rate by a decreasing increment. However, as the mean transit time from the precursor stage to invasion is approximately 10 years,[8] the screening intervals can be spaced fairly widely and still allow the program to be highly effective in reducing the cervical cancer risk. The appropriate time to begin screening and the appropriate screening interval can be chosen by each health authority to maximize the yield consistent with available monetary and other resources. At least one of the smears should be timed to coincide with the peak prevalence of the high-grade precursor lesions in countries in which resources are limited.

It is important to note that in previously unscreened populations in which there is a high prevalence of disease, the initial several screens will detect a very large number of invasive cancers and their precursors. The health care system must be prepared for this large influx of new cases of neoplasia. In a country with a poorly developed medical infrastructure, the output of a screening program can easily overwhelm the gynecological, surgical, and radiotherapy services.

Papanicolaou smear screening requires a well organized general and medical infrastructure, well organized and well equipped laboratories, and cadres of trained cytotechnologists and pathologists to screen and interpret the collected slides. In addition, it requires that effective means of following patients with abnormal smears be in place before the program is established and that trained gynecologists, adequate clinics, and treatment facilities be available to deal with the relatively large number of women who are detected as having abnormalities during the course of the screening campaign. All these tasks require a significant investment in facilities and personnel and a continuing high level of monetary investment to maintain these services.

Because of the perceived, and probably very real, difficulties in initiating and maintaining a population-based Papanicolaou smear screening program, various authors have suggested alternatives to Pap smears in developing a cervical cancer control program.[9] One of these, referred to as "downstaging," proposes that women's cervices be examined visually during a speculum examination in an effort to detect invasive cancers at an early stage when they are potentially more curable. Even this relatively simple approach requires the availability of a well organized medical infrastructure, laboratories, and pathologists capable of processing and interpreting the biopsies, and, most importantly, a follow-up mechanism to identify and recall patients with cervical cancer and its precursors and to treat those patients. Because of the extremely high prevalence of cervical cancer in developing countries, it would be anticipated that, even in a downstaging detection program, very large numbers of cancer cases would be discovered in the initial and in subsequent screens and that a very significant investment in radical surgery and radiotherapy units would have to be made to accommodate the treatment of the large numbers of detected cases. One of the principal disadvantages of this approach to downstaging is that the lesions will be detected principally at the invasive stages when major therapeutic responses are required, rather than at the intraepithelial stage when treatment can be much less radical and hence less costly.

There is great interest in newer molecular approaches to the detection of women potentially at risk for developing cervical neoplasia, particularly since the development of new tests to detect HPV DNA using relatively simple hybridization procedures.[10] Although these detection technologies are expensive at the present time, there is little question that new technology will be developed which will allow the mass application of HPV DNA detection at a substantially reduced cost. Such tests, which will be automated or semi-automated for processing and interpretation, offer the potential for screening for HPV-related neoplasms in less developed countries without the necessity of training large numbers of cytotechnologists and organizing screening laboratories. This opens the possibility that prescreening programs using HPV DNA detection could be initiated in large population bases to be followed

by conventional Pap smears in those patients in whom positive results are obtained. Those women whose smears are positive could be assessed by colposcopic examination, biopsies, and endocervical curettage and appropriate follow-up diagnostic and therapeutic procedures. However, it is important to emphasize that even with the newest high technology detection modalities the problems relating to follow-up, diagnosis, and treatment will remain and that this part of the intervention equation should not be ignored when consideration of a screening program is being made.

It is likely that a better understanding of patient treatment modalities, coupled with simpler and cheaper detection techniques, will make it possible in the relatively near future to be able, realistically, to consider programs which may lead to meaningful cervical cancer detection and treatment programs in the less developed world.

