Prognostic implications of oral health status in HIV-positive women in St. Petersburg, Russia

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PROGNOSTIC IMPLICATIONS OF ORAL HEALTH STATUS
IN HIV-POSITIVE WOMEN
IN ST. PETERSBURG, RUSSIA

by

Anna Vinogradova

A Thesis
Submitted to the University at Albany, State University of New York
in Partial Fulfillment of
the Requirements for the Degree of
Master of Science

School of Public Health
Department of Epidemiology and Biostatistics
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Objective: To assess state of oral health in HIV-positive women in St. Petersburg, Russia and to study the association of oral health with pregnancy status and other factors in this sample.

Design: Cross-sectional.

Methods: Data were collected retrospectively from the dental and medical charts of the 500 HIV-infected females who attended the Dental Department of St. Petersburg AIDS Center’s during January-June 2011. The recorded information included demographic and social characteristics, pregnancy status, decayed (D), missing (M), filled (F) teeth (T), clinical presentation of periodontal disease, oral manifestations, CD4 cell counts, HIV viral load, and receipt of antiretroviral therapy. The association of oral health with pregnancy status and other factors was examined in bivariate and multivariate analyses.

Results: The mean DMFT index was 13.5 (6.0), higher than the index in studies of non-HIV women in Russia; the incidence of oral lesions was low (16.2%). The oral health status of pregnant and non-pregnant women was similar.

Conclusion: High caries prevalence and oral lesions may have a substantial impact on health and quality of life in this vulnerable population. There should be more emphasis on assessment of dental health and provision of care for HIV-infected women who attend HIV clinics.
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1. INTRODUCTION

1.1. *Human Immunodeficiency Virus (HIV)*

Human immunodeficiency virus, HIV, was first described in humans in 1981. Two years later at the Pasteur Institute laboratory in Paris, F. Barre-Sinoussi and L. Montagnier isolated lymphadenopathy associated virus (LAV) in human tissue [1]. A member of the lentivirus family, HIV is classified as a retrovirus because the genetic material in the core is single-stranded RNA. Reverse transcriptase decodes the genetic information from the RNA and converts it into DNA, allowing the viral genome to integrate with the host’s DNA. Other viruses, such as herpes simplex or hepatitis B, may stimulate cell activity which, in turn, activates HIV replication [2].

1.1.1. *HIV transmission*

The HIV virus is transmitted through multiple pathways, including:

1) contact with blood or blood-derived fluids,

2) shared needles used for injection of illegal drugs,

3) work in health care fields (medical, dental, laboratory, or other) that involves direct exposure to infected human blood,

4) blood transfusions that have not been screened for HIV,

5) unprotected sexual contact with an HIV-infected partner (e.g., between sex partners, both heterosexual and homosexual),

6) perinatal transmission, which occurs primarily in children born to HIV carrier mothers[3].
1.1.2. Clinical presentation and laboratory tests

Chronic infectious disease caused by human immunodeficiency virus (HIV) progresses from one stage of immunodeficiency to another, culminating in the most severe – AIDS (acquired immunodeficiency syndrome). HIV infection is characterized by impairment of the immune and nervous systems and manifests with the development of severe opportunistic infections and malignant neoplasms. A variety of clinical symptoms of HIV infection are caused by the virus’ special affinity to certain cells of the immune system: T (CD4) lymphocytes (T-helpers), monocytes, macrophages, Langerhans cells, and endothelial and neural cells. Therefore, immunological study of T (CD4) lymphocytes is important in diagnosis [3, 4] and clinicians rely, in part, on T-helper cell counts to define the stage of disease and the severity of the immune system decline. HIV infection is manifested as a paralysis of cellular immunity, which greatly inhibits the ability of the patient to combat opportunistic infections [3]. A second equally important and necessary laboratory test is quantification of HIV RNA copies in one ml of blood plasma - the viral load (VL). The VL is considered to be the main marker of disease progression and monitoring the effectiveness of antiretroviral treatment [3, 5].

1.1.3. New era of HIV disease

A breakthrough in highly active antiretroviral therapy (HAART) in the mid-1990s has allowed clinicians to control disease progression and this way have an enormous impact on life expectancy and quality of life. However, antiretroviral drugs do not eliminate the virus from the human body, and HIV disease becomes a chronic condition [4, 6]. Apart
from the treatment benefits, HAART has several disadvantages, such as high cost and clinical management challenges due to drug-resistance, toxicity and compliance among patients.

1.2 Epidemiology and morbidity of HIV infection

1.2.1. HIV infection prevalence in the world

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), worldwide prevalence of HIV in 2010 was 34.8 million adults, about half of whom are women and 3.4 million are children living with HIV; in 2008, AIDS caused 2.7 million deaths [Fig.1]. Despite the advent of highly active antiretroviral therapy (HAART), the death toll remains high 1.8 million people [7]. However, a recent UNAIDS final report (2010) outlined some positive trends: new HIV infections are declining, AIDS-related deaths are decreasing, and many fewer children were infected.

