THE PATTERN OF NEEDLE-STICK INJURIES

IN ACADEMIC HOSPITALS IN JOHANNESBURG

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Internal Medicine

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DECLARATION

I, Anita Pui Ching Lai, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Internal Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

17th day of OCTOBER, 2016

To my husband, Jeff,

without whom this research report could not have been completed.

To my parents, Kam Fai and Kam Sim Lai,

for their continuous support.

ABSTRACT

Needle-stick injury is a common problem among health care workers (HCWs) all over the world. Globally, in 2000, there were an estimated 1000 HCW-acquired human immunodeficiency virus (HIV) infections through occupational exposure. Limited data are available in South Africa. This descriptive study documents the pattern of needle-stick injuries among registrars in the Academic Hospitals in Johannesburg, South Africa.

A total of 150 registrars across different disciplines in the three Academic Hospitals in Johannesburg were interviewed, using a standardised questionnaire in 2013. The majority of the registrars interviewed (n=123, 82%) had reported a needle-stick injury.

Most of the needle-stick injuries occurred during internship. Most of the doctors were working in the Departments of Surgery and Internal Medicine at the time of their injuries. The most common mechanisms of needle-stick injuries were during insertion of a drip (22%) and suturing (21%). The majority (83%) of the doctors with needle-stick injuries took post exposure prophylaxis (PEP). The combination of zidovudine and lamivudine was the most commonly used regimen. Over half (53%) of the doctors with needle-stick injuries completed the 28 days course of PEP, while the remaining doctors (47%) discontinued PEP due to side-effects and/or because they considered the treatment unnecessary.

The findings in this study are similar to those reported in other studies done previously in different parts of South Africa. Adherence to PEP following needle-stick injury remains a major problem.

ACKNOWLEDGEMENTS

To my supervisors, Prof Charles Feldman and Prof Francois Venter, my deepest gratitude and heartfelt thank-you for your advice, guidance and contribution towards this research report.

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NOMENCLATURE

3TC	Lamivudine
ABG	Arterial blood gas
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral agents
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
BMAT	Bone marrow aspirate and trephine
CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CVP	Central venous catheter
D4T	Stavudine
EFV	Efavirenz
FTC	Emtricitabine
HCW	Health care workers
HIV	Human Immunodeficiency Virus
HJH/RMH complex	Helen Joseph Academic Hospital/Rahima Moosa Mother and Child Hospital
LP	Lumbar puncture
LPV/r	Lopinavir/ritonavir
NRTI	Nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
O&G	Obstetrics and Gynaecology
PEP	Post exposure prophylaxis

PMTCT	Prevention of mother-to-child transmissions
PrEP	Pre-exposure prophylaxis
RAL	Raltegravir
TDF	Tenofovir
WHO	World Health Organisation

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Needle-stick injury is an occupational percutaneous exposure to the blood or body fluids of patients by needle stick or sharp object. [1] It is a common problem among health care workers (HCWs) all over the world. The incidence is around ten percent among HCWs in the United States. [2] In United States of America, a study of needle-stick injuries done at the Johns Hopkins University reported an 83% incidence among the orthopaedic residents. [3] A study done in the Department of Internal Medicine at Yale University School of Medicine reported a 74% incidence in the residents. [4] Another study done by the Department of Family Medicine at the University of Southern California reported a 71% incidence in the medical students and residents during a one year period. [5] A study done in Nigeria reported a 67.9% incidence of doctors in surgery with occupational exposure to patient's blood in a six month period. Of all the occupational exposures, 63.6% was needle-stick injury. [6] There are approximately 96000 cases of needle-stick injuries occurring annually among HCWs in Italy. [7] Limited data are available in South Africa.

One study done in the Department of Obstetrics and Gynaecology (O&G) at King Edward VIII Hospital in Durban in South Africa published in 2000 reported a 13% incidence of occupational exposure to human immunodeficiency virus (HIV) among all the HCWs within the department, including student midwives, professional nurses, medical students, junior interns, interns, registrars and consultants. [8] The majority (94%) of the exposures were needle-stick injuries, with the registrars having the highest incidence.

A further study done at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) and Chris Hani Baragwanath Academic Hospital (CHBAH) in Johannesburg in 2001 reported a 69% incidence of needle-stick injuries among the interns. [9] Overall, 81% of the interns had

needle-stick injuries during either their three years of medical school clinical training or one year of internship. However, only 16% of the needle-stick injuries were officially reported.

In a study at Tygerberg Children's Hospital in Cape Town in 2001, there was a 62% incidence of needle-stick injuries over the preceding two years among all the doctors, including interns, community service officers, medical officers, registrars and specialist paediatricians. Junior staff had the highest incidence with the community service officers having an incidence of 100%. [10]

An additional study, done at Tygerberg Hospital in 2002, reported 16 cases (12%) of needle-stick injuries during a 15-week period among all the final year medical students at the University of Stellenbosch. [11]

A study done on all medical students in the Department of Family Medicine at the University of Pretoria from January 2004 to February 2008 reported a total of 121 cases of needle-stick injuries (Incidence was not reported in this study). [12]

Lastly, a study done in Newcastle Provincial Hospital over a two year period from 2007 to 2008 found that 20 doctors had had a needle-stick injury (Incidence was not reported in this study). [13]

1.2 Mechanisms of injury

The mechanisms by which needle-stick injuries occur include needle recapping, withdrawal of needle, handling or disposal of used needle, needle disassembly, manipulating the needle in a patient, unexpected patient movement and accidental injury by a colleague. The most common mechanism reported in the Tygerberg Children's Hospital in Cape Town was cleaning up after insertion of an intravenous catheter. [10] This

was similar to the findings in the other studies done at the Universities of Pretoria and the Witwatersrand, with intravenous cannulation and venepuncture being the most common mechanisms of injury. [9,11]

1.3 Impacts of injury

The risks of needle-stick injury include the transmission of infections, with the most important ones being HIV, hepatitis B virus, hepatitis C virus and syphilis. HIV seroconversion is a particular concern in South Africa given the high prevalence of HIV of 12.2% in the overall population and of 12.4% in Gauteng. [14] The rate of HIV seroconversion from occupational HIV exposure, including needle-stick injury, is considered to be low. Overall, the rate of HIV seroconversion from needle-stick injury is 0.33 % and from mucous membrane exposure is 0.09%. [15] There were 92 cases of documented occupationally-acquired HIV infection worldwide reported in 1998. [16]

A study done in 2000 estimated that 1000 HCWs around the world had acquired HIV with occupational exposure. [17] The following factors are associated with an increased risk of HIV transmission following needle-stick injury: injury by hollow-bore needle, deep injury, injury with an instrument visibly contaminated with the patient's blood, needle placement in a vein or artery and terminal illness in the source patient. [1,18-20] The following factors are considered low risk of HIV transmission with needle-stick injuries: injuries occurring through a solid needle, a superficial wound, and injuries occurred from a low risk source, such as a patient with an HIV viral load <1500 copies/mL. [1,15,18]

1.4 Post exposure prophylaxis

Following a needle-stick injury with any infectious material, the HCW should immediately wash the cutaneous wound with soap and water. Infectious materials include amniotic

fluid, blood, body fluids contaminated with visible blood, breast milk, cerebrospinal fluid, penile pre-ejaculate, pericardial fluid, peritoneal fluid, pleural fluid, semen, synovial fluid and vaginal secretions. [1,21,22]

Depending on the HIV status of the source patient and the nature and type of exposure, one would consider whether to start antiretroviral post exposure prophylaxis (PEP). If the source patient is HIV-positive and suspected or known to have a resistant strain, expert consultation is recommended for the choice of an optimal PEP regimen. However, initiation of PEP should not be delayed while awaiting expert opinion. [1] If the source patient is HIV-negative, asymptomatic and has no clinical evidence of Acquired Immunodeficiency Syndrome (AIDS), no further testing for HIV infection is indicated. PEP is thus not indicated as it is extremely unlikely that source patient would be in the window period of HIV infection without any symptoms of acute retroviral syndrome. [1]

PEP using antiretroviral agents aims to prevent HIV infection following exposure to infectious materials. Animal models show that systemic infection does not occur immediately following initial exposure. [1] It takes at least 24 hours for the HIV virus to replicate in the dendritic cells of the skin and tissue before it spreads to the regional lymph nodes and then to the systemic system. This allows time for PEP to limit the replication of the virus in the initial target cells or lymph nodes and thus prevent or inhibit systemic infection.

The 2008 guidelines for PEP prepared by the Southern African HIV Clinicians Society recommended triple therapy if the HIV status of the source patient was positive or unknown and if there was percutaneous exposure, mucocutaneous splash or contact with an open wound with blood or potentially infectious fluids. [22] The triple therapy recommended consists of two nucleoside reverse transcriptase inhibitors (NRTIs) and one

boosted protease inhibitor. Subsequently, the World Health Organisation (WHO), in 2014, recommended triple therapy, although two drugs therapy is considered effective. [23] The preferred backbone regimen for PEP is tenofovir (TDF) and lamivudine (3TC) or emtricitabine (FTC). The preferred third drug is lopinavir/ritonavir (LPV/r) or atazanavir/ritonavir (ATV/r). The other alternative options for a third drug include raltegravir (RAL), darunavir/ritonavir and efavirenz (EFV). Of note, both the Centers for Disease Control and Prevention and the New York State Department of Health AIDS institute in the United States of America published updated guidelines on PEP in 2013, and October 2014 respectively. [24,25] They both recommended TDF, FTC plus RAL as the preferred initial PEP regimen. Lately, the South African HIV Clinicians Society also published an updated guideline on PEP with RAL recommended as the preferred third drug for PEP. [26]

The efficacy of triple therapy PEP in preventing HIV infection following occupational exposure is unknown. Zidovudine (AZT), one of the NRTIs used in PEP, has been shown to reduce HIV transmission in both occupational and mother-to-child settings. [1,27] Use of PEP is further supported by the efficacy of TDF-FTC in reducing the risk of HIV transmission as pre-exposure prophylaxis (PrEP) by 51%. [28] The use of triple therapy for PEP is supported by its superiority to dual therapy in both treatment and prevention of mother-to-child transmission (PMTCT) settings. Historically, PEP is not 100% protective. There have been six reported cases of HCW worldwide having seroconverted following occupational exposure despite having received AZT containing combination therapy PEP within two hours of exposure. [29] The factors which might contribute to the failure of PEP include the presence of antiretroviral-resistant strains of HIV in the source patient, exposure with a large amount of body fluids, initiation of PEP after 72 hours post-

exposure, duration of PEP less than four weeks, and possible factors related to the host (e.g. cellular immune system responsiveness) and/or to the source person's virus.