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Contraceptive Safety

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It is estimated that over 400 million women in developing countries are using some form of "modern contraception." Although the patterns of contraceptive use vary widely around the world, the choice of a method of contraception – and the potential health effects – is an issue which touches most women at some time or another in their lives. It is clear that, overall, the effects of using effective contraception have been overwhelmingly positive for women's health, mainly through the direct effect of preventing pregnancy and the morbidity and mortality associated with pregnancy. But women are also concerned about the non-contraceptive health effects of individual methods of contraception. Increasingly, the choice is not whether or not to use an effective method of contraception, but rather which method carries the best combination of acceptability, efficacy, and balance of positive and negative side effects, for a given woman or couple. Thus, the relevant comparison is among available methods of contraception, rather than between any given method of contraception and the alternative of no contraception.

Although issues such as ease of use, cost, and convenience play an important role for women in selecting a method of contraception, concern about health effects is also a major issue for women in both developed and developing countries. In my presentation today I plan to review broadly what research has been conducted on side effects of contraceptives, how the research priorities have evolved over time, for both developed and developing countries, to what extent women's concerns have been taken into account, and to what extent women have been involved in setting the research priorities. Finally, I will make some suggestions as to what is needed in the immediate future so as to avoid the pitfalls of the past, and to ensure that the health concerns of women in developing countries are adequately addressed when undertaking research on contraceptive safety.

Virtually all of what we know about the major non-contraceptive health effects of contraceptives comes from research undertaken in North America and Western Europe. The landmark studies demonstrating an increased risk of cardiovascular disease among women using the pill, the protective effect of pills against cancer of the ovary and endometrium, the risk of serious pelvic inflammatory disease among women using IUDs and the impaired fertility

that follows – all of these studies were conducted in a few developed countries. There were a number of reasons for this geographical concentration of research: in part, it reflected the rapidly growing popularity of "modern contraceptives" in the western, developed world; in part, it stemmed from the fact that expertise in conducting such studies was at that time very much concentrated in these countries. Perhaps it also reflected a cultural norm of questioning potential side effects of drugs routinely used; improved health in general allowed for more concern about side effects of drugs such as contraceptives.

In fact, systematic studies to assess the long-term safety of both oral contraceptives and IUDs were not begun immediately after these contraceptives were introduced. In general, the first reports of the major adverse effects of oral contraceptives came from spontaneous adverse drug reporting systems; subsequently, specific studies were initiated to confirm these reports. Since the first sporadic reports of adverse effects of oral contraceptives, an enormous amount of research has been conducted on specific health effects of oral contraceptives. The story is a similar one for IUDs. However, as I mentioned earlier, the vast majority of this research has been conducted in a few developed countries.

More recently, both hormonal contraceptives and IUDs have become widely used in many developing countries. Expanding population and family planning programmes have received a great deal of attention in a number of developing countries, as part of the general economic and social development process, and as part of an attempt to slow down the rate of population growth. A new interest in research on contraceptives accompanied this development. Initially, the main interest was primarily in factors that affected acceptability of specific contraceptives and/or continuation rates. Put simplistically, the main goal was to get as many couples (women) using effective contraception for as long as possible.

This is not to say that there was no interest in the potential adverse health effects of these contraceptives, but this issue was not of high priority for research probably, in part, because it was generally assumed that the studies from developed countries had already addressed these issues. In addition, in the face of massive health problems in these countries, potential adverse health effects of contraceptives understandably received relatively little attention.

Over the past 10 to 15 years or so, the orientation of the research in both developed and developing countries has shifted. In western developed countries, research on contraceptive safety shifted towards "fine-tuning" the findings of the earlier studies. Are there subgroups of women using oral contraceptives who are at an increased risk of developing breast cancer? What role did specific micro-organisms play in the relationship between IUD use and pelvic inflammatory disease (PID)? Issues of acceptability of various contraceptives were

also addressed to a limited extent – were menstrual patterns altered following tubal ligation? Which specific estrogen-progestogen combination in oral contraceptives minimized "breakthrough bleeding"?

