

Occupational blood and body fluid exposure incidents amongst undergraduate medical students over a period of 5 years

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Declaration

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ABSTRACT

Introduction

Exposure incidents involving blood and body fluids represent a major hazard for medical undergraduates. Every medical teaching university experiences the problem of undergraduate medical students sustaining such incidents. Although Post Exposure Prophylaxis (PEP) is readily available and accessible to medical undergraduates following an incident, continuity and quality of care extends beyond the provision of PEP. This includes follow up consultations after receiving PEP according to protocol.

Study Design

This study was performed at the Tygerberg Campus of Stellenbosch University in Cape Town, South Africa to assess compliance with follow up consultations following an exposure incident. The study base consisted of all the medical undergraduates who reported an exposure incident at the Campus Health clinic. Cases were defined as medical undergraduate students of Stellenbosch University who had reported an exposure incident between January 2007 and December 2011. They were identified using the clinic database and records.

Influential factors associated with the exposure incident, including compliance regarding follow up consultations were obtained from standardised reporting forms and medical records. The data was analysed in 2 sections, a cross sectional component (descriptive and analytical) and a retrospective cohort component. Two student cohorts were retrospectively followed from the beginning of their 3rd year to the end of their medical curriculum (6th year).

Results

There were 280 exposure incidents reported in the study period, of which 174 were low risk and were 106 high risk incidents for which PEP was prescribed (37.86% used PEP). For those who had high risk exposures, 90.57% (n=96) attended the 6-week follow up consultation, 48.11% (n=51) attended the 3 month visit and 34.91% (n=37) attended the 6 month follow up visit. There was an increase in the number of exposure incidents from 2010 (n=43) to 2011 (n=76).

Internal medicine accounted for the most number of incidents (n=68), followed by Surgery (n=51), Obstetrics and Gynaecology (n=44), and Paediatrics (n=42). Drawing blood was the most common reported activity associated with exposures. Of notable importance was recapping, disposing of needles and insertion of blood into sample tubes. These activities accounted for 63 of the 280 exposure incidents. The 4th year students were the least at risk for exposure incidents compared to 3rd, 5th, 6th years. The annual average cumulative risk of having an exposure incident was found to be 5.7% (95%CI=4%-8%) and 6.8% (95%CI=5%-9%) amongst the 2 student cohorts over the duration of 4 years (clinical exposure time).

Recommendations

There is an urgent need for the number of exposure incidents to be reduced, e.g. needle recapping and disposal, and insertion of blood in sample tubes cause numerous preventable incidents. Various other strategies can be implemented in order to reduce the number of incidents across all undergraduate years of study. It is envisaged that by reducing the number of exposure incidents, there will be a subsequent decrease in the number of individuals requiring PEP. The importance of ensuring compliance with regard to follow up consultations needs to be emphasized. Factors that lead to noncompliance need to be investigated in a separate study.

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LIST OF ABBREVIATIONS

PEP: Post Exposure Prophylaxis

IV: Intravenous

TAH: Tygerberg Academic Hospital

PPE: Personal protective equipment

ETT: Endotracheal tube

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Exposure incidents involving blood and other body fluids represent a major hazard for medical undergraduates. They are at risk of exposure to dangerous pathogens on a daily basis. These students may be exposed to injuries from contaminated sharps, needle stick or splashes with blood or other infectious body fluids.

Within the legal framework in South Africa, the position and status of students within the occupational setting is unclear to most parties involved, since no act refers to or provides a definition for “students” in this setting. Some arguments are forwarded for legally considering medical students as “employees” in terms of occupational legislation: Firstly, in terms of the Occupational Health and Safety Act⁽¹⁾, students may in fact be considered as “employees”, since the definition covers “any person who works under the direction or supervision of an employer or any other person”. For medical students such direction and supervision are provided by both the university (who sends students to work in the hospital as part of their training) and the Provincial Department of Health. Students are required to work under the supervision of a consultant, registrar, or intern who is employed by the Department of Health. Secondly, the Compensation for Occupational Injuries and Diseases Act⁽²⁾ defines an “employee” as a person who has “entered into or works under a contract of service or of apprenticeship or learnership with an employer, whether the contract is express or implied, oral or in writing, and whether the remuneration is calculated by time or by work done, or is in cash or in kind”. On the basis of this definition it is contended that students would be considered as employees, because they have entered into a learnership program and the remuneration is “in kind” (e.g. attaining a mark for passing the clinical rotation). None of these arguments have ever been tested in a South African court of law and there is thus still ambiguity regarding the position of medical students in this setting.

Every medical teaching university experiences the common problem of undergraduate medical students sustaining sharps and splash injuries. Universities should start to take steps in order to decrease the rate of exposure to blood and body fluid incidents amongst their medical undergraduates. Intervention programmes need to be developed on unique studies performed in their environment, by identifying problem areas and trends.

1.2 Literature Review

Information is lacking on the number of undergraduate medical students who successfully completed follow up appointments after receiving Post Exposure Prophylaxis (PEP) secondary to exposure to blood or bodily fluids. No journal articles were found when database searches were performed on PubMed and Scopus in relation to medical students taking PEP and following up on the required follow up dates which typically are at 6 weeks, 3 months and 6 months following an incident, according to protocol. However, a search done on Google scholar yielded two articles that vaguely discuss students as part of a larger healthcare worker study groups ^(3,4). Student representation was 2% in the one study and no further details specifically relating to follow up were mentioned. Follow up results were based on 2 groups of healthcare workers as an entire group and represented as adherence, partial adherence and failure to follow up which was 56%, 26% and 18% for the one group and 53%, 33 % and 14 % for the second group ⁽³⁾. The other study, based on healthcare workers in Taiwan, reported a 56.4 % follow up for seroconversion testing ⁽⁴⁾.

PEP is normally given after doing an assessment of the injury risk, which takes into account the type of body fluid exposed to, the nature of the injury, and the HIV status of the source patient. The percentage of students proceeding to use PEP after a blood and body fluid exposure incident can vary, based on this risk assessment. The prevalence of HIV infection in patients is higher in the developing world compared to first world countries. The source patient is a determining factor when doing a risk assessment to initiate PEP; therefore in developed countries the PEP usage will be lower. A study related to occupational exposures done amongst healthcare workers, including students, in Thailand reported PEP usage to be 63.5% ⁽⁵⁾.

Over a 7-year period, 3rd and 4th year students were monitored for exposure incidents at the University of California School of Medicine, where 129 incidents were reported ⁽⁶⁾. A study conducted in Germany showed that incident rates for sharp exposure incidents were higher than mucosal related incidents ⁽⁷⁾. In the United States of America (USA), a survey conducted among 17 medical centres found that 59% of recently qualified doctors reported having sustained a needle stick injury as medical students ⁽⁸⁾. No specific information was given relating to the undergraduate year ⁽⁸⁾. In China a survey was

conducted in all five academic years amongst students majoring in clinical medicine, nursing, dentistry, medical technology, pharmacology, acupuncture/massage and it was noted that 12.6% suffered a needle stick injury in the preceding month, with a total of 131 injuries reported ⁽⁹⁾

A recent survey on 4th year students in Sri Lanka found that one or more injuries were experienced by 95% of medical students ⁽¹⁰⁾. A study conducted in China amongst found medical students in their 5th year had the highest number of needlestick injuries ⁽⁹⁾. Studies conducted in Australia and USA found the 3rd and 4th year medical students were the groups that had the most needlestick injuries ⁽¹¹⁾⁽¹²⁾. They found no statistically significant difference between the 4th and 5th year groups ⁽¹¹⁾. Another study found that 3rd and 4th year groups had similar number of needlestick injuries ⁽¹³⁾.