Sub-Saharan Africa has the highest prevalence, accounting for fully two-thirds of all infected people (22.5million). South and South-East Asia together have the second greatest prevalence of people living with HIV; steady increases in HIV infection throughout Eastern Europe and Central Asia have generated a total prevalence of around 1.4 million people. The most affected countries are the Russian Federation and Ukraine, but the virus continues to spread in neighbor countries like Belarus, Kazakhstan, Kyrgyzstan and Uzbekistan. Among those living with HIV/AIDS in Eastern Europe and
Central Asia, 79.0% of the newly infected are young – 15 to 30 years old. In recent decades, the Russian Federation has seen the most rapid increase in incidence with 589,581 HIV-infected individuals in 2010.

1.2.2. HIV infection incidence and prevalence in Russia

Russia has one of the largest HIV epidemics in Europe, with 639,979 registered cases and 58,633 new HIV cases in 2011, an incidence 20.0% higher than during the previous years [Fig.2]. The prevalence of HIV infection in the country is still dominated by men (64.9%), however, this gap is closing due to increased incidence among women in recent years. By November 25, 2011, 226,000 HIV-positive women (35.6% of all reported cases of HIV infection) were registered in Russia. The HIV/AIDS epidemic in Russia is regionally concentrated in Samarskaya, Irkutskaya, Leningradskaya, St. Petersburg, Sverdlovskaya, Orenburgskaya, Ulyanovskaya, Tumenskaya, and Chelyabinskaya regions. Early in the epidemic HIV transmission primarily occurred (> 90.0%) among injection drug users (IDUs) by sharing injecting drug equipment. However, in recent years, there has been an increase in sexual transmission of infection (from 6.0% in 2001 to 25.0-27.0% in 2004, and a dramatic rise in 2005 (43.0% of all newly diagnosed HIV infections); this generalization of the epidemic poses a great threat to the public health and the economy.

By the end of 2009, 73% of people living with HIV/AIDS (PLWHA) were between 15 and 30 years old when diagnosed. The proportion of new infections occurring among 15-19 year olds has notably decreased from 24.7% in 2000 to 2.9% of new infections in
2009. However, this cohort apparently continues to become infected as evidenced by the increasing proportion of new infections among 30-40 year olds: 9.9% in 2000 to 36.9% in 2009. The Russian Federal AIDS Center annual report [8] suggests that there is an increased number of risky behaviors among people of reproductive age, and some learn they are HIV-positive well after manifestations of the disease were noted. Delayed diagnosis coupled with a generalizing epidemic among a population of reproductive age means this virus will continue to spread rapidly through wide swaths of the populace.

1.2.3. Feminization of HIV epidemic in Russia

In Russia, HIV infection is still dominated by men (64.9% in 2010). However, since 2002 there has been an increase in the proportion of women with more than 207 000 HIV-positive women (35.1% of all reported HIV cases). During 2004-2010, 41-43% of new HIV infections were among women, that is double the rate in 2000 (20.6 %) [Fig.3]. The age distribution among women is the following: 25% of the HIV-positive are 15-20 years old and 59% are 21-30.

The main transmission route for men continues to be injecting drug use; the primary means of transmission for women is sexual contact. Transmission of HIV to individuals who never injected drugs mainly occurs through unprotected sexual contact with an HIV-infected IDU [9]. The current trend of women actively involved in HIV transmission and, specifically, the increased role of sexual transmission among women of childbearing age, is exacerbating the problem of HIV mother-to-child transmission during pregnancy and childbirth. This development is particularly concerning given that women are considered
a more vulnerable population due to social, cultural and economic inequalities [7]. Furthermore, HIV is also among the major causes of death for women of reproductive age worldwide [10].

1.2.4. Vertical transmission in Russia

The total number of registered children born to HIV-positive mothers was 5231, with the diagnosis of HIV infection confirmed in 263 children, of whom 139 were on antiretroviral therapy [8]. Prevention of mother to child transmission (PMTCT) program in the country reached 83.0% of HIV-positive women in 2007 [10]. Russia was among 19 countries to exceed the 80% PMTCT threshold of coverage and decreased the vertical transmission rate from 19.4% in 2001 to 9.6% in 2008 [11, 12].

In summary, the HIV epidemic in the Russian Federation is characterized by: an increasing incidence of infection due to sexual transmission of HIV, continuing transmission among IDUs, generalization of the epidemic to the heterosexual population, the spread of HIV infection among pregnant women, and, consequently, an increase in the number of births to HIV-infected women.

1.2.5. HIV infection in St. Petersburg, Russia

The results of surveillance suggest that HIV began circulating in this large city in 1982. By 1991 there were only a few cases of infection registered; in 1996, drug users were actively involved in the epidemic process and with peak incidence in 2000. Sexual HIV
transmission has risen from 7.6 in 2006 to 38.0 % in 2010. The most affected age group is between the ages of 18 to 30 years (66.2%), yet a steady increase in the number of cases of HIV in older age groups (over 30 years) has been noted.