PEP adherence is a major problem among the HCWs who may not complete the full course of PEP, which in turn reduces the efficacy of PEP. Several international studies have shown that HCWs do not adhere to the full PEP regimen (four week course) mainly due to drug side-effects. [1,19,29-32] Similarly, a local study done at King Edward VIII Hospital in Durban, South Africa, found that most of the HCW discontinued PEP due to side-effects of the drugs, with gastrointestinal upsets being the commonest side-effect. [8] Other common side-effects of PEP included headache, lethargy and malaise. [1,8,10,19,29-31] Other serious side-effects of PEP noted include hypersensitivity reactions, skin reactions (including Stevens-Johnson syndrome), hepatitis (with one case requiring liver transplantation), nephrolithiasis, rhabdomyolysis and pancytopenia. Most of these severe side-effects are particularly associated with nevirapine (NVP). [1] Due to the possible severe toxicity of PEP, it is often recommended that the HCW has blood tests done at baseline and two weeks after the initiation of PEP. [1,20] However, no data are available to support the concept that doing blood tests helps to reduce side-effects of PEP.

As mentioned previously, HIV seroconversion is possible despite completion of a full course of PEP. It is thus essential to test the HIV status of the HCW, using enzyme-linked immunosorbent assay, at baseline, and at six weeks, three months and six months post exposure. [22]

1.5 HCW Counselling

Counselling is an important aspect of management post needle-stick injury. [2,20,22,23] The following components need to be addressed during counselling:

- Psychological component; there is a substantial emotional effect of needle-stick injury. Depression and anxiety are the main areas that need to be addressed.
- Importance of adherence to the four week duration of PEP.
- Drug side-effects; importance of blood monitoring and evaluation for possible drug interactions.
- Need to report any acute illness during the follow up period as it may be a symptom of acute retroviral syndrome or drug reaction.
- Importance of behavioural change to prevent secondary transmission during the follow up period. These include sexual abstinence or use of condoms to prevent secondary sexual transmission and to avoid pregnancy, avoid breastfeeding, and avoid blood, plasma, organ, tissue, or semen donation.[1]

1.6 Preventative measures

The mainstay of preventative measures is compliance with universal precautions. This includes use of gloves during procedures and when handling blood or body fluids of patients, use of eye protection during procedures, disposal of needles or sharp objects in the "sharps" bin, avoidance of resheathing needles, avoidance of bending, breaking or manipulating used needles by hand and lastly immediate hand washing with soap and water if the skin surfaces are contaminated with blood or body fluids of the patient. [21,22] More readily availability of "sharps" bins and use of safer needle devices are also recommended. [2,9,10] In terms of surgical procedures, the following measures have been recommended: use of double gloves, use of staples instead of sutures to close skin, use of vascular clips to ligate pedicles, use of electrocautery over knife, use of laparoscopic rather than laparotomy approaches, not leaving exposed needles or sharp objects on the operating field and avoiding undue haste. [2,33,34]

1.7 Aims and objectives

Limited data are available in South Africa regarding needle-stick injury and PEP, therefore the aim of this study was to describe the pattern of needle-stick injury among registrars in the Academic Hospitals in Johannesburg, South Africa.

Study objectives:

1. To describe the frequency of prior needle-stick injuries among registrars.
2. To describe the demographics of doctors with needle-stick injuries.
3. To describe the nature of needle-stick injuries.
4. To describe the use of, access to, and compliance with, PEP.

2.0 METHODOLOGY

2.1 Study design

This was a prospective, descriptive study.

2.2 Study population and sample

The research took place at three academic hospitals in Johannesburg, South Africa, during the period January to December 2013. The hospitals studied included the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), the Helen Joseph Academic Hospital/Rahima Moosa Mother and Child Hospital complex (HJH/RMH) and the Chris Hani Baragwanath Academic Hospital (CHBAH). The study population was registrars across a spectrum of specialities including Internal Medicine, Surgery, Obstetrics and Gynaecology (O&G), Paediatrics, Anaesthetics and Psychiatry. A total sample size of 150 registrars was achieved. The study employed convenience sampling. The inclusion criterion was that the doctors needed to be registrars at the time of the study. The exclusion criterion was any registrar who declined to participate in the study.

2.3 Study methodology

Study participants were interviewed using a standardised questionnaire (Appendix A). The questionnaire was completed anonymously. It was divided into two sections, namely demographic information and needle-stick injury information.

2.3.1. Demographic information

The first section of the questionnaire included demographic information of the participants. Data collected included age, gender, year in registrar training, department, working

hospital and years working as a doctor. In addition, information regarding whether a needle-stick injury had occurred or not was recorded.

2.3.2. Needle-stick injury information

The second section of the questionnaire included questions around the needle-stick injury and would therefore only be applicable to those registrars that had sustained a needle-stick injury. The information obtained was around two major issues; namely, the nature of the needle-stick injury and the use of, access to, and compliance with, PEP.

2.3.2.1 Nature of needle-stick injury information

The nature of the needle-stick injury included questions on the year of the injury, the department at the time of injury, the doctor's status at the time of injury, the time of the day of injury, the HIV status of the source patient, the mechanism of the injury and whether the exposure was low or high risk. The departments recorded at the time of injury included Internal Medicine, Surgery, O&G, Paediatrics, Anaesthetics, Psychiatry and 'other' (department other than the ones listed above). The participant's status at the time of injury was categorised as student, intern, community service officer or medical officer and registrar. Time of the day of injury was categorised as working hours of eight in the morning (8am) to four in the afternoon (4pm) and after hours of 4pm to 8am. HIV status of the source patient was categorised as positive, negative or unknown. Mechanism of injury was categorised as insertion of drip, phlebotomy, lumbar puncture (LP), insertion of central venous catheter (CVP), drawing of blood for arterial blood gas (ABG), bone marrow aspirate and trephine (BMAT), suturing and "other" (mechanism of injury other than the ones listed above). Participants were requested to specify what the mechanism of injury under the category of "other" was. Low-risk injury was defined as those which occurred through a solid needle, appeared superficial, and occurred from a low risk source,

such as a patient with an HIV viral load <1500 copies/mL. [1,15,18] High-risk injuries were defined as those involving a hollow-bore needle with presence of visible blood on the device, or exposure from a needle that was in an artery or vein of the source patient.

2.3.2.2 Use of, access to, and compliance with, PEP information

The information obtained around the use of, access to, and compliance with, PEP included questions on whether advice regarding PEP was obtained, and from whom, the PEP regimen used, the time between injury and access to PEP, the details of where the PEP was obtained, the duration of PEP, the reason for not completing 28 days of PEP if appropriate, any side-effects of PEP and whether the PEP regimen was changed and if so to what regimen. The person from whom advice regarding PEP was obtained was categorised as consultant, expert, casualty officer, medical registrar and "other". Participants were requested to specify from whom they obtained advice under the category of "other". The ARV used for PEP were categorised as combination of AZT and 3TC, Truvada (containing TDF + FTC), combination of AZT, 3TC and LPV/r, combination of Truvada and LPV/r, combination of TDF, 3TC (or FTC) and EFV and other. Time between injury and access to PEP was categorised as less than two hours, between two and 24 hours, between 24 and 72 hours and after 72 hours. Sources of PEP were categorised as public hospital which belongs to the Department of Health, private sector and "other". Reasons for not completing 28 days of PEP were categorised as side-effects, being considered unnecessary, deciding to stop as efficacy uncertain and stopping for no reason or because of forgetting to take doses. Side-effects of PEP were categorised as nausea, vomiting, headache, diarrhoea, fatigue, dizziness, change of taste, decreased appetite and other.

2.4 Data analysis

Data was entered into a Microsoft Excel 2010 spreadsheet and then transferred to GraphPad Prism 4 (GraphPad Software, San Diego CA) for statistical analysis. Most results were presented with frequencies, except for the age of the doctors. The age of the doctors was presented as the mean and standard deviation. The differences in sustaining needle-stick injuries between male and female doctors, the difference in completing a full course of PEP between male and female doctors, the difference in compliance between doctors taking AZT-based and TDF-based regimens, the difference in compliance between doctors taking TDF and FTC and TDF, FTC and a third drug, and the difference in compliance between doctors taking AZT and 3TC and AZT, 3TC and a third drug were compared using the Fisher's exact (2-tail) test and the level of statistical significance was set at $P<0.05$.

2.5 Ethics

The study was approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (Appendix B, page 41). Written informed consent was obtained from the participants before their completion of the questionnaire. Approval from the hospital management of the Academic Hospitals to undertake this study was not requested as this study did not involve patient care.

3.0 RESULTS

3.1 Demographic results

There were 150 doctors interviewed with questionnaires. The mean age of the doctors interviewed was 31.5 ± 2.5 years with a range from 27 to 49 years old. The gender of the sample was equally distributed with 75 registrars being male and 75 being female. Most registrars interviewed were in their third year of registrar training and belonged to the Department of Internal Medicine. Figure 3.1 shows the frequency distribution of the year of registrar training. Figure 3.2 shows the frequency distribution of the department of the registrars. Over half of the doctors interviewed were working at CMJAH at that time. Figure 3.3 shows the frequency distribution of the hospital where the registrars were working. The majority of the doctors interviewed had been working as a doctor for five years. Figure 3.4 shows the frequency distribution of the number of years working as a doctor. Table 3.1 shows a summary of the demographic results.