There are various factors that have been found to be associated with higher risk for exposure to blood and body fluids as a result of exposure incidents. Recent research suggested that some of these factors that play a role are that there is a lack of knowledge ⁽¹⁴⁾⁽¹⁵⁾ among students in some undergraduate years as well as the fact that some of those affected are recently qualified doctors. Failure to report due to fear of further progress in studies ⁽¹⁶⁾ and failure to adhere to universal precautions ⁽¹⁴⁾ were amongst other established factors.

Although gender ratios of exposure incidents are given in the literature, none of these studies provided the gender ratios in the class and therefore the association with gender could not be estimated ^{(17) (18)}. A study conducted by Parks, *et al* found that more incidents occurred during the day than at night, however taking into account the number of students it was found that the risk was higher during the night than the day ⁽¹⁹⁾. Surgical, Internal medicine, obstetrics and gynaecology, orthopaedics and accidents and emergency disciplines are the top 5 varying ranked disciplines found in various studies related to exposure incidents amongst students ⁽⁹⁾⁽⁶⁾⁽²⁰⁾⁽²¹⁾⁽²²⁾.

Needlestick injuries during the processes of phlebotomy and venipuncture (drawing blood) were the most common finding in various medical student studies ⁽¹¹⁾⁽¹⁸⁾⁽²⁰⁾⁽²¹⁾. Injuries related to recapping were also common, including incidents related to the

disposal of needles ⁽²¹⁾. There were four studies that found most needle injuries were associated with the activity of suturing ⁽¹⁰⁾⁽²²⁾⁽²³⁾⁽²⁴⁾.

The foregoing literature review relates to various studies conducted in different countries. Each of the universities follow their unique medical undergraduate program. Some of these training programs are 5 years – a fact that is not specifically mentioned in the literature. Therefore relative comparisons would be difficult in most instances. Some important studies conducted in South Africa were also identified. The last study conducted at Tygerberg Hospital in 2002 was a cohort study amongst final year medical students. This study illustrated that recapping of needles ranked as the most frequent activity associated with a sharps injury, followed by an injury sustained while discarding a used needle. It was noted that there was at least one incident per week over a 15-week period ⁽²⁵⁾. The departments concerned were Obstetrics and Gynaecology, Internal Medicine and Surgery. The most common type of injury was a hollow needlestick injury ⁽²⁵⁾. The majority of incidents occurred when the students were on call i.e. after hours (17h00-7h00)⁽²⁵⁾. Another South African study conducted at Addington hospital in Durban looked at recently qualified medical doctors and found that 62% of first year interns had an exposure incident within their first year of leaving medical school ⁽²⁶⁾. A cross sectional survey conducted between Johannesburg Hospital and the Chris Hani, Baragwanath hospital, found that that 56.1 percent of newly qualified doctors had needlestick exposure incidents during their student years and 28.6% had mucocutaneous exposure as students ⁽²⁷⁾.

This study focused on the 3rd, 4th, 5th, and 6th year of the medical undergraduate as well as trends amongst the individual years from 2007 through to 2011. The purpose of this study was to evaluate the follow up adherence patterns after students received PEP secondary to exposure to blood or body fluids; to obtain analytic data regarding the number of students who opted to use PEP; and to determine any possible associations with risk factors (e.g. the undergraduate year of study). None of this information pertaining to medical students had been examined before. This study should provide valuable information to the Faculty of Medicine and Health Sciences and Tygerberg Academic Hospital (TAH) regarding undergraduate medical students receiving PEP.

1.3 Aims and objectives

The aim of the study was to establish the number of undergraduate medical students who had a blood and body fluid exposure incident, those that required PEP arising from such incidents, and those who completed their PEP follow-up visits.

1.3.1 Primary objective

The primary objective of this study was to determine the proportions of undergraduate medical students over a 5 year period, from the 1st of January 2007 to 31st December 2011, who:

- reported an exposure incident to blood or other body fluids that occurred at TAH and other hospitals and subsequently referred to the Campus Health Clinic
- qualified for PEP (in terms of the policy as discussed in study setting)

1.3.2 Secondary objectives

The study also had the following secondary objectives:

- To determine the proportions of students who proceeded to complete the follow-up visits at 6 weeks, 3 months and 6 months following an incident requiring PEP
- To establish the average annual cumulative risk of exposure incidents among two cohorts of undergraduate medical students followed through to the end of their undergraduate studies over a 4-year period.
- To determine the association of exposure incidents with specific factors over the study period.

During the analysis of the data, the following objectives were added retrospectively:

- To determine the relative risk of exposure incidents in medical undergraduates with regard to associated factors.
- To determine the cumulative risk of exposure incidents over the study period.

