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Moran GJ, Amii RN, Abrahamian FM, Talan DA (2005). Methicillinresistant Staphylococcus aureus in community-acquired skin infections. Emerg. Infect. Dis. 11: 928-930.

Pitout JDD, Church DL, Gregson DB, Chow BL, McCracken M, Mulvey M, Laupland KB (2007).

Molecular epidemiology of CTXM-producing Escherichia coli in the Calgary Health Region: emergence of CTX-M-15-producing isolates.

Antimicrob. Agents Chemother. 51: 1281-1286.

Pelczar JR, Harley JP, Klein DA (1993). Microbiology: Concepts and Applications. McGraw-Hill Inc., New York, pp. 591-603.

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Journal of AIDS and HIV Research

Table of Contents:Volume 5Number 9September 2013

ARTICLES

Research Articles

Ocular manifestation of HIV/AIDS infection among patients receiving highly active Anti retro viral therapy (HAART) in a tertiary eye care centre Azonobi Richard Ifeanyi, Udoye Ezenwa, Tebepah Tarilah and Opubiri Ibeinmo R	322
Clients' satisfaction with anti retroviral therapy services in a tertiary hospital in Sokoto, Nigeria Oche, M. O, Raji, M. O, Kaoje, A. U, Gana, G, Ango, J. T, Okafoagu, N, Adamu, H, Oladigbolu, R. A and Umar, A. S	328
Nutritional status and KAP about HIV/AIDS among floating drug addicted and commercial sex workers in Dhaka City, Bangladesh A. K. Obidul Huq, Tanni Chowdhury, Masud Rana, Jahangir Alam, S. M. Golam Moktadir and M. Z. Manir	334
African University Students' Knowledge of HIV/AIDS and knowledge transfer Tuntufye Selemani Mwamwenda.	341
Low HIV testing among single male migrants reporting sex with a female sex worker, Maharashtra, India V. Sampath Kumar, L. Jeyaseelan, Neeta Rao, Anna Joy, M. Thenmozhi and Karen Kelley	347

Journal of AIDS and HIV Research

Table of Contents: Volume 5 Number 9 September 2013

ARTICLES

_					_		
D	00	00	W.C	h /	\rti	\sim	00
-		-a		II /-	NI LI	w.i	123

Decentralized HIV/AIDS pharmacovigilance in South Africa: Mpumalanga as pilot province for national roll-out Dheda, M.	357
Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) as God's directive Tuntufye Selemani Mwamwenda	366
Decentralized HIV/AIDS pharmacovigilance in South Africa: Mpumalanga Success & Moving Forward Dheda, M. Distefano, K. Sunduzwayo K. Williams, F and Kambafwile, H	370

Vol. 5(9), pp. 322-327, September, 2013 DOI 10.5897/JAHR2013.0238 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Ocular manifestation of HIV/AIDS infection among patients receiving highly active Anti retro viral therapy (HAART) in a tertiary eye care centre

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Accepted 14 June 2013

The pattern of ocular manifestation of human immune deficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) infection in Bayelsa state, Nigeria is presently unknown. In order to effectively control HIV/AIDS infection in the state, it is important to know the ocular manifestation of HIV/AIDS infection in this locality. The purpose of this study was to ascertain the eye manifestation of HIV infection in patients receiving highly active anti retroviral therapy (HAART). A descriptive study was carried out on all consecutive HIV infected patients including those with the advanced stage of the disease. They were all receiving highly active anti retroviral therapy at the "Heart to Heart" clinic of the Niger Delta University Teaching Hospital (NDUTH). The study took place over a period of 16 months. A detailed medical history followed by a comprehensive ocular examination was carried out on each patient, and the findings were recorded. A total of 150 HIV positive patients were examined during the period of this study. They were 57 males and 93 females, with a male to female ratio of 1:1.6. Twenty one patients with ages ranging from 8 to 66 years old presented with ocular manifestation of HIV/AIDS infection. They had a mean age of 41.48 years old (standard deviation (SD) ± 13.98). The prevalence of ocular manifestation of HIV/AIDS infection was found to be 14% (95% confidence interval (CI), 8.4 to 19.6). HIV related microvasculopathy and uveitis (each 24%) were the commonest ocular manifestation in this population followed by retrobulbar optic neuritis (19.2%) and Herpes zoster ophthalmicus (9.6%). HIV related microvasculopathy, uveitis and retrobulbar optic neuritis were responsible for over 2/3 of ocular manifestation. Herpes zoster ophthalmicus, cytomegalovirus retinitis and conjunctiva microvasculopathy were rare findings.

Key words: human immune deficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), disease, ocular, highly active anti retroviral therapy (HAART), tertiary, eye centre.

INTRODUCTION

Human immunodeficiency virus infection (HIV) and the advanced form of the disease, acquired immune deficiency syndrome (AIDS) since its first report in the United States of America in 1981 has become a worldwide pandemic, with over 33.4 million persons globally living with the disease (MMWR, 1981; Martins

and Peter, 2009). Over 90% of persons infected with the virus (HIV) live in developing countries, particularly those of Sub-saharan Africa and South-East Asia (UNAIDS, 2003). In Nigeria, HIV infection was first reported in 1986 (Mohammed et al., 1988). The epidemic has since then spread across the country like wild fire, with the national

average prevalence currently at 3.6% (Fed Ministry of Health, 2010) despite all the concerted effort recruited to combat it. HIV is a multi-systemic disease affecting various systems and organs of the body including the eye. The ocular manifestation of HIV/AIDS was first reported by Holland et al. (1982) (Holland et al., 1982). Ocular manifestation may be the primary presentation of the disease (Sahu et al., 1999). Studies have shown that 70 to 80% of AIDS patients will experience an ocular manifestation at any point in time during the course of the disease (Saraf and Ernest, 1996). The frequency and form of ocular manifestation is variable, depending on the stage of HIV infection (Jabs, 1995).

In the early stage of the disease (CD4 count > 500 cells/µl), ocular manifestations are uncommon, usually in the range of 11.9%, while in advanced disease (CD4 < 50 cells/µI) it may approach 100% (Turner et al., 1994; Cunningham and Margolis, 1993). Ophthalmic manifestations are usually non-specific in the early stage of HIV infection but later gives way to specific ocular manifestations such as microvasculopathies (for example, cotton wool spots, haemorrhages and others), and diseases (for example, eye molluscum contagiosum, keratoconjunctivitis sicca and herpes zoster ophthalmicus) as the disease progreses. As the immune system undergoes further suppression, opportunistic infections such as cytomegalovirus, cryptococus, and Toxoplasma gondii becomes obvious (Maclean et al., 1996; Ndoye et al., 1993).

The prevalence and the spectrum of ocular manifestation of HIV/AIDS differs from one environment to the other (Susan, 1995). In North West Ethiopia, Asefa et al. (2006) found that 60% of HIV/AIDS patients studied have ocular manifestations and retina microvasculopathy was the commonest ocular lesion seen (24%) (Asafe et al., 2006). Kehinde et al. (2005) in Northern Nigeria found the prevalence of ocular manifestation of HIV infection to be 12.3%, majority (69.6%) of the complications being due to Herpes zoster ophthalmicus (Kehinde et al., 2005). In Benin City, South-southern Nigeria, a prevalence of ocular manifestation of 4% was found among a group of HIV positive patients and herpes zoster ophthalmicus was the commonest, with a prevalence of 2.7% (Osahon and Onunu, 2007).

To ensure the optimal care of HIV/AIDS patients, it is important to know the ocular manifestation of HIV/AIDS infection in that particular environment. Presently, information is not available on the ocular manifestation of HIV/AIDS infection in Yenagoa, Bayelsa State, Nigeria. This study was therefore conducted to fill this gap in knowledge.

MATERIALS AND METHODS

Duration/place of study

This study took place over a period of 16 months (September, 2010 to January, 2012) at the Eye Clinic of the Niger Delta University

Teaching Hospital, Okolobiri.

A descriptive study was carried out on every consecutive HIV positive patients receiving treatment (highly active anti-retroviral therapy - HAART) at the Heart-to-Heart Clinic of the above mentioned institution. HIV positive patients referred from other units of the Hospital to the Eye Clinic were also included in this study. Their baseline data such as age, sex, and recent CD4 count were recorded in a proforma designed for the study. They were then classified according to the World health Organization (WHO) clinical staging criteria for AIDS definition. Patients that have been previously classified by the managing physician were not reclassified as the information was obtained from the patient's record. A brief ocular history was also obtained followed by visual acuity assessment and a detailed anterior and posterior segment examination. Visual acuity assessment was done by an ophthalmic nurse at a distance of 6 m using a snellen acuity chart. Those whose visual acuity showed an improvement with pin hole were referred to the optometrist for refraction. The anterior segment examination was done using a pen torch and a slit lamp biomicroscope (Haag-Strait). The posterior segment examination was done using direct and indirect ophthalmoscope (Keler) as necessary. Tropicamide (1%) dilatation was done in those whose pupil were too small for detail fundoscopy. Those that presented with tumour formation had excisional biopsy and the histology report was documented.

Consent/ethical approval

As at the time of this research, an ethical committee has not been set up for this institution. However, the recommendation of the International Committee on Ethics on Researches involving Human Subjects were strictly adhered to. Consent was obtained from the subjects by the referring physcian at the time of consultation at the "Heart to Heart" clinic.

Statistical analysis

Data was presented as frequencies, mean, standard deviation and percentages. They were analysed using the statistical package for social scientists (SPSS) version 16 and a scientific calculator.

RESULTS

A total of one hundred and fifty (150) HIV positive patients were examined during this period. They were 57 males and 93 females. Their ages ranged from 8 to 66 years, with a mean of 36.88 years \pm 10.36 SD. Of this number, twenty one presented with ocular features of HIV/AIDS infection giving a prevalence of 14.0% (95% CI, 8.4 to 19.6). They were 9 males and 12 females (Table 1). Their ages ranged from 8 to 66 years, with a mean of 41.48 years \pm 13.98 SD. The clinical staging of the HIV positive patients with ocular manifestation is shown in Table 2. Majority (85.7%) were in stage 3 of the disease while a minority (4.8%) each were in stage 2, 4 and 5 of the disease, respectively.

The ocular manifestation of HIV/AIDS in the study population is shown in Table 3. HIV microvasculopathy and uveitis were the commonest ocular manifestation, with each constituting 24% of cases seen. This is followed by retrobulbar optic neuritis and herpes zoster

Table 1. Age and sex distribution of patients in the study population.

A == (+=====)	Sex	Sex (n%)	
Age (years)	Male	Female	- Total
0 - < 10	1(4.8)	-	1(4.8)
10 - < 20	-	-	-
20 - < 30	-	-	-
30 - < 40	3(14.3)	7(33.6)	10(48)
40 - < 50	2(9.6)	1(4.8)	3(14.3)
50 - < 60	1(4.8)	4(19.2)	5(24)
60 - < 70	2(9.6)	-	2(9.6)
> 70	-	-	-
Total	9(43.2)	12(57.6)	21(100)

Table 2. Clinical staging of patients

Stage	Number	Percent
2	1	4.8
3	18	85.7
4	1	4.8
5	1	4.8
Total	21	100.0

ophthalmicus (19.2 and 9.6%, respectively). Cytomegalovirus retinitis, squamous cell papilloma, infective conjunctivitis, episcleritis and conjunctiva microvasculopathy each constituted 4.8% of cases seen. The CD4 count of patients with ocular features of HIV/AIDS infection is shown in Table 4. More than half (52.8%) of the patients have CD4 counts of less than 150 cells/µl, while 42.4% have CD4 counts of between 150 to less than 350 cells/µl.

DISCUSSION

The prevalence of ocular manifestation of HIV/AIDS infection in this study was found to be 14.1% (95% CI, 8.4 to 19.6). This is similar with the findings of Kehinde et al. (2005) in Northern Nigeria where a prevalence of 12.3%. was found (Kehinde et al., 2005). However, this is at variance with findings in Ethiopia (Asefa et al., 2006), Morocco (Lamzaf et al., 2011) and Brazil (Muccioli et al., 1994) where the prevalence of ocular manifestations was found to be 24.3, 60 and 52%, respectively. Studies have shown that the clinical presentation of HIV related diseases may be modified positively by HAART (Whit cup, et al., 1997). The patients involved in the above studies were not on HAART. Similarly, it has been found that the frequency and nature of ocular complications of HIV infection is related to the stage of the disease (Kestelyn et al., 1985; Biwas et al., 2000). Majority (85.7%) of the patients studied were in stage 3 of the

disease. These observations may be responsible for the lower prevalence of ocular complication of HIV/AIDS observed in this population.

HIV related microvasculopathy and uveitis were the commonest manifestation of HIV/AIDS infection in this population accounting for 24% (95%CI, 19.7 to 29.7) each of ocular manifestations. This is consistent with the findings of Asefa et al. (2006) in Ethiopia, Sahoo (2010) in Tanzania and Ndoye et al. (1993) in Dakar, Senegal where HIV related microvasculopathy constituted 24, 25 and 22% of ocular complications, respectively. However, our findings are lower than 50% reported by Biwas et al. (2000) in India. Jabs (1995) in his study have found that the occurrence of HIV retinopathy is related to the stage of the disease. In the early asymptomatic stage of the disease, HIV retinopathy is a rare occurrence, occurring in 3% of patients. As the disease progress to the symptomatic stage (AIDS related complex), the frequency of occurrence of HIV retinopathy increases to 34%. In advanced infection (AIDS), 50% of the patients presented with HIV related retinopathy.

The majority of our patients (85.7%) were in the intermediate stage of the disease (stage 3). This may explain why the occurrence of HIV related retinopathy is lower than that reported by Jabs in more advanced stage of the disease. Uveitis is not uncommon in HIV infection (Pathanapitoon et al., 2008; Mwanza, (2001). It was responsible for 24% of ocular manifestations in this population. This is similar with 25% recorded by Nwosu et al. (1996) in Eastern Nigeria and at variance with 7.4 and 15.8%, respectively reported by Asefa et al. (2006) in Ethiopia and Ebano et al. (2007) in Cameroon, respectively. The causes of uveitis in this study were determined clinically. Majority (60%) of the uveitis were presumed to be due to toxoplasmosis while in the remaining (40%), the cause of uveitis was not determined because of absence of appropriate laboratory backup and poor patient compliance to follow up.

Retrobulbar optic neuritis is a common complication of HIV infection and can be a first sign of HIV infection (Alimanovic and Ibisevic, 2007; Liu et al., 2005). In our study, retrobulbar optic neuritis was responsible for 19.2% (95% CI, 2 to 36.2) of the ocular complications. Half (50%) of the patients were unilaterally blind while the remaining half (50%) were bilaterally blind. In Lagos, western Nigeria (Akinsola et al., 1997), retrobulbar optic neuritis was responsible for 9.0% of the cases studied. In this era of HIV/AIDS pandemic, ophthalmologists must have a high index of suspicion of HIV associated retrobulbar optic neuritis in order to ensure early diagnosis and treatment.

Herpes zoster ophthalmicus is a commonly encountered infection among HIV positive patients (Umeh, 1998; Owoeye and Ademola-Popoola, 2003). Herpes zoster ophthalmicus was found in 9.6% (95% CI, 3 to 22) of our patients with HIV/AIDS infection. This observation is similar with 8.5 and 12.3%, respectively recorded by Ndoye et al. (1993) in Senegal and Ebano et al. (2007) in

Table 3. Ocular manifestation of HIV/AIDS infection in the study pop	ulation.
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Ocular manifestations	Number	Percent
HIV related retinopathy	5	24
Uveitis	5	24
Retrobulbar optic nuritis	4	19.2
Herpes zoster ophthalmicus	2	9.6
Cytomagalovirus retinitis	1	4.8
Squamous papiloma of the conjunctiva	1	4.8
Infective conjunctivitis	1	4.8
Bilateral episcleritis	1	4.8
Conjunctiva microvasculopathy	1	4.8
Total	21	100.0

Table 4. CD4 count of the study population.

CD4 count (cells/µl)	Number	Percent
0 - < 50	4	19.2
50 - < 100	3	14.4
100 - < 150	4	19.2
150 - < 200	2	9.6
200 - < 250	2	9.6
250 - < 300	4	19.2
300 - < 350	1	4.8
> 350	-	0
Not available	1	4.8
Total	21	100.0

Cameroon. However, our finding is higher than 6.2 and 5.0%, respectively recorded by Georgis et al. (2007) in Addis Ababa and Soumendra (2010) in Tanzania.In northern (Kehinde et al., 2005) and eastern (Nwosu et al., 1996). Nigeria, 69.6 and 75%, respectively of the patients with HIV/AIDS infection presented with herpes zoster ophthalmicus. In Lome, Ayena et al. (2010) reported that herpes zoster ophthalmicus was the second commonest ocular manifestation of HIV infection (19.6%). The disparities noted above may be due to individual patient's intrinsic factors and the fact that they were at different stages of immune supression in different population groups studied. The patients in our study and those in Lome were at different stages of treatment with highly active anti-retroviral therapy (HAART), while the ones in northern and eastern Nigeria as far as we know were not. The lower incidence of Herpes zoster ophthalmicus in our study compared to the ones in northern and eastern Nigeria may be due to the effect of HAART.

Even in the era of HAART, cytomegalovirus (CMV) retinitis has remained an important cause of ocular morbidity and a predictor of HIV mortality (Lai et al., 2011). However, CMV retinitis was a rare ocular complication of HIV/AIDS infection in this study and was responsible for 4.8% (95% CI, 1 to 9.4) of cases. This is

similar with the findings of studies in Ethiopia (Georgis et al., 2010) and Tanzania (Soumendra, 2010) where CMV retinitis was responsible for 6.2 and 7.2%, respectively of ocular complications of HIV/AIDS infection. However, studies in Brazil (Muccioli et al., 1994) and Thailand (Ausayakhun et al., 2003) have reported a higher frequency of occurrence of CMV retinitis of 25 and 33%, respectively of ocular complications studied. Cytomegalovirus retinitis is known to occur in patients with profound immune-suppression, usually with CD4 count of < 50 cells/µ³ (UNAIDS, 2003; Labetoulle et al., 1999; Jacobson et al., 1997). In our study, 80.8% of the patients have a CD4 count of greater than 50 cell/µ and were all on HAART regimen. Spontaneous resolutions of CMV retinitis have been reported in patients with increased CD4 count related to HAART therapy (Whitcup et al., 1997; Autran et al., 1997). These observations may be responsible for the lower incidence of CMV retinitis in our study population.

One of the patient (4.8% in our study of ocular complication) presented with bilateral squamous cell papiloma of the conjunctiva confirmed by excisional biopsy of that eye (OD). The CD4 count at presentation was 8 cells/mm³. On follow up, the squamous cell papiloma on the unoperated left eye underwent gradual involution until it spontaneously resolved after several months on HAART therapy. On follow up, we discovered a recurrence of the squamous cell papiloma on the unoperated left eye. Investigation revealed stoppage of HAART regimen for a period of few months. Squamous papilomas are known to be caused by infection with the human papiloma virus (HPV) (Jack JK, 2007). This observation may suggest that squamous cell papiloma of the conjunctiva may be a manifestation of a nonopportunistic infection of the conjunctiva caused by HPV.

However, further studies are needed to confirm this observation.

Infective conjunctivitis, episcleritis and conjunctiva microvasculopathy are rare ocular manifestation of HIV/AIDS infection as recorded in this study (4.8% each of ocular complications). This is similar with findings of

studies in Nepal (Jabs, 1995) and Northern Nigeria (Kehinde et al., 2005) where conjunctivitis was responsible for 1.7% and conjunctivitis and episcleritis were responsible for 6.4% of cases seen. Patients with HIV/AIDS infection may present with asymptomatic conjunctiva microvasculopathy (Saraf and Ernest, 1996). This was recorded in 4.8% of our patients with ocular lesions of HIV/AIDS infection. In a study of ocular adnexa and anterior segment manifestation of HIV infection in Makurdi, North central Nigeria, conjunctiva microvasculopathy was the commonest finding (Bologi and Ojiabo, Conjunctiva microvasculopathy present microaneurysms and segmental vascular dilatations and narrowing. The cause of these vascular changes is not clear but are thought to be due to deposition of immune complexes in blood vessels or the direct infection of conjunctiva vascular endothelium by the HIV virus (Engstrom et al., 1990).

CONCLUSSION

HIV related retina microvasculopathy, uveitis and retrobulbar optic neuritis are the commonly encountered ocular manifestation of HIV/AIDS infection (66.7%) in this population. As these diseases has potential to cause profound visual loss, control of HIV/AIDS infection in this population must pay priority attention to them. Squamous cell papilloma of the conjunctiva although not previously reported to our knowledge as one of the neoplasms associated with HIV/AIDS infection was found to be associated with HIV/AIDS infection in this population.

