Quality of Care for Female Reproductive Tract Infections in Public Clinics Compared to Private Practice Settings in Vietnam

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A. Study Purpose And Rationale

We propose a pilot study to assess the quality of diagnosis and treatment of reproductive tract infections in Vietnam relative to WHO guidelines, in both the public clinic and private practice settings.

Sexually transmitted diseases and BIV are a growing concernin Vietriam, particularly in the south.[1,3,25] Estimates of MV prevalence for the country now resemble those seen in Thailand six years ago. [24.25] STD's and related female reproductive tract infections (RTI's) are a leading cause of morbidity and mortality worldwide but are especially burdensome in developing countries, not least because they can facilitate BIV fturismission, [5.6] and have significant complications, which mostly affect women.

Assessment of the quality of current STD treatment services is essential to program development for STD control. The WHO has developed treatment gtndlmes for RTT's that provide a useful standard for assessing current treatment practices. They are based on symptomatic syndromes, for use in primary care settings where laboratory testing is neither widely available nor cost-effective. [7] Although not sensitive enough to use for screening, [8,9] prospective validation studies have shown them to be an effective case-management tool in developing countries for cervicitis, genital ulcers, and Trichomonas.[10-12] A prospective validation study of these guidelines is currently Underway in VietnaM.[13] Although the Current lack of data from Southeast Asia makes predictive values reported in prior studies difficult to generalize to Vietnam, the guidelines were 72% sensitive and 73% specific in diagnosing cervicitis among pregnant women in Zaire, a population with Rn prevalence estimates comparable to those reported for southern Vietnamese antenatal clinic populations! The guidelines have been incorporated into a survey instrument for assessment of STD services. [11] Current WHO guidelines thus appear to provide an adequate standard for assessing quality of rational case management with sensitivity and specificity comparable to other treatment algorithm developed for RTI's. [14-16]

In addition to evolving health cue demands, Vietnam has undergone tremendous social, political and economic changes in the past decade. The effects of these changes on the health cue system are not well Understood [17-18] While an practicing physicians are required to hold public sectorjobs, since 1989 they have been allowed to open private practices. [17, 18] Now wholly two-thirds of outpatient consultations am delivered by the private sector, and the public sector contributes less than 200% of all Medical treatment given.[17.18] Yet little data exists on the quality of care delivered in private practice settings as compared to public clinics, how their patient populations differ, or on how health care resources are utilized in these settings. Deregulation of the importation of Western pharmaceuticals may have led, as in other developing countries [21] to widespread overuse of antibiotics, leading to cases of toxicity and developing antibiotic resistance.[20] Particularly in a country with limited health care resources [17-20,22] it is important to determine the effectiveness of the available modes of care delivery for a growing public health problem such as STD's, and possible points for intervention to improve cost effectiveness.

B. Study Design/Statistical Analysis

This is a prospective, observational study of provider behavior in two practice settings.

A pilot study will first be conducted of providers in a single antenatal health clinic in Cantho who also see patients in the private practice setting. A team of medical students from the university hospital in Cantho will be trained as Observers, to apply study questionnaires, to perform surveys of practice sites, and to record observations of patient-provider encounters. Physicians from the same university will be

trained as Scorers to apply WHO guidelines to the encounters observed to arrive at a "standard" diagnosis, and to score the providers' diagnostic and treatment (based on providers' diagnoses) performances relative to WHO guidelines. After informed consent is obtained from the providers, they will be asked to provide schedules of private practice hours with the understanding that observers will make unannounced visits to both clinic and private practice settings.

Observer and Scorer variability will be assessed prior to the start of data collection in encounters with providers not part of the study using teams of two independently observing and scoring the same encounters. Differences will be noted, training repeated as necessary prior to proceeding. Surveys will be done of the clinic and each provider's private practice setting. In private practice settings, in a ratio of at least one observer per provider, data collection will begin and continue on consecutive days for a target of 15-20 patients with reproductive tract symptoms per provider Informed consent will be obtained from patients by the provider. Observers will be present for the entirety of the encounter including consent, history and physical examination, any dispensation of medication/injections, and counseling/follow-up discussions. If complete physical exams were not performed by the provider, they will not be performed by the observer. After the encounter, observers will apply the patient questionnaire and clarify with the providers any rationale they may have for diagnostic and treatment decisions made. Concurrently, the procedure will be repeated for each provider during his/her climc'hours on consecutive days with a goal of 20-40 encounters with patients with reproductive tract symptoms.