In developing countries, during this same time period, the assumption that the results from the United States- and the United Kingdom-based studies were directly applicable to the entire world began to be questioned. Governments and family planning programmes in developing countries became increasingly concerned about potential adverse health effects of the contraceptives they were promoting, and that were now being widely used. Women's status and educational level increased in many developing countries, and women themselves became more vocal in their concerns about the safety of the contraceptives they and their friends were using. It began to be recognized that studies needed to be conducted in developing countries in order to assess the safety of contraceptives for Third World women. As a result, several large-scale multinational studies were initiated primarily by WHO's Special Programme of Research, Development and Research Training in Human Reproduction, on a number of safety issues, including IUD use and PID, hormonal contraceptives and cancer, and oral contraceptives and cardiovascular disease. These studies deliberately included developing country centers from different areas of the world. More recently, research on contraceptive safety and on behavioral and social factors affecting use of fertility regulation, has received high priority within the research and development component of WHO's Special Programme.

A major problem has emerged in this process. We really have not determined which side effects of contraceptives are applicable to women throughout the world, and which are not. This is of critical importance, since it has major implications for the scope of research that is still needed in developing countries. As an example, we know that oral contraceptive use lowers the risk of ovarian cancer among women in the United States and the United Kingdom. Can we assume that oral contraceptive use has the same effects on the risk of ovarian cancer among women in Kenya or in India? Or do we have to repeat studies of oral contraceptives and ovarian cancer virtually in every area of the world? Aside from issues of feasibility, this would be a very costly exercise. On the other hand, it is not wise to assume that all results on contraceptive safety from a few developed countries are directly applicable to all parts of the world. While there is a general acceptance that research on contraceptive safety must be undertaken in developing countries, more thought is needed as to which issues are of highest priority, given what we know from developed countries, and given the resources available. It will not be possible to replicate all studies of contraceptive safety in all areas of the world.

There are also issues of contraceptive safety, which are relevant only to some developing countries, and which would not have been addressed in developed countries. Examples include the safety of hormonal contraceptives for women infected with schistosomiasis, potential interactions between hormonal contraceptives and anti-malaria medication, and the effects of oral contraceptives on iron-deficiency anemia or vitamin deficiencies.

Further complicating the situation are those issues which are known to be culturally specific. Although amenorrhea may occur equally frequently among women in Pakistan using the implantable contraceptive, NORPLANT,® as compared to women in Sweden, the attitudes and reactions of the women to the amenorrhea may be dramatically different – which is ultimately what matters.

All of this leads to another relevant question: who determines what the research priorities are? Are the priorities set for research on contraceptive safety in developing countries truly relevant to and of high priority for developing countries, given other health problems in these settings? And are they truly high priority vis-a-vís women's health? To what extent are women involved in the setting of research priorities in developing countries?

There are no simple answers to these questions. There is no single group of people that determines research priorities on contraceptive safety issues for the world. A wide variety of individuals, groups, governmental institutions, and international bodies play a role. The more powerful among these individuals and institutions obviously carry more weight and have more influence. Within WHO's Special Programme of Research in Human Reproduction, which has the specific mandate within WHO to undertake research on contraceptive safety, it is encouraging that there is a deliberate effort to include both men and women on the main decision-making committees. Thus, both those contributing resources and those receiving financial support are represented on the highest level, for example, the Policy and Coordination Committee. At the more technical scientific review level, experts from around the world, including the developing world, participate in the decision-making process, as members of the Scientific and Technical Advisory Group, and as members of steering committees.

At least until recently, women have not generally been extensively involved in the global decision-making, especially at the highest levels, even though virtually all of the research implications directly concern women's health. The lack of involvement of women is especially marked in countries where feminism has so far had little impact and where women's status remains low. In general, these are also countries where women's health has received insufficient attention.