In 2011, St. Petersburg ranked fourth among the regions of the Russian Federation with 42,117 of HIV cases reported since 1987, including women 13,144 (33%) [Fig.4]. HIV infection is detected in 0.4-0.5% of pregnant women (on average, 1 out of 200-250 pregnant women are HIV-positive).

A significant increase of births to HIV-infected mothers has been noted as well: 147 births in 2001, 415 in 2005, 394 in 2008, 501 in 2009. In 2005, those registered in antenatal clinics at various stages of pregnancy comprised only 76.2% of HIV-infected pregnant women; more than 20% of HIV-infected pregnant women had not been registered in the clinic during pregnancy and their HIV infection was detected on admission for labor and delivery. This leaves insufficient time to protect against perinatal transmission.

According to the City AIDS Center, St. Petersburg is now experiencing a trend of sexual transmission, following closely on the heels of parenteral transmission, and feminizing the epidemic. All age groups are affected by HIV disease and many of them will soon be moving into the stage of secondary disease with its diverse, attendant clinical manifestations. These patients seek care in different healthcare facilities for surgical, dermatovenerological, and dental care [13].
1.3. Oral manifestations and caries in HIV infection

1.3.1 HIV infection and oral health

It is known that HIV affects different organs and systems, as well as the oral tissues. Diseases of the oral mucosa in HIV disease are symptomatic manifestations, sometimes with an atypical clinical presentation [14, 15]. The lesions on the oral mucosa are the earliest manifestations of HIV infection and may be the first available HIV-related symptoms, especially for dentists.

Because the first clinical signs of disease are lesions of the mouth, dentists in the United States as early as the 1980s began to take an active part in the diagnosis of HIV infection, describing the manifestations of the oral mucosa and periodontal tissue, which were observed among these patients. Based on the analysis of epidemiological surveys, the study of oral health in patients with HIV infection World Health Organization [16] developed a description of oral diseases associated with HIV infection and guidelines for dentists. These key recommendations included that the dentist should know the HIV-associated manifestations and their prevalence in the oral cavity and pathogenesis of the disease, the dentist may also participate in the HIV diagnosis, and certainly that dentists provide HIV-infected individuals with adequate dental care.

The clinical presentation of HIV infection has been thoroughly studied. It is well known that the immunodeficiency of HIV infection causes a rapid degradation of local immunity in the mouth followed by a change in the oral mucosa condition which is often among the earliest clinical symptoms [17]. Clinical manifestations of HIV infection in the oral
cavity vary, and may be of different etiologies: fungal, viral, bacterial or mixed. They often predict progression of the disease, opportunistic infections and tumors [16]. Identifying the pathology of the oral mucosa facilitates diagnostic and preventive measures in HIV-infected individuals. Early diagnosis of HIV disease and detection of immune system decline, which may precede the progressive destruction of the oral tissues, are vitally important for the patient’s quality of life. Lack of attention to treatment of acute infectious manifestations in the oral cavity can lead to complications. Careful examination of the oral mucosa and periodontal tissues may not only help identify the patient with HIV infection, but also the disease stage.

Local immune system changes in the oral cavity also lead to the development of dental caries [16]. However, presence of caries is associated not only with HIV, but also other viruses (hepatitis B, C, etc.). Studies of dental caries in patients with viral hepatitis B and/or C indicate a high rate of cavities and large index of decayed, filled and missing/extracted teeth (DFMT) index. This dental index is 8% higher in patients with HIV/AIDS and IDUs with co-infection of viral hepatitis compared to patients without hepatitis [18].

1.3.2 Oral manifestations and caries among HIV-positive women

Several studies have been performed in the US have identified differences in oral manifestations among HIV-positive men and women, such as lesions of hairy leukoplakia (22.0% vs. 6.0%, respectively) and Kaposi’s sarcoma had higher prevalence in men than women. The most common infection, oral candidiasis, is directly related to immune status. In a Nigerian study, oral candidiasis was the most common oral lesion and was
equally prevalent among genders (78.6% in females and 78.7% in males). In a German study conducted among HIV-positive women, oral manifestations were observed in 39.0% of the patients without respect to the mode of transmission [19].

The women`s interagency HIV study (WIHS) performed in multiple centers across the US has identified that in HIV-positive women the presence of oral candidiasis was associated with a CD4 count <200 cells/mm³, cigarette smoking, and heroin/methadone use; the presence of hairy leukoplakia was not related to CD4 count, but was associated with high viral load [20, 21]. It has also been noted that protease inhibitor based HAART therapy is a significant risk factor for developing reduced salivary flow rates and salivary gland enlargement [22, 23].

Another sub-study of WIHS concluded that HIV-positive women are at a greater risk for xerostomia and salivary gland hypofunction in comparison with HIV-negative women, and the main predisposal factors are low CD4 cell counts and HAART. In addition, serostatus is related to salivary gland disease manifested by glandular enlargement, tenderness, and absence of saliva during examination [24, 25].