C. Site: Cantho, capital of Cantho Province in southern Vietnam

a. Subjects

a. Providers based at the antenatal health center who also have private practices (maximum of 10 or random sample of equal numbers of male and female providers).
b. All consecutive female patients who come. to either setting on observation days, regardless of chief complaint, or whether it is the first visit of the Symptomatic episode. Women who do not volunteer a reproductive tract symptom or have one elicited from them during theencounter will be excluded from the primary analysis.

A secondary goal of the study is to describe the patient populations that choose to seek care at each practice setting Therefore no effort will be made to match patients in the clinic or private practice settings. Obviously diflerences in patient populations can have an effect on provider diagnosis and treatment behavior In data analysis, the potential impact of these differences will be examined.

b. Measurements

(see questionnaires) Survey of providers including demographic data, training, and clinical experience.

Survey of sites, including hours of operation, staff, diagnostic equipment and lab testing availability, cost and availability of medications, and consultation fees.

Recording of symptomatic and medical history questions asked by the provider, if reproductive tract symptoms reported or elicited, findings on physical exam and speculum. exam if done, lab tests performed, diagnosis (whether communicated to patient, recorded in chart, or communicated to observer), any treatment administered or prescribed, any secondary prevention or partner referral counseling given, any follow-up provided, duration of encounter and time for treatment dispensation.

Survey questionnaire of patients after the provider encounter, including demographic data, knowledge of condom use, the costs to the patient of the encounter, review of symptomatic and pertinent medical history not asked by physician. If a provider did not perform a complete physical exam, it will not be performed by the investigator. Complete provider questionnaire including clarification of rationales for diagnosis/treatment decisions made..

Scorers blinded to the providers, patients, and practice setting of each encounter will first apply WHO guidelines to arrive at the "standard" syndromic diagnosis, then score the providers on whether they agreed or diagreed with guidelines on diagnosis, and score providers on correctness of treatment given the providers' diagnosis. Guidelines do recommend drug substitutions for pregnant patients and those with

common drug allergies, but not every clinical contingency can be anticipated. Other drug substitutions by providers will be reviewed in the context of the information recorded during the encounter.

D. Analysis

Error analysis will be done to determine where errors cluster, degree of inter-observer, inter-scorer variability . prior to study beginning.

Frequency distributions of all variables between the two practice site types will be recorded.

Patients who did not volunteer or from whom reproductive tract symptoms were not elicited during the encounier will be excluded from the primary analysis, unless they were given a diagnosis of an RTI, but will beincluded in descriptive analyses of the two patient populations and in analyses of prescribing behavior.

Primary outcomes of interest are correctness diagnosis relative to WHO guidelines, and correctness of treatment by guidelines given provider diagnosis, which will be analyzed using Chi-squares of provider diagnosis and treatment performance (agree or disagree with WHO guidelines) by practice setting, stratified by women with an RTT by WHO guidelines and women without RT1 by gaidelmes. Secondary outcomes of interest are performance scores as described above stratified by specific WHO diagnostic groups (gonoffhea/chlamydia, Trichornonas, etc.) and provider and practice setting characteristics. Data will be analyzed by comparison of proportions for categorical variables, and t-tests for continuous variables.

Other outcomes of interest include measures of questionnairetsurvey items included in the WHO "core drug-use indicators"26 list (average # drugs prescribed per encounter, % drugs prescribed by generic name. % encounters with an antibiotic prescribed, % encounters with an injection prescribed, % drugs prescribed from the national essential drugs list or formulary, average comiltation timeldispensation time, % drugs prescribed that are dispensed, % drugs adequately labeled, % patients understanding correct dosage, availability of key drugs and copy of essential drugs list at practice site), as well as a comparison of the patient populations in the two practice settings by demographic variables, knowledge of STD risk and prevention, and health care seeking behavior

Results of the pilot study will be used for power calculations and sample size estimates for the subsequent study.

E. Study Procedures

See above. Observation should take 15min/pt, survey 10min, scoring 5min, physician questionnaire 5 min 4 40min/pt. Tlus study does not involve any invasive procedures outside those deemed necessary for patient care by the provider, or any study medications.

F. Study Questionnaires

See documents affached below):

Provider questionnaire, Site evaluation form, Encounter survey, Patient questionnaire, Performance evaluation form

G. Study Subjects/Recruitment

For recruitment, see above. Include: AD female patients seen at a study site on observation days.' Exclude: Exclude men from entry. Exclude from the primary analysis women who do not volunteer or have elicited reproductive tract symptoms during the encounter unless they were given a diagnosis of a reproductive tract infection

H. Confidentiality

Providers will be coded with unique identifiers. Patients will be coded to identify only by their provider and site numbers. All data on individual participation in the study will be kept strictly confidential.