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Vol. 5(9), pp. 328-333, September, 2013 DOI 10.5897/JAHR2013.0247 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Clients' satisfaction with anti retroviral therapy services in a tertiary hospital in Sokoto, Nigeria

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Accepted 24 July, 2013

Patient satisfaction towards services has become a tool to gain attention and value amongst the patients as well as health care providers. Satisfied patients are more likely to comply with prescribed treatment and advice from the doctors; they are also more likely to return for additional care especially for those on long term treatment like human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS). This study aims to assess the satisfaction of people living with HIV/AIDS with services provided at anti-retroviral therapy centre in a tertiary hospital in Sokoto state, Nigeria. The study was a descriptive cross-sectional design carried out in Usmanu Danfodiyo University Teaching Hospital (UDUTH) in November, 2012. A total of 257 respondents were recruited into the study using systematic sampling. A set of semi structured questionnaire was used to obtain data from the respondents. Most of the respondents were females, Hausa/Fulani, HIV stage 2 disease and had been on Anti-retroviral therapy (ART) between 2 to 5 years. They were generally satisfied with most of the services rendered by the clinic. Dissatisfaction was expressed on only 3 components of the clinic services, home visits, the adherence unit and availability of drugs. The binary logistic regression model was able to distinguish between respondents who reported and those that have not reported satisfaction with the services of the centre; P < 0.005. Though our study shows most of the respondents were generally satisfied with services, there is still need for improvement of services in some areas where the patients showed dissatisfaction. There is a need to maintain high standards in all areas of services provided to ensure that patient optimize need to utilize the services and improve their general wellbeing.

Key words: Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), patient satisfaction, antiretroviral treatment, people living with HIV/AIDS.

INTRODUCTION

The Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) pandemic is a major public health problem with an estimated 33.33 million people living with the virus globally (Bhagat et al., 2011). It has become the greatest threat to humanity worldwide.

The first case in Nigeria was reported in 1986 and since then, it has rapidly spread to every community in the country, reaching exponential levels with a national estimate of HIV/AIDS prevalence rate of 3.7% in 2011, this translated to an estimated 3.4 million people living

with HIV/AIDS in Nigeria as at the end of 2011 (UNAIDS, 2011).

Over the past decade, the rapid expansion of antiretroviral treatment (ART) in Africa and Asia has dramatically reduced HIV-related morbidity and mortality, and transformed HIV into a chronic illness (World Health Organization (WHO), 2011). There are many antiretroviral treatment centers in hospitals across Nigeria that offers services ranging from diagnosis, staging, routine investigations treatment and routine follow-up. With all these, it still remains a challenge to achieve the universal access target of high quality of HIV/AIDS health care services and optimal patient satisfaction in many lowincome countries with the hardest hit of HIV epidemics (Wolfe et al., 2010; Reda and Biadgilign, 2012; Srikantiah et al., 2010). Patient satisfaction has been defined as the patient's "Personal evaluation of providers' ability of health care services". It reflects provider's ability to successfully deliver care that meets patients' expectations and needs (kagashe and Rwebangila, 2011).

A number of factors influence patients' satisfaction with including care services patients' demographic characteristics, physical health status, patients' personal understanding and expectations from various health care services that is, doctors, nurses, laboratory and pharmacy services (kagashe and Rwebangila, 2011). Hence, patient satisfaction with health care reflects the quality of services from the patients' perspective that supplements traditional indicators such as survival outcomes or processes of care (Crane et al., 2007). In the same vein, the measurement of patient satisfaction could help health managers come up with measures to evaluate the performance of health care delivery system in addition to identifying patients in need of additional attentions or other interventions aimed at improving their health care (WHO, 1997).

Measuring patient satisfaction will enhance appropriate communication and building of stronger health workerpatient relationship based on identified gaps and barriers to effective performance of HIV/AIDS prevention and control programs from the patients' perspective. Although, several studies have documented challenges with HIV/AIDS prevention and control programs in Nigeria (Olawookere et al., 2008), however what remains unknown is the magnitude and patterns of client satisfaction with anti-retroviral therapy services in tertiary hospitals in North Western Nigeria that have different socioeconomic and cultural beliefs from areas where studies have been reported. The Usmanu Dan Fodiyo Teaching Hospital (UDUTH) is a tertiary health facility that serves as a referral centre for Sokoto. Kebbi and Zamfara States and Niger Republic. The hospital therefore serves both urban and rural communities and registration for any ailment is unrestricted. Patients are charged according to services rendered - user fee charges.

This study aims to assess the satisfaction of people living with HIV/AIDS with services provided at antiretroviral therapy centre in Usmanu Danfodiyo University Teaching Hospital (UDUTH).

METHODOLOGY

Usmanu Danfodiyo University Teaching Hospital (UDUTH), the study center, is located within Sokoto metropolis. It is a tertiary health institution with 700 bed capacity, serving as referral center to several hospitals within the North-Western region. It offers general and specialty services to patients at the General outpatient department (OPD) and various specialty outpatient clinics including the ART clinic. The ART clinic is run by a multi-disciplinary team of specialists from internal medicine, paediatrics, public health and haematology departments of the hospital. The study was a descriptive cross-sectional design carried out in November, 2012. The study population comprised of People Living with HIV/AIDS (PLWA) attending the ART clinic of the Teaching Hospital (UDUTH). Using the formula for cross sectional study (Kirkwood and Sterne, 2003) and a prevalence of 18.5% from a previous study (Getenet and Haileamlak, 2008), a total of 257 respondents were recruited into the study using systematic sampling technique.

The instrument of data collection sought information on respondents' socio-demographic characteristics, satisfaction with services in monitoring and evaluation unit care provider in consulting room, treatment support specialist (TSS), basic care package (BCP), adherence unit, clinic's pharmacy unit community support services (CSS) and satisfaction with laboratory services. The questionnaires were administered by trained research assistants (RAs) after obtaining informed verbal consent from the respondents. A total of 250 questionnaires were found to be suitable for analysis, giving a response rate of 97%.

The questionnaires were entered into and analyzed using statistical package for social sciences (SPSS) statistical software package version 17. Analysis of data started with description of data using mean and standard deviation for quantitative variables, counts and frequencies for qualitative variables. This was followed by inferential statistics (multivariate, logistic regression) which were used to identify the major determinants of patient satisfaction at alpha level of 0.05. Ethical approval for this study was obtained from the ethical committee of the teaching hospital. Participants were informed of the objectives of the study that participation is voluntary, that they could opt out at any stage of the interview and all information will be treated as highly confidential. Informed consent was obtained from all participants in the study.

RESULTS

The ages of the respondents ranged from 15 to 61 years with mean \pm SD of 34 \pm 9 years, while 51.4% were within the 30 to 44 years age group. Up to 75.2% of the respondents were resident in urban areas while 14.8% were from rural areas. Thirty six (14.6%) of them were students, 28.5% were civil servants, 30.1% were business men/women and farmers accounted for 22% of them. With respect to their educational qualification, 10% of them had no form of education, 24.1% had only Quranic education while 18.9% had up to tertiary level education. Majority of the respondents (64.3%) were in

Table 1. Socio-demographic characteristics of respondents.

Variable	n (%)
Age (years)	(/4)
15-29	85 (34.4)
30-44	127 (51.4)
45-59	30 (12.1)
60-75	5 (2.0)
Total	247 (100)
Mean = 34±9 years	211 (100)
,	
Sex	
Male	113 (45.2)
Female	137 (54.8)
Total	250 (100)
Tribe	
Hausa/Fulani	141 (56.4)
Igbo	44 (17.6)
Yoruba	31 (12.4)
Others	34 (13.6)
Total	250 (100)
Residence	
Urban	188 (75.2)
Rural	62 (24.8)
Total	250 (100)
Education	
None	25 (10)
Quranic	60 (24.1)
Adult education	28 (11.2)
Primary	7 (2.8)
Secondary	82 (32.9)
Tertiary	47 (18.9)
Total	246 (100)
Occupation	00 (4.4.0)
Student	36 (14.6)
C/S	70 (28.5)
Business	74 (30.1)
Farmer	54 (22)
Others	12 (4.9)
Total	249 (100)
Store	
Stage	454 (04.0)
Stage I	151 (64.3)
Stage II	72 (30.6)
Stage III	12 (5.1)
Stage IV	0
Total	235 (100)

Table 1. Contd.

Duration on art (years)	
<2	23 (11.3)
2-5	139 (68.1)
>5	42 (20.6)
Mean±SD = 4±2 years	204 (100)

stage I of the disease, followed by those in stage II (30.6%), then stage III (5.1%). About 68% of them have been on drugs for 2 to 5 years, while 20.1% have been on drugs for more than 5 years (Table 1).

Table 2 shows some of the services offered by the clinic, where 151 (61.9%) of the respondents said they have never been visited at home by any treatment support staff (TSS) and of the 93 (38.1%) that were visited, 92.5% of them said health education talk was given to them during the visit, 45.2% said supportive kits were given to them. Up to 61.9% of them said basic care (BC) packages were given to them and 60.2% (N = 145) said they have experienced out of stock (O/S) of some of the commodities supplied by the clinic. Only 1 (0.4%) of them said he would not recommend the center to others.

Table 3 shows the satisfaction of respondents with the services of the clinic, where most of them were generally satisfied with the different sections/services of the clinic. All the respondents expressed satisfaction with the clinic triage system and explanation given to them by the care providers. Dissatisfaction was expressed on only 3 components of the clinic services, with highest dissatisfaction expressed on home visits by TSS staff (13.5%), followed by dissatisfaction with the adherence unit (0.8%), then on availability of drugs (0.4%). A few of the respondents were only fairly satisfied with some of the services offered by the clinic.

Table 4 is the model of the binary logistic regression used to assess factors that determines the overall satisfaction of people living with HIV/AIDS with services provided at anti-retroviral therapy centre. The model contained five independent variables namely age, educational attainment, health education sessions. provision of supporting kit, and duration on ART. The model was statistically significant χ^2 (9, N = 172) 17.2; P < 0.005, indicating the model was able to distinguish between respondents who reported and those that have not reported satisfaction with the services of the centre. The model was able to explain between 19.5% (Cox & Snell R Square) and 29.1% (Nagelkerke R Square) of variance in overall satisfaction status of respondents and correctly classified 17.2% of cases. However, only two of the independent variables (education attainment and age) had significantly contributed to the model. The strongest predictor of satisfaction with the ART services

Table 2. Provision of some services by the clinic.

VARIABLES	Yes [n (%)]	No [n (%)]	TOTAL [n (%)]
Have you ever been visited at home by TSS staff? (n=93)	93 (38.1)	151 (61.9)	244 (100)
Was health education given by the TSS staff	86 (92.5)	7 (7.5)	93 (100)
Was any supportive kit given during their visit? (n=245)	42 (45.2)	51 (54.8)	93 (100)
Have you been given any Basic care package? (n=241)	150 (61.2)	95 (38.8)	245 (100)
Have you ever experienced out of stock (O/S) with respect to any commodity usually given at the clinic? (n=240)	145 (60.2)	96 (38.9)	241 (100)
Would you recommend this center to someone? (n=240)	239 (99.6)	1 (0.4)	240 (100)

Table 3. Satisfaction of respondents with services of the clinic.

		Satisfaction (%)			
VARIABLE	Satisfied [n (%)]	Fairly satisfied [n (%)]	Dissatisfied [n (%)]	- TOTAL (%) [n (%)]	
Satisfaction with clinic triage	243 (100)	0	0	243 (100)	
Satisfaction with courtesy of care providers	240 (99.2)	2(0.8)	0	242 (100)	
Satisfaction with explanation given by care providers	241 (100)	0	0	241 (100)	
Satisfaction with waiting time in the waiting area	240 (99.2)	2(0.8)	0	242 (100)	
Satisfaction with condition of consulting room	241 (99.6)	1(0.4)	0	242 (100)	
Satisfaction with consultation time	240 (99.6)	1(0.4)	0	241 (100)	
Satisfaction with adherence unit	245 (98.4)	2(0.8)	2 (0.8)	249 (100)	
Satisfaction with availability of drugs	243 (98.8)	2(0.8)	1 (0.4)	246 (100)	
Satisfaction with services of the pharmacy	242 (99.6)	1(0.4)	O	243 (100)	
Satisfaction with services of CSS unit	244 (99.6)	1(0.4)	0	245 (100)	
Satisfaction with home visit by TSS staff	192 (83.5)	7(3)	31 (13.5)	230 (100)	
Satisfaction with waiting time in the laboratory	243 (99.2)	2(0.8)	O	245 (100)	
Satisfaction with overall services of the clinic	241 (99.6)	1(0.4)	0	242 (100)	

Table 4. Determinants of satisfaction with TSS staff home visit.

Predictor variables	В	SE	Wald		Ci~	Exp(B)	95% C.I. for EXP(B)		
Predictor variables	В	SE	vvaiu	ui	Sig.	odds ratio	Lower	Upper	
Health education sessions	0.15	0.62	0.06	1	0.81	1.12	0.35	3.92	
Provision of supportive kit	0.29	0.34	0.73	1	0.39	1.33	0.70	2.60	
Age	-0.04	0.02	3.91	1	0.04	0.96	0.93	1.00	
Educational attainment	-1.55	0.63	5.97	1	0.01	0.62	0.46	0.73	
Duration on ART	0.05	0.08	0.42	1	0.52	1.05	0.89	1.24	
Constant	1.07	0.96	1.25	1	0.26	2.92	-	-	

SE = standard error, df = difference, sig = significance.

was age of respondents with an odd ratio of 1.96 (CI = 93 to 1.00) likelihood of being satisfied compared to other variables.

DISCUSSION

The mean age of the respondents was 34 ± 9 years,

which is similar to what was observed in previous studies (Tran and Nguyen, 2012; Devnani et al., 2012). These similarities in mean age seen at the ART clinics may reflect the fact that most people present to the clinic within the age range of 30 to 40 years. About 51% of the respondents were within 30 to 45 years age group, similar to a previous study carried out in Uyo South-east

Nigeria (Opara et al., 2007). About 35% of those enrolled into the study had attained secondary level education, which is far lower than what was reported in a previous study carried out in Vietnam (Tran and Nguyen, 2012). This is not surprising given the fact that the area of study was reported to have 50 and 70% of males and females as illiterate (National Population Census (NPC), 2008).

More than half of the respondents were females. A previous study (Olowookere et al., 2008), however reported a much higher percentage of females in their study. This higher percentage of women seen at the clinic could both be due to the fact that females are more exposed to the disease or that women are more conscious of their health than men and therefore tend to seek for medical attention more.

The respondents were generally satisfied with most of the services rendered by the clinic. All respondents interviewed were satisfied with the clinic triage system as well as explanations as given by the care providers. Similar observations were in a previous study where almost all respondents were satisfied with the manner the clinic sort out their clients (PSS-HIV, 2002; Beck et al., 1999). Satisfaction with other services such as courtesy of care providers, waiting time in the clinic/laboratory, and condition of the clinic were all rated very high. Similar findings were also reported in several studies (PSS-HIV. 2002; Beck et al., 1999; Tsasis et al., 2000; Helena et al., 2008; Bhagat et al., 2011; Karunamoorthi et al., 2009). Even though satisfaction with waiting time was rated very high in this study, it was observed to be lower in a previous study conducted in some Primary Health Centers in South Africa (Wouters et al., 2008). The higher level of satisfaction observed in this study may not be unrelated to the fact that this center is a tertiary center with more man power, thus being able to cater for larger number of patients within a reasonably short time as against the primary health Care centers (PHCs). The overall satisfaction with the clinic services was rated very high, as it was reported in a previous study conducted in India (Bhagat, 2011). These high levels of satisfaction expressed by respondents should encourage care providers and donor agencies to continue providing high quality services in order to sustain patients' satisfaction.

Conduct of health education during the visit, provision of supportive kit and duration on ART were not found to be significantly associated with respondents' satisfaction with the visit. Supportive kits that were given to clients during home visits include insecticide treated nets (ITNs), drinking water guards, condoms, plumpy nuts and action meals. From practical significance, the health education sessions, home visits and the provision of some of these items to clients go a long way to improve the compliance of patients and improve the patient — health worker relationship as it is a form of social support which was reported to be effective for the management of chronic

diseases (Redding et al., 2000), even when they are statistically not significant (Ellis, 2010). This human behavior is a three-way, dynamic, reciprocal process in which personal factors, environmental influences, and behavior interact continuously and is influenced by changes in the environment and the individual determination to desire, pursue or continue towards the desired behavior despite daunting challenges (Bandura, 1989). Patients are meant to be supported/managed by their respective family members in order for the family members to appreciate the management of the disease and provide an enabling environment devoid of stigmatization.

CONCLUSION

The overall results indicated a small effect size of 96% (odds ratio (OR) = 1.96; CI = 93 to 1.00) with P values less than 0.05 especially for age indicating both practical and statistical significance. It is however, important to note that, even though most of the respondents were generally satisfied, a small percentage of the respondents expressed dissatisfaction with some aspects of the clinic's services, especially in the area of home visits by the TSS staff and the adherence unit. This shows that despite the high level of overall satisfaction, there is still need for improvement of services in some areas especially home visits by TSS staff. This will go a long way in building the confidence of the patients and ensuring adherence to treatment guidelines.

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Vol. 5(9), pp. 334-340, September, 2013 DOI 10.5897/JAHR2013.0248 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Nutritional status and KAP about HIV/AIDS among floating drug addicted and commercial sex workers in Dhaka City, Bangladesh

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Accepted 1 July, 2013

A cross sectional study was carried out among the 100 floating drug addicted people and 50 commercial sex workers in Dhaka city, Bangladesh. About 26% of sex workers and 36% of drug addicted were aged 20 years. Only thirty six percent of the sex workers and 38% of the drug addicted were married. Among the sex workers, 50% were illiterate whereas 42.9% of the drugs addicted were primary educated. About 78% of the sex workers and 86% of the drugs addicted had monthly income ranges from TK 5,001 to TK 10,000 (1 US\$ = 80.00 TK). Among the drug addicts, 94% of the sex workers and 85% of drug addicted had knowledge on human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and more than ninety percent (94%) of the sex workers and 78% of the drug addicts had knowledge on route of transmission of HIV/AIDS. For example, they could state that HIV/AIDS can be spread through needle sharing behavior, shaving blade and unprotected sex with HIV positive partners. Majority of respondents were found to have multiple sex partners, and among them only 26% of sex workers and 21.7% of drug addicts were found to use condom regularly. The prevalence of malnutrition among sex workers and drug addicts were 52 and 62%, respectively, and mean body mass index (BMI) of both was 18.54. They (57%) were suffering from various degrees of malnutrition.

Key words: Awareness, commercial sex workers, drug addiction, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), nutritional status.

INTRODUCTION

In the present age, human immunodeficiency virus (HIV) infection is a devastating global problem (Mann et al.,

1998). More than 40 million people worldwide are now badly affected with HIV infection (Mohs et al., 1990), of

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which 90% are in the developing countries including South and Southeast Asia (Geddes et al., 1998).

Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) has also been spreading all over the world; an alarming number of people have already died with HIV/AIDS. Nowadays, HIV infection is rapidly spreading in third world countries like Bangladesh. United Nations program on AIDS (UNAIDS) estimates that as high as 12,000 HIV affected people are living all over the country. The first case of HIV/AIDS in Bangladesh was detected in 1989. However, UNAIDS estimates that the number of people living with HIV in the country may be as high as 12,000, which is within the range of the low estimate by United Nations Internation Children Education Fund (UNICEF's) State of the World's Children Report (2009). The overall prevalence of HIV in Bangladesh is less than 1%, however, high levels of HIV infection have been found among injecting drug users (7% in one part of the capital city, Dhaka) (BSSS, 2006). Due to the limited access to voluntary counseling and testing services, very few Bangladeshi's are aware of their HIV status.

Although still considered to be a low prevalence country, Bangladesh remains extremely vulnerable to an HIV epidemic, given its terrible poverty, overpopulation, gender inequality and high levels of transactional sex. The appearance of a generalized HIV epidemic would be a disaster that poverty-stricken Bangladesh could ill-afford. It is estimated that without any intervention, the prevalence in the general adult population could be as high as 2% in 2012 and 8% by 2025 (world AIDS day report, 2008).

Lack of knowledge and social norm, taboos on HIV, high prevalence of HIV infection in the neighboring countries, increased population movements both internal and external, increased number of sex workers (street/floating, brothel, hotel based) and high prevalence of STD are main factors that make Bangladesh at high risk of spreading HIV/AIDS. Crime, violence, poverty, sexual disease, inadequate health care facilities etc. are all major problems in Bangladesh. In addition to infliction of these difficulties, the entire society is now being afflicted by the drug addiction problem (National drug demand reduction strategy. 1995). Most of the drug addicts are young adults, and the number is increasing with time (Danya et al., 1996).