CHAPTER 2: METHODOLOGY

OVERVIEW OF THE DIFFERENT COMPONENTS (DESIGN) OF THE STUDY

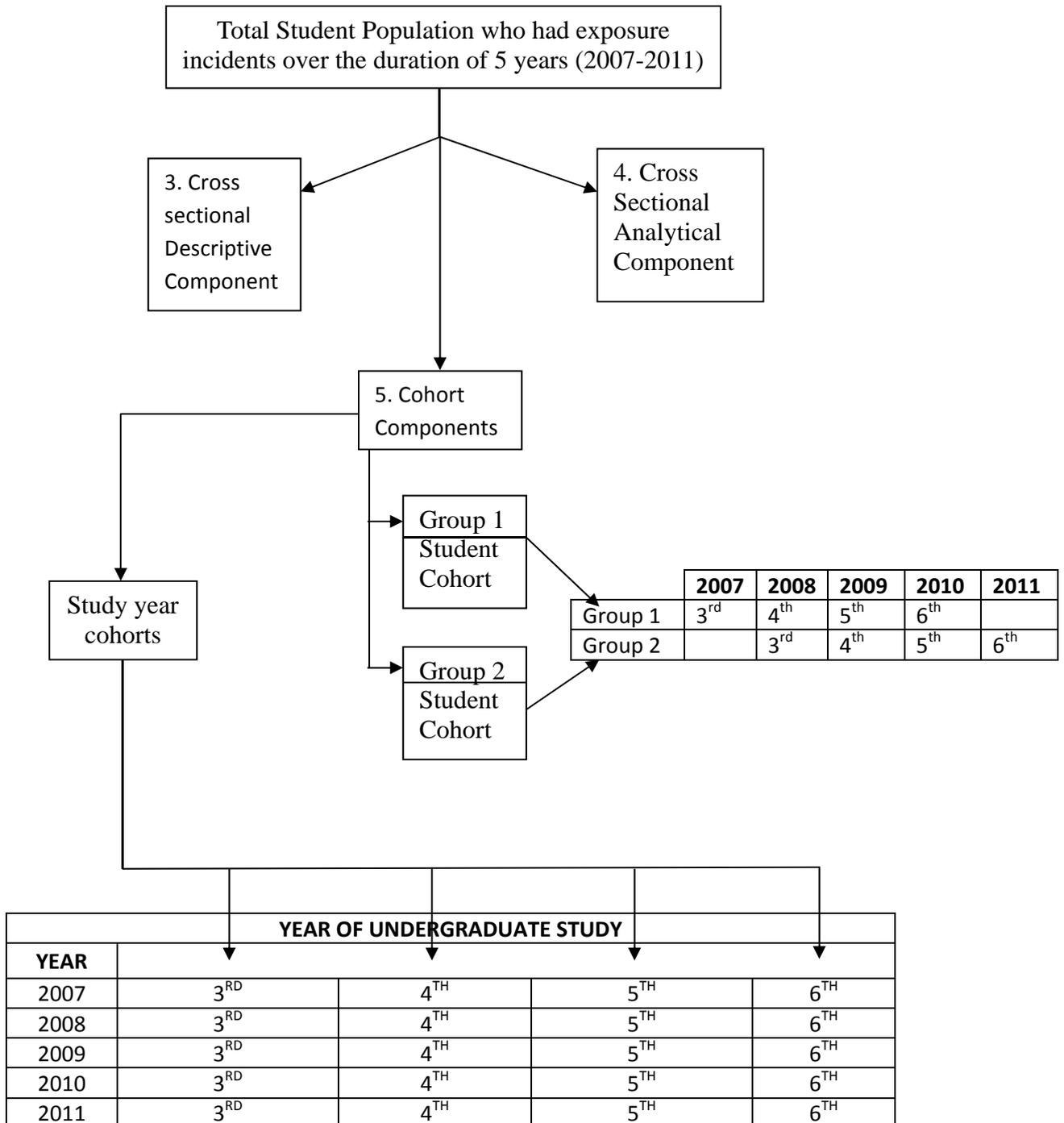


Figure 1: Overview of study design

2.1 Study design

This study had three separate components. Firstly a descriptive (cross sectional) component detailing the clinical characteristics of the exposure stratified by year of study, activity performed, gender, department where the exposure incident took place, time of occurrence and anatomical location. These were obtained from medical records. Observed trends in occupational injuries and PEP use were also analysed using data from medical records. The period prevalence of exposure incidents was calculated over a 5-year period (from 1st of January 2007 through to 31st December 2011).

Secondly, a cross-sectional (analytical) section was used to calculate odds ratios to determine the measures of association between risk factors and the exposure incidents. A non-parametric test (Cochran's Q) was used to evaluate compliance with PEP follow up visits at 6 weeks, 3 months and 6 months. The data obtained from the medical records allowed for the establishment of the cross sectional component.

Thirdly, a retrospective cohort study was conducted to assess the trends in occupational exposures as well as the risk factors associated with the exposure over a 5-year period. Two separate retrospective cohorts were also identified and followed up until the end of their 6th year of the medical curriculum. The first cohort was the 3rd year class of 2007 which was followed up until the end of 2010. The second cohort was the 3rd year class of 2008, which was followed up until the end of 2011. Cohorts were established using the class lists obtained from the student administration division of the University

2.2 Study setting

The study was conducted at the Campus Health clinic of the Faculty of Medicine and Health Sciences of Stellenbosch University (Tygerberg Campus). Undergraduate medical students who received PEP at the Campus Health clinic from 1st of January 2007 through to the 31st December 2011 after having an exposure incident related to blood and body fluids at Tygerberg Academic Hospital (TAH) and those that had exposure incidents at clinics outside TAH (Karl Bremer hospital, Eben Donges hospital, Paarl hospital and various day hospitals) who were managed at the Campus Health clinic were eligible for inclusion.

TAH is located in Parow, Cape Town in the Western Cape Province of South Africa. This is a tertiary referral level hospital and is the largest hospital in the province, and the second largest hospital in South Africa. It is a teaching hospital in conjunction with the Stellenbosch University Faculty of Medicine and Health Sciences. The hospital's primary drainage area is the eastern sub-district of the Cape Town metropole, with some 3.6 million residents ⁽²⁸⁾

'More than 90,747 patients are admitted and more than 500,000 outpatients visit the hospital annually. The average length of stay was 6.5 days with an average occupancy of 71.6%. The average number of operations performed each year were 25878 ⁽²⁸⁾. All medical undergraduates will at some point rotate in the hospital through various disciplines in order to gain knowledge and further their clinical skills. Students are also required to perform various small procedures under supervision, which include amongst others, the drawing of blood, blood cultures, fine needle aspirations, insertion of chest drains, and placement of intravenous lines and assisting in theatre with surgical procedures.

Students can experience exposure incidents when they come into contact with patients' blood or body fluids via needle/sharp injury, splash or contamination on broken skin. Students should use standard precautions (as they are taught) at all times in order to minimize the risk of exposure to a patient's blood and/or body fluids. However injuries can still happen and the following protocol is prescribed in case such an incident occurs. The student should report immediately to the Occupational Health Clinic during normal working hours (weekdays 07:00–16:00) or to the medical emergency ward (on public holidays and after hours). PEP should be started within 1 to 2 hours (but not later than 24 hours). The exposed students received counselling and the contact (source) patient's blood was sent for HIV and Hepatitis B testing (after obtaining informed consent from the patient).

TAH provided stat doses as well as starter packs and the students were immediately referred to the Campus Health clinic where decisions on the necessity of retroviral prophylaxis were taken based on the level of risk associated with an exposure and the source patient's HIV result. The student was then required to sign the prophylaxis consent form, if prophylaxis was necessary. After further evaluation of the student, PEP

was issued and a follow-up was required accordingly at 6 weeks, 3 months and 6 months. Databases are kept containing information of all the undergraduate medical students seen at the Campus Health clinic. These databases were evaluated from 1st of January 2007 through to 31st December 2011 for the purposes of this study.

For those injuries that occurred outside of TAH (i.e. at other healthcare facilities that are part of the training platform), the student was provided with emergency prophylaxis treatment (referred to as a “starter pack”) and was referred to the Campus Health clinic for further management. The same follow-up procedures were followed as for those that had sustained injuries at TAH.

2.3 Study participants

The study participants were undergraduate medical students who were registered with the Stellenbosch University Faculty of Medicine and Health Sciences (1st of January 2007 through to 31st December 2011), who had exposure incidents while performing clinical duties at TAH and other clinical training sites and who were seen by Campus Health clinic following an exposure Incident.

2.3.1 Inclusion criteria

All undergraduate medical students, who were registered with Stellenbosch University, were eligible for inclusion if they met all of the following criteria:

- Reported a blood and/or body fluid exposure incident between 1st of January 2007 through to 31st December 2011 at the Campus Health clinic
- Registered for the MBChB degree (all years)

2.3.2 Exclusion criteria

The following exclusion criteria were applied during this study:

- Elective students (including foreign/ international students) from other universities doing their training at TAH
- Students receiving PEP for exposure incidents outside of clinical work (e.g. for unprotected sex)

- Students registered for a degree other than MBChB

2.4 Data sources

The database of exposure incidents for medical undergraduates at the Campus Health clinic at Stellenbosch University and the database at the Occupational Health Clinic of TAH were reviewed for information concerning exposure incidents for the purposes of this study. The study participants were identified from the databases; and the clinical records of the participants were also reviewed in order to capture the variables for analysis.

Denominator data regarding the number of undergraduate students in each undergraduate year of study (3rd, 4th, 5th, 6th), classified into each year (2007, 2008, 2009, 2010 and 2011), and gender data were obtained from the administrative division of Stellenbosch University. The denominator data was used for both the cross sectional component and the cohort component calculations.

2.5 Cross sectional descriptive component

After confirming the exposure incident from the database, clinical records were obtained and the following variables were captured for each participant:

- Exposure incident classified as those that took place at TAH or other (various day hospitals, Karl Bremer, Eben Donges, Paarl and Stikland hospitals)
- Gender (categorized as male/ female);
- Year of occurrence (classified as 2006, 2007, 2009, 2010, 2011);
- year of undergraduate study (1st, 2nd, 3rd, 4th, 5th, 6th);
- Clinical posting when incident took place i.e. which clinical division; (Obstetrics and Gynaecology, Internal Medicine, Surgery, Psychiatry, Paediatrics, other and not defined)
- Mechanism of incident (splash, sharp incident);
- Anatomical site (hand, finger, forearm eye, other.); Other included sites which were not one of the above mentioned categories
- Time of day that the injuries occurred (8am to 4pm classified as working hours and 4pm to 8am classified as after hours);

- Type of activity when the incident occurred (drawing of blood, setting up IV line, recapping, disposal of needle , insertion of blood into sample tubes, during suturing , assisting in surgery , other and not defined)
- PEP provided (classified as yes or no)
- Completion of follow up visits as per protocol after exposure to blood or body fluid exposure incident and having received PEP (yes or no for each of the visits at 6 weeks 3 months, and 6 months).