Another study observed a 1.2 fold higher caries prevalence among HIV-infected women in comparison with HIV-non-infected and further research among Latin HIV-positive and HIV-negative women, an increase was not observed suggesting that socioeconomic or cultural factors could play more important role in dental caries than HIV [26]. Such factors do, of course, figure prominently in the clinical presentation and course of dental caries, lesions, and oral mucosa manifestations.
1.3.3. Underuse and barriers to dental care

Unmet dental needs is one of the most frequently reported among HIV individuals in the United States [27, 28, 29], especially among hard to reach HIV individuals and it is after HIV diagnosis that changes dental care utilization [30]. Among those with HIV, overall health and quality of life is certainly affected by having painful manifestations in the mouth, which in turn leads to difficulty in maintaining antiretroviral drug regimens, and can obviously oral intake and nutrition and overall affects well-being [28, 31]. A 5.5 years comparative quality of life report (HIV-positive vs. women at-risk) showed average 10.0% poorer quality of life in HIV-infected women [25].

Several authors have identified the major barriers to oral health care: anxiety, fear of dentist and confidentiality/rejection, low motivation, along with social and economic factors, stating they play more important role than current HIV-status [32, 33]. Currently there are several studies devoted solely to female cohorts.

The major barriers among asymptomatic HIV-infected women were poverty and fear of the dentist [32, 34]. To be more precise, a cross-sectional survey found that 27.0% of women stated fear, 21.0% could not make an appointment or did not know where they could receive care, 16.0% did not have sufficient resources, and 9.0% felt discriminated against. More than 40.0% of them agreed with the necessity of oral care, and 43.0% stated they had not visited the dentist during the previous year. Shiboski and colleagues identified that nonuse of dental services was associated with unemployment, race, perceived poor oral health, and having two or more children.
1.3.4 Pregnancy and oral care

According to the Surgeon General’s Report, Findings on Oral Health and other oral care guidelines, it is recommended that oral health professionals focus attention on women who are pregnant or planning a pregnancy and provide comprehensive preventive dental care, examination and necessary treatment [35-37]. Pregnancy is the time to place a high priority for oral health. Pregnant women frequent experience bleeding gums, increasing the risk of gingivitis in the second trimester of pregnancy. It is known that elevated estrogen and progesterone increase the formation of plaque on teeth. However, regular oral hygiene reduces plaque formation and, thus, reduces the risk of gum disease during pregnancy. This is of particular importance given the well-documented association between bacteria in the diseased gum tissue and premature labor [38, 39]. According to estimations by the National Institutes of Health, a notable 18% of total annual pre-mature births in the US (250 000) correlates with infectious disease in the oral cavity [40].

At present only a few studies of oral manifestations among HIV-positive pregnant women exist. One study conducted in Johannesburg, South Africa, revealed that HIV-positive pregnant and non-pregnant females shared a similar prevalence of oral lesions associated with HIV infection, but those women with HIV infection experienced a slightly higher prevalence of oral candidiasis [41]. In conclusion, tooth decay, demineralization of enamel, gingivitis, and periodontal disease in combination with HIV-associated oral manifestations can lead to decreased quality of life, preterm/low-birth weight babies, spread of bacteria to the new-born child, and spread of the bacterial infection in the body [39].
1.3.5. Oral health care for HIV-positive individuals at the AIDS Centers in Russia

Healthcare services for HIV-positive individuals are provided by regional AIDS centers in Russia. In the cities of Moscow and St. Petersburg, Yekaterinburg, and Kaluga, the AIDS Centers have dental offices. The city of St. Petersburg is a pioneer in this area with the first dental department at the Center to provide the important dental care (therapeutic, orthopedic, surgery) needed by approximately 2500 HIV-positive individuals annually. An algorithm for outpatient care was developed to optimize the services provided by dentists who serve HIV-infected patients [42]. This algorithm includes three main steps:

1. Medical history review, initial examination of the patient (oral cavity assessment, check for HIV-associated oral diseases).

2. Diagnosis and additional tests, treatment plan, including the follow-up (counseling with specialists: infectionist, dermatologist, neurologist): indications for patient, timeline and the type of treatment and preventive measures, taking into account the stage of HIV infection.

3. Dental treatment including follow-up. This section includes an element of psychological assistance (counseling), to support and motivate, assist to form treatment adherence.

The proposed algorithm optimizes the work of a dentist working at the AIDS Center, and generally contributes to the quality of life of HIV-infected people, the vast majority of whom are in the most socially active age group (20-35), with one of the priorities being early detection and timely clinical examination of patients. The dental department at St. Petersburg AIDS Center has an outpatient examination system based on the study of oral health status in HIV-positive individuals receiving HAART [43]: asymptomatic
HIV-infected patients should be examined once a year, before the start of antiretroviral therapy and 3 months after starting treatment, twice for HIV-infected pregnant women. At present, though, the internal referral system within the Center is not comprehensive enough to capture all patients who would benefit from care. This disadvantage, coupled with the lack of patient motivation, means opportunities are missed to provide care.