It is estimated that there may be as many as 4.6 million Bangladesh who use drugs, of which 91% are adolescent/youth (Family Health International, 2004). While the vast majority of drug users are male and heroin smokers, FHI estimated in 2004 that there are at least 20,000 to 40,000 injecting drug users (IDUs) in Bangladesh, of which, at least 5,000 are concentrated in Dhaka itself. Fifteen (15) out of 24 districts surveyed by

the National Assessment of Situation and Responses to upload/Opiate use in Bangladesh (NASROB, 2001) showed the presence of IDUs. A significant number of IDUs are extremely marginalized and live on the streets and out of any social structure which put them in more vulnerable situations. In the recent period, Bangladesh has a concentrated HIV epidemic among IDUs.

The last HIV sero-surveillence report (6th round, 2005) found a dramatic rise in HIV prevalence from 1.7% in 2001 to 4.9% in 2005 among injecting drug users (IDUs) in central Bangladesh. In one locality of central Dhaka, the rate of HIV infection among IDUs was found to be 8.9%. This increasing rate is a threat to the public health sector, when 10% of the total population are affected by HIV/AIDS, known as epidemic. But when 5% among the high risk group populations (such as- IDUs, commercial sex workers, men who have sex with men, track driver) are affected by HIV/AIDS, then it is considered as an alarming and epidemic condition (Islam et al., 2000). It has been observed from another study that among the HIV/AIDS high risk group populations, 4% IDUs, 0 to 2% sex workers, and 0 to 0.3% men who have sex with men, hijras are HIV positive. Among them, IDUs are most risky group populations. As IDUs are hidden part of our society, so when HIV spread among the IDUs, it means it also severely affects all spheres of life (National Research Council, 1997).

Floating drug addiction and commercial sex workers has been increasing in Bangladesh in both urban and rural community (Rabbni, 1992). There are 105,000 sex workers in Bangladesh, of whom about 100,000 are female sex workers. Among them, more than 40,000 female sex workers live in Dhaka city. Most female sex workers are adolescent or young women, with the majority aged 15 to 18 years. In most cases, female sex workers would have retired by age 30 (Alam, 2010). Young women and girls involved in commercial sex in Bangladesh are at extremely high risk of physical and sexual violence, victimization as well as a range of negative health outcomes. This vulnerable group of population often conforms to a vast range of circumstances that in turn, likely influence their risks for poor health and violence and oppression (Decker et al., 2010). The sexual life of the addicted is in a vulnerable state where risky sex behavior is common. Most of the addicted usually have unprotected sex with multiple partners, which ultimately results in their suffering from sexually transmitted diseases and even from HIV infection (World Health Organization (WHO), 2002).

However, it has been realized that drug addiction and HIV/AIDS has been recognized and considered as most damaging National Health and social problems, therefore it should be addressed immediately. Considering these facts, the objectives of the present study has attempted

to address the socio-demography, HIV/AIDS awareness and risk factors among drug addicted and sex worker in Bangladesh.

METHODS AND MATERIALS

Study design

A cross sectional purposive study was carried out (aged 19 to 45 years) among 100 drug addicted and 50 sex workers from different parts of the Dhaka city during July to December, 2012. They were taking different types of drugs, principally using Yabba, heroin, cannabis, phensedyl, (codeine, ephedrine and promethazine), tidigesic (buprenorphine) and pethedine injections. The inclusion criteria of participants of drug users are addicted from at least five years and taken at least one type of drug use regularly. The sex workers included those who stayed day and night on the road sides and parks, and regularly engaged in sexual activities at least one year.

Development of questionnaire

A semi-structure questionnaire was developed, containing both closed and open questions in accordance with the study objectives to obtain relevant information such as socio-demographic conditions, anthropometrial, drugs and sexual lifestyle, HIV/AIDS related information etc. All questions were designed, pretested with another city, modified and resettled to obtain and record information easily. Any modification necessary were then made and a final recoded, pretested questionnaire was drawn up. Well trained health workers (5 males and 3 females) were recruited from Dhaka University Hospital to collect the information appropriately. The data was validated by a supervisor at every five sample as a repeated survey on the next week.

Anthropometric assessment

The anthropometric data were collected based on standard methods. Age of the subjects under study was recorded by self report and confirmed through probing national Identity card. Measurements of weight and height were obtained from all subjects. The subjects were weighed wearing minimal cloths and bare footed. Three weight measurements were obtained using a bathroom weighing scale and the average was calculated and recorded to the nearest 0.5 kg. The height was measured with a wooden measuring board without shoes and the average was calculated and recorded to the nearest 0.1 cm. Body mass index (BMI) is the best method of measuring the nutritional status of the respondent.

$$BMI = \frac{Weight \ in \ kg}{Height \ in \ m^2}$$

Data analysis

After verbal consent of each respondents both drug users and commercial sex workers, the data were collected by interviews. The data set were first checked, cleaned and entered into the computer

from the numerical codes on the form. The data was edited if there is any discrepancy and then cleaned. The frequency distributions of the entire variables were checked by using statistical package for social sciences (SPSS 20.0) windows program. For tabular, charts and graphical representation, Microsoft word and Microsoft excel were used.

RESULTS

Table 1 shows the comparison of the background information of the selected sex workers and drug users. It has been found from the table that most of the sex workers were female and the number of male and female drug addicted were 78 and 22%, respectively. It also shows that 26% of sex workers and 36% of drug addicts were below 20 years age group. About 30% of sex workers and 10% of drug addicts were found in the age group of 21 to 25 years. Twenty two percent of sex workers and 18% of drug addicts were found in the age group of 26 to 30 and 12% of sex workers and 10% of drug addicts were found in 31 to 35, and 10% of sex workers and 26% of drug addicts were above 35 years. It was also found that 44% of the sex workers and 42% of the drug addicts had passed primary classes while only 6% of the sex workers and 22% of the drug addicts had passed secondary classes. Among the sex workers, half of them were illiterate, whereas in drug addicts, 34% were illiterate. Based on marital status, it has been found that 36% of the sex workers and only 38% of the drug addicts were married. Twelve percent of the sex workers and 46% of the drug addicts were unmarried and 18% of the sex workers and only 12% of the drug addicts were widows. But among the commercial sex workers, more than one third (34%) were divorced and it was markedly indicated that their conjugal life is very short or however many reasons appeared to break their marriage; on the other hand, only 4% of the drug addicts were divorced. The monthly family income of 78% of the sex workers and 86% of the drug addicts were found to be in the Tk 5001 to 10,000 income group, and 2% of the sex workers and 12% of the drug addicts had income within Tk 5,000 and only 20% of the sex workers and 2% of the drug addicts had income over Tk 10,000.

Table 2 shows preliminary knowledge about HIV/AIDS among the commercial sex workers and drug users. Almost 94% of the sex workers and 78% of drug addicts had knowledge on how HIV/AIDS transmitted diseases by different routes. It was observed that sex workers and drug user's knowledge about the transmission routes of HIV/AIDS or transmission is not highly satisfactory. About 86 and 78% sex workers and drug addicts were known that needle sharing is the important transmission route of HIV/AIDS. But about 22 sex workers and 28% drug addicts thought drinking water in same glass spread HIV/AIDS. However, 44, 64, 52, 88 and 92% sex workers

Table 1. Comparison of the background information of the selected sex workers and drug users.

Devenuetes	Sex	worker	Drug addicts			
Parameter	Number	Percent (%)	Number	Percent (%)		
Sex						
Male	0	0	78	78		
Female	50	100	22	22		
Total	50	100	100	100		
Age in years						
Up to 20	13	26.0	36	36.0		
21-25	15	30.0	10	10.0		
26-30	11	22.0	18	18.0		
31-35	6	12.0	10	10.0		
36-40	4	8.0	8	8.0		
41 and above	1	2.0	18	18.0		
Total	50	100	100	100		
Educational Status						
Illiterate	25	50.0	34	34.5		
Primary	22	44.0	42	42.9		
Secondary	3	6.0	22	22.6		
Total	50	100	100	100		
Marital status						
Married	18	36.0	38	38.0		
Unmarried	6	12.0	26	46.0		
Widow	9	18.0	12	12.0		
Divorced	17	34.0	4	4.0		
Total	50	100.0	100	100.0		
Per capita monthly income (Tk.)						
Up to 5000	1	2.0	12	12.0		
5,001-10,000	39	78.0	86	86.0		
>10,000	10	20.0	2	2.0		
Total	50	100	100	100		

knew the transmission route of HIV/AIDS were through the following respective means, saliva, from mothers to the fetus, transmitted via breast feeding from mother to baby, by shaving blade and transmitted by copulation with HIV/AIDS infected person.

Among the respondents, more than half (66% of sex workers and 60.9% of drugs addicted) of the respondents used condom occasionally and 26% of sex workers and 21.7% of drug addicts used condom regularly during their sexual intercourse. Only 8% of sex workers and 17.4% of drug addicts did not use condom. More than half, 78% of the drug addicts were expanding on drug almost 200

Taka daily. 16% were expanding on up to 100 Tk. Again, 6% were expanding on drug over Tk. 200 daily. On the other hand, 65.7% sex workers were expending almost 200 taka.

The social lifestyle was found to have a greater influence on drug addiction. It appeared Table 3 that among the total responses individuals, 19% sex workers and 32.4% of drugs addicted said that the symptom of AIDS appears within one year. 7.1% of sex worker and 8.1% drugs addicted said it 1 to 3 years, 31% of sex workers and 16.2% of drugs addicted said 3 to 6 years and 38.1% of sex workers and 43.2% of drugs addicted

Table 2. Comparison of knowledge regarding HIV transmission and prevention methods.

		Sex	worker	Drug addicted		
Parameter		Number	Percent (%)	Number	Percent (%)	
17 1 1 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Yes	47	94	78	78	
	No	3	6	22	12	
transionnation	Total	50	100	100	100	
	Needle sharing	43	86	39	78	
	Transmitted by saliva	22	44	9	18	
nowledge on mode of HIV ansformation ransmission routes of HIV/ADIS* se of condom	Transmitted from mother to the fetus	32	64	30	60	
Transmission routes of HIV/ADIS	Transmitted via breast feeding from mother to baby	26	52	21	42	
Knowledge on mode of HIV ransformation Total Nee Transmission routes of HIV/ADIS* Up 1 101	Transmitted by saving blade	44	88	36	72	
	Transmitted by copulation with HIV/AIDS attacked person	46	92	38	76	
	No	4	8.0	8	17.4	
lles of soundary	Irregularly	33	66.0	28	60.9	
Use of condom	Regularly	13	26.0	10	21.7	
	Total	50	100	46	100	
Transmitted by saliva Transmitted from mother to the from saliva Transmitted from mother to the from saliva Transmitted via breast feeding from saliva Transmitted by saving blade Transmitted by copulation with Final Saliva No Irregularly Regularly Total Up to 100 101-200	Up to 100	10	28.6	16	16	
Evenending manay on drug daily	101-200	23	65.7	78 22 100 39 9 30 21 36 38 0 28 0 10 0 46 6 16 7 78 6	78	
Expanding money on drug daily	>200	2	5.7	6	6	
	Total	35	100	100	100	

^{*}shows the multiple responses.

said more than 9 years.

It appeared from Figure 1 that the mean height of the addicts (male) and sex workers (female) were162.90 and 158.66 cm, respectively which are slightly above the average height of the adult (162.8 cm for male and 157.8 cm for female) and mean weight of the addicts and sex workers were

46.74 and 48.60 kg. The mean BMI of the addicts were 18.54 kg/m² which almost became normal. More than 57% of the drug addicts and sex workers were suffering from various degrees of chronic Energy Deficiency (CED), of which 14, 15 and 28% were in CED-111, CED-11 and CED-1, respectively. 39% of the addicts and sex workers

had normal BMI and 4% were overweight.

DISCUSSION

Drug addicts and commercial sex workers severely affect human society. They affect social

Table 3. Distribution of the respondents by their knowledge on times taken to appear symptoms of HIV/AIDS.

Deenenee	Sex	worker	Drug addicted				
Response	Number	Percent (%)	Number	Percent (%)			
Within one month	15	35.7	20	27.0			
1 to 3 months	10	23.8	28	37.8			
3 to 6 months	12	28.6	22	29.7%			
6 months to one year	5	11.9	4	5.4			
Total response	42	100.0	74	100.0			
No response	8	-	26	-			

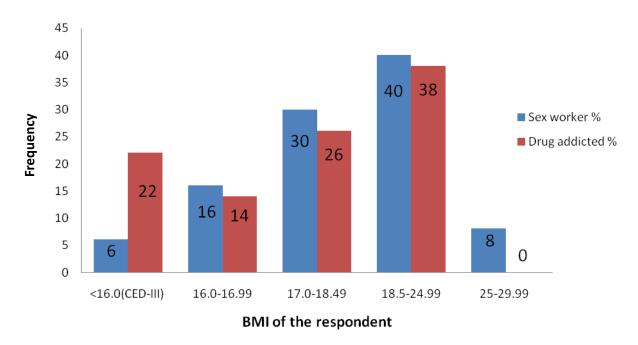


Figure 1. Prevalence of nutritional status between the sex workers and drugs user.

and environmental life of a society. So they are being addressed as national, social and health problems in Bangladesh. In this study, socio demographic status, drug habits, sexual lifestyle, knowledge and practices of risk factors about HIV/AIDS, nutritional and anthropometrical status of 100 male drug addicts and 50 female sex workers were recorded and analyzed. This study reveals that drug addicts and sex workers have poor nutritional status and they are suffering from varying degrees of chronic energy deficiency. Their drug habit also affects their nutritional status. Their high risky behavior such as unprotected sex with multiple sex workers is also present, since nutritional deficiency is the main cause of immunodeficiency. Their high risky behavior and immunodeficiency may influence susceptibility to

HIV infection. An efficient careful nutritional intervention and HIV/AIDS awareness raising program would be of particular importance in the overall management among drug addicts and sex workers, as well as of HIV infected or AIDS patients.

Only education and consciousness will not prevent HIV epidemic. As we know, USA is the most civilized industrial nation in the world. But studies show that HIV infection rate is still high. Moreover, other sexually transmitted diseases (STDs) are also increasing at an alarming rate. The annual incidence of syphilis is 130,000, gonorrhea 1.4 million, chlamydia 4 million, pelvic inflammatory disease 420,000 and genital herpes about 500,000. Muslim societies in love with Western life style are also catching up. Another important point needs

to mull over that emphasis on condoms give a false impression about the safety. Food and Drug Administration (FDA) study showed that new condoms had breakage rates of up to 9% and there was a 38% leakage rate of HIV-size particles (AIDS virus is one-fifth the size of the sperm) in the condom tested. So condoms are not totally risk-free to prevent HIV infection.

Blaming certain groups also allows societies to avoid responsibility of dealing with the epidemic. This defiance can be dangerous. Government may hide cases, fail to gather correct data or not care for people with HIV/AIDS. Officials may use figures of detected cases rather than estimated cases to downplay the level of the epidemic in the country. People at risk may be denial. They may assure a false sense of security by believing only "outsiders" or marginalized groups can become infected. Stigmatizing an AIDS patient as being sinful or deserving punishment serves little purpose. Besides the fact that many AIDS patients contracted the disease without being sinful, stigmatizing AIDS patients actually further promotes the spread of the disease.

CONCLUSION

Intravenous drug users and sex workers play a major role in spreading HIV/AIDS in Bangladesh. It could be possible to prevent HIV transmission in commercial sex by practicing protected sex that is, by using condom. In HIV prevention, condom has an important role but use of condom among half of the addicted and sex workers could be protected. We have cultural norms and values. So when we talk about HIV/AIDS and its way of prevention, then some sorts of constraints and limitations has to to be faced. But it is necessary to overcome such constraints by taking appropriate steps. It should be remember that,"AIDS kill?", bachte hole jante hobe." Drug addicted and sex workers cannot take food properly due to their addiction, floating habit, and lack of money. So they are nutritionally poor, as a result their immune system cannot develop properly so they are easily infected with HIV viruses and other communicable disease. So it is necessary to ensure their nutritional condition through proper diet. In this connection, Government and NGOs could play an important role. HIV, drug addiction and prostitution are important public health, social and ultimately national issue. So it is necessary to explore the real picture by research and other type of activities. The results of this study may uncover the real picture among the addicted people.

ACKNOWLEDGEMENT

The authors highly acknowledged a group of MPH students, Daffodil International University who help to collect the information, and the respondents of both drug addicted and commercial sex workers who gave the knowledge about HIV/AIDS and personal information.

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Journal of AIDS and HIV Research

Full Length Research Paper

African University Students' Knowledge of HIV/AIDS and knowledge transfer

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Accepted 23 July, 2013

The objective of African University students' knowledge of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) and transfer of knowledge sought to examine the extent to which African university students are knowledgeable about HIV/AIDS transmission, infection and prevention, and its impact on sexual behaviour change. Descriptive statistics in the form of frequency, percentage and chi-square were used as method of data analysis. The sample comprised 366 participants drawn from three universities located in Kenya, South Africa and Tanzania. The results showed that the level of HIV/AIDS knowledge among the participants was very high, and that such knowledgeability had an impact on participants' sexual behaviour change. It was concluded that such findings serve as reinforcement to the concerted effort in HIV/AIDS public education. Such effort ought to be kept in place, particularly for the fact that there are still some misconceptions about HIV/AIDS which call for timely intervention.

Key words: Sexual behavior change, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) infection, HIV/AIDS knowledgeability, transfer of learning, African students.

INTRODUCTION

Acquired immune deficiency syndrome (AIDS) is a condition that dis-empowers the body immune system from fighting diseases (Summerfield, 1990; Wikipedia, 2013). The presence of human immunodeficiency virus (HIV) can be confirmed by use of test. If the test results are positive, it means the person is HIV positive, meaning that the person is infected and capable of transmitting it to others. According to Naswa and Marfatia (2010) an adolescent contracts HIV once and remains infected and infecting so long as he/she lives. At such stage, the person has not as yet reached the stage of AIDS, though she or he has commenced moving in such direction. Along with this, he/she is not yet vulnerable to opportunistic diseases.

In many parts of the world, HIV/AIDS has attained the status of pandemic, which means large areas are affected, and HIV/AIDS continues spreading (Kibombo et al., 2007; Ebeniro, 2010; Janckie et al., 2011). In this regard,

Facente (2001) warns that, whereas there has been a visible decline of the rate of HIV to AIDS, there has been an increase in the contraction of HIV/AIDS.

Since HIVAIDS is not curable though manageable, prevention remains the only surety for combating it; hence, the motivation for the numerous studies on HIV/AIDS knowledge, attitudes, beliefs and perceptions. Moreover, the present investigation is informed by the stated motivation, as well as the many studies undertaken in the quest for a relief, as far as HIV/AIDS is concerned. Macintyre et al. (2004) pointed out that HIV risk perception is considered an important antecedent for one's adoption of protective behaviour, in so far as contracting HIV/AIDS is concerned. Njogu and Martin (2003) argue that, given the challenge of HIV/AIDS that adolescents encounter in their present and future life experience, it is vital that their awareness of the risks associated with sexual behaviour is made abundantly

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clear, and the corresponding transfer of such awareness to real life experience as expected.

Van Wyk (2006) reported of an investigation whose objective was to examine university students' perceptions, attitudes and awareness towards HIV/AIDS at a South African University in the Northwest Province. The study was based on a sample of 290 students whose age ranged from 18 to 23 years, both males (41%) and females (59%). The results showed that the majority of participants were knowledgeable about HIV/AIDS. While the majority of participants had a knowledge that was quite detailed regarding HIV/AIDS transmission and prevention, a small number of participants were not that well informed, moreover there were others who denied the existence of HIV/AIDS.

Tagoe and Aggor (2009) advanced the argument that many university students in Africa are not that well informed about HIV/AIDS (Katjavivi and Otaala, 2003). As a matter of fact, many university campuses provide an environment that is conducive to the contracting and transmission of HIV/AIDS (Tagoe and Aggor, 2009). Such assertion is supported by the following factors: The age at which students are at university ranges from 19 to 49 which is the cohort for the large age group contracting HIV/AIDS both in Africa and other parts of the world; rise in the students population comprising African and international students; transactional sex among male and female students; use of alcohol and drugs among students which predisposes them to engage in sexual activity that might lead to HIV infection.

Based on this understanding, Tagoe and Aggor (2009) carried out a study on the university students' perceptions, attitudes, knowledge in relationship to students' sexual behaviour. The sample was based on 375 university students in Ghana. Overall, students had adequate knowledge about HIV/AIDS and its transmission through: blood transfusion, sharing sharp instruments, sex with an infected person. In terms of prevention, they mentioned the use of condom, being faithful to one uninfected partner and being abstinent.

In Namibia, De Beer et al. (2012) investigated the extent of HIV/AIDS prevalence, knowledge and attitudes among university students. The participants were drawn from the University of Namibia as well as the Polytechnic constituting a sample of 5,000 participants. The end results showed that the HIV/AIDS knowledge was good, though there were some misconceptions regarding HIV/AIDS transmission and perception of one's possible risk of contracting HIV was rather low. Some of the participants tested were HIV positive, and yet they had not been aware of such status, which is the more reason for improvement in awareness campaigns.