There has also been little systematic involvement of feminist groups or of "consumer groups" speaking on behalf of women, even in countries where feminist groups are well-established as an important voice for women's health concerns. Feminist groups have generally not been asked to participate in the decision-making process, and have thus too often remained uninformed about the rationale behind decisions taken regarding research priorities – and also uninformed about the results of the research as well. One result of this has been a regrettable schism between policy makers and even researchers on the one hand, and women's groups on the other. The situation has not maximized the likelihood that women's concerns will be taken into account.

International organizations play an important role in determining research priorities for contraceptive safety in developing countries. These organizations have only recently realized the importance of involving women in decision-making and in establishing links with women's groups concerned primarily with women's health in developing countries. WHO's Human Reproduction Programme has made some important "first steps" recently. Women's consumer groups were formally involved in a Symposium on Safety Requirements for New Contraceptive Steroids, and a Symposium on the Assessment of the Safety and Efficacy of Vaccines to Regulate Fertility. Furthermore, an increasing number of women at higher levels within the Programme has fostered the development of informal links with women's groups, both within and outside of WHO. The Population Council has also sponsored meetings with the International Women's Health Coalition, on quality of care, for example.

My impression is that there persists among feminist groups a general dissatisfaction about the focus of research on contraceptive safety – that insufficient attention is being paid to health effects which may not be life-threatening, but which directly concern women. I also have the impression that there is insufficient understanding on the part of some feminist groups as to what research has been conducted and what it has shown. For example, I still hear allegations that women who use Depo Provera (DMPA) risk impaired fertility, when this has been clearly shown not to be the case. I believe much of this "misinformation" to be a direct result of the lack of communication between researchers and women's groups. As I have been told by numerous women who are concerned about women's health, but who are not trained as scientists, it is often very difficult to understand the technical scientific articles that describe the research findings, and the popular syntheses of the articles in the lay media are not always accurate. I am told that even for women trained as scientists, but in fields other than reproductive health, it is difficult to understand the relative merits of various studies and thus the overall conclusions that can be drawn. The discrepant findings from several studies on oral contraceptives and breast cancer is a good example of a case in which it is very difficult for someone not directly involved in discussions with experts in this subject, to know what, if any, conclusions to draw.

What can one conclude from all of this? What changes are needed so as to ensure that women's concerns about women's health are adequately taken into account, especially in developing countries, when decisions are made about research on contraceptive safety? How can direct links between decision-makers and women's groups be fostered in international and national settings?

I am not convinced that the priorities of the past have been "all wrong." Tremendous progress has been made in identifying the major health effects of contraceptives such as oral contraceptives and IUDs. Issues such as the link between oral contraceptives and cancer and the risk of serious pelvic infection linked with IUDs are of major concern to women. There is rightly a growing recognition that these issues are of critical importance in developing countries, as well as developed ones. I have reviewed some of the reasons for the relatively slow development of research on contraceptive safety in developing countries. However, we still need to undertake research on issues directly relevant to developing countries, such as the safety of various contraceptives in the presence of diseases endemic in developing countries. We also need to identify those safety issues which have been studied in developed countries, but need further study in developing countries.

It is right, too, that research on major health effects has, in general, preceded research on side effects that are less "serious" from a direct health point of view. Side effects that are troublesome to women, or that influence women's decisions to change contraceptives, fade in comparison to the need to know, for example, that sequential pills (no longer used) increase the risk of endometrial cancer, a life-threatening condition.

Many developing countries are just beginning to set up mechanisms to determine research needs vis-a-vís contraceptive safety. Many of the decisions are still being made largely by developed country donor agencies and by international organizations. Recognition is slowly growing among the decision making groups that women and women's groups concerned with women's health need to be involved. This recognition needs to be fostered. The advantages for both "sides" in establishing direct links need to be pointed out and emphasized. We need to identify the most constructive ways for women and feminist groups to be involved in decision-making about contraceptive research. Having specific mechanisms for collaboration would greatly enhance the likelihood of success. Finally, the initiative needs to come from both sides. Too often, both feminist groups and national and international decision-making bodies have been too distrustful of each other even to approach the other for needed information, to discuss concerns, or to explore possible collaboration.