This review documents the generalization and feminization of the HIV epidemic in Russia and St. Petersburg, underscoring the exigency of proactive dental care among HIV-infected individuals, especially women. To our knowledge, there are no prevention programs and nor dental studies performed among HIV-positive women in Russia. An epidemiological window of opportunity therefore exists to conduct a cross-sectional study of prognostic implications of oral health status among HIV-positive women to inform managing, organizing and structuring oral care for HIV-positive women, including during pregnancy.
2. JOURNAL ARTICLE

Oral health status of HIV-positive women in St. Petersburg, Russia, 2011

Introduction

Russia has one of the largest HIV epidemics in Europe, with 589,581 registered cases and 58,633 new HIV cases in 2010. Thirty-five percent of infections are in women, with new cases among women caused predominantly by heterosexual contact (65%), followed by injecting drug use (IDU, 35%). In reproductive-age women HIV transmission during sexual contact has risen notably in recent years, from 8% in 2006 to 38.0% in 2010 [8]. St. Petersburg is the second largest city in Russia, with a population of about 5 million. In the city, 39,809 HIV cases have been reported since 1987, including 13,144 women [8]. St. Petersburg has the unfortunate distinction of having the most HIV-positive pregnancies in Russia [44].

St. Petersburg AIDS Center (CAC) is a regional city center with a dental department that provides specialized care for nearly 3,000 HIV-positive individuals annually. The goal of the study is to characterize overall oral health status among HIV-positive women who attended the Dental Department in the last six months of 2011 and to study the association of oral health to pregnancy status and to HIV factors. In light of the risks of poor oral health in pregnant women [45, 46], we also wanted to ascertain if pregnant women had poorer oral health than non-pregnant women.
Methods

The sample included all 500 women between 18 & 45 who presented to the Dental Department during the period January-June, 2011. Approval for the study was provided by the Institutional Review Board of CAC.

Trained reviewers extracted data from the records for the first dental visit of each subject during the study period. They recorded oral health measures, including DMFT index, which is decayed (D), missing (M), and filled (F) teeth (T) [47]. Supragingival calculus, a periodontal disease, was classified as early, moderate and advanced. HIV-associated oral lesions were classified according to standard diagnostic criteria [48]. Poor oral health was defined as meeting any one of three criteria: DMFT index above the mean, moderate or advanced periodontal disease, and/or presence of candidacies.

The records review also provided current pregnancy status and demographic information, including education, employment, and marital status. The recorded HIV data included the date of diagnosis, defined as date of the first positive HIV antibody test ELIZA (Organics, Israel) followed by HIV-1 Western blot (Du Point, USA); HIV transmission route, and date of start of highly active antiretroviral therapy (HAART). Also recorded were CD4 count (cells/mm³), assessed using FACSCalibur (BD Biosciences, San Jose, CA) and HIV viral load (copies/ml) measured by the Abbot RealTime HIV-1 (Abbott Laboratories, Abbott Park, IL).

Statistical methods

Data was entered into Microsoft Office Access 2007. Stata 12.0 software was used for the data analyses. Descriptive statistics (frequency and percent for categorical factors, mean
and standard deviation for continuous factors) were computed for pregnant and non-pregnant women and for categories of other factors.

Bivariate analyses of predictive factors with poor oral health included estimation of the prevalence ratios with 95% confidence intervals. The Chi square test at a significance level of less than 0.05 was used to identify statistically significant findings. Poisson regression analysis with robust variance estimates was used to fit relative risk main-effect models associated with poor oral health [49]. Potential confounders included in the model were age, education, employment, pregnancy, CD4 cell count and HIV viral load (HIV VL). Interaction terms were included to identify effect modification.

**Results**

At their first dental visit 220 women were pregnant and 280 were not pregnant. Descriptive statistics are shown in Table 1. Characteristics of pregnant and non-pregnant were generally similar, except for HAART status: only 46.0% of non-pregnant women were on HAART compared to 73.0% of pregnant women.

The oral health measures are shown in Table 2. HIV oral lesions were present in 16.4% of the women; 11.6% had any periodontal disease; and the mean DMFT was 13.5. Pregnant and non-pregnant women had similar profiles generally. However rates of gingivitis and moderate/advanced periodontal disease were higher in pregnant women.

Table 3 assesses the association of selected factors with poor oral health. The only significant predictor of poor oral health was CD4 count; the prevalence of poor oral health for CD4 counts <200; 200-500, >500 cells/mm$^3$ were 77%, 58%, and 53%, respectively. Other HIV related factors significant in bivariate analyses were not
significant when CD4 count was adjusted for in the model. The p-value with a Bonferonni correction for multiple comparisons is \( p = 0.21 \).