Ching et al. (2005) made a study of 375 Nigerian university students' HIV knowledge, perceived susceptibility for HIV and sexual behaviour. They reported that female students were more knowledgeable than their counterparts. On the other hand, male students were

more knowledgeable on the risk of HIV transmission through oral sex. The female respondents were more knowledgeable on the errorneous belief that antibiotics protect one from HIV infection. Moreover, female students knew more about needle sharing in steroid use. The overall results showed that participants' knowledge of HIV/AIDS was high, though when it came to application, some did not do well, given that they engaged in sexual activity that was rather risky and likely to lead to the transmission of HIV. They further considered themselves to be of low susceptibility to HIV/AIDS infection.

Ebeniro (2010) aimed at examining the level of awareness of HIV/AIDS among university students in Nigeria. Participants constituted the largest population of those infected with HIV/AIDS. Moreover, the participants comprised those who engaged in risky behaviour, drug addiction and premarital sex, all of which are likely to increase the probability of being HIV/AIDS infected. The sample comprised 162 females and 162 males, and their age range was 20 to 24 years drawn from three universities. The results showed that the difference in gender perceptions of HIV/AIDS were associated with socio-economic factors, culture and tradition In response to the behaviour aspects of the questionnaire, 89% were aware that HIV is transmitted sexually; 81% knew that HIV could be contracted as a result of using unsterilized equipment; 89% were aware about transmission through contaminated blood or through injection. There were 31% of the participants who had misconceptions, as they were of the view that HIV/AIDS could be contracted as a result of physical contacts, kissing, hugging and hand shake with an infected person. There were 6% of the participants who did not believe that HIV/AIDS existed and had no knowledge of how it is transmitted.

The study observed that despite the presumed correlation between knowledge and transmission of HIV/AIDS, participants engaged in behaviour that predisposed them to HIV/AIDS infection. For examples, they did not take the necessary precautionary measure in the form of condom; freely used alcohol; they had multiple sex partners.

Odu and Akanle's (2008) study sought to investigate: the relationship between the knowledge of HIV/AIDS and students' sexual activity; different types of sexual behaviour and whether university students have a basic grasp of HIV/AIDS concepts. The sample was made up of 1,420 university students aged 15 to 30 years drawn from four universities in Nigeria. The results of data analysis showed that the majority of students were sexually active; engaged in high risk sex relationships; casual, same sex, multiple sex partners and sex in exchange for money and favours. Their knowledge of HIV/AIDS was very high. There were also misconceptions regarding the cure of AIDS. There was a significant relationship between knowledge of HIV/AIDS and their sexual behaviour.

Milanzi and Komba (2005) looked at the spread of HIV/AIDS from a different perspective. To begin with, they argued that in the last twenty years, the spread of HIV/AIDS has continued without end in sight, and therefore proposed a different approach and strategy which HIV/AIDS transmission and prevention can be brought under control by voluntary counselling testing (VCT) which were considered and ascertained to be both effective and cost effective in enhancing behaviour change among university students (Milanzi and Komba, 2005).

The objective of the study was to examine the perceptions and attitudes regarding VCT based on a sample of university students drawn from three universities and the Institute of Finance Management in Tanzania. The results showed that the use of VCT facilities was on the increase, as more students made use of the facilities; there was increase in budget for the operation of the service. As regards perceptions and attitudes, there was indication of willingness to participate in knowing more and being counselled, though when it came to being tested, there was some reluctance on the part of some students who indicated that they would engage in such exercise at a later date. The majority of participants were of the view that VCT was a useful approach tor the prevention of HIV/AIDS transmission and infection.

In summary, the review of literature shows that the majority of African university students have a sound knowledge of HIV/AIDS transmission, infection and prevention. It is also clear that the transfer of such knowledge applies to some studies, while to others it was not observed. There is therefore both correlation and no correlation between knowledge and application in their sexual change of behaviour. It must also be noted that, although the level of HIV/AIDS knowledgeability is good, there are a considerable number of university students whose knowledge of HIV/AIDS is unsatisfactory; hence the need for more HIV/AIDS public education to eliminate the existing knowledge deficit, thus the motivation for the present undertaking.

METHODOLOGY

Sample

Participants who took part in this investigation were drawn from three African universities, geographically located in Kenya, South Africa and Tanzania. Their distribution was as follows: 100 students from Tanzania: 102 from Kenya and 164 from South Africa.

Procedure

For each university, the lecturers offering a module in education administered the questionnaire to the participants. This was preceded by briefing students on what the questionnaire was all about, and that responding to the questionnaire was voluntary. As such, they were free to either respond to the questionnaire, or choose not to respond to the questionnaire. There was no report of some of the potential participants refraining from responding to the

questionnaire for all the three universities.

Measuring instrument

A questionnaire comprising 25 statements and questions commonly used for testing respondents' HIV/AIDS knowledge, perceptions, attitudes, beliefs was used. Each statement and question had three options, namely "Yes, No, Don't know". Participants were asked to tick whatever option they thought was true of their HIV/AIDS knowledge. For confidentiality purposes, respondents were advised not to write their names or name of the university affiliated to. They were, however, requested to indicate their gender and date of birth. While the questionnaire comprised 25 statements and questions. only 19 for Kenya and South Africa and 17 for Tanzania were included in the statistical analysis. This was so because there was lack of clarity in the six statements/questions they responded to, so that either way they answered would mean the answer was correct. With the Tanzanians, additional questions being excluded were because there was no response for the two questions for all the participants. It is unknown why this was so.

RESULTS

Following the scoring of the questionnaire, descriptive statistics in the form of frequency, percentage, chi-square and probability were used as displayed in Table 1. In response to sharing a cigarette with someone who has AIDS, the correct response for the three universities was: Kenya 79%, South Africa 90%, Tanzania 85% all of which were significant at p < 0.001. In response to the statement of drinking water from the same cup with an AIDS person, the response was 85% for Kenya, 93% for South Africa and 84% for Tanzania. In both countries, the χ^2 was significant at p < 0.001. Similar outcomes held true for sharing food, using the same toilet seat and sharing clothes with an HIV/AIDS person. The respondents did not think that interacting with such persons would lead to the transmission of HIV/AIDS.

In response to kissing someone with HIV/AIDS, the response was as follows: Kenya 42%, South Africa 81% and Tanzania 61%. While South Africa and Tanzania participants did not think one would contract HIV/AIDS by kissing an infected person, Kenyans were of the view that such behaviour would lead to being infected. Taking care of an HIV/AIDS person was rejected as being a source of HIV/AIDs transmission by 96% Kenyans, 77% South Africans and 68% Tanzanians, all of which was statistically significant at p < 0.001. Receiving blood transfusion from an HIV/AIDS person was accepted as a source of HIV/AIDS transmission. The same held true for having sexual relationship with an infected person. All participants did not think that mosquito bites and shaking hands with an infected person would lead to contracting HIV/AIDS.

Responding to the statement that there is a cure for AIDS was rejected by 80% Kenyans, 70% South Africans and 88% Tanzanians, and the rejection was statistically significant. HIV/AIDS being God's punishment for engaging in sex out of wedlock was rejected by 51%

Table 1. Participants' correct responses frequencies, percentage, Chi-squares and probability N = 366.

No.	Statement	Kenya N = 102				South Africa N = 164				Tanzania N = 100			
NO.		Freq.	%	χ²	Р	Freq.	%	χ²	Р	Freq.	%	χ²	Р
2	Sharing cigarette with AIDS person	81	79	97.5	0.001	148	90	245	0.001	85	85	115	0.001
3	Sharing a cup with AIDS person	87	85	123.6	0.001	150	93	253.7	0.001	84	84	121	0.001
4	Sharing food with infected person	100	98	121.6	0.001	156	95	290.7	0.001	87	87	135.5	0.001
5	Using same toilet seat AIDS person	88	86	125.7	0.001	143	87	207	0.001	85	85	121.7	0.001
6	Kissing an AIDS person	43	42	32	0.001	133	81	173	0.001	61	61	43	0.001
7	Taking care of AIDS person	98	96	81	0.001	127	77	185.6	0.001	68	68	47.6	0.001
9	Sharing clothes with AIDS person	93	91	153.9	0.001	138	84	201	0.001	77	77	102.7	0.001
10	Blood transfusion from AIDS person	102	100	136	0.001	150	91	264	0.001	100	100	136	0.001
11	Having sex an infected person	102	100	120.5	0.001	149	91	255	0.001	100	100	136	0.001
12	Shaking hands with AIDS person	98	96	152.5	0.001	149	91	252.5	0.001	-	-	-	-
13	Mosquito bite	88	86	108	0.001	76	46	59.6	0.001	-	-	-	-
14	There is no cure for AIDS	82	80	94.8	0.001	114	70	125.7	0.001	88	88	76.7	0.001
NI-		Kenya N = 102			South Africa N = 164			Tanzania N = 100					
No.	Statement	Freq.	%	χ²	Р	Freq.	%	χ²	Р	Freq.	%	χ²	Р
16	AIDS is punishment for engaging in sex outside marriage	52	51	14.5	0.001	92	56	43.5	0.001	71	71	68	0.001
17	AIDS persons should be avoided	94	92	113.4	0.001	115	70	117	0.001	80	80	102	0.001
21	Stand a chance of	56	55	21	0.001	33	20	42.7	0.001	22	22	8.6	0.001
21	Contracting AIDS?												
22	Careful in relationship with gender counterpart to avoid AIDS	98	96	80.5	0.001	144	88	240.9	0.001	73	73	74.5	0.001
23	Should AIDS children be in the same school with those who do not have AIDS?	73	72	73	0.001	105	64	86	0.001	67	67	70	0.001
24	Would you sleep with an AIDS person?	43	42	44.4	0.001	92	56	77	0.001	49	49	23	0.001
25	Would you sit next to an AIDS person?	83	81	207	0.001	143	87	219	0.001	67	67	57	0.001

Kenyans, 56% South Africans and 71% Tanzanians. The rejection by both Kenyans and South Africans was marginal, implying that those accepting the statement were close to those who disagreed with statement. Avoidance of HIV/AIDS persons as much as possible, as a means of prevention from contracting infection was rejected by all the three sets of participants. The scores in percentage were: 92% Kenyans, 70% South Africans and 80% Tanzanians.

Participants were asked whether they thought there was a chance of their being infected with HIV/AIDS, to which a large number from South African and Tanzanian participants responded negatively. This means that they did believe that it was possible for them as individuals to contract HIV/AIDS. The response from Kenyan participants

was marginally positive. In response to whether participants on the basis of their HIV/AIDS awareness or knowledge were careful in their relationship with members of the opposite sex, the positive responses were as follows: Kenya 96%, South Africa 88% and Tanzania 73%, all of which were statistically significant. This was interpreted to signify the transfer of knowledge to sexual behaviour change. Statements and questions relating to sleeping with and sitting next to a person with HIV/AIDS, as a source of infection were rejected by all participants. HIV/AIDS children going to the same school was accepted by South African participants and rejected by both Kenyan and Tanzanian participants.

In summary, the analysis of data has shown that the majority of participants from the three

universities had a good knowledge of HIV/AIDS transmission, infection and prevention; though this does not rule out the misconceptions observed among those who were successful and those who did not do so well on the questionnaire. The analysis has further shown that there was transfer of knowledge inasmuch as the number of successful candidates in their knowledge of HIV/AIDS was comparable to those who indicated that they were careful in their relationship with members of the opposite sex, for the purpose of guarding themselves contracting against HIV/AIDS.

DISCUSSION

This investigation sought to establish the extent

to which African university students in Kenya, South Africa and Tanzania are familiar with knowledge relating to HIV/AIDS. The investigation further sought to establish whether knowledgeability on HIV/AIDS was transferable to sexual behaviour change among the participants. Both aspects of the investigation were confirmed so far as African university students had a good knowledge of HIV/AIDS. Similarly, the investigation showed that there was transfer of learning, since students indicated, in all the three institutions of higher learning, that they were careful in their sexual behaviour in relationship to their gender counterparts. Such findings are both comparable and in contrast with what has been reported in the literature review. In terms of comparativity, there are researchers who have reported similar findings, as what has been observed in this investigation. For example, Van Wyk (2008) studied undergraduate students' knowledge, perceptions and attitudes in the North-West Province of South Africa and concluded that, participants were quite detailed in their knowledge of HIV/AIDS transmission and prevention. In Ghana, Tagoe and Aggor (2009) presented a contrast in that the sample used did not show that they were well informed about HIV/AIDS.

De Beer et al. (2012) reported that Namibian university students were considered good in their HIV/AIDS knowledge, though there were some misconceptions among some of them. Ebeniro (2010) made a study of university students from three Nigerian universities and concluded that their knowledge of HIV/AIDS was very high. Similar results were reported in an investigation carried out by Odu et al. (2008) in Western Nigeria. These examples are adequate to show that their findings were in harmony with the present investigation findings.

In terms of correlation between knowledge of HIV/AIDS and its application, there are studies that found similar results and those that did not observe such correlation. For example, Odu and colleagues reported a significant correlation between knowledge of HIV/AIDS and its transfer to sexual behaviour change. Ebeniro did not observe such a correlation. According to Davis et al (2007) a high knowledge of HIV/AIDS did not serve as a deterrent for engaging in high risk sexual behaviour among university students to the point that they did not believe in the use condom for safe sex. Given the low number of studies showing a correlation between HIV/AIDS and transfer of knowledge for sexual behaviour change makes the present investigation a contribution to knowledge.

Conclusion

The objective of this investigation was to establish the extent to which African university students are know-ledgeable about HIV/AIDS, and how such knowledge impacts on their sexual behaviour change. This was confirmed by the high level of HIV/AIDS knowledge they have in their possession, and that such knowledge has

an impact on sexual behaviour change, given that they expressed their being careful in their inter-relationship with members of the opposite sex, solely on the basis of avoiding contracting HIV/AIDS.

The results of this investigation have several implications in the efforts for the prevention of the spread of HIV/AIDS. With such knowledge, it is anticipated that African university students and many others will guard against being infected. This is particularly so in view of the fact that there is so far no cure for AIDS, and the only option left is that of prevention. Unlike many other studies, this investigation has shown that HIV/AIDS knowledgeability is correlated to applying knowledge to sexual behavior change. Such findings offer hope to those engaged in HIV/AIDS public education that, their effort is not in vain, as it does bear fruit, notwithstanding the research which has reported to the contrary. The findings further draw attention to the fact that, though the level of knowledge is high, there are still bottlenecks, where there are misconceptions, for which there is need for more refined effort and strategies for halting the spread of HIV/AIDS.

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academic Journals

Vol. 5(9), pp. 347-356, September, 2013 DOI 10.5897/JAHR2013.0256 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Low HIV testing among single male migrants reporting sex with a female sex worker, Maharashtra, India

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Accepted 26 July, 2013

Most parts of India have a high level of circular migration, with people migrating to urban areas for work whilst maintaining contacts with their family members in their villages. In India, an estimated 40% of the 2.1 million people living with human immunodeficiency virus (HIV) do not know that they are infected. The aim of the paper is to describe and present the factors associated with HIV testing and counseling among the single male migrants in Maharashtra, India. This study covers 4,595 single in-migrants. Information was collected using a Structured Interview Schedule covering demographic, socioeconomic profile, sexual history, knowledge, behaviour, and HIV testing. Of the total migrants, 1,814 (52%) reported having had sex with female sex worker (FSW) in the last year. Of these migrants, 80% have not had HIV testing ever. However, there has been no HIV testing in 89% of the migrants who had sex with people other than sex workers. As compared to younger migrants (≤24 years), older migrants were less likely not to test for HIV. Awareness of HIV testing and counseling services and exposure to an HIV prevention intervention program were significant. HIV prevention campaigns and counseling and testing strategies must take into consideration that migrants come from various parts of the country and have different linguistic, social and cultural backgrounds.

Key words: Human immunodeficiency virus (HIV) testing, migrants, access to health services, prevention program.

INTRODUCTION

Most parts of India have a high level of circular migration, with people migrating to urban areas for work whilst maintaining contacts with their family members in their villages. Migrants bear a heightened risk of acquiring human immunodeficiency virus (HIV), which results from the environment in which they work and live, including separation from family and spouse for long periods of isolation, and social norms in large migrant communities

(Ford and Chamrathrithirong, 2007; Saggurti et al., 2009; Singh et al., 2006).

In India studies have documented HIV transmission in rural communities linked to the seasonal return of migrant males (Gangakhedkar et al., 1997; Halli et al., 2007), providing evidence that inter-state migration in India could fuel the HIV epidemic, by moving it from high-risk groups in high-prevalence states to the home districts of

migrants. A study conducted in rural Jharkhand of India reported migrants having sex with sex workers and with casual female partners in their hometowns (Shah et al., 2007). The National AIDS Control Organization (NACO) of India recently reported sentinel surveillance data (2008 to 2009) that showed an increase in HIV prevalence in northern states such as Uttar Pradesh, Odisha, West Bengal, Madhya Pradesh, Bihar, Gujarat and Rajasthan (NACO, 2010), all of which have high net out-migration. A large study conducted in a sub-set of these states (Uttar Pradesh, Bihar and Odisha) showed a strong association between migration and HIV (Saggurti et al., 2011). The majority of these migrants go to Maharashtra, which is an industrialized state with opportunities for employment.

HIV prevalence among India's 200 million migrants in India is estimated as 0.99% (NACO, 2010). Based on evidence generated through pilot programs with migrant groups, India's National AIDS Control Program (NACP) focuses strategically on the estimated nine million short-stay migrants who are considered to be most vulnerable to HIV infection (NACO, 2010), supporting prevention programs at migration sources and destinations throughout the country, including HIV counseling and testing. HIV testing is a critical gateway to prevention, care and treatment services, and knowledge of HIV status among HIV-infected persons has consistently been associated with reduced HIV-transmission behaviors (Denison et al., 2008; Sherr et al., 2007).

In India, an estimated 40% of the 2.1 million people living with HIV do not know that they are infected (India National AIDS Control Organization unpublished data, 2012). While studies on access to HIV testing have been reported among other high risk groups in India (Beattie et al., 2012; India HIV/AIDS Alliance, 2009), no studies in India have documented the factors inhibiting access to HIV testing among migrant populations.

This paper describes and identifies the factors associated with HIV testing and counseling among the population of single male migrants (unmarried or living without their spouse) in Maharashtra, India. This study provides valuable information on this migrant population, and will be used to prioritize HIV prevention, testing and counseling approaches tailored to migrant populations in the state.

METHODOLOGY

This paper draws its findings from a cross sectional study in Maharashtra State, assessing the knowledge, behaviour and attitude of single in-migrants. This study was a part of the larger National Behavioural Surveillance Survey (BSS) conducted in six states in India. The survey covered 4,595 male migrants in Maharashtra, aged 15 to 49 years, who reside away from their family (irrespective of their marital status) and visit their home at least once in a year.

Sample size

A study on HIV risk behaviors among migrants in Maharashtra State reported that 12% of migrants had engaged in sex with a female sex worker (FSW) (Tata Institute of Social Sciences and Population Council, 2007). In order to estimate the number of migrants having sex with FSWs with a 95% confidence interval, a precision of 2.5% and with a drop-out rate of 10%, a sample size of 775 migrants per stratum was used. If we repeat a similar study, we may not get the same prevalence of 12%. It will vary and the variability would be around 2.5%. That is, ninety five percent of the time the estimate which we get from this study would be somewhere between 9.5 and 14.5%.

Sampling

The state of Maharashtra has a population of 112 million (Office of the Registrar General, 2011). Maharashtra comprises of six geographical divisions (a division has approximately six districts); each of these divisions was considered as a stratum. Mapping estimates for migrants in the State were used to develop a sampling frame; these estimates included information on the number and size of enumeration sites, congregation points at work sites, construction sites and place of residence by district. The mapping exercise was undertaken at each migrant site employing ethnographic walks, key informant interviews, snowballing interviews and the Delphi technique. The enumeration of migrants at the congregation points (sites where migrants congregate either for work or residence) was carried out and served as a sampling frame. A sample of 775 was allocated to each division, and based on the probability proportionate to size (PPS) method; migrants were selected from the districts covered under these divisions. Based on the sampling frame, sites (congregation points) were selected from each district. The required number of migrants was selected randomly using the random number table in the field.

Data collection

State-wide data collection was undertaken by 72 field investigators experienced in conducting behavioral surveys, and was supervised by 18 experienced researchers. Supervisors and investigators underwent four days training on the survey process and data collection tools.

Respondent recruitment

investigators approached potential respondents enumeration sites near to either the work site or the residence site. Using the sampling plan, the field investigators approached the participants by randomly selecting them from the sampling frame and were explained on the survey, and elicited information regarding age, whether they had migrated with their family, and whether they travel home at least once a year. The respondents meeting the inclusion criteria of age 15 to 49 years, migration to the place of destination without family, and travel to their home town at least once a year, were invited to participate in the survey. Prior to interviewing the respondent, the purpose of the study and the confidentiality of the information collected were explained and oral consent was taken. No incentives were provided to the participants. A suitable place was identified to conduct interviews in the field to ensure privacy.