I. Risks/Benefits

This is a minimal risk study for patients. For providers, the study may represent a risk of increased regulation or other government involvement in either practice setting, but also offers the opportunity to contribute to a realistic understanding of the strengths and weaknesses of the current care delivery system.

J. Compensation

Involvement in the study will be voluntary and there will be no compensation for patients or providers. Neither should they incur any costs.

K. Minors

Ideally we would like to include all female patients with reproductive tract symptoms. This will be reviewed with

regard to Vietnamese laws/regulations regarding consenting minors and parental notification.

L. References

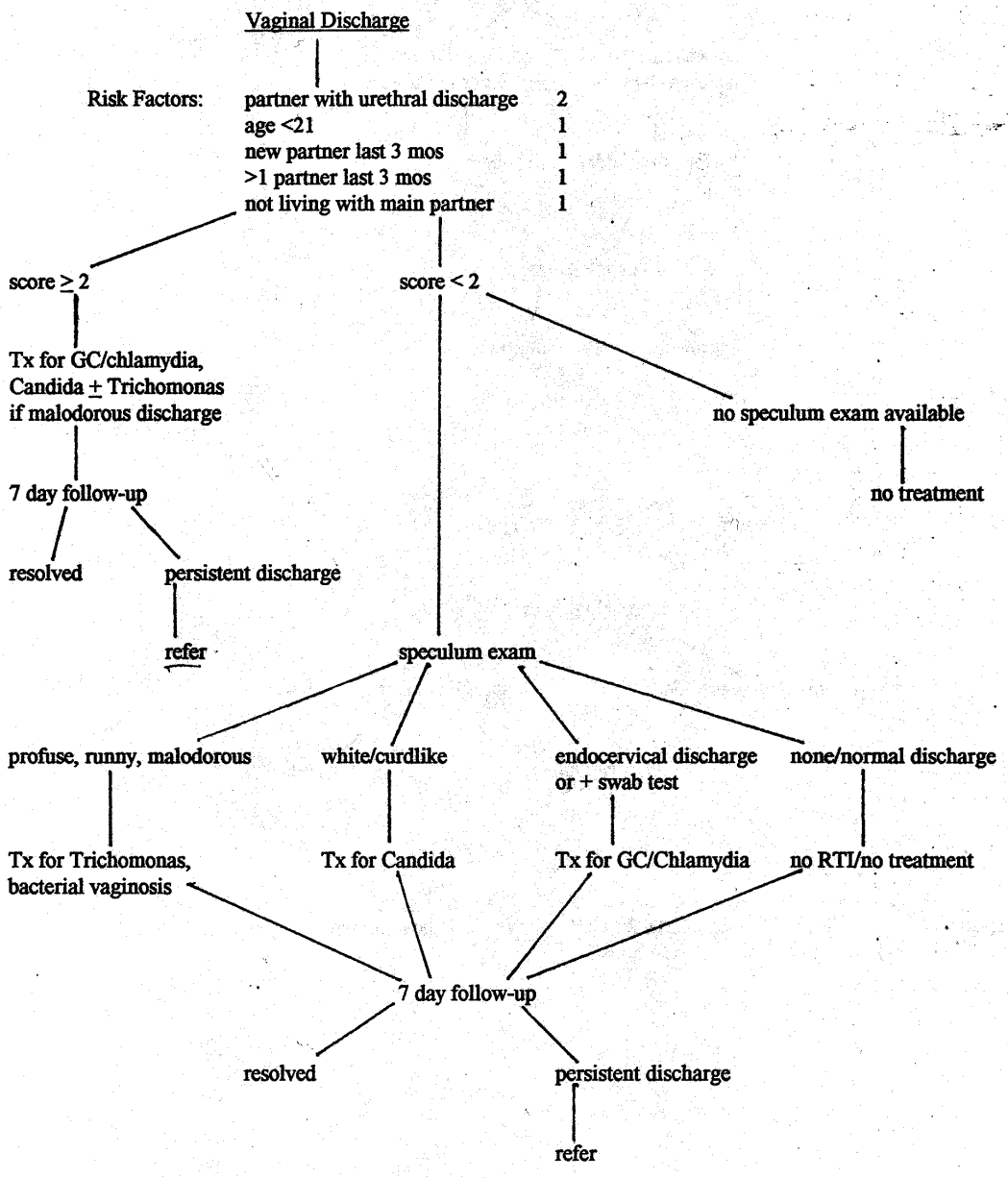
1. Neburkar VR et al., IRV Type I Subtype E in Commercial Sex Workers and Injection Drug Users in Southern Vietnam, AIDS Res. and Human Retroviruses, 1996, (12)9:841-43.
2. Nguyen HT and Wolffers L IRV Infection in Vietnam, Lancet, (343)410.
3. World Health Organization, AIDS Surveillance Report, Wesem Pacific Region, 1995.
4. Menu E et al. IRV Type I Thai Subtype E Is Predominant in South Vietnam, AIDS Res. and Human Retroviruses, 1996, (12)7:629-33.
5. De Schryver a and Melneus A, Epidemiology of Sexually Transmitted Diseases: the Global Picture, Bulletin of the World Health Organization, 1990, (68)639-54.
6. Chin J, Current and Future Dimensions of the HIV(AIDS Pandemic in Women and Children, Lancet 1990, (336)221-4.
7. World Health Organization, Management of Patients with Sexually Transmitted Diseases: Report of a WHO study group, 1991, WHO Technical Report Series, #810. Recommendations for the Management of Sexually Transmitted Diseases, 1993.
8. Vuylsteke B et al., Clinical Algorithms for the Screening of Women for Gonococcal and Chlamydial Infection: Evaluation of Pregnant Women and Prostitutes in Zaire, Clinical Infectious Diseases, 1993, (17):82-8.
9. Behets FMT et al., Control of sexually traiismitted diseases in Haiti: Results and implications of a baseline study among pregnant women living in Cite Soleff shantytowns, J of Infectious Diseases, 1995, (172):764-71.
10. Behets, FMT et al. Management of Vaginal Discharge in Women Treated at a Jamaican Sexually Transmitted Disease Clinic: Use of Diagnostic Algorithms Versus Laboratory Testing, Clinical Infectious Diseases, 1995, (21)1450-55.
11. Bryce, J et al. Quality of Sexually Transmitted Disease Services in Jamaica: Evaluation of a Clinic-Based Approach, Bulletin of the World Health Organization, 1994, (72)239-47.
12. La Ruche G et al., Therapeutic Algorithms for Management of STD's in Cote d1voire, Bulletin of the World Health Organization, 1995, (73) 305-313.