**Discussion**

To our knowledge, this report is the first to explore the dental health status of HIV-positive women in Russia. Our assessment supports evidence gathered from other countries indicating oral disease, especially untreated caries, among HIV-positive women is still common, as is the under use of dental services. Previous studies by Mulligan et al [50] and Nelson et al [51] revealed HIV-infected women had higher dental indices, apart from root caries, than in the HIV-negative women. Phelan et al [26] found a 1.2-fold higher caries severity among HIV-positive women over HIV-negative women. Mulligan et al [25] reported a median DMFT index of 13.0 among HIV-positive women in San Francisco. Similarly, in this study, the mean DMFT of 13.5 was higher than the mean 10.7 in two general population samples of HIV-negative women in Moscow [52, 53].

In other studies of oral lesions in the HIV-infected women of the Women's Interagency HIV Study (WIHS) oral cohort, oral candidiasis and hairy leukoplakia were most commonly observed [54, 55]. Other investigators [56, 57] did not find higher rates of oral and periodontal disease among HIV-positive pregnant women, compared to non-pregnant women, apart from higher candidiasis rates.

Adeyemi et al [41] studied periodontal disease among HIV-positive African women with just over half (53.3%) of study women in the second trimester of pregnancy and observed necrotizing ulcerative gingivitis in 24.3% and necrotizing ulcerative periodontitis and
linear gingival erythema in 4.3%. Periodontal conditions of various types in pregnant women were more prevalent among HIV-positive than HIV-negative women. In our data, the prevalence of gingivitis was 80% higher in pregnant women and the percentage of moderate and advanced periodontal disease was 36.0% higher.

Antiretroviral therapy is associated with a reduction of recurrence and incidence of HIV-associated oral manifestations [21, 58-61]. A few studies have been devoted to evaluating the relationship of oral lesions and CD4 cell count with HIV viral load. Several authors [21, 32, 34, 56, 60, 61] have observed association of oral lesions among patients with low CD4 (< 200 mm\(^3\)). In this study only 16.2% of HIV-positive women had oral lesions probably because the majority (57.8%) had received treatment for about a year (11.32 (16.68) months).

Margiotta et al [62], and Chattopadhyay et al [63] reported an increase of oral lesions among individuals with low (< 200 mm\(^3\)) and median (200-500 mm\(^3\)) CD4 counts. Our results agree that the CD4 cell count appears to be an important factor with respect to the development of oral lesions. HIV-associated oral disease is observed among individuals with high viral load [62, 64, 65]. We also recorded high lesion occurrence among patients with a high viral load (>10K, data not shown).

The data from comparative studies of HIV-positive versus HIV-negative female cohorts revealed poorer oral health (increased rate of oral lesion, dry mouth condition) among seropositive women [32, 34, 67- 69]. These figures and our results suggest that additional efforts should be directed toward providing oral care (creating awareness/attracting this target group) to reproductive age women with positive HIV-status attending AIDS Centers.
Some limitations of this study include, first, the diagnosis of caries and periodontal diseases was based on clinical presentation only. X-rays are rarely used in the Clinic, because most women cannot afford the co-pay. Thus, it is likely that our prevalence estimates are underestimates. Second, our data was restricted to a sample from one health center only, but it is the only treatment center in the city designated for HIV care. Third, information on alcohol, smoking and drug use could be obtained from medical records. Fourth, the St. Petersburg HIV Center is underutilized by some high-risk groups (e.g., sex workers and active IDUs), so these groups are under-represented. Further studies among HIV-infected women should be carried out throughout Russia with sampling frames specifically designed to capture these underserved populations.

These clinical findings and epidemiologic data indicate a small and rapidly closing “window of opportunity” to address the burgeoning dental needs of HIV-positive women of reproductive age before they affect the next generation in utero.
3. EPIDEMIOLOGIC CONSIDERATIONS

The necessity of a more profound and comprehensive study of HIV-associated dental diseases does not lose its significance, but also shifts to practice. According to dental experts [69,70], this is largely due to the introduction of antiretroviral treatment and various innovative regimens of highly active antiretroviral therapy (HAART), that affect main links of disease pathogenesis as well as largely change clinical presentation and incidence of HIV-associated lesions of oral cavity [71]. It also determines the feasibility of amending the existing and creating new treatment and dispanserization algorithms of HIV-associated pathology.

A new aspect of the urgency to the problem associated with the study of oral health status among HIV positive women arises with increase of women involved in the HIV epidemic in Russia and their vulnerability. Limited access to a full range of dental care services, fair oral care knowledge along with low motivation among HIV-infected women results in poor dental hygiene and a risk factor for oral diseases like caries and periodontal disease. Untreated oral conditions lead to decreased quality of life [14, 72], transmission of oral bacteria to their children, and in pregnancy give rise to the risk to the fetus of premature delivery and low birth weight.