Interview schedule

The structured interview schedule included 160 questions designed to be completed in approximately 45 min. The schedule was translated in Hindi and Marathi, which are the local languages in the study area.

Data management

Survey responses were back-translated into English. Data validation included full review of 10% of the completed interviews by survey supervisors, including spot checks (visits to the field to ascertain if people were interviewed) and response checks (reviews of completeness of the Interview Schedule and consistency of responses). Data were double-entered into a central database.

Measures

The structured interview schedule covered the following modules: socio demographic characteristics, alcohol consumption, sexual history and behavior, condom use, exposure to an HIV prevention intervention, stigma and discrimination, knowledge about HIV/sexually transmitted infections (STI), experience of STI symptoms, testing for HIV, and awareness of and accessibility to HIV-related services. The key outcome variable for this analysis is reported HIV testing. The respondents were asked if they had ever been tested for HIV. It was clarified to them before posing the question that they are not asked to state their HIV status while answering this question. Duration of migration was measured from the month and year the migrants reached their destination in Maharashtra for employment and for the purpose of analysis was categorized as less than or equal to two years and more than two years, consistent with the standard definitions used in the BSS in India. Occupation was classified as industrial worker, construction worker, self-employed, and others (sugar cane cutter, fish vendor, musician, cook, and currently not working). Exposure to an HIV prevention intervention was defined as having been contacted in the past year by a peer educator from a non-governmental organization (NGO) implementing an HIV prevention program among migrant populations. Socio demographic characteristics like age, education, duration of stay at destination, income, marital status, occupation, self risk perception, STI infection, awareness of HIV testing, and exposure to intervention, were taken as independent variables for logistic regression analyses.

Statistical methods

In the sub-population of 1,814 single male migrants (SMM) who reported having sex with an FSW in the last 12 months, we assessed the association between socio-demographic characteristics and HIV testing through bivariate (unadjusted) analyses. using chi-square tests with Yates' correction. The variables that were significant in the bivariate analyses (p ≤ 0.20) were selected for multiple logistic regression analyses. The independent variables included in the multivariable logistic regression analysis were age (≤ 24 (reference); 25 to 29; 30 to 34; 35+), level of education [no schooling; up to middle school; secondary level; and above secondary level (reference)], income [≤ Rs3000; 3001 to 5000; >5000 (reference)], occupation [industrial worker (reference); construction worker; self-employed; and others]. The dependent variable was HIV testing among SMM who reported having sex with an FSW. Statistical package for social sciences (SPSS) version 16.0 software was used to analyze the data.

RESULTS

The survey was conducted in two rounds from January to March, 2009 (Phase I, 24 districts), and October to December, 2009 (Phase II, 11 districts). A total of 4,698 (99%) individuals consented to the survey and 4,595 (97.8%) completed interviews.

Characteristics of study sample

The socio-demographic distributions of this study population are described in Table 1. Overall, 44% were young (≤ 24 years), 51% were married, and 43% had achieved secondary education or higher. The majority were industrial workers (65%), and 87% of the study population had a monthly income of Rs ≤ 5000/month. Over 60% came from states characterized by NACO as having high HIV prevalence, 29% from states with increasing prevalence, and 9% from low-prevalence states. The majority of this population was living with co-workers (62%), with small numbers reporting that they were living with a non-spousal sexual partner (8%), non-parental relatives (12%) or alone (18%). Over half (54%) reported that they had been working away from home for > 2 years. Less than quarters (22%) were hired through contractors. The behavior characteristics of the study subjects are presented in Table 2. Overall, awareness about HIV was high (94%). Over 68% were aware of a facility that provides HIV testing. Only 5% felt that they were personally at risk for HIV. Condom use varied by type of sexual partner, with 21% reporting condom use during last sex with a regular partner, compared to 59% with casual partner, 63% with a male partner, and 97% with a commercial partner. STI symptoms were reported by 19% overall. Most SMM surveyed reported never using alcohol (63%) or other addictive substances (80%); 11% reported injection drug and 6% (of 3,323 respondents) reported sex with a male partner in the last year.

Almost a quarter of the total sample (24%, n = 1,106) reported no female sexual partners in the last 12 months. Of those reporting a regular female sex partner in the last year, 44% reported additional sex partners, of which 21% reported commercial sex partners, 24% reported both commercial and regular partners, 5% were casual partners, and 3% both casual and commercial partners (Figure 1). Among those sexually active, 1,814 (52%) reported having had sex with FSW in the last year.

Correlates of HIV testing

The correlation between proportion of migrants who were not tested for HIV and age, education of migrants is presented in Figure 2a and b, respectively. There is a 'u'

Table 1. Socio-demographic and behavioral characteristics of single male migrants in Maharashtra India, by sexual history in the last 12 months.

Characteristics	Total (N=4,595)%	Client of Sex Worker (N=1,814)%	Non-Client of Sex Worker (N=1,675)%	No female partners (N=1,106)%
Age				_
15 – 19	11	4	4	34
20 – 24	33	34	20	49
25 – 29	25	29	30	12
30 – 34	17	20	24	2
35+	14	13	22	3
Married	51	51	80	6
Occupation				
Industrial worker	65	64	68	61
Construction worker	19	20	18	18
Self employed	11	11	10	15
Others	5	5	4	6
Education				
No Education	11	7	13	13
Up to middle (1st to 7th)	46	48	42	50
Secondary (8th to 10th)	32	33	34	29
Above Secondary	11	12	11	8
Monthly Income (in Rs.)				
≤3000	30	28	23	45
3001 to 5000	57	60	60	46
>5000	13	12	17	9
State of Origin (by HIV prevalence)				
High HIV prevalence	62	58	66	63
Vulnerable States (increasing HIV prevalence)	29	36	24	24
Low HIV Prevalence	9	6	10	13
Living Arrangements				
Living with non-spousal sexual partner	8	11	5	10
Living with relative (not parents)	12	12	12	11
Living with co-worker	62	59	63	65
Living alone	18	19	20	14
Duration of migration > 2 years	54	63	62	27

shape (curve linear) relationship between age and the proportion of migrants who were not tested for HIV. This indicates that the migrants who were below 30 years and above 40 years were more likely to have not tested for HIV. The r² was 80%, suggesting a significant fit. Similarly, there is a linear relationship between education of migrants and proportion of migrants who were not

tested for HIV. The r² was 93%, suggesting a significant fit. We focused the multivariate analyses on those SMM at risk for HIV based on reported sex with an FSW. The bivariate and multivariate analysis of socio-demographic characteristics of SMM who had sex with FSWs and who had never tested for HIV is presented in Table 3. The mode I included socio-demographic variables (age,

Table 2. Behavioral characteristics of single male migrants in Maharashtra India, by sexual history in the last 12 months.

Characteristics	Total (N=4,595) %	Client of sex Worker (N=1,814) %	Non-client of Sex worker (N=1,675) %	No female partners (N=1,106) %
Hired through contractor	22	19	24	24
Use of Alcohol				
Often/very often	5	7	5	4
Sometimes/rarely	32	33	41	12
Never	63	60	54	84
Use of other addictive substances				
Often/Very often	4	3	5	4
Sometimes/Rarely	16	13	21	12
Never	80	84	74	84
njection drug use in last year	11	8	14	10
Sex with Male in Last Year (n=3323)	6	6	3	10
Natch pornographic films				
Often/very often	4	8	2	1
Sometimes/rarely	51	65	42	42
Never	45	27	56	57
Condom Use				
During last sex with regular female partner	21	29	16	25
During last sex with casual female partner	59	65	55	14
During last sex with commercial partner (FSW)		97		
During last sex with male partner n=193)	63	53	73	71
History of STI				
STI symptom	19	29	12	11
Attended free medical check-up for STI	10	13	10	5
Heard of HIV or AIDS	94	98	94	85
Exposure to HIV Information in Last Year				
Billboard, poster or leaflet	86	91	84	75
Personal discussion with HIV educator	19	19	20	16
Attended a group education session	7	8	7	5
HIV risk perception chances of "person like me" being				
Very high	5	5	4	4
Moderate	13	17	11	10
.ow	29	38	25	23
low No chance	53	36 40	60	23 63
Feel personally at risk	5	9	2	2
Aware of HIV Testing Services (n=976)				
Aware that government provides testing	66	74	65	52
Aware of a facility that provides testing	68	74	73	51
HIV testing (ever)	13	20	11	5

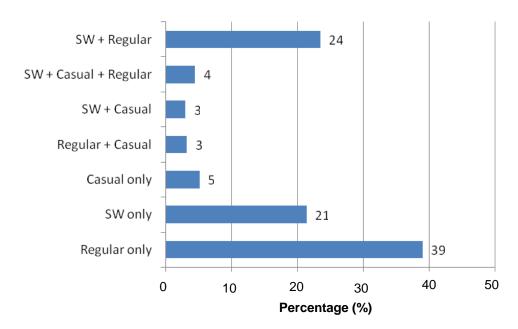


Figure 1. Mix of female sex partners reported among single male migrants in Maharashtra, India. SW-sex worker.

marital status, education, occupation, income, duration of migration), knowledge of HIV, self-risk perception, reported STI infection, awareness of HIV testing services, and exposure to an HIV prevention intervention. Among the socio-demographic correlates, only age was found to be significantly associated with HIV testing (P < 0.01). Compared to migrants ≤24 years of age (reference group), older migrants were less likely to have not tested for HIV, although this only reached statistical significance for those 25 to 29 (OR = 0.51, 95% CI 0.34 = 0.75) and 35 to 49 (OR = 0.36, 95% CI 0.20 = 0.65). Self-risk perception (OR = 1.91, 95% CI 1.22 = 2.98), awareness of HIV testing and counseling services (OR = 11.65: 95%) CI 8.31 = 16.33), and exposure to an HIV prevention intervention (OR = 4.39, 95% CI 3.23 = 5.97) were significantly associated with HIV testing among SMM.

DISCUSSION

India has shown remarkable success in limiting the spread of HIV infection in the country, and in the last 10 years has documented more than 50% decline in new HIV infections largely as a result of successfully targeting those at highest risk for HIV with HIV prevention programs (UNAIDS, 2011). The National AIDS Control Program currently targets SMM based on the likelihood that they act as a bridge population, bringing HIV from high prevalence areas where migrants work, to their wives and partners in their low prevalence home

communities.

It has been well documented that the migrant labor system, with a preponderance of male laboring jobs and long familial separations causes breakdowns in family and sexual patterns (Hunt, 1989). Risks in the population studied here were primarily related to sex with an FSW, with over half of the sexually active population reporting this activity. In Maharashtra, HIV seroprevalence among FSWs is high (7.4 %, Maharashtra State AIDS Control Society, 2009).

India has an estimated 200 million migrants, the largest concentrations of which are in Maharashtra State. In our study, the vast majority of the migrants were from high prevalence states (60%) or from vulnerable states with increasing HIV prevalence (29%). Although the contribution of migration to the spread of HIV in India, and in particular in the states with high out-migration, has not been quantified, recently published estimates of HIV incidence in India, revealed that these states which were previously low HIV prevalence, especially in Northern India have shown an increase in the number of new infections over the past two years (Ministry of Health and Family Welfare, Government of India, 2010). For example, in Odisha the number of new infections doubled between 2005 and 2010 (National Institute of Medical Statistics and National AIDS Control Organization, 2010).

A case-control study conducted among HIV testing clients in two communities in India which were both recognized as source communities for out-migration, found elevated sero prevalence among those reporting a

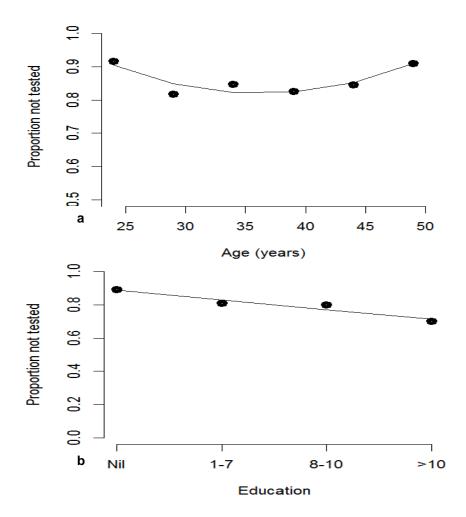


Figure 2. (a) age and (b) education of migrants and HIV not tested.

history of migration (Ganju et al., 2012). Studies have also documented the potential role of sexual networks in migrants' home communities in transmitting HIV, for both married and unmarried migrants (Ganju et al., 2012). Our study also documents sexual mixing, with almost a third (31%) of migrants reporting sex with both an FSW, and other casual or regular partners.

As would be expected, awareness of HIV testing and counseling services was strongly associated with HIV testing. Exposure to an HIV prevention intervention also had a statistically significant association with reported HIV testing. Migrants who were not exposed to an HIV prevention intervention were nearly four times less likely to be HIV tested, compared to those who were exposed to an intervention. The study also found statistically significant association between self-risk perception and HIV testing. A higher proportion of migrants who lacked self-risk perception did not report to have sought HIV testing. Our findings of low uptake (20%) of HIV testing

among SMM in India are consistent with the findings reported among migrants in the U.S. and Europe. HIV testing uptake among migrant populations ranged from 21 to 73% in-migrant populations studied in the U.S. (Huang et al., 2008; Levy et al., 2005; Lopez-Quinteroet al., 2005; Ostermann et al., 2007; Uribe et al., 2009) and from 23 to 64% in the populations studied in Europe (Dougan et al., 2005; Forbes et al., 2008; Sadler et al., 2006; Tarig et al., 2007).

In our study, the primary barriers to HIV testing among SMM were lack of awareness of HIV testing and counseling services, low self-risk perception and lack of exposure to an HIV prevention intervention. These findings are consistent with the findings of studies conducted among migrants in other countries, including Botswana (Weiser et al., 2006), Uganda (Gage and Ali, 2005), Portugal (Dias et al., 2011), and other European countries (Deblonde et al., 2010). In our analysis, we did not observe significant associations between socio-

 Table 3. Bivariate and Multivariate Analysis of Socio-demographic and Risk Variables by Reported History of HIV Testing.

	HIV not tested						
Variables	Total	Y		P value	OR	95% CI	P value
Age		N	(%)				
≤24	681	591	86.8		1.00	<u>-</u>	_
-2 25 - 29	535	402	75.1		0.51	0.34 - 0.75	0.001
30- 34	368	287	78.0	0.000	0.61	0.36 - 1.03	0.067
35-49	230	174	75.7		0.36	0.20 - 0.65	0.007
Marital status							
Married	934	713	76.3		1.00	_	_
Unmarried	880	741	84.2	0.000	0.98	0.66 - 1.46	0.932
Level of education							
Illiterate	132	117	88.6		1.62	0.80 - 3.31	0.181
Up to Middle School	864	700	81.0		1.11	0.71 – 1.73	0.641
Secondary	599	483	80.6	0.000	1.47	0.93 – 2.31	0.098
Above Secondary	219	154	70.3		1.00	-	-
Income (Rs./month)							
≤ 3000	505	388	76.8		0.93	0.55 – 1.56	0.772
3001 <i>–</i> 5000	1088	890	81.8	0.067	1.06	0.66 – 1.69	0.823
>5000	221	176	79.6	0.007	1.00	-	-
Occupation							
Occupation	1150	004	70.0		1.00		
Industrial worker	1159	904	78.0		1.00	- 0.05	-
Construction worker	369	324	87.8	0.000	1.40	0.95 – 2.06	0.092
Self employed Others	202 84	163 63	80.7 75.0		1.14 0.81	0.72 – 1.81 0.42 – 1.56	0.566 0.523
Cilicis	04	00	70.0		0.01	0.42 1.00	0.020
Duration of migration							
≤ 2 years	664	511	77.0	0.009	1.00	-	-
> 2 years	1150	943	82.0	0.009	1.31	0.95 – 1.80	0.094
Self-risk perception							
Yes	162	110	67.9	0.000	1.00	-	-
No	1652	1344	81.4	0.000	1.91	1.22 – 2.98	0.005
Awareness of HIV/AIDS							
Heard of HIV or AIDS	1776	1417	79.8	0.007	1.00	=	-
Not heard of HIV or AIDS	38	37	97.4	0.007	4.67	0.62 - 34.93	0.133
STI infection							
Reported history of STI	1295	1071	82.7	0.000	0.82	0.61 – 1.11	0.192
No reported history of STI	519	383	73.8	0.000	1.00	-	-
Awareness of HIV testing services							
Aware of services	256	89	34.8	0.000	1.00	=	-
Unaware of services	1558	1365	87.6	0.000	11.65	8.31 –16.33	0.000
Exposure to intervention							
Reported previous exposure	351	197	56.1	0.000	1.00	-	-
No previous exposure	1463	1257	85.9	0.000	4.39	3.23 - 5.97	0.000

demographic variables and HIV testing except for age.

These barriers are closely interrelated and could be addressed by implementing a behavior change communication program complemented by effective service delivery for the migrant population. Continued efforts are required to better target those migrants most vulnerable to HIV with appropriate prevention messaging. Sexual mixing must also be addressed in this population. Timing messaging and interventions to precede important holidays and other periods when migrants are likely to return home is also important. That nearly half of young SMMs reported no sexual activity in last 12 months also suggests an opportunity to reach this population before sexual risk-taking begins.

Limitations

Although this study provides valuable new information on HIV testing among SMM, the data presented must be considered in light of their specific limitations. First, data from this study were based on self-reports of participant behavior; responses to some questions could have been influenced by the participant's perception of a socially desirable response. However, the training of field investigators and monitoring the quality of the survey likely mediated this effect. Second, because the sample covered an entire state of India, the findings do not fully reflect the variation in behaviors across the state. Local context such as availability of brothels vary at different migrant sites which could influence high risk behavior. Third, because we used retrospective cross-sectional data, causation cannot be attributed to any of the observed associations.

CONCLUSIONS

This is the first study in India to document factors associated with HIV testing among migrant populations. Specifically, our study investigated the predictors of testing among SMM in Maharashtra who reported risk behaviors for HIV, and in which a high proportion (80%) reported that they had never been HIV tested. We found that the most important factors impacting HIV testing behavior related to a lack of information and awareness of HIV prevention and HIV testing. These results highlight the need to reach SMM with targeted information and behavior change communication, backed up by services that are accessible to this population.

HIV prevention campaigns and counseling, and testing strategies must take into consideration that migrants come from various parts of the country and have different linguistic, social and cultural backgrounds. Interventions should be grounded in outreach and community mobilization, empowering migrants with knowledge of HIV/AIDS and of availing them quality services. These interventions should also address the barriers faced by migrants in accessing HIV services, for example through expanded community-based and mobile HIV services. It will also be important to document the specific challenges migrants have in accessing health services, including hours of service availability, lost wages, and lack of official residence status in the locality.

ACKNOWLEDGEMENTS

The authors would like to thank James Browder, Deputy Director, Health Office, USAID for his comments and editorial support. The views expressed herein are those of the authors and do not necessarily reflect the official policy or position of the United States Agency for International Development.

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Vol. 5(9), pp. 357-365, September, 2013 DOI 10.5897/JAHR2013.0257 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Decentralized HIV/AIDS pharmacovigilance in South Africa: Mpumalanga as pilot province for national roll-out

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Accepted 8 July, 2013

The South African National Department of Health have successfully completed the implementation of a new decentralized patient-centred pilot pharmacovigilance programme in Mpumalanga province. The objective was to integrate the programme into the daily activities of healthcare providers at treatment level. Firstly, we carried out a one-day pre-training site visit to ascertain the training needs and readiness for the programme. Thereafter, we facilitated four one-day interactive pharmacovigilance training sessions for 69 healthcare providers. Further, we provided them with resource materials for successful program initiation at facility level. We then evaluated the effectiveness of the training and program through a before-after study. At baseline, 80 % of the workers reported no previous PV training while 7% reported an initial training when joining the facility, 4% received training at least once a year and 9% gave no response. Further, 67 % of the participants reported that they had no active pharmacovigilance programme at their institutions and only 16 % reported an active programme. The proportion of healthcare workers indicating an increased understanding of pharmacovigilance and awareness of the importance of reporting ADRs increased significantly after the training. A marked improvement in individualized patient management was also observed. We have successfully piloted a decentralized pharmacovigilance program in Mpumalanga province which has resulted in improved pharmacovigilance activities in ARV therapy. Stakeholders in South African pharmacovigilance have endorsed our model to be rolled out to the rest of the country.

Key words: Pharmacovigilance, decentralized, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS).