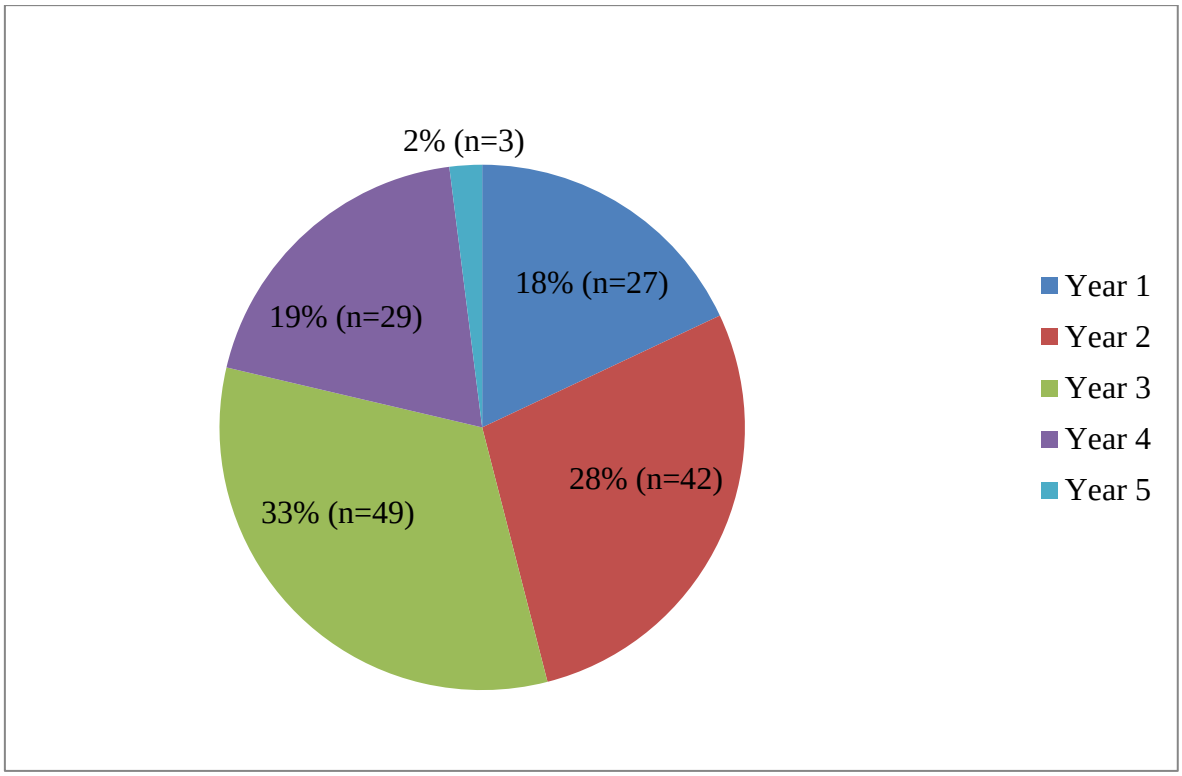

Figure 3.1 Frequency distribution of the year of registrar training

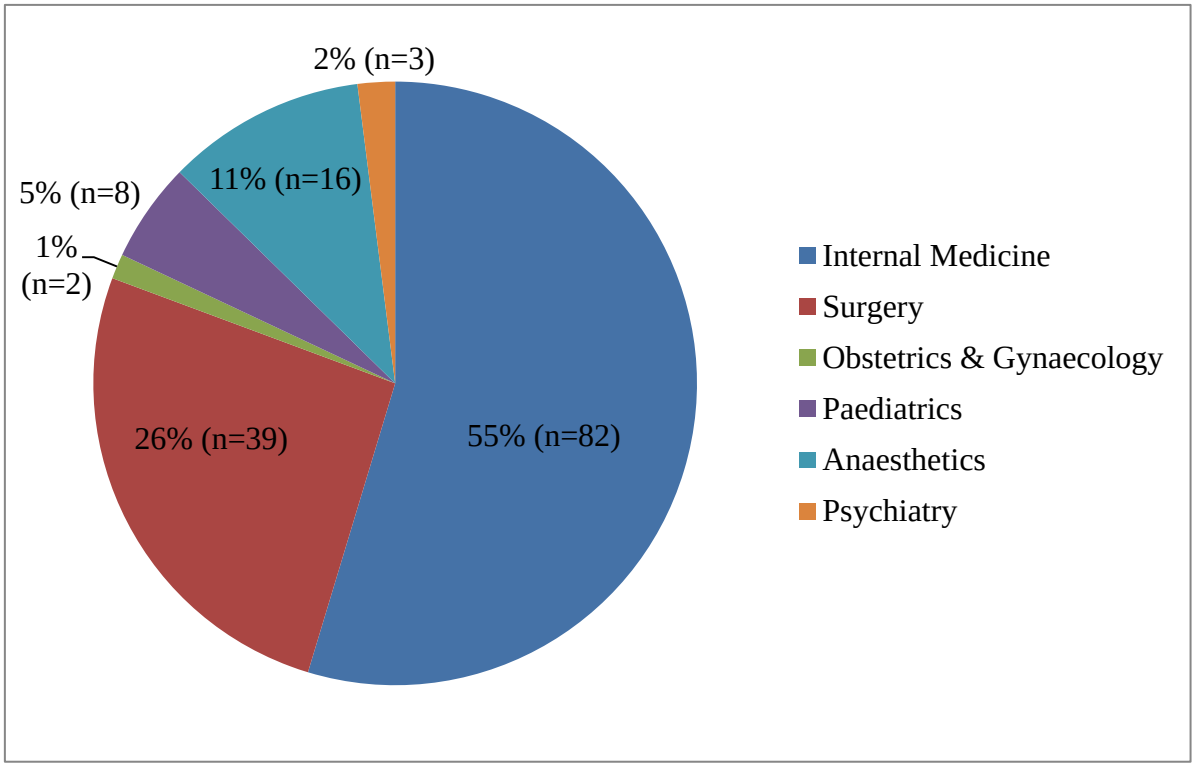

Figure 3.2 Frequency distribution of the department of the registrars

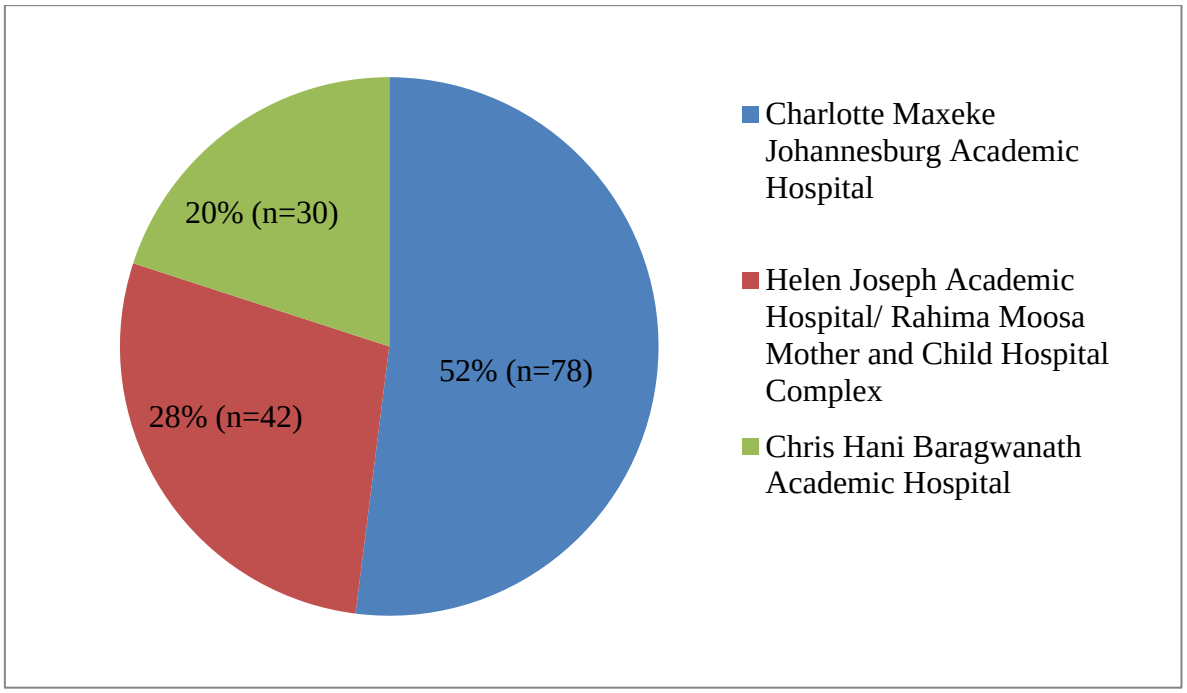

Figure 3.3 Frequency distribution of the hospital where the registrars were working