3.1. Selection of study participants and representativeness of the sample

Cross-sectional type of study along with a convenience sample was allowed to collect information in limited resources settings and assist in further organizing and providing adequate care.
The sample of individuals is representative as there are similarities in study sample of HIV-positive women and those involved in the epidemic support the generalizability of our study results. In 2009 73% of PLWHA were between 15 and 30 old when diagnosed and 86.7% of female participants in the study were from 18 to 34 years old. Despite the domination by men (64.9%) that are involved in HIV epidemic in Russia [8], during 2004-2010 years the number of new HIV infections doubled among women (from 20.6% in 2000 to 41%-43% in 2010).

A convenience sample that was used in this study minimized volunteerism of patients. The entire accessible population within almost two season’s period (winter, spring) was selected, that included seasonal variations and peak times of patient flow.

Current sample of HIV positive women comprises female visitors only those regularly attending St. Petersburg HIV Center and that excludes sero-positive females that were too sick and were in hospital, or just registered at the Center without perceived dental care need, and high-risk groups e.g. sex workers, and active drug-users women. The restriction of the data is to one health center only. Further studies among HIV-infected women should be carried out throughout Russia. This limits the generalizibility of the results.

3.2. Limitations of the study

Alike any cross-sectional study, our study’s limitations included factors which may have bias estimates. First, the diagnostics of caries and periodontal diseases was based on clinical presentation. Caries diagnosis is primarily made by examination with dental
mirror and explorer. Dental x-ray radiographs assist in revealing "hidden caries"- not visible to the naked eye, e.g. caries between the teeth. Patients in this study were examined by three trained dentists, two of them have more than 15 years of experience. It decreases to certain extend diagnostic and lesion registration errors. Another clinical variable that was collected was clinical presentation of periodontal disease. Examination of gums is essential for evaluation of periodontal condition. Several components are included such as probing of pockets (between the tooth and the gum) around teeth, analyzing gum recession, bite, tooth mobility, etc. Dental X-ray is mandatory for an accurate diagnosis of periodontal disease. This diagnostic procedure allows to determine the amount and location of bone loss, the size and shape of the roots, and other components necessary for further treatment. In our study x-ray radiographs were not performed, so the number of periodontal disease is underestimated due to sole clinical presentation and the severity of the disease in unknown.

Less than half (44.0%) were pregnant mainly in the first trimester (26.8%), 15.6% in the second, and only 1.6% in the third trimester. Bivariate analysis comparing pregnant and non-pregnant women found no significant differences between groups across all factors investigated. Misclassification could occur among those with early pregnancy and manifestation and the severity of pregnancy-associated manifestations in the oral cavity are observed mainly during second or early third trimester.

Antiretroviral therapy was prescribed according to international guidelines [73] by a committee of doctors working at St. Petersburg AIDS Center. Another limitation is the cross-sectional nature of data which allows to report only association between oral health status and its predictors rather than to investigate the casual patterns.
3.3. *Further steps*

The results of our study suggest addressing unmet dental needs among HIV-positive women disregarding their pregnancy status. Further studies among HIV-infected women should be carried out throughout Russia. Another cross-sectional study could be done by conducting a self-administered survey. It would assist in assessing information about perceived oral health status and dental needs of HIV-positive women. As well as explore the reasons barriers to receiving oral health care in general and at the dental department at the AIDS Center, along with oral hygiene habits and oral products usage, nutrition habits. Finally, the aforementioned study and future interventions should proceed to ensure access and low–cost dental care among HIV-infected individuals, especially among women.
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60. MacPhail LA, Komaroff E, Alves ME, Navazesh M, Phelan JA, Redford M.  


TO: Anna Vinogradova

FROM: Office of Regulatory Research Compliance

DATE: November 15, 2011

SUBJECT: Review of IRB Screening Form - SFL # 111: "Prognostic Implications of Oral Health Status in HIV-positive Women in St. Petersburg, Russia"

Maintenance of high ethical standards in research and scholarship is a central and critical responsibility of the University. This includes, but is not limited to, compliance with all requirements affecting specific aspects of the conduct of research such as the protection of human subjects.

Because your study involves secondary data analysis of de-identified data, it is not covered under the human protections regulations as defined in Title 45 CFR §46.102(d) (f) and (f) of, and therefore, does not require Institutional Review Board (IRB) approval. Please note that only the IRB and Office of Regulatory Research Compliance staff may make this determination.

Please contact the Office of Regulatory Research Compliance at 518-442-9050 or oorr@uamail.albany.edu if there are questions.

Adrienne D. Bonilla, Esq.
Assistant Vice President for Research
Director/Research Compliance Officer
Office of Regulatory Research Compliance

Cc: Louise-Anne McNutt
APPENDIX B: FIGURES

FIGURE 1. Estimated global prevalence of HIV. Source: UNAIDS, 2010

FIGURE 2. HIV prevalence in Russian Federation. 