INTRODUCTION

South Africa (SA) has one of the highest prevalence of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) infected people in the world and is home to 17.8% of the reported 34 million people living with HIV/AIDS worldwide. This epidemic is a well-documented leading cause of morbidity and mortality in the country. (UNAIDS, 2010, 2011; World Health

Organization (WHO), 2006; Medical Research Council of South Africa (MRC SA), 2010) In 2004, the SA government introduced the first guidelines on free antiretroviral therapy (ART) to treat HIV/AIDS patients in their public health facilities (Allen et al., NDoH, 2004). Today, South Africa has the world's largest ART programme and by the middle of 2011 an estimated 1.9 million people in

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the country were receiving ART (Mayosi et al., 2012; Johnson, 2012; Pillay, 2012). This is approximately one-quarter of the total number of people on ART globally (WHO, 2011). Research has shown that ART increases the physical and emotional quality of life for people living with HIV/AIDS (Wouters et al., 2009; Ruud et al., 2009; Ruud et al., 2010). However, even with ART, HIV/AIDS patients face many challenges. They remain at risk of adverse drug reactions (ADRs) and other complications short and long term (Mehta et al., 2007).

ADRs are common, yet often preventable, are causes of morbidity and mortality (Lazarou et al., 1998; Pirmohamed et al., 2004; McDonnell and Jacobs, 2002). A meta-analysis of 69 prospective and retrospective studies conducted in various regions of the world found that approximately 6.7% of all hospitalisations were as a result of ADRs (Wiffen et al., 2002). Patients with HIV/AIDS and are on ART, are at increased risk due to the effect of the disease as well as the complex drug regimens that they take (Mehta et al., 2007). Consequently, the improved treatment outcomes and quality of life may be negated by ADRs especially at the start of the treatment (Wouters et al., 2009). Many patients have been reported to have toxicity concerns and on many occasions they are reluctant to start or adhere to the treatment (Mascolini et al., 2008; Padarath et al., 2006; Roberts et al., 2000; Weiser et al., 2003; Chesney, 2003). Thus, ADRs may severely jeopardize confidence in the safety of ART thereby altering patient adherence, reducing treatment efficacy and increasing the risk for the emergence of secondary drug resistance. They are a major public health problem and impose a considerable financial and economic burden on health systems (Patel et al., 2007).

Prevention and management of side effects from drugs used to manage HIV/AIDS remains a challenge to clinicians, patients, drug regulators, researchers, governments, healthcare professionals, family members and all those affected. Acute and long-term side effects and mild to severe (and sometimes fatal) reactions continue to affect patients' decisions to start treatment, continue treatment, and adhere to prescribed regimens. New adverse events and toxicities are continuously being identified as people live longer on ART.

The availability of numerous new drugs and drug combinations makes it critical to systematically monitor adverse events linked to ART. The goal of ART is to restore the body's immune system, decrease the viral load, decrease opportunistic infections and, above all, to improve the quality of life of patients initiated on treatment (Dybul et al., 2002). Therapy therefore requires intensive quality assurance in order to ensure optimal patient outcomes, and the prevention and management of side effects through pharmacovigilance (PV). South Africa has had a poorly developed PV programme since

the inception of the Comprehensive HIV/AIDS Care Management and Treatment plan (CCMT) in 2004 (RSA NDoH CCMT, 2003). At best, ADRs are only intermittently identified and systematic reporting in all provinces is rare (Dheda, 2007). Identification, intervention and effective case management of ADRs especially at treatment level has therefore become a priority in this country as it affects the required comprehensive management, care and support of HIV/AIDS patients. A robust PV system would therefore provide one of the greatest opportunities for improved patient outcomes and quality of life. South Africa is one of the developing countries that has registered its pharmacovigilance with the World Health Organisation (WHO) programme, however, the system remains much less than ideal probably due to the lack of resources, infrastructure and expertise (WHO, 2006; SPS MSH, 2011). It is critical for South Africa to have a wellstructured and coordinated pharmacovigilance programme.

Mpumalanga is a province in South Africa which according to the 2007 community survey by Statistics South Africa has a rural population in its 3 districts of Ehlazeni, Nkangala and Gert Sibande of 3,643,435 which constitutes 66% of the provincial total (Statistics RSA, 2007). According to the National Antenatal Sentinel HIV and Syphilis Prevalence survey in SA carried out between 2007 and 2009, Mpumalanga has an HIV prevalence rate averaging 34.7% (RSA NDoH, 2010). In October, 2012, the Mpumalanga provincial government estimated that 111,402 patients were on ART (Mahlangu, 2011). Like the rest of the country, this province has relied on spontaneous reporting by HCPs to the National Pharmacovigilance Centre (NPC) of the National Department of Health (NDoH) as the cornerstone of monitoring medication safety and ADR reporting especially in the HIV/AIDS treatment programme. Spontaneous ADR reporting is a passive approach which is the most practical and cost-effective method widely used in the world. It must however be properly set up and managed, sometimes in combination with other methods in order to get optimal benefits. There are a few other methods used today to report and detect ADRs including cohort studies, analyses from automated databases, randomized controlled trials and Prescription Event Monitoring (PEM).

From the number of reports we have received at the NPC in the past, what is clear is that spontaneous reporting has not worked for SA. HCPs have been expected to spontaneously report ADRs to the NPC and then wait for case management instructions from the NPC of the NDoH. This system of reporting has been marred with underreporting with the focus mainly on medicine safety rather than patient safety. It has too little focus on how side effects should be managed and above

all, the NPC lacks the resources to monitor and attend to cases of side effects reported from all the treatment sites. A dismal number of ADR reports have been received from Mpumalanga and in fact, between July and September, 2006 there were no recorded ADR reports from the province (Dheda, 2007). Previous research has attributed ADR underreporting to unfamiliarity, lack of pharmacovigilance knowledge, diffidence, lethargy, indifference and complacency by HCPs and that medical education and training may promote more effective reporting (Pérez García et al., 2011; Lopez-Gonzalez et al., 2009).

In SA generally and Mpumalanga in particular, the PV approach was neither fully designed, properly strategized nor extended to the clinical setting to take into consideration the daily management of patients in various healthcare settings. There exists insufficient infrastructure to support the PV needs of a rapidly expanding ART programme. Furthermore, most HCPs are not trained in recognising and reporting ADRs. The prevention, detection and management of side effects, establishment of causality and subsequent individual case interventions at facility level have for a long time remained a significantly weak link in ensuring quality of care, quality of life and improved patient outcomes in the SA ART programmes.

In our effort to strengthen the National HIV/AIDS PV activities, we recently successfully completed a decentralized PV pilot programme in Mpumalanga province. We identified this as the pilot province in which to initiate the programme due to the dismal ADR reporting rate and the enthusiasm the HCPs demonstrated to learn about the programme. It was our view that integration of this programme in HCPs daily activities is a missing key component in SA PV that would result not only in improved ADR reporting, but also intervention and effective case management at treatment level with improved patient outcomes. The appropriate monitoring, both clinical and laboratory, can detect ADRs at relatively early stages when they are treatable. Undetected ADRs may result in preventable morbidity and/or mortality.

In this programme, our aim was to identify gaps, provide effective training to HCPs as well as identify clusters as decentralized PV centres throughout the province. Further, we aimed at the formation of multidisciplinary committees in these clusters to meet on a regular basis to discuss individual cases as this would provide a forum at which they could convene and offer different views and expertise as it relates to specific patient cases, in order to improve patient treatment outcomes. We envisage that this programme will realise downstream benefits such as an increased number of HCPs with PV knowledge that would directly benefit both the patients and reporting HCPs.

METHODOLOGY

The training was conducted in three districts, Ehlazeni, Gert Sibande and Nkangala of Mpumalanga Province in South Africa, known for its high prevalence of HIV/AIDS and high number of patients on ART. The province comprises undeveloped and underdeveloped rural villages and farms. Initiation and evaluation of the programme was in three phases namely pre-training, training and continued monitoring and support.

Phase I

During September, 2010, we carried out a one-day pre-training site visit to the province. This visit was an opportunity to liaise with key members and stakeholders in the Provincial Department of Health (PDoH) in order to ascertain their needs and readiness for establishing our proposed PV programme. We conducted a combination of meetings, interviews and discussions with senior members of the PDoH and the districts. The success of the programme centred on maintaining a good relationship and open communication with them. After a review of our pre-training site visit, our overall hypothesis was to set up a well-structured and highly participative decentralized programme that would integrate pharmacovigilance into primary health care practice. Specifically, we envisaged that this could be achieved by firstly providing structured one-day workshops on adverse drug reactions and pharmacovigilance to nurses, pharmacists and physicians. Through these, we would establish multidisciplinary decentralized PV clusters at clinic level who going forward, would hold monthly review meetings where they can discuss suspected and/or confirmed cases of ADRs. This would result in not only an increased number of reports at clinical level, but also a measurable improvement in patient outcomes as these decentralized structures create smaller and more effective safety feedback loops. As part of the larger feedback loop and from the increased number of reports received, the NPC would then be able to monitor trends and generate important safety information which can be fed back to the reporters/clusters.

Phase II

We sent out invitations requesting that at least one doctor, one pharmacist and one nurse per healthcare facility in the province attend the training. Feedback from all facilities was only obtained in May, 2011. The training workshop is designed to be highly interactive including a variety of learning approaches such as lectures, group discussions and case studies. The trainees were introduced to the NPCs planned decentralized approach to PV and the HIV-specific ADR tool with a user guide. The latter is an ADR report form designed for the ART programme. It is used to collect demographic data, medical history, concomitant mediations, suspected/confirmed ADRs (both from clinical examination and laboratory results) and ADR outcomes. The participants also learned about clinical case review with a focus on PV as well as the formation of clusters and selection of committee members. Further, they received materials and literature such as the HIV/AIDS PV orientation and training manual and a copy of the baseline assessment tool (Appendix 1) used to assess their knowledge before the training as reference sources. These sources would assist them to identify co-morbidities and clinical complexity of distinguishing signs and symptoms of ADRs from those caused by AIDS, concomitant therapy capability and early warning indicators

by which to detect potential drug resistance cases. Furthermore, the HCPs were trained to be more proactive about asking their patients of possible ADRs and were encouraged to complete the HIV/AIDS ADR tool and fax the completed tool to the NPC. They were also given the SA ART pocket guide on prevention and management of side effects and drug interactions (Fomundam et al., NDoH, 2005). A fourth one-day training session was offered as a "mop-up" for those facilities or HCPs that were unable to attend the initial session held in their district. Central locations were chosen for the training venues to minimize associated travel and lodging costs.

Training design, instruments and analysis

We administered a structured questionnaire for data collection (available only in English). A before-after study design was employed in which HCPs completed questionnaires prior to, and immediately after the training session.

Measures/questionnaire

Data were collected on the existing infrastructure at their various facilities, staff members' knowledge and prior training in PV, as well as HCPs practice as it relates to reporting ADRs. In addition, data was collected on additional support facilities and HCPs would require from the NPC to increase the success of the programme. Participants were also asked to score on a scale of 1 to 5 (1 being "Knew nothing about the topic" and 5 being "Very knowledgeable") their confidence and knowledge of pharmacovigilance, reporting and case management.

Phase III

Three months after the training, we conducted a retrospective review of the PV reports from the provincial districts of Nkangala, Ehlanzeni and Gert Sibande. We considered the improvement of reporting patterns, quality and completeness of reports. interventions and effective case management at treatment level in the facilities. This did not involve the use of questionnaires. This paper does not report on the use of experimental or new protocols and was not set up as a study or research project but is part of the South Africa National Department of Health pharmacovigilance programme. The brief retrospective review was done internally as part of an evaluation, so as to improve patient quality of care. By its very nature, ART in HIV/AIDS treatment exposes patients to a high risk of treatment failure, possible drug resistance and consequently death, so it was felt that this vital information should be published in a reputable open source journal. Publication of such information without approval by an ethics committee is not unprecedented in operational research and has previously been allowed especially when it is in public interest to have such information published as it would probably bring benefits to the people whose autonomy may be harmed by its publication (Gollogly, 2006). The autonomy of the patients and participants in this case is protected because their identity is withheld from the data reviewers. Consequently, neither informed consent nor ethics approval was sought or deemed necessary because this is an epidemiological review in which it was impossible to identify the participants.

RESULTS

Our pre-training site visit revealed that training was requir-

ed by multidisciplinary teams of HCPs consisting of doctors, nurses and pharmacists, and that they required an on-going support mechanism and communication. It also revealed the requirement of assistance in setting up structured PV programmes, strategies of integrating ADR reporting in their daily activities and intervention and effective case management at treatment level.

For the training, a total of 69 HCPs from the three districts were available. They constituted 20% medical doctors, 44% nurses and 36% pharmacists. At baseline, 67% of the participants reported they had no active PV programme at their institutions and only 16% reported an active programme. Further, 80% of the HCPs reported no previous PV training while 7% reported an initial training when joining the facility, 4% received training at least once a year and 9% gave no response. All 69 HCPs reported previously encountering at least one or more adverse drug reactions. In a simple exercise which did not critically explore linkage to suspected drugs and/or patient outcomes, HCPs were asked whether they had encountered a particular ART ADR (from a list of 25) and their responses recorded. They were then asked whether they had reported the reaction. It was found that the HCPs would report the ADR less than half the time. Figure 1 illustrates the number of adverse drug reactions that have been encountered per HCP versus the number that have been reported.

From the baseline evaluation of additional support needed by the HCPs, we found that 80% of the participants indicated a need for PV training and reference sources. 83% said they required training on ADR intervention and management, 75% needed help with design and use of ADR report forms, 71% agreed to the need for increased communication between the district and provincial levels. 70% of the participants said they wanted feedback on ADRs reported. 67% of the participants required computer training to polish up on their skills (Figure 2)

Twenty-six PV clusters were identified and committees formed to meet on a monthly basis to discuss individual patient cases. The clusters are in the provincial districts, formed by a hospital and its surrounding feeder clinics with a designated hospital/clinic serving as a coordinating facility. Committees consist of multidisciplinary teams of healthcare professionals including doctors, nurses, pharmacists, social workers, laboratory technicians and dieticians. The trained HCPs convened cluster level meetings to introduce our HIV/AIDS and TB tool and the NPC decentralized PV programme and these have since been integrated into the facilities at that level.

After the training, the proportion of healthcare workers indicating an increased understanding of PV and awareness of the importance of reporting ADRs increased. Of the 3 participating districts, the one with more medical doctors present from the facilities came out of the training

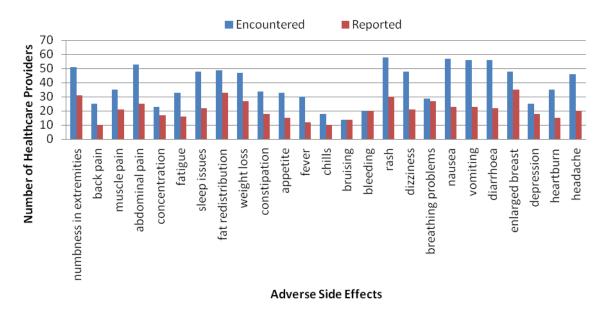


Figure 1. Number of adverse side effects encountered *versus* reported in Mpumalanga. N = 69.

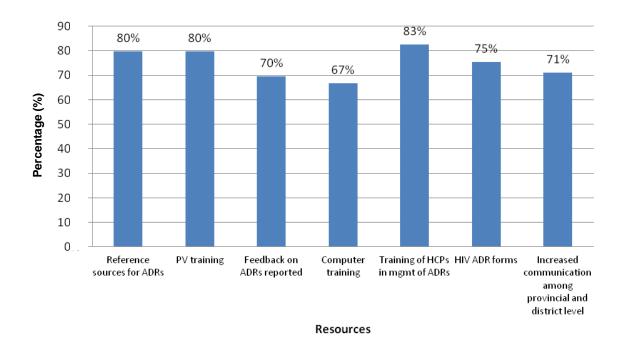


Figure 2. Areas of support needed by the Mpumalanga HPCs for the success of the PV program n = 69.

with an overall higher score of 4.16 knowledge gained compared to 3.0 at baseline (Figure 3).

In the three months following the training and formation of PV clusters and committees, the NPC received 314 completed ADR reports compared to no reports for a similar period in 2006. Of the 314 reports, 47 patients had concomitant health conditions and complications (Table

1). These conditions are becoming increasingly important as a consequence of increased life expectancy resulting from effective ART. Preventing or managing these conditions in ART often involves poly-pharmacy and hence the increased risk of drug-drug interactions. 86% of all the ADR reports were received from medical doctors from the districts. The management of these

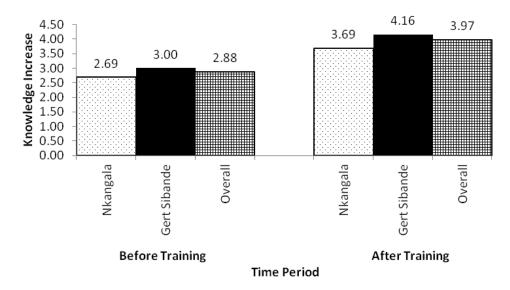


Figure 3. Increase in knowledge amongst the HCPs after training n = 69.

Table 1. Patients reported with concomitant health conditions and complications from Mpumalanga. N = 47.

Concomitant conditions	Frequency	Percent (%)
Hypertension	14	29.2
Pregnancy	15	31.3
Tuberculosis	6	12.5
Diabetes	4	8.3
Hepatitis	4	8.3
Kaposi's Sarcoma	1	2.1
Cryptococcal meningitis	1	2.1
Haemorrhoids	1	2.1
Lower Respiratory tract infection	1	2.1
Lymphoma	1	2.1
Total	48	100.0

N = 47 One patient was pregnant and had hepatitis.

ADRs should be based on the ADR/side effect, concomitant medications, concomitant disease/condition, interactions (drug-drug and drug-condition interactions), convenience, co-morbidities, and adherence. Consequently, we trained all HCPs on how to individualise treatment to enhance adherence and improve treatment success. This was facilitated by working through actual cases from various ART sites.

DISCUSSION

All HCPs have a role to play in maintaining the balance between a medicines benefit and risk. At baseline we found that 80% of the participants had no previous PV training and 67% said there was no active PV programme at their institutions. This could be a reflection of the statistics for the rest of SA and may be an indication of poor knowledge, attitude and practice amongst HCPs. Further, we found that the number of ADRs reported was very low compared to those encountered highlighting the extent of under-reporting with the spontaneous reporting system which as discussed above has been the cornerstone of the existing SA PV system.

Our baseline assessment of additional support required by the HCPs and their institutions is suggestive of, and is a confirmation of our suspicion that they suffer from the lack of resources to report, monitor and attend to ADRs. This corroborated by our observation that understanding and reporting of ADRs increased after the training supports the argument that training, on-going support, and decentralizing PV and integrating it into HCPs daily activities can improve practices with regards to reporting ADRs as well as intervention and effective case management at treatment level. This is particularly important in HIV/AIDS management programmes. The potential value of this decentralized programme is that it may result in the establishment of "mini" PV centres or clusters and this will have a positive downstream effect through increased numbers of HCPs with knowledge and increased PV bias. Consequently, both the patient as well as the reporting HCP at treatment level will benefit.

With continued support from the NPC to the Mpumalanga facilities via follow-up phone calls, faxes, emails or through phone calls as issues arise, the programme will show benefits with regards establishing causality of medications and ADRs, if required and summarising reported cases for discussion, as necessary. The new practice now is that upon completion and review of monthly PV meetings at cluster or treatment level, all ADRs are being forwarded to the NPC. This information will be reviewed for trends within the clusters, districts, and/or provinces. Should unique trends in the data provided come to the attention of the NPC, this information will be communicated to the treatment centre and appropriate feedback given. Further, the NPC will review trends and identify potential cohort studies to address specific safety concerns. General practice recommendations will be made to the programme directorates and the NDoH and other key organisations. Specific drug related safety concerns requiring regulatory considerations will be reported to the Medicines Control Council (MCC).

A strength of our brief analysis and conclusions is that the post-training assessment was done a reasonable three months after the training. We plan to have continuous interactions with the clusters to ensure the retention of knowledge and skills acquired during the training. Like the other provinces, Mpumalanga province is part of South Africa's Nurse initiated Management of Antiretroviral Therapy (NIMART) initiative intended to provide patients with a comprehensive continuum of care. Consequently, we will continue to train more nurses as well as other HCPs from various professional backgrounds such as pharmacists, laboratory technician and counsellors to mention but a few.

One limitation of the before-after design we have reported herein is that confounding is hard to rule out. In addition, one of the challenges in operational health service-based research and programmes such as ours is logistic limitations imposed by day-to-day service delivery obligations, which interfere with careful design of the assessment of a programme or intervention. (Theobald et

al, 2009). Nonetheless, the improved ADR reporting patterns we have experienced, the improved knowledge amongst HCPs and better case management we have now observed at treatment level is reassuring.

In summary, participants who underwent the training reported improved knowledge of ADR reporting and a greater confidence in identifying and managing ADRs after the training in comparison to baseline. The effects of the training were similar for all the professions of HCPs that participated.