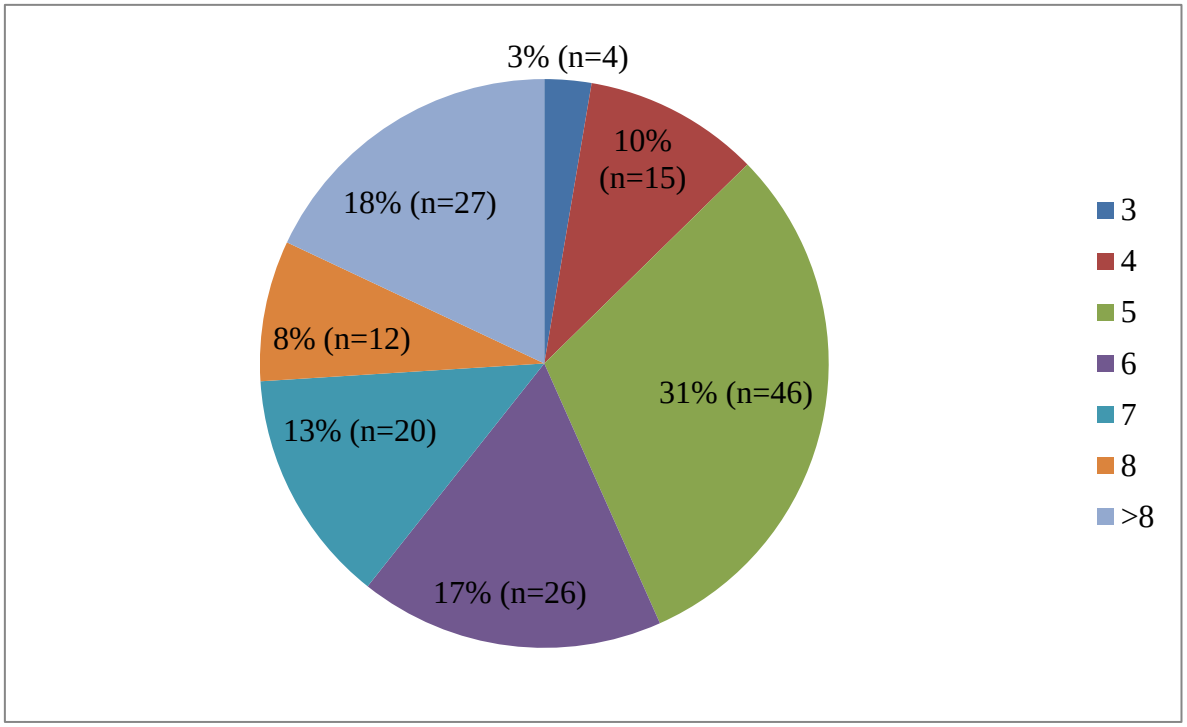

Figure 3.4 Frequency distribution of the number of years working as a doctor

Table 3.1 Summary of demographic results

Age	
Mean ± SD (in years)	31.5 ± 2.5
Gender	
Male, no. (%)	75 (50)
Female, no. (%)	75 (50)
Year of registrar training	
Year 1, no. (%)	27 (18)
Year 2, no. (%)	42 (28)
Year 3, no. (%)	49 (33)
Year 4, no. (%)	29 (19)
Year 5, no. (%)	3 (2)
Department of registrar	
Internal medicine, no. (%)	82 (55)
Surgery, no. (%)	39 (26)
Obstetrics & Gynaecology, no. (%)	2 (1)
Paediatrics, no. (%)	8 (5)
Anaesthetics, no. (%)	16 (11)
Psychiatry, no. (%)	3 (2)
Hospital where the doctors were working	
Charlotte Maxeke Johannesburg Academic Hospital, no. (%)	78 (52)
Helen Joseph Academic Hospital/ Rahima Moosa Mother and Child Hospital Complex, no. (%)	42 (28)
Chris Hani Baragwanath Academic Hospital, no. (%)	30 (20)
Number of years working as doctors	
3, no. (%)	4 (3)
4, no. (%)	15 (10)
5, no. (%)	46 (31)
6, no. (%)	26 (17)
7, no. (%)	20 (13)
8, no. (%)	12 (8)
>8, no. (%)	27 (18)

3.2 Details of needle-stick injuries

From the year of 1997 to 2013, a total of 123 registrars (82%) reported a needle-stick injury. The most number of needle-stick injuries per individual was seven and the least number of needle-stick injuries was nil. The total number of needle-stick injuries reported was 241.

3.2.1 Nature of needle-stick injuries

The gender distribution of the doctors with previous needle-stick injuries was almost equal [(male: 58 (47%) and female: 65 (58%) (P = 0.202)]. The majority of the needle-stick injuries occurred when the doctors were working in the Department of Surgery followed by Internal Medicine. Figure 3.5 illustrates the departments where the doctors were working at the time of injury. Most of the needle-stick injuries occurred when the doctors were interns (37%). Needle-stick injuries occurred in 67 cases when doctors were registrars (28%). This is illustrated in figure 3.6. A total of 55 doctors sustained injuries when they were registrars with eight doctors sustaining two injuries during their registrar training and two doctors sustaining three injuries. Figure 3.7 illustrates the frequency distribution of the department where the doctors sustained needle-stick injuries as registrars. Out of the 73 needle-stick injuries that occurred within the Department of Internal Medicine, 30 of them were registrars (41%). 23 out of 74 injuries within the Department of Surgery occurred when the doctors were registrars (31%). The time of injury was distributed equally between normal working hours and after hours. Most of the source patients were HIV-negative (n=132, 55%) with 77 of the source patients being HIV-positive (32%) and 32 having an unknown HIV status (13%).

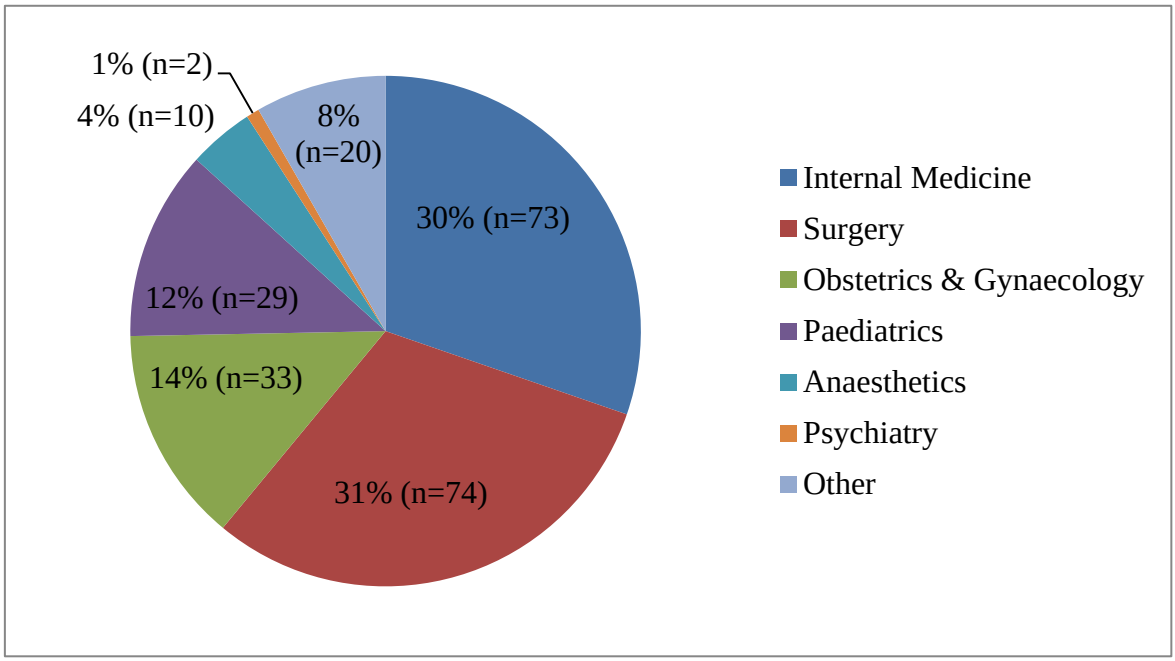

Figure 3.5 Frequency distribution of the department of the doctor at the time of injury

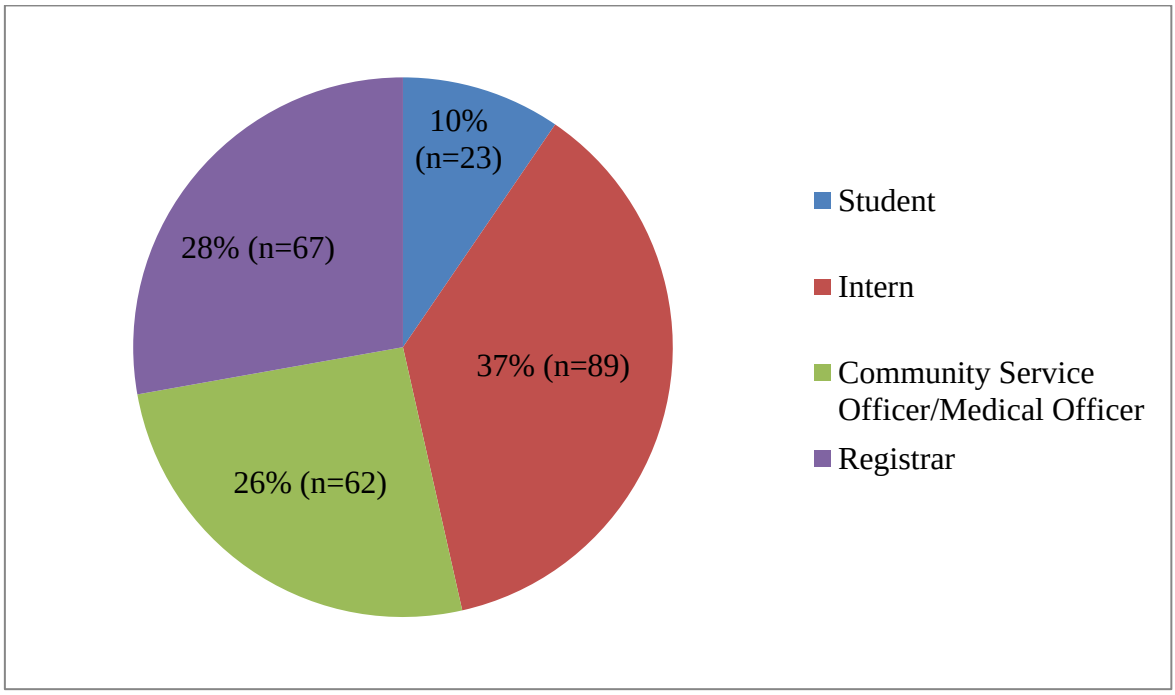

Figure 3.6 Frequency distribution of the position of the doctor at the time of injury