## APPENDIX TABLES

### TABLE I. Baseline characteristics of HIV positive women by pregnancy status attending St. Petersburg AIDS Center, Russia (n=500).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Level</th>
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<th>Pregnant</th>
<th>p-value</th>
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<td></td>
<td>N=500</td>
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<tr>
<td></td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
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<td>Age (years)</td>
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<td>77</td>
<td>15.4</td>
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</tr>
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<td></td>
<td>25–34</td>
<td>364</td>
<td>72.8</td>
<td>204</td>
<td>72.8</td>
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<tr>
<td></td>
<td>35–45</td>
<td>59</td>
<td>11.8</td>
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<td></td>
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<td>22.8</td>
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<td>56</td>
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<td>382</td>
<td>76.4</td>
<td>218</td>
<td>77.8</td>
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<tr>
<td></td>
<td>Other (widow, divorced)</td>
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<td>1.8</td>
<td>6</td>
<td>2.2</td>
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<tr>
<td>Transmission Route</td>
<td>Sexual</td>
<td>330</td>
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<td>179</td>
<td>63.9</td>
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<td></td>
<td>Parenteral</td>
<td>170</td>
<td>34.0</td>
<td>101</td>
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<tr>
<td>Number Of Years With HIV Diagnosis</td>
<td>&lt;1</td>
<td>151</td>
<td>30.2</td>
<td>78</td>
<td>27.9</td>
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<tr>
<td></td>
<td>1-4</td>
<td>179</td>
<td>35.8</td>
<td>105</td>
<td>37.5</td>
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<td>5-9</td>
<td>155</td>
<td>31.0</td>
<td>88</td>
<td>31.4</td>
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<td>≥10</td>
<td>15</td>
<td>3.0</td>
<td>9</td>
<td>3.1</td>
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<td>CD4 cell count (cells/mm3)</td>
<td>&lt;200</td>
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<td></td>
<td>200-500</td>
<td>269</td>
<td>53.8</td>
<td>158</td>
<td>56.4</td>
</tr>
<tr>
<td></td>
<td>&gt;500</td>
<td>165</td>
<td>33.0</td>
<td>86</td>
<td>30.7</td>
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<tr>
<td>Treatment</td>
<td>Not on HAART</td>
<td>211</td>
<td>43.0</td>
<td>151</td>
<td>53.6</td>
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<tr>
<td></td>
<td>On HAART</td>
<td>285</td>
<td>57.0</td>
<td>125</td>
<td>46.4</td>
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Table II. Oral status among pregnant and non-pregnant HIV-positive women attending AIDS Center St. Petersburg, Russia (n=500)

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<th>Variable</th>
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<th>Pregnant</th>
<th>p-value</th>
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<td>N=280</td>
<td>N=220</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Oral Lesions</td>
<td>None</td>
<td>427</td>
<td>85.4</td>
<td>234</td>
<td>83.7</td>
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<tr>
<td></td>
<td>Mixed</td>
<td>5</td>
<td>1.0</td>
<td>5</td>
<td>1.7</td>
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<tr>
<td></td>
<td>Candidasis</td>
<td>50</td>
<td>10.0</td>
<td>27</td>
<td>9.6</td>
</tr>
<tr>
<td></td>
<td>Oral hairy leukoplakia</td>
<td>17</td>
<td>3.4</td>
<td>14</td>
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<tr>
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<td>Linear gingival erythema</td>
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<tr>
<td>Periodontal Disease</td>
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<td>392</td>
<td>78.4</td>
<td>222</td>
<td>79.3</td>
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<td>Gingivitis</td>
<td>43</td>
<td>8.6</td>
<td>18</td>
<td>6.4</td>
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<tr>
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<td>Early periodontitis</td>
<td>36</td>
<td>7.2</td>
<td>26</td>
<td>9.3</td>
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<td>Moderate periodontitis</td>
<td>22</td>
<td>4.4</td>
<td>11</td>
<td>3.9</td>
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<td>Advanced periodontitis</td>
<td>7</td>
<td>1.4</td>
<td>3</td>
<td>1.1</td>
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<td>DMFT</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
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<tr>
<td>Total Index</td>
<td>13.5 (6.0)</td>
<td>13.7 (6.1)</td>
<td>13.2 (5.8)</td>
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<td>Decayed Teeth</td>
<td>4.4 (4.1)</td>
<td>4.5 (4.3)</td>
<td>4.3 (3.8)</td>
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<td>Filled Teeth</td>
<td>3.1 (3.7)</td>
<td>3.1 (3.7)</td>
<td>3.0 (3.7)</td>
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<td>Missing Teeth</td>
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<td>6.3 (4.8)</td>
<td>6.0 (4.9)</td>
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Table III. Association of selected factors with poor oral health (DMFT index above the mean, moderate or advanced periodontal disease, and/or presence of candidacies)

<table>
<thead>
<tr>
<th>Variable</th>
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<th>%</th>
<th>Adj. PR</th>
<th>p–value</th>
<th>Adj. PR</th>
<th>95%CI</th>
<th>p–value</th>
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<tr>
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<td>25–34</td>
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<td>35–45</td>
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<td>(Ref.)</td>
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