These variables were summarised using descriptive statistics with graphical representation. The denominator used was total number of enrolled undergraduate students per year stratified into gender and year of study. They were expressed as percentages. The total number of incidents was used as the denominator when expressing departmental involvement, time of day, activities , PEP follow up consultations and anatomical location. Where detailed information was missing it was classified in the “not defined” category. Where data was not unique and where it had a low frequency, it was combined into the category called “other”. The total number of incidents over the 5 year period was expressed as incidents per week over the 5 year period.

The period prevalence was established over the period of 5 years (1st January 2007 to 31st December 2011), taking into account the number of exposure incidents over this 5 year period and obtaining denominator data regarding the number of undergraduate students in each undergraduate year of study (3rd, 4th, 5th, 6th), classified into each year (2007, 2008, 2009, 2010, 2011). The denominator was taken as the midpoint of this population group.

The amount of clinical time spent (in months) per year of study was obtained from the administration division. The 3rd years spent 5 months of clinical time, 4th years 5 months of clinical time, 5th years 7.5 months of clinical time and 6th years 10 months of actual clinical time. The number of incidents were standardised to 12 months and briefly mentioned in the discussion. This standardization and appropriate results are discussed further in the cohort section.

2.6 Cross sectional analytical component

Associations

Exposure incident associations with the following variables were investigated: sharp injuries, mucocutaneous splash incidents, after-hours injuries, and working-hour injuries, drawing blood incidents, eye injury and finger injuries. Exposure incidents were confirmed with the database records. Clinical records were then obtained over a period of 5 years (1st of January 2007 to 31st of December 2011). These clinical records were investigated and information obtained from here was classified as follows:

- Type of injury (sharp or mucocutaneous),
- Drawing blood incident (yes or no),
- Finger injury (yes or no), eye injury (yes /no) and
- Time of day (working hours or afterhours). Working hours was classified as 8am to 4pm and after hours was classified as 4pm to 8am

The chi squared test was used for non-parametric data (categorical data related to the incident). After the chi squared test indicated that the results were not related to chance ($p < 0.05$) the odds ratio (with 95% confidence interval) was used to assess associations. The Fishers exact test was used where expected frequencies were too small. For unbiased parameter estimate, where the data was missing from the records, the subsequent data was omitted from the analysis and the remaining data was analysed.

Adherence to follow up

Exposure incident cases were first confirmed. All the identified cases were investigated to establish if they went on to use PEP. After confirming a high risk exposure with subsequent provision of PEP, these clinical records were then investigated further to obtain information regarding follow up visits. The follow up visits were classified as having attended the 6 weeks follow up (yes/ no), attended the 3 months follow up (yes/no) and attended the 6 months follow up (yes/no).

The Cochran's Q test, which measures the same observation on the same individual on 3 or more occasions, was used to assess the students' adherence to follow-up consultation at 6 weeks, 3 months and 6 months.

2.7 Cohort components

Student cohorts

A student cohort was defined as a 4 year period where students were exposed to clinical medicine during their undergraduate program (3rd year to 6th year) and where all the exposure incidents took place. The one student cohort started in 2007 as a 3rd year and completed 6th year in 2010. The 2nd student cohort started in 2008 as a third year and completed their 6th year in 2011. The numerator data relating to the exposure incidents was established by firstly confirming from the database that an exposure incident took place and then, investigating both the year and year of study which was documented in the clinical records at the time of the incident. The collected data was then grouped together as student cohort 1, 3rd year for 2007, 4th year for 2008, 5th year for 2009, and 6th year in 2010. Similarly for student cohort 2, the procedure followed: 3rd years for 2008, 4th year for 2009, 5th years for 2010, and 6th years for 2011. Denominator data pertaining to the number of undergraduate students for both career cohorts over the 4 year period was obtained from the Stellenbosch University administration division i.e. the total class numbers of 3rd years for 2007, 4th year for 2008, 5th years for 2009 and 6th years for 2010. In the same way denominator data for student cohort 2 was established. The cumulative risk (with the 95% confidence interval) over a year for the 2 cohort groups was calculated for their 3rd year, 4th year, 5th year, and 6th year and it was added together and then divided by 4 years to obtain the annual average cumulative risk over the 4 year period.

Annual cumulative risk for year of the undergraduate study, annual average cumulative risk, and annual average relative risk over the 5 year period

The annual cumulative risk was established via confirmation of the exposure from the database and investigating medical records of exposure incidents to identify the study year of the undergraduate (3rd, 4th, 5th, 6) as well as the year of the incident i.e. 2007, 2008, 2009, 2010, 2011. This exposure incident data was then stratified as year of study for the 5 years concerned i.e. 3rd year data for 2007, 2008, 2009, 2010, 2011. Denominator data for each third year group (2007, 2008, 2009, 2010 and 2011) was

established by obtaining total class numbers for 3rd years for each of the years concerned. This was expressed as annual cumulative risk for 3rd years for each of the years concerned. The numerator was the number of the incidents over each year and the denominator was the class total at the beginning of each year. After establishing the annual cumulative risk for the 5 years (2007, 2008, 2009, 2010, and 2011) for the 3rd years, it was added up and divided by 5 to give the average annual cumulative risk over the period of 5 years.

The same procedure of gathering the information, representation and calculation was used for the 4th year, 5th year and 6th year to establish annual cumulative risk and annual average cumulative risk for each of the years concerned. After establishing annual average cumulative risk between each year of study (3rd, 4th, 5th, 6th year) the annual average relative risk was established between each of the year groups i.e. 3rd vs 4th, 3rd vs 5th and 3rd vs 6th over the 5 year period. This was done by dividing the annual average cumulative risk between each year of study by the other groups' annual average cumulative risk. The same principal was used to assess the association between the other years of study (4th, 5th, and 6th)

Annual risk and annual average cumulative risk

The annual cumulative risk was established by confirmation of the exposure from the database and investigating medical records of exposure incidents to identify the year of the incident i.e. 2007, 2008, 2009, 2010 and 2011. This exposure incident data was then stratified as year of study for the 5 years concerned i.e. 2007, 2008, 2009, 2010 and 2011. Denominator data for each year (2007, 2008, 2009, 2010, and 2011) was established by obtaining total class numbers for all years for each of the years concerned. This was expressed as annual cumulative risk for each of the years concerned. The numerator was the number of the exposure incidents over that particular year and the denominator was the class totals (for all study years) at the beginning of that particular year. After establishing the annual cumulative risk for the 5 years (2007, 2008, 2009, 2010, and 2011) this was added up and divided by 5 to give the average annual cumulative risk over the period of 5 years.

Standardization of annual average cumulative and relative risk based on time spent in clinical rotations

The actual clinical time spent per year of the undergraduate was obtained from the administrative division. Standardization was performed in combination with the annual proportion of clinical time spent (in months) per year of study (3rd year 5 months , 4th year 5 months , 5th year 7.5 months and 6th year 10 months of clinical time). The obtained data was standardised accordingly to represent 12 months annual average cumulative risk per year of the undergraduate. Annual average relative risk was calculated based on the standardised cumulative risk

Male and female annual cumulative risk, average cumulative risk, and relative risk

The annual cumulative risk was established by confirming exposure from the database and investigating medical records of exposure incidents to identify the gender as well as the year of the incident i.e. 2007, 2008, 2009, 2010, and 2011. This exposure incident data was then stratified as year of study for the 5 years concerned i.e. male/female exposure incident data for 2007, 2008, 2009, 2010, 2011. Denominator gender data for each year group (2007, 2008, 2009, 2010 and 2011) was established by obtaining total male/ female class numbers for each of the years concerned. This was expressed as annual cumulative risk for males/ females for each of the years concerned. The numerator was the number of the incidents over each year males/ females and the denominator was the class total of males/ females at the beginning of each year.