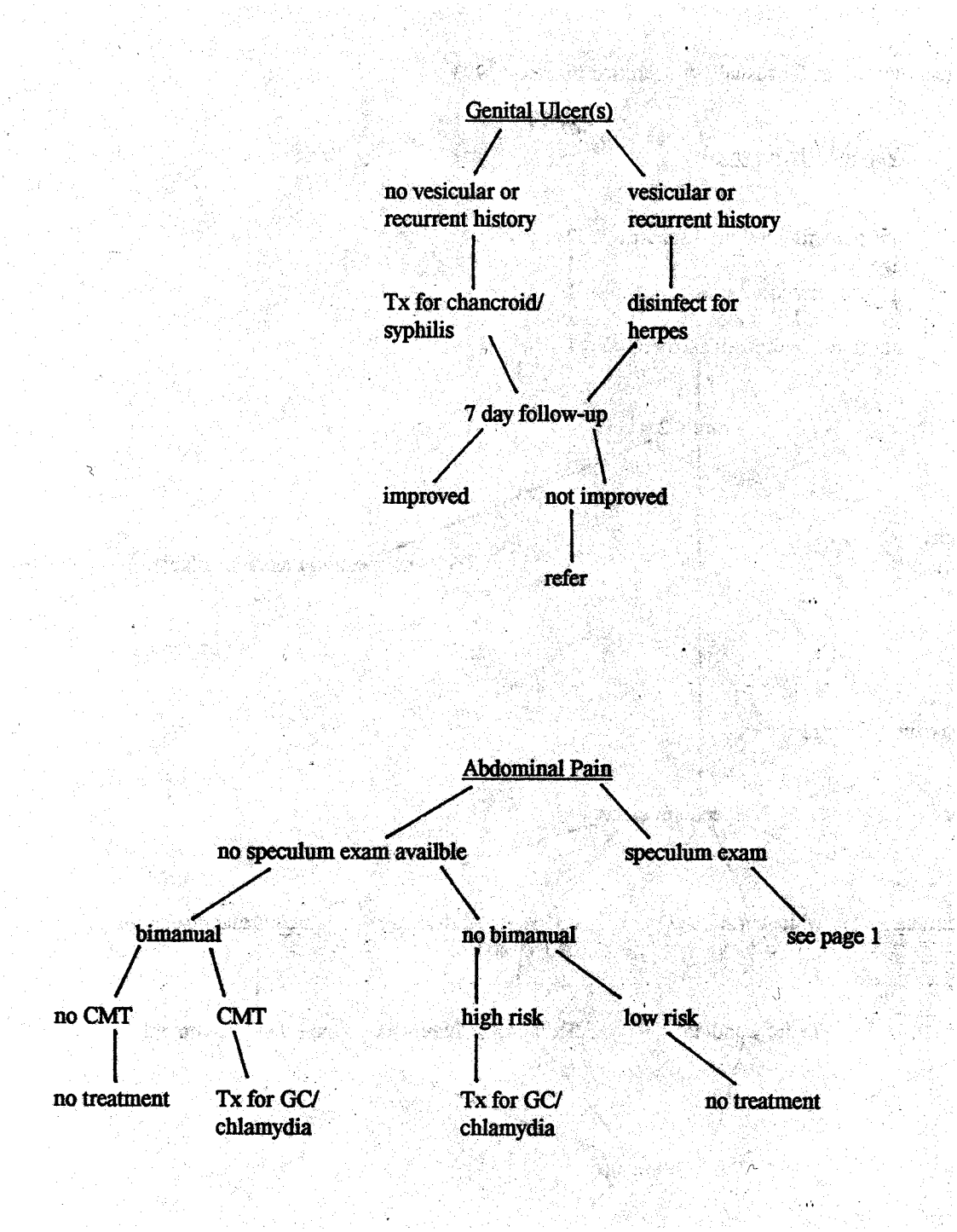
13. Jamie Uhrig, UNAIDS-Vietnarn, personal communication
14. Braddick MR et al., Towards Developing a Diagnostic Algorithm for Chlamydia trachomatis and Neisseria gonoffhoeae Cervicitis in Pregnancy, Genitourinary Medicine, 1990, 66:62-65.
15. Johnson BA et al., Derivation and Validation of a Clinical Diagnostic Model for Chlamydial Cervical Infection in University Women, JAMA, 1990, (264)24:3161-5.
16. Centers for Disease Control, Sexually transmitted diseases clinical practice guidelines, May 1991.
17. Gellert GA et al., The Influence of Market Economics on Primary Health Care in Vietnam, Journal of the American Medical Association, 1995, (273)19:1408-52.
18. Witter S, "Doi Moi" and Health: The Effect of Economic Reforms on the Health System in Vietnam, International Journal of Health Planning and Management, 1996, (11):159-72.
19. Nguyen HT et al., The Pursuit of Equity: A Health Sector Case Study from Vietnam, Health Policy, 1995, (33)191-204.
20. Wolffers L The Role of Pharmaceuticals in the Privatization Pro~ess in Vietnam's Health-Care System, Social Sciences and Medicine, 1995, (41)9:1325-32.
21. Trostle J, Inappropriate Distribution of Medicines by Professionals in Developing Countries, Social Sciences and Medicine, 1996, (42)8:1117-20.