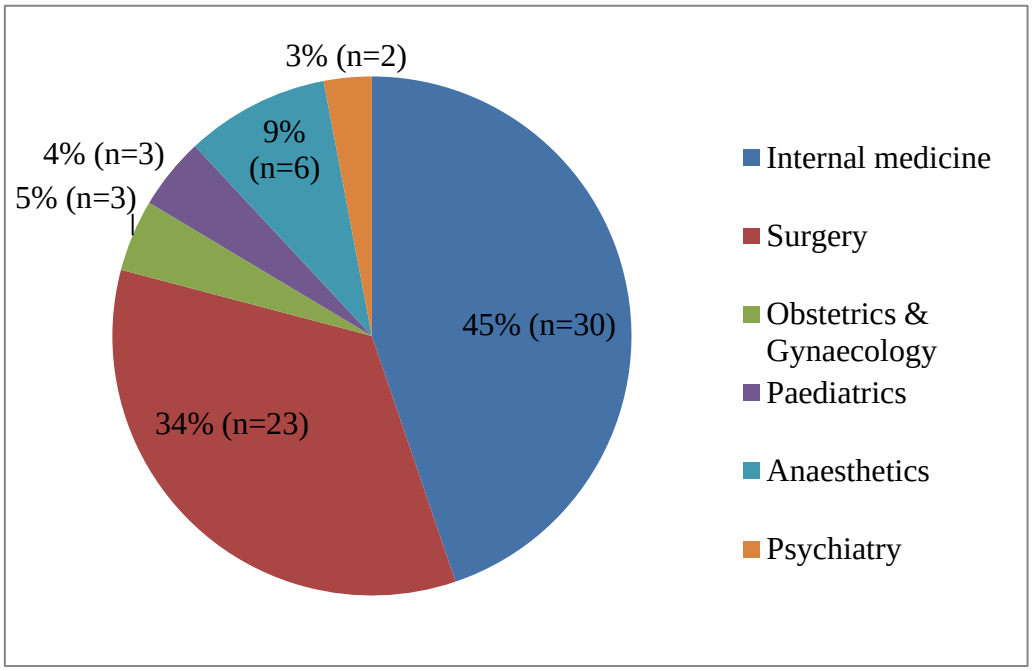

Figure 3.7 Frequency distribution of the department where the doctors sustained injuries as registrars

Figure 3.8 illustrates the frequency distribution of the mechanisms of injury. The most common mechanism of injury was reported as “other” (24%). However, there were 22 different categories of mechanism of injury within the category of “other” and the most common ones were injury caused by colleague (12 incidents) and surgical procedure (11 incidents). One doctor could not remember the mechanism of injury. Table 3.2 lists all the mechanisms of injury reported as ‘other’. The most common single mechanism of injury was insertion of drip (52 incidents). The risk of exposure was classified as high in more than 80 % of the incidents (n=213).

Table 3.2 List of mechanisms of injury reported as “other”

Arterial line insertion (n=5)	Cerebrospinal fluid tap (n=1)
Cleaning up (n=1)	Fine needle aspirate (n=1)
Glucose finger prick test (n=1)	Injury by colleague (n=12)
Intercostal drain insertion (n=4)	Intercostal drain removal (n=1)
Intravenous injection (n=3)	Local anaesthetic injection (n=1)
Mantoux test (n=1)	Needle sticking out of “sharps” bin (n=1)
Patient movement (n=1)	Per vaginal examination (n=1)
Pleural biopsy (n=2)	Pleural tap (n=1)
Quinton line insertion (n=2)	Recapping of needle (n=1)
Surgical procedure (n=11)	Suprapubic catheter insertion (n=1)
Unable to recall (n=1)	Unattended needle (n=5)

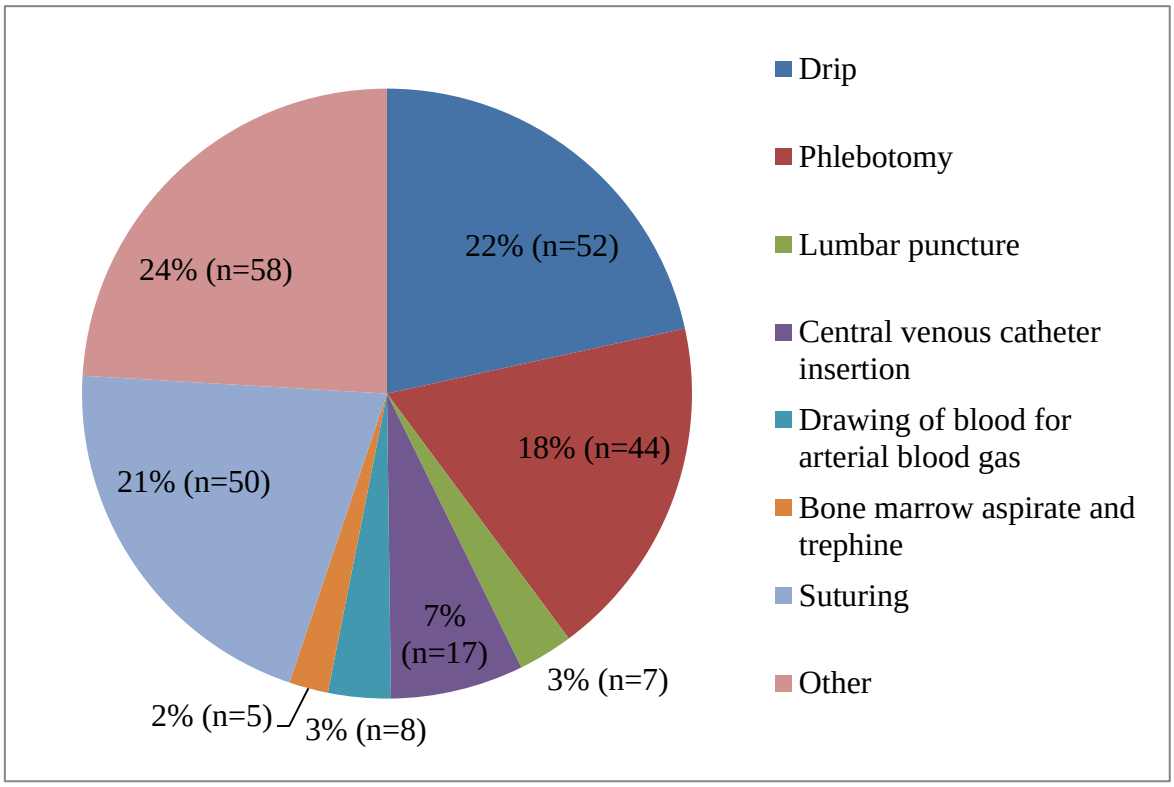

Figure 3.8 Frequency distribution of the mechanisms of injury

3.2.2 Use of, access to, and compliance with, PEP

The majority of the registrars had obtained advice regarding PEP (n=149, 62%). The advice was mostly sought from the category labelled "other", with the nurses in Infectious Diseases (n=14) and theatre nurses (n=5) being the most frequently consulted in this category. However, the individuals from whom advice was mostly obtained were the consultants and the casualty officers. Figure 3.9 illustrates the source of advice regarding PEP.

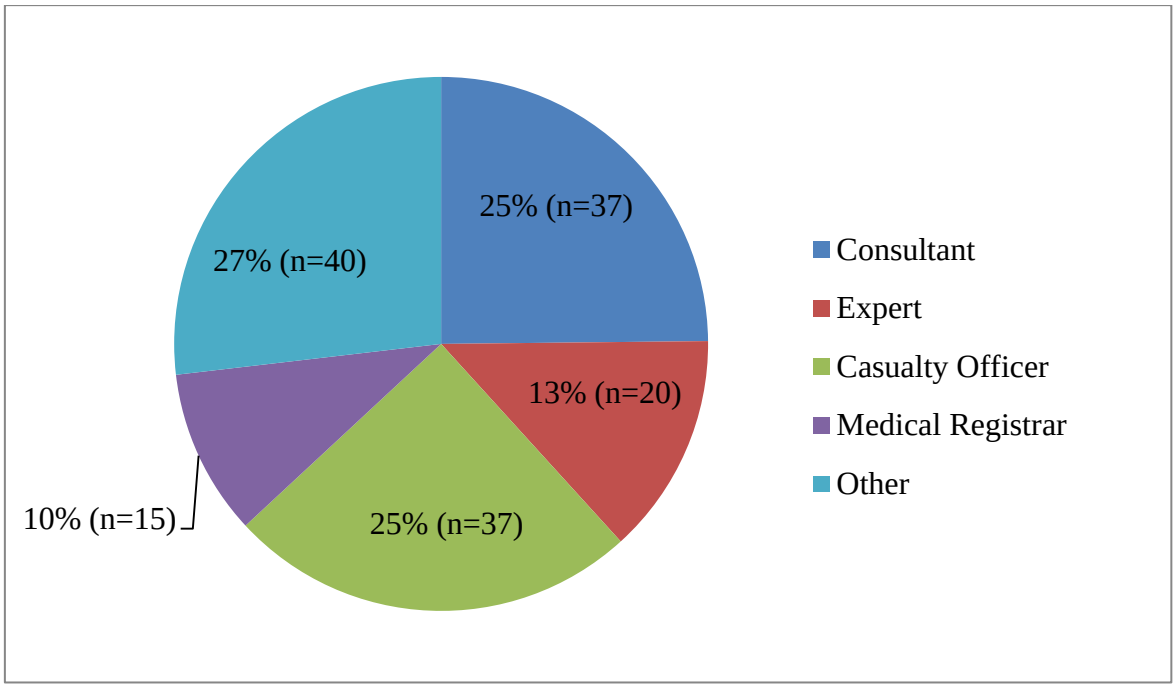

Figure 3.9 Frequency distribution of the source of advice sought regarding PEP

The majority of the doctors did take PEP (n=199, 83%). Most of the doctors took PEP using the combination of AZT and 3TC. Figure 3.10 illustrates the frequency distribution of the ARV regimen used for PEP. PEP after needle-stick injury was readily accessible with the majority obtaining PEP within two hours (n=136, 68%). 30% of the doctors had access to PEP within two and 24 hours (n=59), 2% within 24 and 72 hours (n=4), and none

after 72 hours. ARVs were primarily obtained from the public hospital (n=162), followed by the private sector (n=34), other (n=2) and both public hospital and private sector (n=1).