After establishing the annual cumulative male/ female risk for the 5 years (2007, 2008, 2009, 2010, and 2011), it was added up and divided by 5 to give the average annual cumulative risk for males/ females over the period of 5 years. The same procedure of gathering the information, representation and calculation was used for the 4th year, 5th year and, 6th year to establish annual cumulative risk and annual average cumulative risk for each of the years concerned. After establishing annual average cumulative risk for the genders (male and female) the annual average relative risk was established between gender groups (male vs. female) over the 5 year period. This was done by dividing the annual average cumulative risk for females by the males' annual average cumulative risk. The same methodology was used to establish the annual average relative risk for the other variables concerned which were:

- Working hour's vs. after-hours exposure incidents.
- Common activities and anatomical location related to exposure incidents.

2.8 Statistical analysis

Stata 12.0 software (Stata Corp, College Station, TX, USA) and the PhStat[®] add-in for Microsoft[®] Office Excel[®] 2010 (Microsoft, Redwoods, WA, USA) were used for statistical analysis.

In the descriptive aspect, the nature of the categorical data was statistically analysed using Stata 12.0 (Stata Corp, College Station, TX, USA). Where data was not unique and where it had a low frequency, it was combined into the category called "other". These variables were summarised using descriptive statistics with graphical representation. They were described in terms of proportions and expressed as percentages.

Data in the analytic cross sectional aspect of the study was analysed using PhStat[®] add-in for Microsoft[®] Office Excel[®] 2010 (Microsoft, Redwoods, WA, USA). The chi squared test was used for non-parametric data (categorical data related to the incident). After the chi squared test indicated that the results were not related to chance ($p < 0.05$) the odds ratio was used to assess associations. The Fishers exact test was used where expected frequencies were too small (< 5). A 95% confidence interval was used. These tests were 2 sided with a 5% significance level used. For unbiased parameter estimate, where the data was missing from the records, the subsequent data was omitted from the analysis and the remaining data was analysed. The Cochran's Q test, which measures the same observation on the same individual on 3 or more occasions, was used to assess the students' adherence to follow-up consultation at 6 weeks, 3 months and 6 months. A 95% confidence interval was used with alpha set at 5%.

Data in the cohort section of the study was analysed using the PhStat[®] add-in for Microsoft[®] Office Excel[®] 2010 (Microsoft, Redwoods, WA, USA). The parameters of risk, cumulative risk, and relative risk for variables stratified by: year, year of study of the undergraduate, males, females, working hours, after hours, anatomical location and activity were estimated using 95% confidence intervals, with alpha set at the 5% significance level. The averages (related to the variables mentioned above) for these various tests were also calculated using the PhStat add in.

2.9 Missing Data

Although there was confirmation in terms of the database of incidents of exposure, when the medical records were accessed for more detailed information, it was found that there were some missing variables (such as details not completed by the attending doctor at the time of the incident). These were classified as “not defined” in the descriptive component and were omitted from the analysis for the cross sectional component and cohort components.

2.10 Study Size and Sampling

No sample was taken for the study. All students in the study base were included or excluded in accordance with the exclusion and inclusion criteria of the study.

2.11 Ethical Considerations

Ethical approval (S12/11/288) from the Health Research Ethics Committee (HREC) of Stellenbosch University was obtained prior to the beginning of the study. The following ethical principles were adhered to during the performance of this study:

Autonomy and informed consent

It was difficult to obtain informed consent from all the participants in the study, since many of them had already left the Faculty of Medicine and Health Sciences upon completion of their studies, making the obtaining of written informed consent exceptionally difficult, if not impossible. The researcher thus formally requested a waiver of informed consent from the HREC. The waiver did not adversely affect the rights and welfare of the study participants. Confidentiality was maintained throughout the study as each participant was given a unique study number. The list with identifiable data and unique study numbers was not available during data analysis, which was performed anonymously.

Beneficence

Participants in this study did not directly benefit from participation in this study. However, the information obtained from this study may benefit future students if the information is used by the Stellenbosch University Faculty of Medicine and Health Sciences in order to improve training, teaching and development and adherence to PEP

Non-harm

This research project was observational in nature and no intervention was planned for the study, thus it involves no more than minimal risk.

Justice

There was no discrimination in terms of gender, race, religion or any other orientation in this study. All those who are eligible for inclusion (in accordance with the inclusion and exclusion criteria) were included.

Confidentiality

The data obtained during this study was managed with due regard for the confidentiality of all participants. The primary study investigator had access to the data captured with a username and password, as well as full access to clinical records of the participants. The data was collected and stored on encrypted excel sheets on the primary study investigators personal laptop. Two data sheets were available, where the student numbers (patient id) was on one excel document, and the other contained numbers corresponding to the collected information. This data sheet with the student numbers (patient id) was assigned a numerical value, e.g. student number (numerical value 1)

1..... 14242525, and

2.....12354265.

The assigned numerical value e.g. number 1, 2, was used on a separate data collection sheet. The student numbers with the assigned numerical numbers remained on a password protected file on the primary investigators personal laptop and if the wrong password is entered more than 4 times it would delete the file.

CHAPTER 3: CROSS SECTIONAL DESCRIPTIVE COMPONENT

3.1 Results

A total of 280 medical undergraduates had exposure incidents to blood and bodily fluid over the study period of 5 years (2007 – 2011). The 280 participants comprised of 232 medical undergraduates who were exposed at TAH and 48 were exposed at other health facilities (e.g. various Day hospitals, Karl Bremer, Eben Donges, Paarl and Stikland hospitals).

The 5 year period represented a total of 260.89 weeks. This amounts to 1 exposure incident (1.07) every week over the five year period. The number of exposure incidents varied annually over the 5 years: 47 in 2007, 64 in 2008, 50 in 2009, 43 in 2010 and with a rise in 2011(n=76)

The period prevalence of exposure incidents was 35.44 % over the 5 year period.

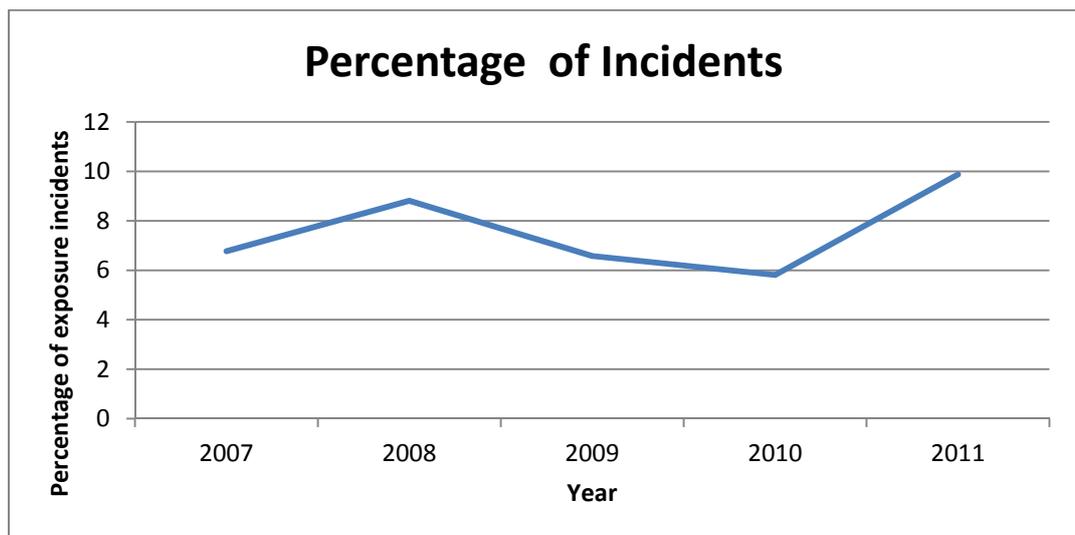


Figure 2: Line graph of percentage of incidents annually over a period of 5 years (2007 January – December 2011).