Ladinsky JL and Levine RE, The Organization of Health Services in Vietnam, Journal of Public Health and Policy, 1985, (6)225.

22. Ensor T and Pharn SB, Access and Payment for Health Care: the Poor of Northern Vietnam, International Journal of Health Planning and Management, 1996, (2)69-83.
23. Abellanosa I and Nichter K Antibiotic Prophylaxis Among Commercial Sex Workers in Cebu City, Philippines, Patterns of Use and Perceptions of Efficacy, Sexually Transmitted Diseases, 1996, (25)5: 407-12.
24. Fox E, Nfission Report: AIDS Prevention and Control: Surveillance of HIV in Vietnam. Report to the Global Programme on AIDS. WHO: Geneve, Oct. 17-Nov 15, 1993.
25. Hogerzeil, HV et al. Field Tests for Rational Drug Use in Twelve Developing Countries,,The Lancet, 1993, (342)1408-10.
26. Levine WC et al. Development of Sexually Transmitted Diseases Treatment Guidelines, 1993, Sexually Transmitted Diseases, 1994,(21)2supp:S96-100.

WHO treatment algorithms for sexually transmitted diseases, 1993




Genital Ulcer(s)
no vesicular or recurrent history
vesicular or recurrent history
Tx for chancroid/ syphilis
disinfect for herpes
7 day follow-up
improved
not improved
refer
Abdominal Pain
no speculum exam availble
speculum exam
bimanual
no bimanual
see page 1
no CMT
CMT
high risk
low risk
no treatment
Tx for GC/ chlamydia
Tx for GC/ chlamydia
no treatment