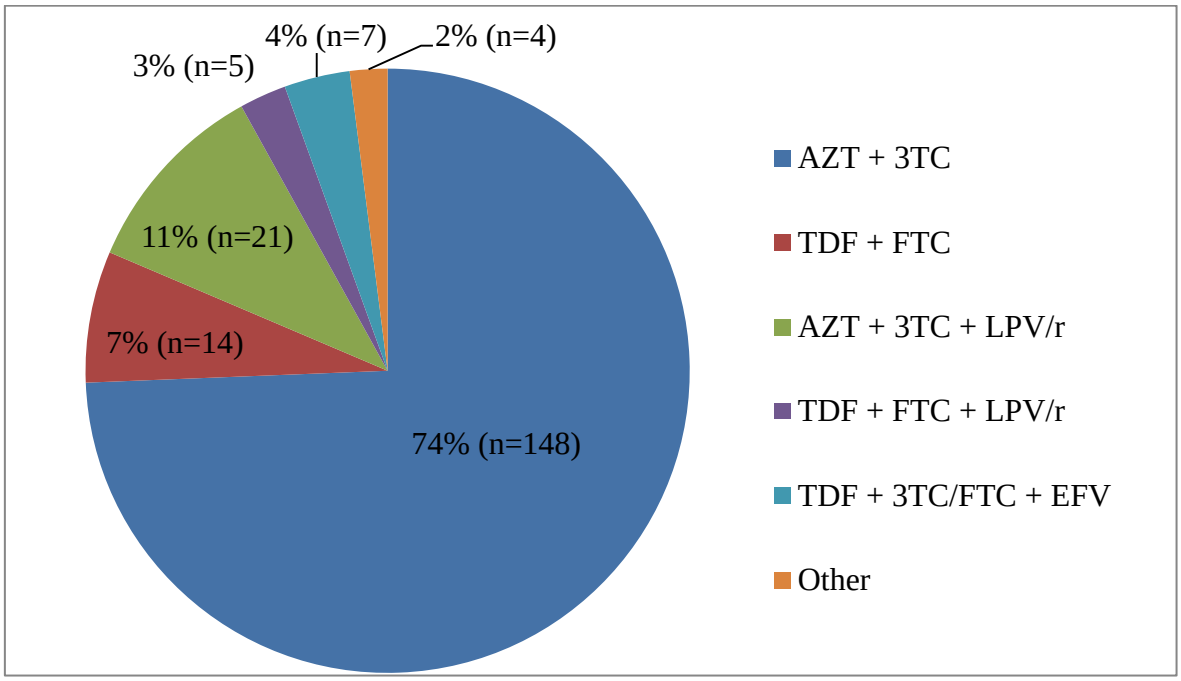

Figure 3.10 Frequency of the ARV regimens used for PEP

The majority of doctors completed 28 days of ARVs. Of the doctors who sustained needle-stick injuries, 40% of male doctors (23 of the 58 male doctors) and 52 % of female doctors (34 of the 65 female doctors) completed a full course of ARVs ($P = 0.205$). Overall, 54% of doctors taking AZT-based regimen completed a full course of ARVs as compared to 44% of doctors taking TDF-based regimen ($P = 0.41$). A total of 43% of doctors who took TDF and FTC completed 28 days of ARV and 46% of doctors who took TDF, FTC/3TC and a third drug completed the course ($P = 1.0$). A total of 55% of doctors who took AZT and 3TC completed a full course of ARV and 50% of doctors who took AZT, 3TC and a third drug completed the course ($P = 0.826$). For those who did not complete the course of the ARVs, one day was the least number of days that ARVs were taken (Table 3.3). The main reason why doctors did not take PEP at all was because they thought it was

unnecessary (n=26). There was one case of needle-stick injury where doctors did not take PEP due to the side-effects of the drugs and six cases of needle-stick injuries because of efficacy unknown. The main reason for doctors failing to complete the full PEP course was due to drug side-effects as well as being considered unnecessary (figure 3.11). Nausea, vomiting, fatigue and decreased appetite were the most commonly reported side-effects of the PEP (figure 3.12). Severe unusual side-effects were reported, such as agranulocytosis (n=1), renal stones (n=1), hydronephrosis (n=1) and tardive dyskinesia (n=1). Other unusual side-effects are listed in table 3.4. In only 7% of the injuries (n=14) was the PEP regimen changed and they were mostly changed to TDF + 3TC/FTC. Table 3.5 shows the regimens to which treatment was changed.

Table 3.3 Duration of ARVs for PEP

Number of days of ARVs for PEP	**Number of needle-stick injuries**
1-10	62
11-20	23
21-27	9
28	105