CONCLUSION

This is the first time that such a decentralized PV programme has been introduced in South Africa to address shortfalls in the existing PV activities. The field of HIV/AIDS and TB PV/ADR management provides one of the greatest opportunities for improving patient outcomes and quality of life. We have successfully made PV an integral part of the daily activities of HCPs in Mpumalanga and as observed from the improved reporting patterns, this is expected to foster a culture of prioritizing patient safety at treatment level. This decentralised PV model constitutes a patient-centred approach by which to prevent and manage side effects. It works to establish better communication between the various healthcare disciplines providing care for each patient, capacitating the NDoH in collating aggregate data, trending of reported cases and giving valuable feedback to treatment sites, the regulatory authorities and the HIV/AIDS and TB directorates. It emphasises proper management of side effects at all levels, while prioritising disease control. A meeting that had most of South Africa's key players and stakeholders in PV in attendance has recently endorsed our model as ideal to roll-out to other provinces of South Africa. It remains our vision to cascade and expand this programme to all the other provinces, as well as to the correctional services and to the military healthcare services.

ACKNOWLEDGEMENTS

This publication and its contents are solely the responsibility of the author and do not necessarily represent the official views of any of the sponsors. We wish to thank the following:

- 1. Broadreach Health for funding the logistical and technical support for this training.
- 2. Dr. NJ Ngomane, for helping to pave the way, organisationally and administratively, to allow Mpumalanga Province to be the first to receive this comprehensive training in HIV/ AIDS pharmacovigilance.

- 3. Dr. N Simelela, South African National Aids Council, Pretoria, South Africa for supporting the initiation of this pharmacovigilance process.
- 4. Ms. Phindile Myanga, PDoH, Mpumalanga South Africa for all her efforts as liaison officer in Mpumalanga.
- 5. Drs Henry Fomundam, Bulumko Futshane and Lesego Mawela for training the participants and being resource persons.
- 6. Linda Thompson and Linh Diep of the NPC, NDoH, Pretoria for assistance and support throughout the training process.
- 7. Drs Yogan Pillay and Thobile Mbengashe, NDoH for their support throughout the process.
- 8. Dr Henry Kambafwile for his support in the finalising of this publication.

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Appendix 1. Section of the baseline assessment tool giving example of assessment questions.

NATIONAL PHARMACOVIGILANCE CENTER: DECENTRALISED HIV/AIDS & TB PHARMACOVIGILANCE TRAINING PROGRAMME PRE-TEST





INSTRUCTIONS: This test will establish your current level of knowledge about pharmacovigilance and adverse drug reactions. This will help to guide the tutors to ensure that you receive the most appropriate training to enable you to function optimally in your expanded role.

WHERE RELEVANT SELECT THE BEST RESPONSE GIVEN.	
What do you understand about pharmacovigilance?	
2. Which objective of pharmacovigilance is most important? (select one only)	
☐ To identify the safety of drugs	
☐ To calculate the incidence of Adverse Drug Reactions (ADRs)	
☐ To identify predisposing factors to ADRs.	
☐ To identify unrecognized ADRs.	
3. Which regulatory body is responsible for monitoring ADRs? (select one only)	
☐ National Comprehensive Care, Management and Treatment HIV/AIDS & TB Programme (CCMT)	
Medicines Control Council	
☐ Health Professions Council of South Africa	
☐ South African Pharmacy Council	
☐ South African Nursing Council	
South African Medical Council	
☐ National HIV/AIDS Sexually Transmitted Infections and TB Programme Unit (HAST)	
☐ National Pharmacovigilance Center	
☐ National Adverse Drug Event Monitoring Center	

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Vol. 5(9), pp. 366-369, September, 2013 DOI 10.5897/JAHR2013.0259 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) as God's directive

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Accepted 23 July 2013

Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) as God's directive aimed at investigating the tenet that HIV/AIDS is God's punishment for those who engage in sexual intercourse outside the institution of marriage. A quantitative method in the form of descriptive statistics comprising frequency, percentage, chi-square and probability was used for data analysis. The sample comprised a diverse sample of 581 high school and university students drawn from America, Kenya, South Africa and Tanzania. Statistically, the majority of participants did not subscribe to the tenet that HIV/AIDS is God's directive for punishment for those who engage in sexual behaviour outside the holy matrimony. It was concluded that such tenet must be rejected and combated through public education, as it does not contribute to the prevention of HIV/AIDS transmission and deprive those infected from seeking relief for their physical, social, and spiritual painful suffering.

Key words: Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), transmission, God's intervention. God's judgement, forgiveness, compassion.

INTRODUCTION

In many countries, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) is associated with committing sin or immorality. In Sub-Saharan Africa, religion has played both supportive and detrimental roles for those who are infected by HIV/AIDS. There are churches which for the purposes of maintaining and asserting moral ground and moral authority have made it very clear to their church members by drawing a link between sexual transgression and AIDS as sin and immorality (Mbonu et al., 2009; Kopelman, 2002; Phiri, 2004; Du Toit, 2012; Dete, 2012).

For example, church members are not united in holy matrimony before taking an HIV test. There are HIV church members who have had their membership suspended because they are considered sinners for contracting HIV/AIDS. Kopelman (2002) expresses the view that HIV/AIDS affects Sub-Saharan Africa more than any other part of the world, and yet they are least equipped to combat it. This therefore calls for intervention from nations endowed with wealth and necessary recourses. However, the HIV/AIDS infected persons may be distanced from those ready to be of assistance, because of beliefs such as it being a punishment from God for engaging in sexual activity outside marriage. "Religious versions hold that God punishes them in order to castigate, encourage virtue, warn, rehabilitate (Kopelman, 2012) or maintain some cosmic order". Along similar train of thought, Hartwig et al. (2006) point out that there exists HIV/AIDS in Su-Saharan Africa which presents hindrance to HIV/AIDS prevention and intervention

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which has been associated with faith-organizations which play a double role in the fostering and mitigating stigma.

Such religious and secular beliefs are not only untenable, but also are devoid of cogency, place blame on HIV/AIDS infected persons rather unjustly and further jeopardize the compassionate care patients deserve (Clifford, 2004; Du Toit, 2012; Mbonu et al., 2009). It is argued therefore that such views are dangerous and irrational, on account of their influencing policies and cost lives (Kopelman, 2002).

Phiri (2004) cites that there are people who regard HIV/AIDS as God's punishment for enjoying sexual immorality, and goes on to say that there are medical professional personnel who hold the view that they need not attend to HIV/AIDS patients because doing so would be interfering with God's work of punishing sinners. As a matter of fact, those who are HIV/AIDS positive also subscribe to the thought that they are punished as a result of engaging in sexual immorality (Rude 2003: Denis, 2003). Such belief does not bring relief to the HIV/AIDS infected, as it intensifies their suffering. It is proposed that attributing to God as punishing those who contract HIV/AIDS must be rejected (Phiri, 2004). Van Dyk and Van Dyk (2007) made a study of 1,352 regarding their view that HIV/AIDS was punishment. In response, the majority did not agree with the statement, but 16.7% supported that, indeed it was God's punishment for sinners. Manzell et al. (2011) cited one of the participants in their research arguing that, HIV/AIDS is but a scourge visited by God, because society has turned its back against religion and morality.

Similarly, Smith (2004) cites as follows: "This place is like Sodom and Gomorrah... are being punished for their sins. If people did not have sex here and there, if society were not corrupt, there would be no AIDS...Yes, it is God's punishment, but we have brought it on ourselves". According to Dete (2012) many people in Sub-Saharan Africa are eager to know more about HIV/AIDS and how they can get cured from such terrible disease, but the response they receive from some of their churches is that of hopelessness, as they are convinced beyond doubt that HIV/AIDS is but God's punishment for people who engage in sin. HIV/AIDS people are stigmatised through negative attitudes toward them. This is reflected by those who are not accepted in churches because they are living with HIV/AIDS; those who used to be members have been stripped of their membership; those who held important office or played an important role in church activities have been denied of such roles (Dete, 2012; Mbonu et al., 2009; Clifford, 2004; Du Toit, 2012; Hartwig et al., 2006; Kopelman, 2002).

From a biblical perspective, Barton (2012) is of the view that there will be no cure for HIV/AIDS, because such discovery will be in conflict with God's punishment for sin of immorality. On the other hand, Houdmann (2013)

argues that all diseases constitute a judgement from God. Therefore HIV/AIDS and all other diseases in the world are part of God's judgement in a world that is cursed of its creator God. On a sober note, nevertheless, Houdmann (2013) advances the argument that it is not for Christians to say a specific disease such as HIV/AIDS is God's judgement. He concludes that irrespective of the nature of disease one has, our responsibility comprises: being ministers of grace, love, mercy, forgiveness and compassion.

In summary, for the past two decades, both religious and secular organizations have had two positions on HIV/AIDS perception and interpretation. These positions are that HIV/AIDS is God's punishment for people who engage in immoral sexual activity falling outside the marriage institution. The second position has been that, HIV/AIDS patients need care, love and treatment rather than condemnation for what is referred to as immorality of sexual nature. Both positions have support from research findings that have been rather extensive during the last two decades. In view of the above, the present investigation sought to find out the extent to which a diverse sample would either support or reject the proposition that indeed HIV/AIDS is a directive from God's wrath against those who have turned against his commandment by engaging in sexual activity outside the sanctioned holy matrimony.

METHODOLOGY

The sample of the present investigation comprised adolescents drawn from high school students based in Nairobi, Kenya and university students consisting of American, Kenyan, South African and Tanzanian participants both males and females. The total number of participants added up to 581 with a distribution of 157 Kenyan high school students, 102 Kenyan university students, 164 South African university students, 100 Tanzanian university students and 58 American college students.

Measuring instrument

The questionnaire comprised one question soliciting a response on the basis of three options, namely "Yes, No, Don't Know". All that was expected was to tick the option that was descriptive of what they knew about HIV/AIDS. The question read as follows: "AIDS is a punishment for those who break God's law which says it is wrong to have sexual intercourse outside marriage"

Procedure

Since the researcher could not be in all places at the same time, arrangement was made for university lecturers to be responsible for administering the questionnaire to their respective students. This was done after meeting what was expected of them by their institutions in administering such a questionnaire. The responding to the questionnaire was preceded by the lecturer concerned explaining to the participants what was expected of them. They

Table 1. Frequency percentage Chi-square and probability

No.	Country	Freq.	%	X ²	Р
1	America N=58	54	93	94.5	0.01
2	Kenya N=102	52	51	14.5	0.01
3	Kenya (High School) N=157	78	57	29.7	0.01
4	South Africa N=164	92	56	43.5	0.01
5	Tanzania N=100	71	71	68	0.01

N = 581

were also advised that they had the choice of responding to the questionnaire, if they so wished. In addition to the statement, participants were to fill in their gender and date of birth. For the purpose of confidentiality, participants were not permitted to write their names or institution of affiliation. On completion of the questionnaire, the lecturers collected the papers which were sent to the researcher in New York for scoring and analysis.

RESULTS

Descriptive statistics in the form of frequency, percentage, chi-square and probability were used as a method of data analysis as displayed in Table 1.

HIV/AIDS is a punishment for those who break God's law which says, it is wrong to have sex outside marriage. The response to the statement for America was 93%, Kenya high school 57%, Kenya university 51%, South Africa 56% and Tanzania 71% who did not go along with the statement that, HIV/AIDS was a penalty for breaking God's law. In terms of chi-square, the results were as follows: χ^2 (2df, N = 155) = 29.7, \chi^2 (2df, N = 100) = 14.5, < p = 0.01, Kenya university; χ^2 (2df, N = 162) = 43.5, < p = 0.01, South Africa; χ^2 (2df, N = 98) = 68,(2df, N = 56) = 94.5, America. All the values ofthe chi-square were statistically significant in favour of those who rejected the statement that HIV/AIDS is a punishment from God for sexual immorality. In summary, the analysis of data showed that adolescents at high school level as well as at university level have a united stand that, HIV/AIDS is unrelated with God's wrath against sinners.

DISCUSSION

The objective of this investigation was to find out the extent to which adolescents would confirm that HIV/AIDS is God's directive to have people punished for engaging in sexual behaviour outside wedlock. The results showed that the majority of participants in all the four diverse groups did not agree with the premise that God was indeed using HIV/AIDS as a plague to discipline sinners.

Such findings are in harmony with what other researchers have reported as well as those who have reported different findings. In terms of comparison and confirmation, a few findings will be cited.

Mbonu et al. (2009) present their case in the form of stigma against those who are infected and affected and that as a result, the infected encounter medical problems as well as social problems, particularly in human relations. Moreover, such stigma promotes secrecy and denial which ultimately are catalysts for transmission of HIV/AIDS; HIV/AIDS people are not eager to undergo tests, seeking care following diagnosis, quality of care provided to those who are HIV positive. Correctly interpreted, the argument advanced is in agreement with the findings of the present findings.

Similarly, Phiri (2004) takes the position that HIV/AIDS being interpreted as a directive from God for those engaged in sexual immorality ought to be rejected with the contempt it deserves. This is further confirmation of the present findings. Moreover, the present findings are in alignment with those of Houdmann (2013) who argues that even though all diseases, including HIV/AIDS, constitute a judgement from God; it is not for Christians to say a specific disease, such as HIV/AIDS is God's judgement. Instead, he proposes the approach of extending to the infected grace, love, mercy, forgiveness and compassion.

In contrast, the present findings are in disagreement with those of Barton (2012) who is of the view that science is unlikely to discover a cure for HIV/AIDS as this would be contrary to God's judgement over those who engage in the forbidden sexual behaviour outside the holy matrimony. Van Dyk and Van Dyk (2007) study in South Africa showed that 69% of the respondents did not agree with the statement and 16.7% were in support of the statement that HIV/AIDS is God's directive for sinners. This was contrary to what was observed in the present investigation. The findings of this investigation are in contrast to what has been reported by Manzell et al. (2011) and Smith (2004) who indicated that respondents categorically agreed with the concept of HIV/AIDS being God's wrath against sinners who take sexual intercourse as pleasure out of wedlock.

According to Dete (2012), HIV/AIDS people are stigmatised through negative attitudes towards them, reflected by those who are not accepted in churches, because they are living with HIV/AIDS; those who used to be members have been stripped of their membership, and those who held important office or played an important role in church activities have been denied of such roles. Since the findings of this investigation did not agree with the statement, they are in disagreement with the above maltreatment of religious organisations.

In summary, the findings of this study are a rejection of the statement that HIV/AIDS is God's judgement over human beings who do not adhere to his commandment against sexual immorality. At the same time, the findings present a contrast to findings which are in support of the argument that the contrary holds true.

CONCLUSION

People all over the world suffer from various ailments and diseases, but HIV/AIDS is singled out as a direct intervention from God. As it has been argued in the literature review, all ailments and diseases constitute judgement from God in response to human beings failing to adhere to his natural and spiritual laws. It is therefore paradoxical that HIV/AIDS is singled out as being God's wrath against man's sinful nature. As a result of such stance and belief, stigma is created against people suffering from HIV/AIDS, as a result of which their suffering is intensified and aggravated, as they feel isolated and denied of their rightful place in society. Instead of their being afforded compassion, care, love and forgiveness, they are perpetually condemned. This is cruel and devoid of human spirit of love and sense of belonging. As such, the tenet that God punishes people with HIV/AIDS must be rejected in favour of doing the best to relieve their suffering, and the concerted effort to find a cure for HIV/AIDS must continue unabated.

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academicJournals

Vol. 5(9), pp. 370-379, September, 2013 DOI 10.5897/JAHR2013.0262 ISSN 2141-2359 © 2013 Academic Journals http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Decentralized HIV/AIDS pharmacovigilance in South Africa: Mpumalanga Success & Moving Forward

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Accepted 13 July, 2013

This report evaluates the improvement in targeted spontaneous adverse drug reaction reporting and the quality of reports, demographic distribution, regimens implicated, the most commonly reported adverse drug reactions (ADRs) as well as concomitant conditions. Reported cases of ADRs in the Mpumalanga anti retroviral treatment (ART) programme from July, 2011 to February, 2013 were evaluated. A total of 1,756 ADR reports were received from the province. 495 were males (28.9%), 1,057 female (60.19%) and in 204 (11.6%) reports, gender was not reported. 908 were satisfactorily completed, 445 (49%) reported one ADR, 366 (40.3%) two ADRs, and 97 (10.7%) reported three or more. The most commonly reported ADR was peripheral neuropathy and the most prescribed regimen was d4T/3TC/EFV. d4T-containing regimens were the highest suspect drug combinations. Correlations were observed between d4T and the occurrence of peripheral neuropathy and lipodystrophy, nevirapine (NVP) and efavirenz (EFV) with rash while zidovudine (AZT) was observed to be associated with anaemia. Tuberculosis was found to be the most clinically significant concomitant medical condition with the highest frequency (32.3%). The review observed a significant increase in ADR reports as well as ADRs associated with the use of ART. Periodic review of data on the national pharmacovigilance database will reveal interesting trends in future.

Key words: Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), adverse drug reactions (ADRs), pharmacovigilance, decentralized, clusters.

INTRODUCTION

It is well documented that South Africa (SA) has the largest human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) treatment programme in the world, with almost two million people initiated on antiretroviral therapy (ART) (Mayosi et al., 2012; Johnson, 2012). Mpumalanga province is reported to have an HIV prevalence rate by geographic district of more than 35% on average, with age group 15 to 24 being the highest HIV prevalent group in the province (SA NDOH, 2011). An estimated 111,402 people in the province are on ART (Dheda, 2011). The goal of this therapy is to restore the body's immune system, decrease the viral load, decrease opportunistic infections and, above all, to improve the

quality of life of patients initiated on anti-retroviral (ARV) treatment (Dybul, 2002). Therefore, monitoring the safety of this massive treatment programme requires intensive quality assurance in order to ensure optimal patient outcomes, and the prevention and management of side effects. Pharmacovigilance provides one of the best opportunities to achieve this. A robust pharmacovigilance system is crucial in quantifying previously recognized ADRs, identifying unrecognized adverse drug events, evaluating the effectiveness of medicines in real-world situations as well as to decrease mortality and morbidity associated with adverse events (Eguale, 2008). The success or failure of any pharmacovigilance activity

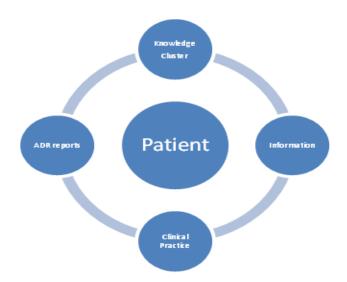


Figure 1. Feedback loop of ADR reports at cluster level.

SA has relied mainly on spontaneous reporting for its pharmacovigilance which has largely been marred by under-reporting. Further, the overall national pharmaco-

depends on the reporting of suspected adverse reactions.

vigilance (PV) approach was not fully designed nor extended to clinical settings to take into consideration the daily management of patients in various healthcare

settings.

The National Pharmacovigilance Centre (NPC) recently reported the successful initiation and setting up of a wellstructured and highly participative decentralized pharmacovigilance pilot program for ART treatment in Mpumalanga Province (Dheda, 2011). It focuses on patient-centred healthcare safety, prevention management of side effects, better communication between the various healthcare disciplines providing patient care, proper management of side effects at all levels, while prioritising disease control. This robust patient-focused decentralized PV process in ART in Mpumalanga is the model and platform for roll-out into the rest of South Africa. This roll-out has the potential of achieving the desired cohesive and dynamic system that will meaningfully impact on clinical care and patient safety in the whole country.

Twenty-six (26) PV clusters have been formed in Mpumalanga Province. Their formation was prescriptive and the provinces, districts, hospitals and clinics decided on what works best for them. Clusters were formed where structures or systems already existed between hospitals and clinics, such as up or down referrals of patients, or where geographic proximity was allowed. The purpose of this decentralization is to bring PV closer to the primary healthcare practice and to increase the general interest in drugs and drug-related problems. Each cluster, consisting of multidisciplinary health care provider (HCP) teams of doctors, nurses,

pharmacists, social workers, laboratory technicians and dieticians, meets monthly to discuss effective intervention and case management strategies per individual patient case. These decentralised structures create a smaller and more effective safety feedback loop which allows faster information flow-back to reporters thereby enhancing patient care (Figure 1). In addition to this, the clusters also have the important task of informing other healthcare professionals about ADR with a focus on the reporting. A copy of each individual case report is faxed to the NPC where it is stored in the national database. The report captures data such as demographics, medications, co-morbidities, outcome and suspect drug assessment. Trends are then monitored from this data generating important safety information which ultimately fed back to the reporters/clusters from the NPC through acknowledgement, ADR information and bulletins describing signals as part of a larger nationwide feedback loop through direct communication with the reporting HCPs or clusters, newsletters, internal memorandums and publication in peer reviewed journals.