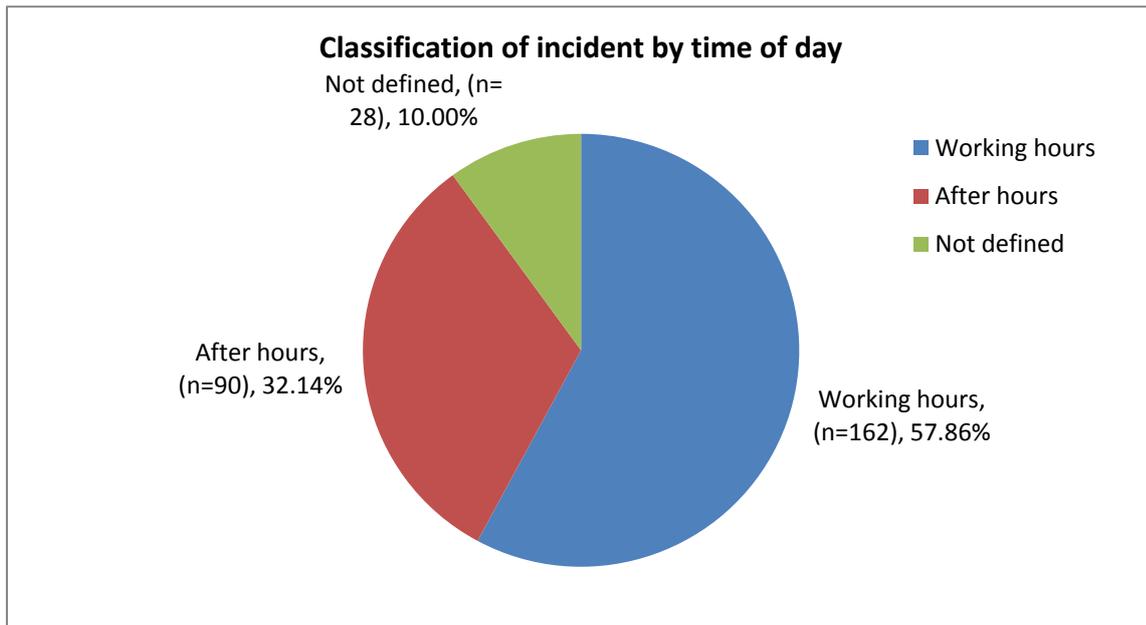


Figure 3: Pie Chart indicating which time of day the exposure incidents occurred (2007 January – December 2011).

Injuries related to mucocutaneous splashes accounted for 29% (n=81) and 71% (n=199) was related to sharp incidents. Female students accounted for 66% (n=184) of injuries and 34% (n=96) occurred in male students. During the 5 year period the exposure incidents of males and females varied annually (figure3)

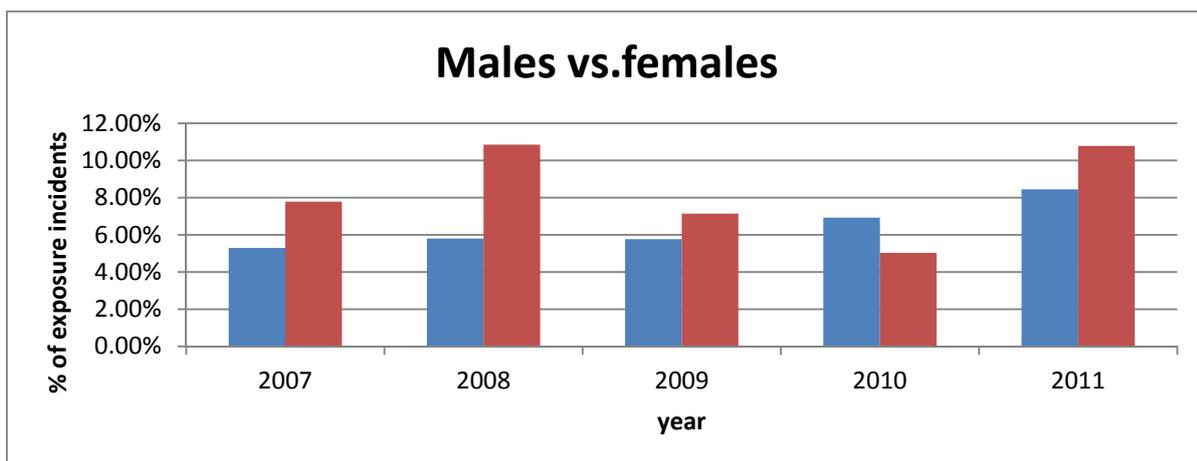


Figure 4: Yearly percentage of exposure incidents by gender (2007 January – December 2011).

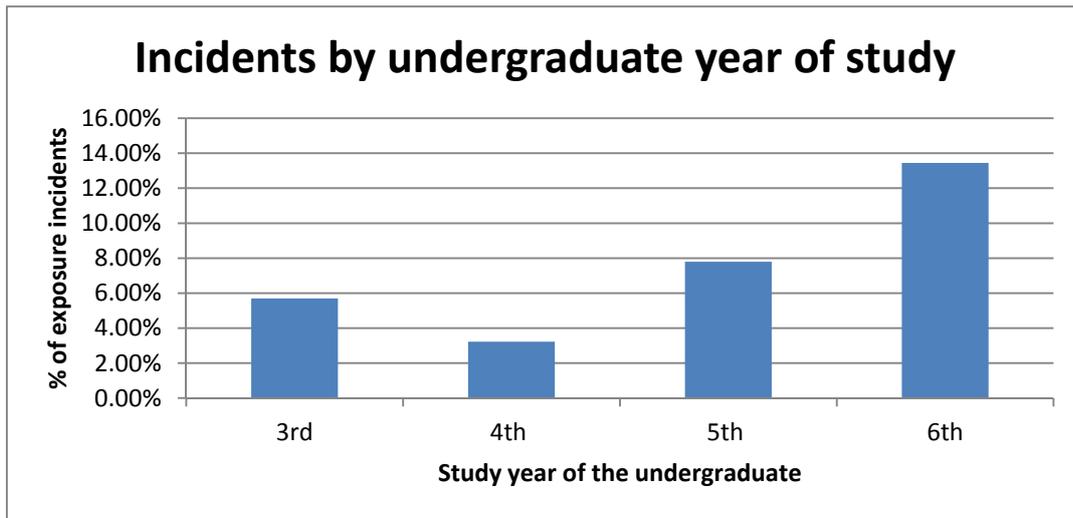


Figure 5: Bar chart of percentage of exposure incidents according to the year of the undergraduate (2007 January – December 2011).