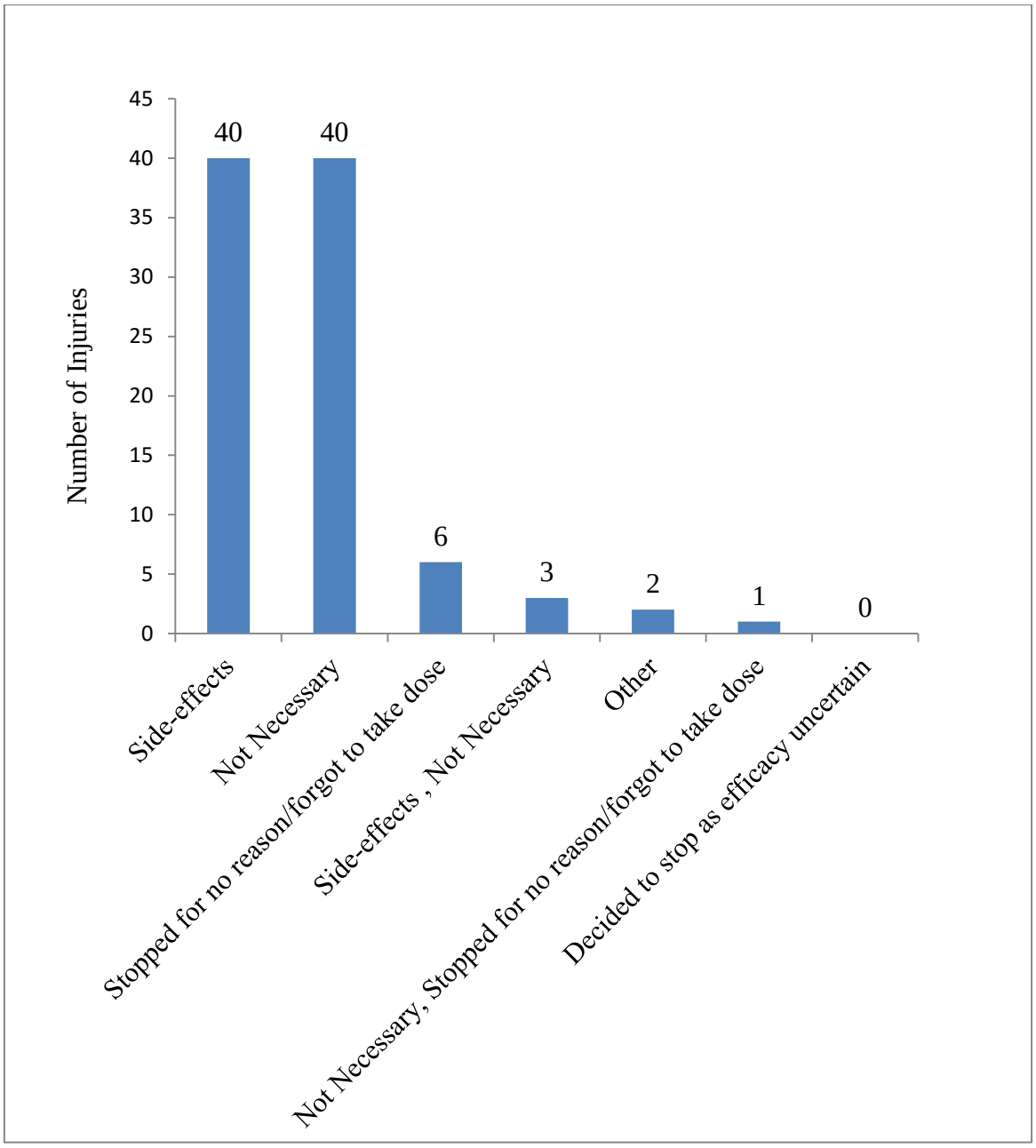

Figure 3.11 Frequency distribution of reason for not completing 28 days of ARVs

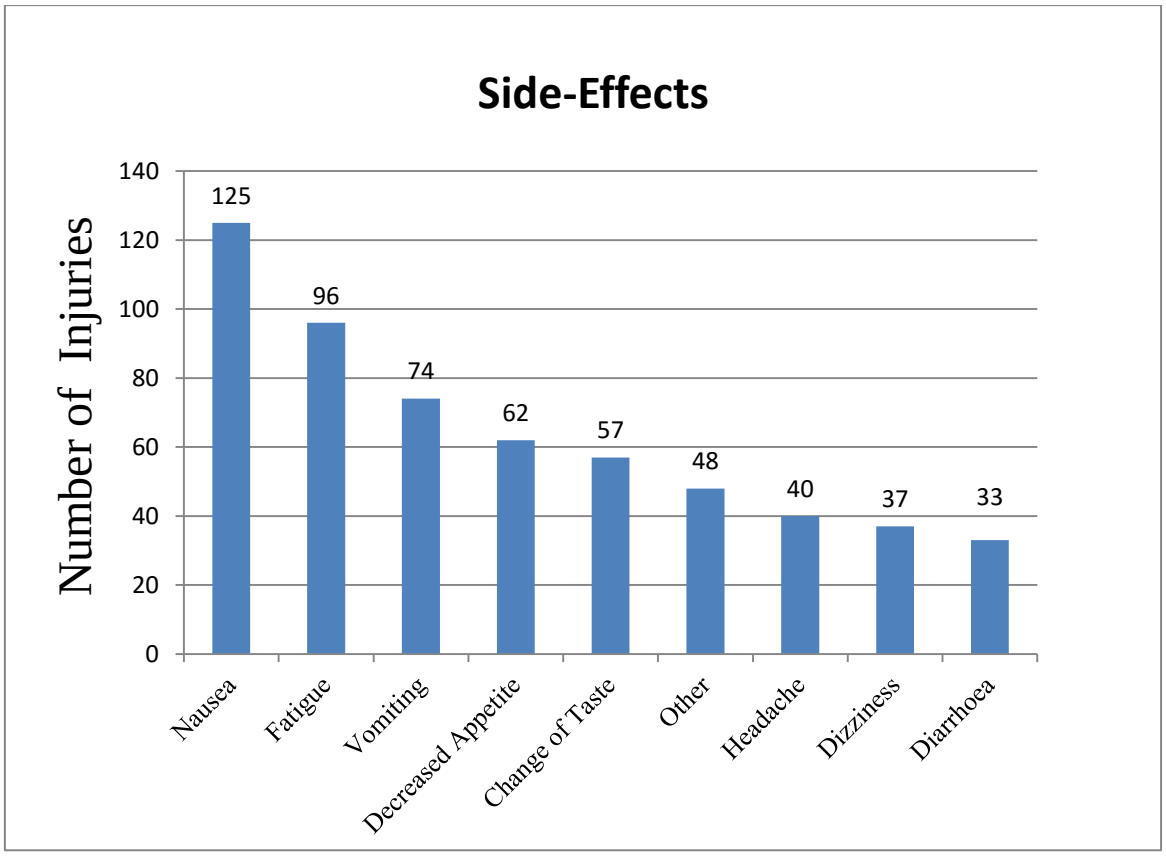

Figure 3.12 Frequency distribution of the common reported side-effects of the PEP

Table 3.4 List of other side-effects of PEP

Abdominal cramps (n=1)	Abdominal discomfort (n=3)
Abdominal pain (n=2)	Agranulocytosis (n=1)
Arthralgia (n=1)	Bad dreams (n=1)
Bloating (n=3)	Depression (n=2)
Dissociation (n=1)	Drowsiness (n=1)
Erythema nodosum (n=1)	Fever (n=1)
Flatulence (n=1)	Gastritits (n=4)
Giddiness (n=1)	Hallucination (n=7)
Heartburn (n=3)	Hydronephrosis (n=1)
Increased appetite (n=1)	Insomnia (n=7)
Liver dysfunction (n=2)	Malaise (n=2)
Myalgia (n=4)	Pancreatitis (n=1)
Psychosis (n=1)	Rash (n=2)
Renal stones (n=1)	Tardive dyskinesia (n=1)
Unwell with certain smells (n=1)	Vertigo (n=1)

Table 3.5 List of drugs to which the PEP regimen was changed

Drugs to which the PEP regimen was changed	**Number of injuries**
TDF + 3TC/FTC	6
TDF + 3TC/FTC + EFV	1
TDF + 3TC/FTC + LPV/r	2
TDF + 3TC/FTC + RAL	2
AZT + 3TC	1
AZT + 3TC + RAL	1
D4T + 3TC	1

4.0 DISCUSSION

4.1 Demographic information

To date, there are only six studies of needle-stick injuries among medical students and doctors in South Africa. Two studies looked at needle-stick injuries among all the HCWs within a department. [8,10] One study looked at needle-stick injuries among interns only in Johannesburg. [9] There were two studies which looked at needle-stick injuries among medical students. [11,12] Finally, one study done in Newcastle Provincial Hospital was of needle-stick injuries among all the HCWs within the hospital. [13] None of the above studies had looked at the registrars in particular. Furthermore, none of the above studies included the lifetime exposure of needle-stick injuries of doctors from their first clinical exposure during the years of medical school, the busy workload during internship to the time of intense training of registrars.

The current study is the first study in South Africa that has studied needle-stick injuries among registrars across different disciplines. This study had a sample size of 150 registrars across five disciplines. Most registrars interviewed were from the Department of Internal Medicine as it has the largest number of registrars at the University of the Witwatersrand. Although most of the doctors were working at CMJAH at the time of interview, registrars rotated between all three of the Academic Hospitals in Johannesburg during their time of training.

4.2 Needle-stick injuries information

The overall incidence of needle-stick injuries is high, both locally and internationally. Locally, the study done at the two academic hospitals in Johannesburg reported that 81% of the interns have had needle-stick injuries during either their three years of medical

school clinical training or one year of internship. [9] Overall, 62% of the doctors working in the Tygerberg Children's Hospital in Cape Town reported needle-stick injuries during a two year period. [10] Internationally, a study done in Nigeria reported a 67.9% incidence of doctors in surgery with occupational exposure to patient's blood in a six month period. Of all the occupational exposures, 63.6% was needle-stick injury. [6] In United States of America, three studies have shown that the incidence of needle-stick injury is greater than 70% among residents. [3-5]

The high incidence (82%) of registrars with previous needle-stick injuries in their lifetime in this study was in keeping with the figures reported in other studies mentioned above, both locally and internationally. [3-6,9,10] This is a major concern even though the HIV seroconversion rate is considered to be low (0.33%). [15]

4.2.1 Nature of needle-stick injuries

The profile of the doctors who sustained needle-stick injuries was similar to those reported in other studies. [4,9,35-39] This includes an almost equal gender distribution, involving mainly doctors working in the Departments of Surgery and Internal Medicine and occurring most frequently during internship. Departments of Surgery and Internal Medicine are the two biggest departments in the Academic Hospitals in Johannesburg. For example, Internal Medicine has 833 out of 3200 beds at CHBAH. The workload at these two departments is thus very heavy. Interns are the major workforce, who perform day to day ward procedures, and as a consequence, they are more prone to be injured during procedures. In addition, interns are less skilled clinically which adds to the risk of needle-stick injuries. 55 out of 150 registrars (37%) sustained injuries during their registrar training with eight registrars having had two injuries and two registrars having had three injuries. This adds up to a total of 67 needle-stick injuries sustained during registrar

training. A study done in the Department of Paediatrics at Tygerberg Children's Hospital showed that most of the needle-stick injuries occurred outside working hours. [10] On the other hand, international studies done in United States of America showed that needle-stick injuries occurred more commonly during normal working hours. [35,40] In contrast to the studies done globally, in the current study the time of injury was equally distributed between normal working hours and after hours in this study. This may be explained by a combination of factors: more procedures are performed during normal working hours, while fatigue during after-hours may increase the likelihood of sustaining needle-stick injuries.

The percentage of HIV-positive sources in the current study was lower than reported in the previous study done at the Academic Hospitals in Johannesburg (32% vs 42.9%). [9] This difference may be due to a few possible factors. Firstly, more HIV-positive patients have currently been initiated on antiretroviral therapy (ART) due to the ART rollout program implemented by the South African government in 2003. [41] Subsequently, more patients were eligible to enrol into the ART program due to the shift of a higher CD4 count threshold of lower than 350 cells/μL from the previous threshold of lower than 200 cells/μL for the eligibility of ART program as published in the revised national guideline in 2013. [42] This has led to a decreased HIV-related mortality by 22% in men and 29% in women as published in a study done in rural KwaZulu-Natal in 2013. [43] This may imply that the HIV-related morbidity is also decreased which results in fewer HIV-positive patients being admitted to hospital for whatever reasons. Secondly, there is a high percentage of the HIV status of the source patient being unknown (13%). The HIV status of the source patient may be unknown because of multiple factors, such as the doctor thinking it is unnecessary to do the test or the source patient cannot be traced or identified (for example, injury was caused by an unattended needle).

The most common mechanisms of needle-stick injuries reported in this study were during insertion of a drip and during suturing. This finding is similar to those reported in other studies reported locally and internationally. The study done in the Department of Obstetrics and Gynaecology in Durban reported caesarean section and venepuncture as being the most common procedures causing needle-stick injuries. [8] Phlebotomy and suturing were the most common procedures causing needle-stick injuries in the study done among interns at CHBAH. [9] Most of the needle-stick injuries in medical students at the University of Pretoria occurred during the insertion of intravenous cannulation and during venepuncture. [12] In studies done in the United States of America, the most common mechanisms of injury reported were suturing, recapping of needles, venepuncture, intravenous manipulation and insertion of intravenous catheters. [4,33,35,38,44] Both the studies done in a German university hospital and in Kenya reported suturing as the most frequent mechanism of injury. [37, 45] Venepuncture, capping of needles and uncapping of used needles were the most common procedures associated with needle-stick injuries in a study done among medical students in Singapore. [46] Insertion of a drip is probably the commonest procedure done during the day to day duty in the wards. Given the high injury-related morbidity and mortality rates in South Africa [47], the Department of Trauma under the Department of Surgery is extremely busy in South Africa. Suturing is a very common procedure done in most departments, especially the Department of Surgery. This may explain why insertion of drip and suturing were the most common mechanisms of needle-stick injuries. Possible interventions to prevent needle-stick injuries sustained during the insertion of a drip and suturing include use of safer needle devices, improvement of skill, and use of blunt suturing needles.