I am optimistic. This mini-plenary session is an example of changes in the right direction. It is exciting to be able to discuss these issues in a forum such as this, which brings together

policy makers, such as Dr. Barzelatto, and feminist groups such as IWHC. By fostering this momentum, we will do a better job of ensuring that women's health concerns are of high priority throughout the world.

Comments

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The International Woman's Health Coalition convened this session to discuss three important issues that are of increasing concern to women in general, particularly to those women living in poverty with limited access to adequate health services. Regardless of whether these women live in developing or developed countries, public scientific and ideological debates and alarming press coverage are increasing concern and confusion about reproductive tract infections, genital cancer and contraceptive safety.

The previous presentations have clearly shown that the three problems analyzed are important, that action is required now since there are reasonably affordable means to improve the situation in each case, and in addition, that there is a great need for more research.

As emphasized by the main speakers, their subjects are interrelated in many ways. These interrelations provide a good opportunity to reflect on broader issues that affect women's health in developing countries in general, particularly because these interrelations have frequently been ignored. It is much easier to raise funds and to mobilize political will if you concentrate on a single important issue.

In the past three decades, the world has seen different initiatives that have, and are having, significant and positive impact on reproductive health in the Third World. First it was Family Planning, which is now evolving from distributing and improving contraceptives to a more balanced approach to fertility regulation, including both contraception and infertility, putting more emphasis on investigating beneficial and harmful side affects, and starting to look at motivations for both usage and discontinuation of contraceptive methods. Then came Child Survival, another successful initiative that has found a positive response in all quarters. More recently, we remembered that mothers are also part of the equation. The Safe Motherhood Initiative has produced a positive and generalized response, by trying to improve not only the scandalous maternal mortality figures, but also by starting to look at the magnitude of suffering created by maternal morbidity. As a consequence, and with the help of the universal concern for the HIV pandemic, sexually transmitted diseases, and more broadly, genital tract infections, have also come to be recognized as most important.

What is still lacking is the general acknowledgement that all of these initiatives are different aspects of one problem area: reproductive health. It has yet to be recognized that competition among programs, which at least should be complementary, make little sense to women in the Third World. Unfortunately, these programs sometimes even work to the detriment of each other, because they are not integrated in terms of delivery of services. But recognition of reproductive health is nonetheless growing in many places.

Let me first quote from a World Health Organization (WHO) document. In the context of the definition of health by the Constitution of the World Health Organization as a "state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity," reproductive health means, "a) that people have the ability to reproduce as well as to regulate their fertility" with the fullest possible knowledge of the personal and social consequences of their decisions, and with access to the means of implementing them; "b) that women are able to go through pregnancy and childbirth safely; and c) that the outcome of pregnancy is successful" in terms of maternal and infant survival, and well-being. "In addition, couples should be able to have sexual relationships free of the fear of unwanted pregnancy and of contracting disease."[1]

Women in the Third World are also making demands in this same direction. On June 5 and 6, 1989, the Brazilian Government's National Council for Women's Rights convened in Brasilia a "National Encounter on Women's Health: A Right to be Won." This meeting analyzed the "dramatic" picture of women's health in Brazil, where problems of high maternal mortality, increasing mortality from breast and cervical cancer and from hypertension, "could be substantially reduced with preventive measures." Inadequate prenatal care, and an excessive number of unnecessary caesarean sections were cited as serious problems. The importance of "clandestine abortion" was presented, not only in terms of maternal mortality and morbidity, but also as an expression of the lack of an adequate policy for sexual education and fertility regulation. "This lack, plus the legal prohibition against interrupting pregnancies, shows a disrespect for a basic right of female citizens to decide about their own bodies and to experience motherhood as a choice." The Encounter denounced the lack of implementation in most of Brazil of the Integral Services for Women's Health Program, approved by the Government in 1983 in response to initiatives of concerned health professionals and feminist groups.[2]