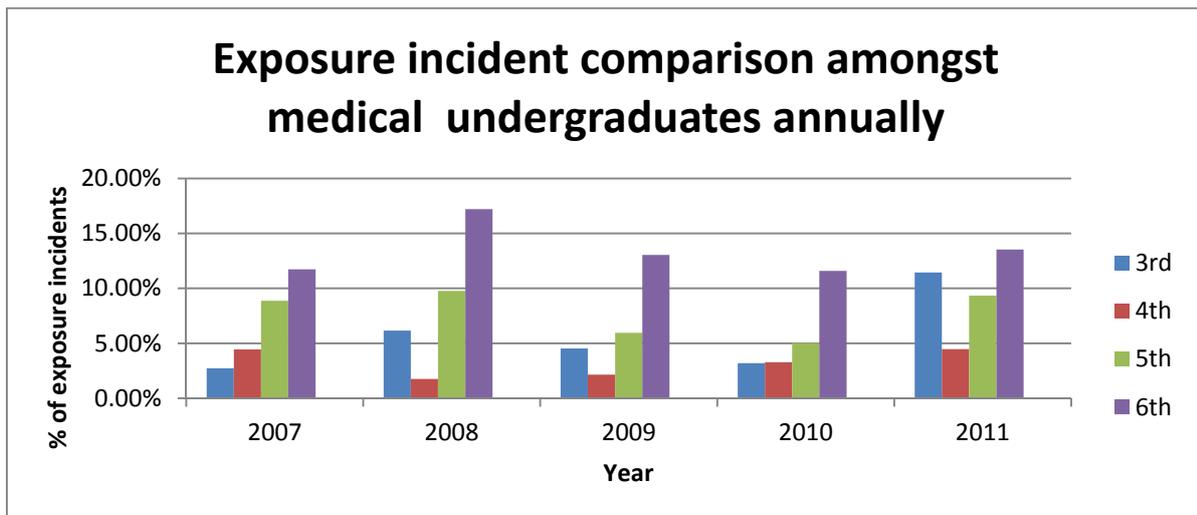


Figure 6: Grouped bar chart comparing total percentage of exposure incidents annually according to the year of the undergraduate (2007 January – December 2011).

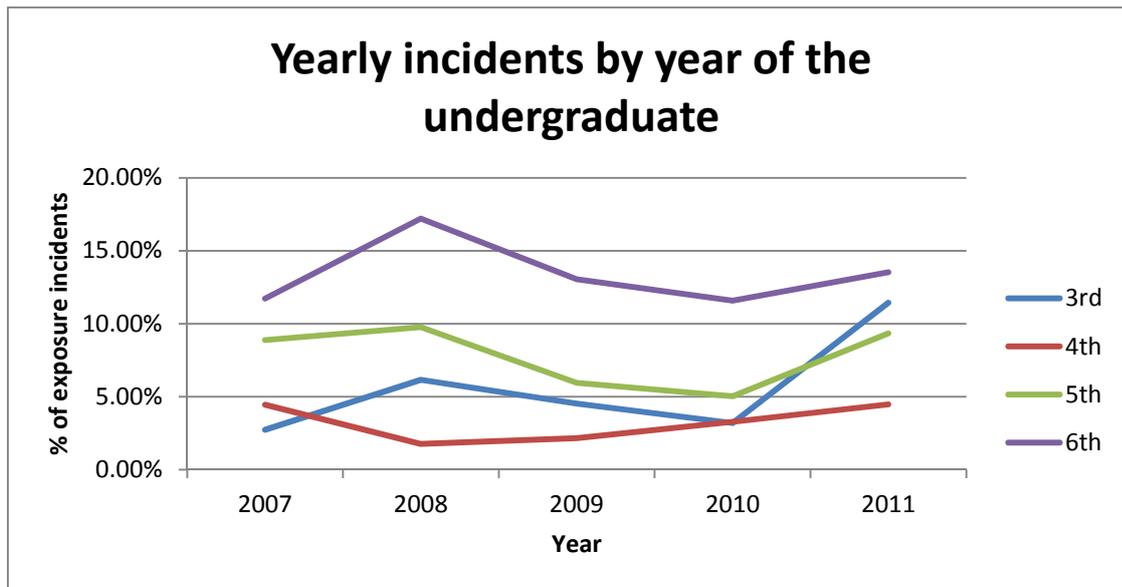


Figure 7: Line graph of percentage of incidents annually based on the year of the medical undergraduate for a period of 5 years (2007 January – December 2011).

During the 5 year period the total numbers of exposure incidents among the various departments were as follows:

- Surgical Department 18%(n=51)
- Internal medicine 24% (n=68)
- Obstetrics and Gynaecology 16% (n=44)
- Paediatrics 15% (n=42)
- Psychiatry 6% (n=16)
- Other (Dermatology Outpatients n=1, Ophthalmology outpatients n=1, Urology ward n=4, cardiology n =4, orthopaedics n=6, Outpatients and ward number not specified n=9) accounted for 8% (n=21)
- Not defined (no mention of any location in clinical records) 16% (n=38)

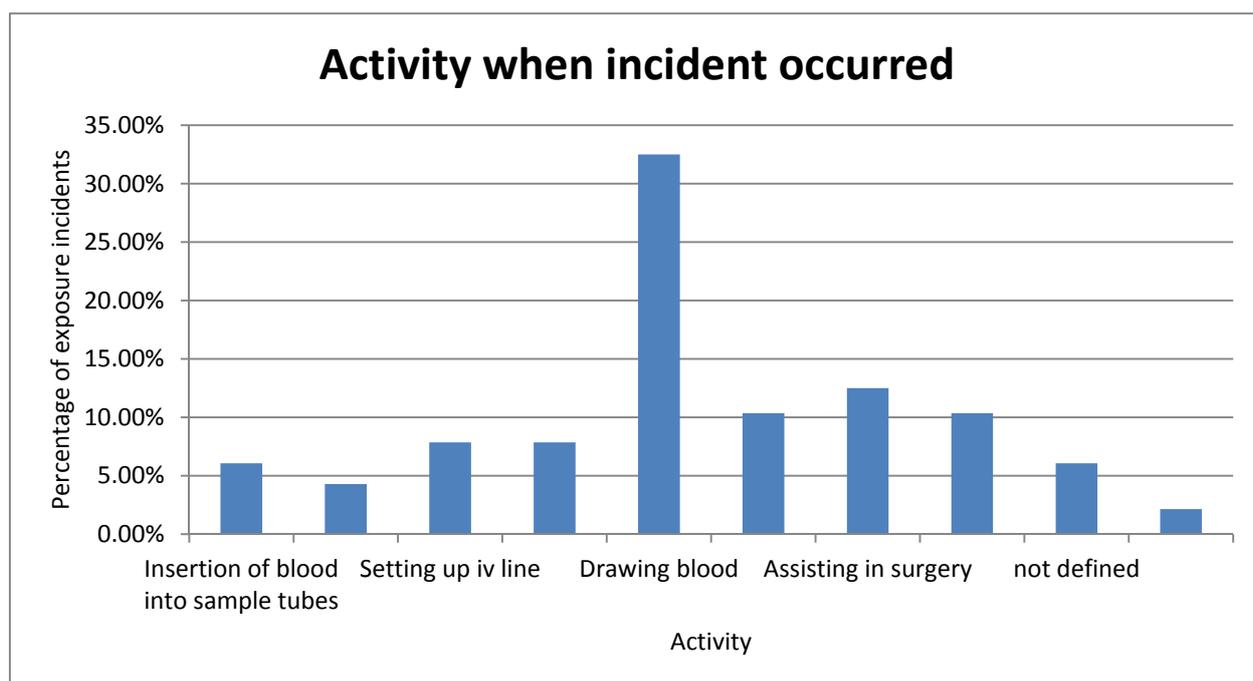


Figure 8: Percentage of exposure incidents by activity performed (2007 January – December 2011).