Some possible preventable mechanisms that were reported by registrars in this study include needle sticking out of the “sharps” bin, unattended needles, and recapping of

needles. This reflects a shortcoming in the education and implementation of universal precautions by doctors as well as nurses. It is usually the responsibility of the nurses to ensure that once the "sharps" bin is three quarters full, it should be sealed. As pointed out in the study done in nursing students in Gauteng, there is a lack of adequate numbers of "sharps" bins in Academic Hospitals in Gauteng. [48] Of note, there was only one incident of recapping of needles as a mechanism of injury in this current study. This risk of needle-stick injuries is very low as compared to the previous studies on needle stick injuries. [4,9,49] In the study done in interns at CHBAH in 1998, 17.4% of needle-stick injuries were due to recapping of needles. [9] Internationally, the study done among registrars in the United States of America in 1990 reported recapping of needles causing 38% of needle-stick injuries in non-surgical registrars. [9] Moreover, the study done among medical students in India published in 2000 also reported recapping of needles being a cause in 69% of the injuries. [49] The low incidence of needle-stick injuries due to recapping of needles in this study as compared to the previous studies may imply that more doctors are now aware of the need for this universal precaution.

4.2.2 Use of, access to, and compliance with, PEP

The majority (n= 199, 83%) of the doctors with needle-stick injuries took PEP. This is similar to those found in other studies done locally. [8,10] Out of the 42 cases of needle-stick injuries without PEP, seven cases occurred in the same surgical registrar. The majority of the doctors who did not take PEP were working in the Department of Surgery (n=16) followed by Internal Medicine (n=10). Over half of the doctors who did not take PEP were male (n=25). The main reason why doctors did not take PEP at all was because they thought PEP was unnecessary. PEP may be unnecessary if the source of the exposure is

HIV-negative or may be assumed to be unnecessary because of advice not being sought (38% of doctors did not seek any advice for PEP).

The combination of AZT and 3TC was the most commonly used regimen of PEP, as recommended by WHO in the 2007 guidelines. [50] Despite the guidelines on PEP published locally in 2008 which recommended triple therapy, most of the doctors studied continued to take two ARV agents for PEP. [18]

PEP is readily available at Academic Hospitals in Johannesburg with most of the ARVs being obtained from the public hospitals and access to PEP within two hours of needle-stick injury. However, there is a problem with access to PEP at rural hospitals in the Limpopo Province with one third of the nurses reporting that PEP were not available at their workplace. [51]

Over half (53%) of the doctors with needle-stick injuries completed a 28 day course of PEP. This finding is similar to the previous studies done in Johannesburg (54%) [9] and in Durban (52%) [8] but much lower than that done in Cape Town (100%) [10]. There was no significant difference between male and female doctors completing the full course of PEP ($P = 0.205$). The main reasons reported for not completing a full course of prophylaxis were because of side-effects and being considered unnecessary to continue the course. The single most common side-effect of PEP reported was nausea, followed by fatigue, vomiting, decreased appetite, change of taste, headache, dizziness and diarrhoea. These were also common side-effects reported in other studies. [8,10]

Only 14 doctors had their PEP regimen changed due to side-effects. Some doctors may have discontinued the PEP after expert advice was sought or the HIV status of the source patient was negative. The most commonly changed regimen was the tenofovir (TDF) - and emtricitabine (FTC) - based regimen. Interestingly, 19 out of the 27 cases who used TDF-

and FTC-based regimens from the beginning reported side-effects, with nausea being the most common. Less than half (n=12) of the 27 cases using TDF-based regimens completed 28 days of PEP as compared to 93 of the 172 cases using AZT-based regimen (P = 0.41). The latest guideline published by WHO in 2014 suggested a two ARV drugs regimen is effective for PEP, but three drugs is preferred. [23] Adding a third drug did not alter compliance in this study. Overall, 43% of doctors who took TDF and FTC completed 28 days of ARV and 46% of doctors who took TDF, FTC/3TC and a third drug completed the course (P = 1.0). Similarly, 55% of doctors who took AZT + 3TC completed a full course of ARV and 50% of doctors who took AZT + 3TC + a third drug completed the course (P = 0.826). TDF and 3TC or FTC are now the preferred backbone regimen for PEP because of significantly lower risk of non-compliance due to their side-effects profile. However, most cases in this study still discontinued the TDF and FTC-based PEP regimens prematurely. It is thus questionable whether the change of PEP regimen published by WHO in 2014 would improve adherence.

4.3 Potential limitations of the study

This study has potential limitations. The study employed convenience sampling; thus the selection of participants was not at random, with most participants being registrars in the Department of Internal Medicine, and so the sample may be biased. The study relied on information recall which may be inaccurate. The HIV status of the doctors was not known in the current study and this may have affected the behaviour of the doctors following needle-stick injuries. The hospital at the time of injury was not recorded, and thus the results may not reflect the true situation in Johannesburg as the needle-stick injuries may have occurred in the hospitals outside Johannesburg. The numbers are too small in each of the different antiretroviral treatment regimen groups to explore differences in compliance

of the doctors with the different regimens. It would have been interesting to study other communicable diseases transmittable by needle-stick injuries other than HIV infection, especially hepatitis B, but these were not the focus of the study.

4.4 Strengths of the study

There are some strengths of the study. The study has a relatively large sample size of 150 doctors, which included registrars across different disciplines in the Academic Hospitals in Johannesburg. This is also the first study we are aware of in South Africa which has included the total exposure to needle-stick injuries of doctors from their training as undergraduates in medical school.

5.0 CONCLUSION

This study is the first in South Africa that looks at the pattern of prior needle-stick injuries among registrars in different disciplines. It was noted that it was in the Departments of Surgery and Internal Medicine that the highest incidence of needle-stick injuries occurred. The most common mechanisms of needle-stick injuries were insertion of a drip and suturing. The findings in this study are similar to those found in the previous studies done in South Africa**.**

The high incidence of prior needle-stick injuries among registrars is worrying. Some of the injuries may have been prevented by improved clinical skills training, use of safer needle devices, use of blunt-tip instead of sharp-tip suturing needle, adherence to universal precautions and increasing the number of "sharps" bin available.

The majority of the doctors who sustained needle-stick injuries took PEP using the regimen of AZT and 3TC. However, almost half of them did not complete the four week course of PEP. The main reasons for stopping PEP prematurely were side-effects or continuation of regimen considered unnecessary.

TDF and 3TC (or FTC) are now the preferred backbone regimen of PEP, as recommended by the WHO in 2014. [23] They are also widely available in South Africa as the combination therapy of TDF, 3TC (or FTC) and EFV is now the first line ARV regimen for HIV-positive patients. [52] Further studies with a larger sample size looking at the adherence to PEP with the new regimen and the effectiveness of counselling on completion of PEP are recommended.

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APPENDIX A

Questionnaire no ____

Age: ____ Gender: M/F
Current position: Registrar year: a. 1 b. 2 c. 3 d. 4 e. other:_____
Department? a. Int medicine b. Surgery c. O&G d. Paeds e. Anaesthetics f. Psychiatry
Hospital? a. CMJAH b. HJH/RMH complex c. CHBH
Years working as a doctor? a. 1 b. 2 c. 3 d. 4 e. 5 f. 6 g. 7 h. 8 i. >8
Have you ever had a needle-stick injury? Yes/No **If no, end questionnaire.**

No of injuries	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Year									
Department at the time of injury a. Int med b. Surg c. O&G d. Paeds e. Anaesthetics f. Psychiatry i. other									
Position at the time of injury a. Student b. Intern c. Comm Service/MO d. Registrar									
Time of the day of injury a. During working hours (8am to 4pm) b. After hours (4pm to 8am)									
HIV status of the source patient : +/ - / ? (unknown)									

Mechanism of injury a. Drip b. phlebotomy c. LP d. CVP e. ABG f. BMAT g. Suturing h. Other and specify									
Low/ high risk exposure *									
Did you get advice regarding PEP? Y/N									
If yes, from whom? a. Consultant b. Expert c. Casualty officer d. Medical registrar e. Other and specify									
Did you take PEP? a. Yes b. No									
ARVs used for PEP a. AZT + 3TC b. Truvada c. AZT + 3TC + Aluvia d. Truvada + Aluvia e. TDF + 3TC + EFV f. Other									
Time between injury and access to PEP a. Less than 2 hours b. Between 2 hours									

and 24 hours c. Between 24 hours and 72 hours d. After 72 hours									
Where did you get your ARVs? a. DOH b. Private sector c. Other and specify									
How many out of the 28 days did you take your ARVs?									
If not 28 days, why? a. Side-effects b. Not necessary c. Decided to stop as efficacy uncertain d. Stopped for no reason/ forgot to take doses									
If you had side-effects, what were they? a. Nausea b. vomiting c. headache d. diarrhoea e. fatigue f. dizziness g. change of taste h. decreased appetite i. other and specify									
Did you change your PEP regimen? Y/N									
If yes, to what did you change?									

* **Low risk injury** — Low risk injuries include those which occur through a solid needle, appear superficial, and occur from a low risk source, such as a patient with an HIV viral load <1500 copies/mL.
High risk injury — High risk injuries include those involving a hollow-bore needle with presence of visible blood on the device, or exposure from a needle that was in an artery or vein of the source patient.

APPENDIX B ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Anita Pui Ching Lai

CLEARANCE CERTIFICATE	**M121058**
PROJECT	The Pattern of Needle Stick Injuries in Academic Hospitals in Johannesburg
INVESTIGATORS	Dr Anita Pui Ching Lai.
DEPARTMENT	Department of Internal Medicine
DATE CONSIDERED	26/10/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 12/11/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof Charles Feldman

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...