They also denounced the lack of Government control over private family planning institutions, which has resulted in almost exclusive use of oral contraceptives as a reversible contraceptive method without adequate medical supervision, as well as in an alarmingly high incidence of tubal sterilization, including among young women. The Encounter made specific demands in relation to each of these and other issues, including decriminalization of

abortion. In particular, they stated that "family planning should be the free option of individuals, as part of health actions within the Integral Services for Women's Health Program, and not be used as an instrument of government demographic policies or for population control of ethnic groups." Since the Encounter took place, the National Council has been reorganized and women's health might still be for some time "A Right to be Won," but the women of Brazil have made an eloquent public statement of their demands.

Feminist groups and health professionals have rarely worked together, and unfortunately, numerous, bitter confrontations over reproductive health issues and lack of mutual trust have characterized much of their relationship. This is not surprising, given not only the lack of mutual feedback, but also the different perspectives that historically motivated these two groups.

Governments and health professionals in most countries became involved out of concern for the "population explosion." Governments were concerned about the impact on development, health professionals were concerned about the massive health consequences of population growth. Both saw the need to regulate the number of births. Better and greater variety of contraceptive methods was a commonly perceived need, and making contraceptives available was their initial exclusive policy.

Feminist groups got involved from the perspective of their human rights, including reproductive rights. Women saw the need to improve their status in order to exercise their rights, so they demanded education, equal job opportunities, and adequate health services, and as part of the latter, reproductive health services. Their complaint has been graphically described by the assertion that women are being considered factories for making babies, whose output has to be controlled, rather than as human beings that should be given the means to make and implement responsible decisions about reproduction.

In addition, feminist groups represent the users, while health professionals represent the providers of services. Conflicts between them are almost inevitable, particularly in developing countries given the poor quality of the health services in general. Many recriminations are justified, but some are not. Furthermore, the needed dialogue and collaboration between feminist groups and health professionals in respect to reproductive health, is also affected by ideological, religious and commercial agendas. Nevertheless, and perhaps because both movements have made considerable progress in their thinking and independently achieved remarkable successes, they are coming together almost naturally. They are certainly helped by initiatives like the one that has brought us together today, which follows in the tradition of numerous IWHC activities to bridge this gap. Adrienne Germain and Jane Ordway have described a strategy to review the so-called "population problem": "A 'reproductive health'

approach, with women at its center, could considerably strengthen the achievements of existing family planning and health programs, while helping women to attain health, dignity and human rights."[3] In this paper they have rightly concluded that such an approach would also appeal to several other constituencies and they have made several concrete suggestions to further improve the present situation.

To conclude this commentary, I would like to add one contributing idea of value in this field, in my view applicable to public health in general. There is a need to encourage and expand the contribution of anthropologists to public health, as "they alone bring to research in health a holistic approach to understanding daily life."[4]

Most social science research applied to health is due to demands from the medical profession and hence, inevitably serves the medical agenda. What must be encouraged is a marriage among equals to improve health. For example, in improving public health indicators to include quality of services, shouldn't social scientists be telling us how to include the perceptions of the people served by these services? "It is too difficult to quantify" is a frequent excuse. I am not convinced that it cannot be done. Furthermore, can we ignore the non-medical factors influencing the behavior of those we are supposed to help? No one questions the need for a multi-disciplinary approach to solving public health problems, nor the need to rely on quantitative techniques. But in addition, let the anthropologists also do "what they do best: telling stories, that is, providing rich descriptions of how people live and why they act the way they do," to quote Cynthia Myntti, an anthropologist.[4] She suggests that "statistically significant" data may be improved and made more relevant if surveys are followed by anthropological investigation. "Thus, chronologically speaking, anthropology takes over where epidemiology and its sister fields in public health leave off," rather, or in addition to, their initial participation in improving survey instruments.

This is an example of how social sciences may be able to make an even more important contribution to solving health problems in general, and specifically, in reproductive health issues.

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