The primary endpoints of this interim review were to monitor the change in practice of ADR case reporting manifested through an increased number of reports from the province, their gender and age distribution as well as identify the most commonly observed ADRs. The secondary endpoints were to conduct an interim review of the quality of submitted reports, the regimens implicated in these ADRs as well as the predominating concomitant medical conditions amongst the people on ART in the Mpumalanga population.

METHODOLOGY

This was a retrospective review conducted on PV reports from the ART program in Mpumalanga province from the districts of Nkangala, Ehlanzeni and Gert Sibande. For the primary endpoints, all the 1,756 reports submitted for patients between 27th July, 2011 and 28th February, 2013 were considered. Only the properly completed 908 reports were taken further into the secondary analysis. The following information was collected: gender, age, suspected drug(s), suspected ADR(s), concomitant medical conditions and outcome for the patient. The incidence was calculated by considering the ratio of number of patients with ADRs and total number of patient reports considered. Data for sex and age were analysed using the sample test of proportions for establish proportional differences using STATA10® (StataCorp, 2007). A p value of < 0.05 was considered as statistically significant.

This paper does not report on primary research and all data analysed were collected as part of routine diagnosis and treatment according to national ART treatment guidelines. It does not report the use of experimental or new protocols and was not set up as a study or research project but is part of the South Africa National Department of Health pharmacovigilance programme. The retrospective review was done internally as part of an evaluation, so as to improve patient quality of care. By its very nature, ART in HIV/AIDS treatment exposes patients to a high risk of treatment failure, possible drug resistance and consequently death so it was felt that this vital information should be published in a reputable open source journal. Publication of such information without

Table 1. Patients reported per district in Mpumalanga n = 1,756.

Characteristic Gender	Ehlazeni	Gert Sibande	Nkangala	Total	Incidence (%) = reported/n
Male	146	292	57	495	28.19
Female	281	652	124	1057	60.19
Unknown	29	149	26	204	11.6

^{*}Unknown: Gender not reported.

Table 2. Age of Patients reporting ADRs in the Mpumalanga province n = 1,756.

Characteristic	Number of ADRs	Number of ADRs	Incidence (%) = reported/n	P Value
Age (years)				
0 – 17	Male 89 Female 131 Unknown 59	279	15.81	
18 – 30	Male 30 Female 156 Unknown 25	211	12.01	
31 – 40	Male 145 Female 364 Unknown 43	552	31.44	<i>p</i> value < 0.001
41 – 50	Male 130 Female 243 Unknown 51	424	24.15	
51+	Male 101 Female 158 Unknown 26	285	16.23	

^{*}Age not reported = 5.

approval by an ethics committee is not unprecedented in operational research. In a similar case, both the WHO Research Council and the Committee on Publication Ethics held decisions in favour of public interest to have such information published as it would probably bring benefits to the people whose autonomy may be harmed by its publication (Gollogly, 2006). The autonomy of the patients in this case is protected because their identity is withheld from the data reviewers. Consequently, neither patient informed consent nor ethics approval was sought because this is an epidemiological review in which it was impossible to identify the patients (Nilstun and Lofmark, 2005).

RESULTS

Primary outcomes

Number of reports, gender and age distribution

During the period under review, a total of 1,756 ADR reports were received from the province. Of these, 495

were males (28.9%), 1,057 female (60.19%) and in 204 (11.6%) of the reports, the gender was not given. The number of ADRs was higher in the female population compared to that found in the male population (Table 1). The reports were categorised into five age groups namely 0 to 17, 18 to 30, 31 to 40, 41 to 50 and 51+. Overall, the incidence of ADR reports per age group was found to be 15.81% (279), 12.01% (211), 31.44% (552), 24.15% (424) and 16.23% (285), respectively (Table 2). The highest number of ADRs was reported from the age group 31 to 40 years with the majority, like the overall proportions given in Table 1, being females (364/552, 65.94%). A strong correlation between female sex and ADRs was found to be statistically significant (*p* value < 0.001).

Commonly reported ADRs

From our reports, the top 10 most commonly reported

Table 3. Top 10 most commonly observed ADRs.

ADR	Number
Peripheral neuropathy	358
Fat and weight loss	234
Lipidystrophy and fat redistribution	327
Weight loss	122
Breast enlargement and/or gynaecomastia	183
Rash	109
Dizziness	101
Fat gain	65
Vomiting	52
Headache	50

ADRs were peripheral neuropathy, fat loss (lipoatrophy), lipodystrophy, weight loss, breast enlargement and/or gynaecomastia, rashes, dizziness, fat gain, vomiting and headache (Table 3).

Secondary outcomes

Although a total of 1,756 reports came from the province, a review of each individual report revealed that only 908 were satisfactorily completed in all fields including patient details and demographics, ART regimen, ADRs, laboratory results, adverse reaction outcome, relevant clinical history, early warning for drug resistance and reporting HCP. The 848 incomplete reports ranged from those that indicated ADR symptoms but no suspected drug, suspected drugs with no ADRs reported or neither symptoms nor suspect drugs, no report of intervention/ treatment outcome carried out and no information on initial regimen among others. They were not considered further because they did not have important key data for the secondary endpoint analysis.

Number of ADRs reported and treatment failures

Of the 908 properly completed reports, 445 (49%) developed one ADR, 366 (40.3%) developed two ADRs, and 97 (10.7%) reported three or more ADRs (Figure 2). One patient on zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP) regimen was reported to have a total of 16 ADRs including peripheral neuropathy, back pain, muscle pain, abdominal pain, unusual fatigue, weight loss, unusual bleeding, rash, dizziness, nausea, vomiting, diarrhoea, depression, heartburn and headache. This patient was among a total number of 103 reported as ART virological, immunological and clinical progression treatment failures. Most of the treatment failures were virological and patients were given iterative intensive

adherence management to counter re-suppression and/or changed to Lopinavir/Ritonavir (LPV/r)-based second line ART.

Reported ARV regimens administered

At the time of this report, the ART programme in Mpumalanga was following the SA National ARV Treatment Guidelines of 2010 (Table 4) (SA NDOH, 2010). All new patients were given Tenofovir (TDF), 3TC, NVP/Efavirenz (EFV). Those currently on Stavudine (D4T)-based regimen with no expected D4T ADRs remained on the drug if well tolerated otherwise it was substituted with TDF. It is noteworthy to mention at this point that the South African Anti-retroviral treatment guidelines for 2013 were implemented after the review of data for this report was completed (1st of April, 2013) and will be discussed in detail in future reports (NDOH, 2013).

Suspected ADR causing ARV drugs

The most prescribed regimen was D4T/3TC/EFV and d4T was the most suspected drug implicated in causing ADRs especially in cases of peripheral neuropathy and lipodystrophy with 144 and 173 cases from the total of the 908 reports, respectively. The top 10 ADRs reported for d4T are given in Table 5. Other selected suspect drugs and ADRs implicated in the reports are given in Table 6

ARV regimens correlation to the most commonly observed ADRs

Figure 3 indicates strong correlation between use of D4T-regimens and the occurrence of peripheral neuropathy amongst the Mpumalanga population on ART. Figure 4 indicates strong correlation between use of AZT or combinations containing it, and the occurrence of anaemia amongst the Mpumalanga population on ART. Figure 5 indicates strong correlation between use of AZT or combinations containing it, and the occurrence of lipodystrophy amongst the Mpumalanga population on ART. The frequency of rashes (Figure 6) suggests a correlation between NVP and EFV to rash. However, the ADR descriptions suggest a few of the events could be attributed to Stevens Johnson's syndrome.

Reported conditions concomitant to ADRs reported

Tuberculosis (TB) was the clinically significant concomitant medical condition with the highest frequency

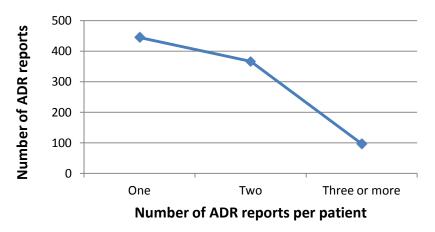


Figure 2. Number of ADRs reported per patient.

Table 4. Standardised SA national ART regimens for adults and adolescents.

First line		
All new patients needing treatment	TDF+3TC/FTC+EFV/NVP	For TB co-infection EFV is preferred. For pregnant women or women of child bearing age, not on reliable contraception, NVP is preferred.
Currently on d4T-based regimen with no side effects	d4T+3TC+ EFV/NVP	Remain on d4T if well tolerated. Early switch with any toxicity. Substitute TDF if at high risk of toxicity (high BMI, older, female, TB treatment).
Contraindication to TDF: renal disease	AZT+3TC+EFV/NVP	
Second line		
Failing on a d4T or AZT- based 1st line regimen	TDF+3TC/FTC+LPV/r	Virological failure must be followed by intensive adherence management, as resuppression is often possible. If repeat VL remains >1000 in 3 months despite adherence intervention, switch.
Failing on a TDF-based 1st line regimen	AZT+3TC+LPV/r	Virological failure must be followed by intensive adherence management, as resuppression is often possible. If repeat VL remains > 1000 in 3 months despite adherence intervention, switch.

(32.32%, 128/365) followed by hypertension (26.01, 103/365), menopause (13.89%, 55/365), and pregnancy (12.63%, 50/365). Others included diabetes and epilepsy (Table 7).

DISCUSSION

A total of 1,057 (60.19%) reports were recorded from females while 495 were males (28.9%). Categorised by age group, it was observed that the majority of ADRs to ART were in the age group 31 to 40 years and with more reports in females than males with 65.94 and 26.26%, respectively. Gender was not reported in 7.79% of the reports for this age group. The correlation between female sex and higher frequency of reported ADRs was found to be statistically significant (p value < 0.001). It is

not clearly understood why gender difference exists in ADRs not only to ART but other therapies as well. Factors cited in similar data reviews include differences in weight and body mass index, hormonal changes unique to females, and the effect of these changes on drug metabolism (Tran et al., 1998; Rodenburg et al., 2011; Anderson, 2005, 2008; Soldin and Mattison, 2008; Zelinkova et al., 2012). Other possible factors include differences in fat composition (thereby affecting drug distribution) and genomic differences influencing the level of enzymes involved in drug metabolism (Harris et al., 1995).

All the patients showed at least one ADR and where the suspect drug was identified, this was discontinued and replaced by another anti-retroviral drug. From all the reports received, including those not properly completed, the most common ADRs were lipodystrophy (327) and

Table 5. ADRs suspected to be caused by D4T.

Suspected drug	ADRs	No of cases reported
	Abdominal pain	19
	Peripheral neuropathy	144
	Rashes	9
	Backpain	7
D4T	Muscle pain	16
D41	Unusual fatigue	8
	Lipodystophy	173
	Weight/fat loss	181
	Unusual fat gain	38
	Breast enlargement	35

Table 6. Other significant suspect drugs implicated in reported cases of ADRs.

Suspected drug	ADRs	No of cases reported
	Rashes	25
NVP	SJS	3
	Itching	1
зтС	Peripheral neuropathy	1
310	Fatigue/muscle weakness	3
A 7T	Peripheral neuropathy	11
AZT	Anaemia	11
	Abdominal pain	4
EFV	Peripheral neuropathy	6
EFV	Rashes	14
	Breast Enlargement	29

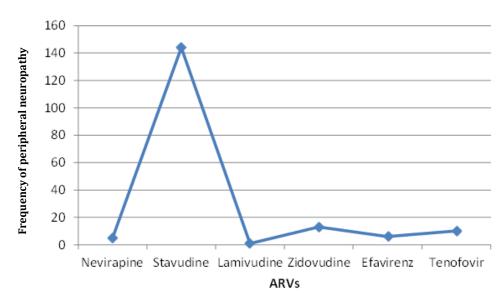


Figure 3. Frequency of occurrence of peripheral neuropathy in reported ARVs.

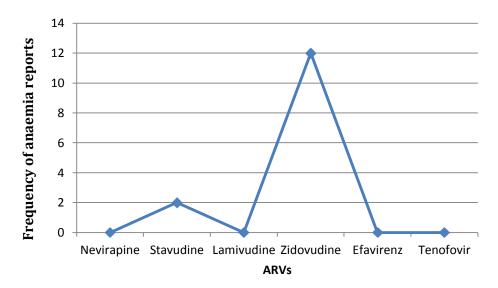


Figure 4. Frequency of occurrence of anaemia in reported ARVs.

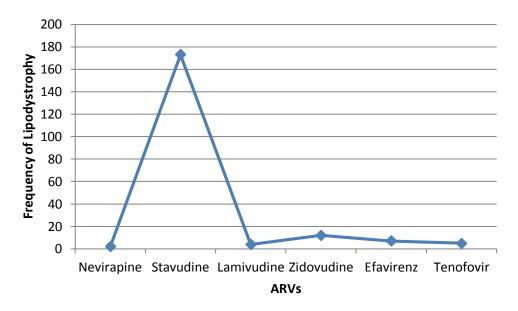


Figure 5. Frequency of occurrence of lipodystrophy in reported ARVs.

peripheral neuropathy (358 cases), mainly with d4T-containing regimens. It was discontinued and replaced with TD4. While peripheral neuropathy is linked to almost all the nucleoside reverse transcriptase inhibitors (NRTIs), it can be seen that d4T-containing regimen is most commonly suspected drug in cases of peripheral neuropathy; or occurring as concomitant medication in some cases. This is in keeping with other ART studies where d4T has been linked to severe peripheral neuropathy (Coetzee et al., 2004; Nomathemba et al., 2011; Simooya, 2012; Bleeker-Rovers et al., 2000; Cornejo-

Juárez et al., 2003). This finding supports the World Health Organization (WHO) recommendation to discontinue the use of d4T-based regimens in adolescents and adult patients due to associated adverse effects.

Although our findings have not been subjected to elaborate statistical analysis and the numbers reported were not significant, an association has been observed between NVP and EFV (fewer and milder cases than NVP) containing regimen and hypersensitivity reactions manifested by pruritus, rashes with indications of Steven Johnsons Syndrome (SJS) in the clinical notes.

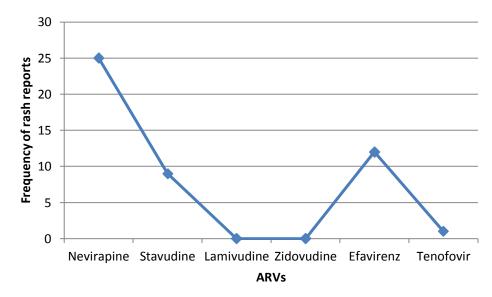


Figure 6. Frequency of occurrence of rash in reported ARVs.

Table	7.	Concomitant	medical	conditions	and	frequency	of
occurrence.							

Concomitant conditions	Frequency	%
Hypertension	103	26.01
Pregnant	50	12.63
Tuberculosis	128	32.32
Hepatitis	5	1.26
Diabetes	36	9.09
Epilepsy	6	1.52
PCP	2	0.51
Karposi sarcoma	4	1.01
Haemorrhoids	1	0.25
Lower respiratory tract infection (LFTI)	1	0.25
Lymphoma	1	0.25
Cryptococcal meningitis	2	0.51
HIVAN	1	0.25
Menopause	55	13.89
Scoliosis	1	0.25
Total	365	100.00

Association of NVP with SJS is well documented (Metry et al., 2001; Rotunda et al., 2003; Namayanja et al., 2005).

Generally, from a review of the treatment outcomes and changes in treatment regimens, it is clear to see that ART in Mpumalanga is consistent with the South African Anti-retroviral treatment guidelines for 2010. The 2013 guidelines have recently been released (1st of April, 2013) and changes from the preceding guidelines will be discussed in more detail in the next report.

D4T-containing regimens were the highest suspected

drug combinations. 3TC, EFV, AZT and NVP were also reported as having caused a number of ADRs. Compared to the frequencies reported on sources such as Medscape, these frequencies are much lower and numbers of associated, expected and/or reported ADRs are fewer (Medscape, 2013). However, it is envisaged that as this programme expands, more reports will be received, comprehensively capturing all ADRs associated with and unique to ART in South Africa.

TB was the most common clinically significant concomitant medical condition reported, with 128 cases from

the 908 completed reports. Although ART can reduce the incidence of TB, people on ART still have higher TB incidence rates (Lawn et al., 2006). This may be due to delayed initiation of ART or the fact that patients present with advanced TB or both (Nunn et al., 2005). Routine screening among people living with HIV/AIDS (PLWH) offers the opportunity to identify those without TB, prevent TB by chemoprophylaxis as well as to diagnose and promptly treat those who are infected. However, coadministration of ART along with anti-TB therapy presents several management challenges, including drug-drug interactions, overlapping drug toxicities and immune reconstitution syndrome. Generally, for all patients who experienced ADRs, preventive measures were prescribed and administered to patients as well as instructions given to avoid ADRs by providing medication counselling to each patient.

One limitation of this review is that minimal statistical analysis has been performed. However, statistical analysis of spontaneous reports itself suffers severe limitations with regards to data reliability in that there is no data collection protocol, adverse reports vary from period to period by drug type and ADR type. Furthermore, there is no certainty that a reported reaction was causal and there may be duplicates in the reports and if undetected, these can severely bias estimated drug-event associations. Spontaneous report data also involves extensive data cleaning as the number of reports increase. There are also many possible non-causal reasons for associations, and interpretation of comparator groups is difficult. We are however focusing on systematic analytical approach, as spontaneous reports are one of the few ways to learn about rare ADRs. They can also form a cornerstone of hypothesis generation and/or a secondary data source for comparisons.

CONCLUSION

This is the first retrospective review of reported ADRs in HIV-positive patients using ART in Mpumalanga by the NPC. The review observed the significant ADRs associated with the use of ART in the local provincial population. In 2011, there were 111,402 people reported to be on ART in the province. At the end of February, 2013, we received a total of 1,756 ADR reports. This number may appear to be only a small fraction of the total (1.6%, 1756/111402) of the estimated total number of patients on ART in the province. However, it should be noted that the decentralised pharmacovigilance program was only launched 19 months ago whereas the ART program has been in existence since early 2004. We therefore expect that in the next few years, the number of reports received will rise towards a number more reflective of the reality.

Although the 1,756 reports seems minimal compared

to the provincial total, and the data has not been subjected to elaborate statistical analyses, these findings that our model decentralised demonstrate of pharmacovigilance reporting of ADRs is capable of producing good epidemiological safety data in HIV patients on ART. They also underscore the importance of pharmacovigilance as a tool which can yield information applicable and relevant to the South African public health sector, ART related ADRs are evident in patients on ART. and this decentralised pharmacovigilance reporting is a good model for roll-out to the rest of South Africa and will help to obtain a complete profile for ADRs due to ARV medicines and inform policy decisions. It is a practical and low cost method that utilises existing financial and human resources.

ACKNOWLEDGEMENTS

This publication and its contents are solely the responsibility of the authors and do not necessarily represent the official views of any of the sponsors. Sincere thanks to Dr NJ Ngomane of the Mpumalanga Provincial DoH, and Dr Yogan Pillay, Dr Thobile Mbengashe, Ms Mandisa Hela and Ms Portia Nkambule of the National DoH, for helping to pave the way, organisationally and administratively, to allow Mpumalanga Province to receive this comprehensive training in HIV/AIDS pharmacovigilance; Ms Phindile Myanga, Mr Dumisani Nkosi, and Ms Nothando Dlamini in Mpumalanga, in coordinating the provincial aspects of organising these training sessions and venues, and making them happen. This pharmacovigilance programme to improve quality of care in HIV/AIDS patients would not have been possible without their support; Mark Paterson of BroadReach Healthcare; and to Dr Almakio Phiri, Mr JP Sallet and Mr Bada Pharasi from MSH SIAPS for funding much of the logistical support; Dr N Simelela (ex CEO) and Fareed Abdullah (current CEO) of the SA National AIDS Council for always being passionate about quality of care of patients and strongly supporting this pharmacovigilance process. This also goes for Rev Zwo Nevuthalu, for providing logistical support to the NPC team; Dr Henry Fomundam and Dr Bulumko Futshane, and to my team at the National Pharmacovigilance Centre (NPC) and Ms Franci Williams in particular for assistance and support throughout the training process; and also to each of the participants in this training and programme. Your participation and enthusiasm during and after the training has motivated my centre to cascade this programme to the other provinces.

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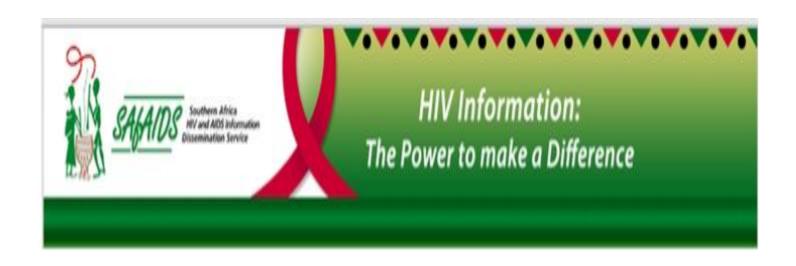
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