During the 5 year period 33% (n=91) of the incidents occurred while drawing blood, 13% (n=35) while assisting in surgery, 10% (n=29) occurred while recapping needle, 8% (n=22) while placing an intravenous line. Needle not been disposed of properly accounted for 8% (n=22) of exposure incidents, 6% (n=17) of the incidents occurred while blood was inserted into laboratory sample tubes, 4% (n=12) occurred during suturing, and 2.14% (n=6) occurred while assisting with a delivery. The category of “other” accounted for 10.36% (n=29), which included the insertion of a chest drain (n=1), assisting during an autopsy (n=1), performing lumbar punctures (n=5), reloading an ampoule (n=3), wound related incidents (n=3), removal of sutures (n=1), ascitic tap (n=1), handling instrument (n=1), minor surgical procedure (n=4), while using blade (n=1), sharps container overfilled (n=2), manual vacuum aspiration (n=1), ETT suction (n=1), anaesthetic procedure (n=2), using a glass slide (n=2); and the “not defined” category accounted for 6% (n=17). The “not defined” category was a category labelled as such when no information was found relating to the activity at the time the incident took place.

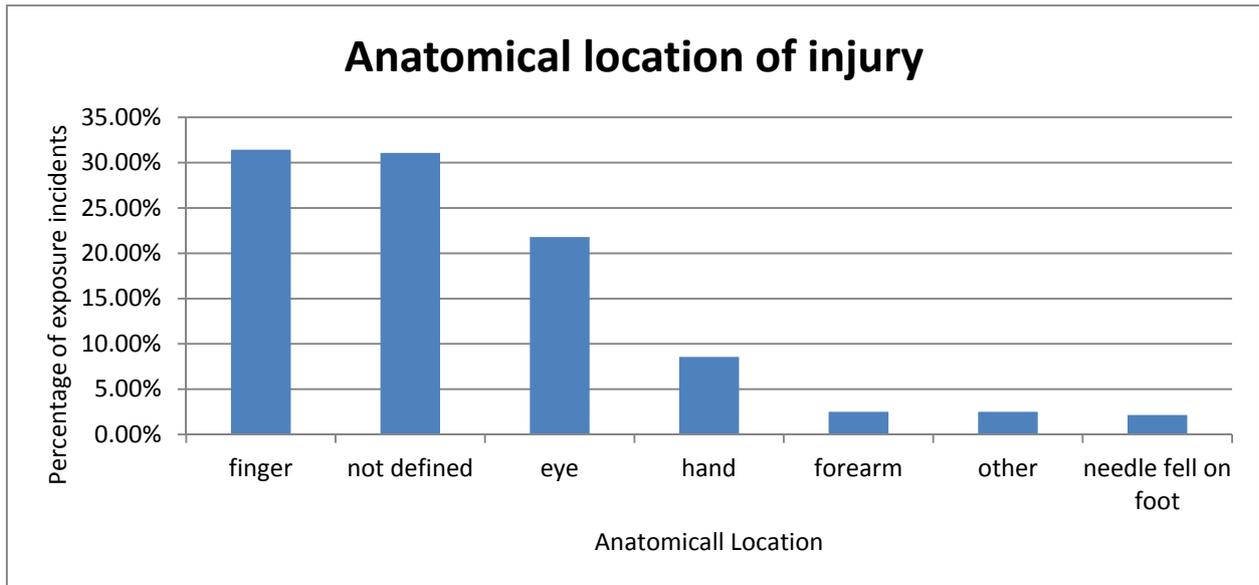


Figure 9: Percentage of exposure incidents related to anatomical location (2007 January – December 2011).

Finger incidents accounted for 31% (n=88) of all incidents, while eye incidents accounted for 22% (n=61). Hand incidents, which was defined as palm of hand to wrist accounted for 9% (n=24). Needle falling on foot accounted for 2.14% (n=6). Forearm and other locations (thigh n=2, elbow n=1, abdomen n=1, leg n=1, face n=1, blood stained socks n=1) both accounted for 3% (2.5% n=7). “Not defined” accounted for 31.07% (n=87), this is where the anatomical location information was missing in the clinical records.

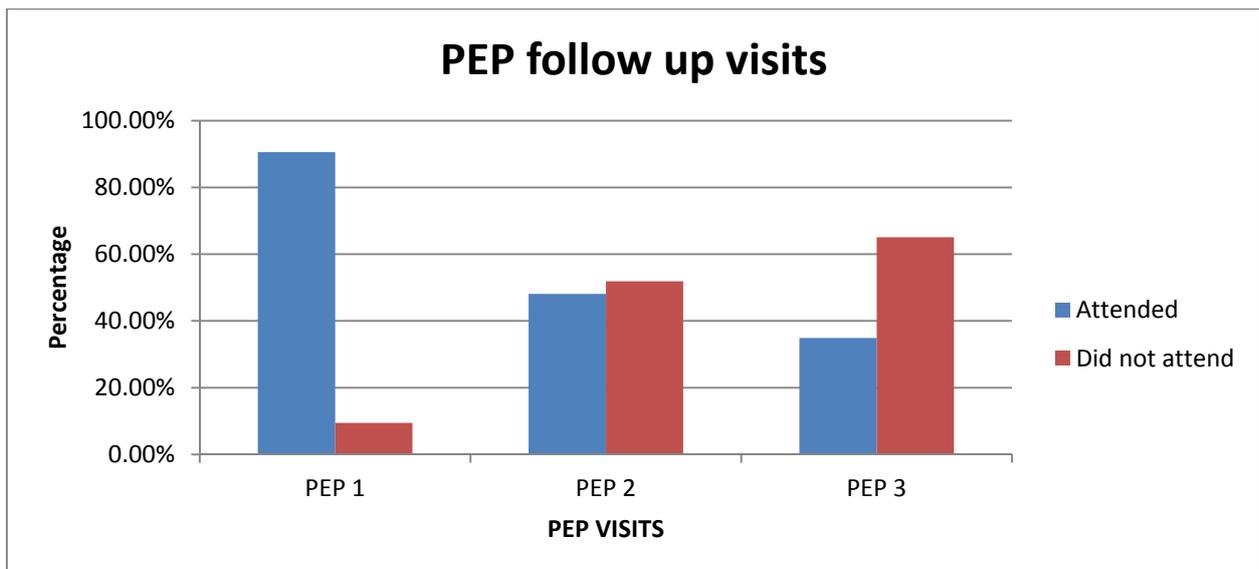


Figure 10: Comparison of Follow up consultation visits at 6 weeks, 3 months and 6 months after high risk exposure incident (2007 January – December 2011).

3.2 Discussion

Hospital location

Incidents occurring at TAH were much higher compared to incidents occurring at other health facilities over the 5 year period, the reason being that up until the end of 2011 at least 80% (% obtained from Campus administration division) of the entire medical undergraduate clinical training took place at TAH.

Number of incidents

There was a steady decrease in the number of exposure incidents up until 2010 with the numbers almost doubling in 2011. Various reasons can be postulated for the rise in the number of exposure incidents; however they need to be explored in a separate study. The total number of incidents (n=289) is considerably less than a recent study conducted over a 5 year period in Mexico (n=432) ⁽²¹⁾.

After hours work vs. Working hours

The number of exposure incidents occurring during working hours was higher than those occurring after hours. The reasons for fewer after-hours injuries were that fewer students did after-hours work and in 2011 a decision was taken by the university that after hours work was to be until 23:00 for medical students. This was for safety reasons. The number of incidents reported by Parks at el also illustrated more incidents taking place during the day than the night over a 5 year period ⁽¹⁹⁾

Males vs. Females

Females were involved in more exposure incidents. This can be expected as the percentage of female undergraduates ranged from 59.56% to 60.52% per year over the study period. (Percentage obtained from Campus administration division). In an Australian study females had more needlestick injuries compared to males ⁽¹⁷⁾ and contrary to this study findings, a study conducted in Tehran demonstrated that males had more exposure incidents compared to females ⁽¹⁸⁾. Medical student gender ratios were not given in these two studies. If we are able to define what a standard population for an

undergraduate medical class is we would be able to make comparisons in relation to the above findings.

Year of the undergraduate

By just examining the 3rd year descriptive data we could say the 3rd year students are relatively inexperienced compared to other years and they start off with major clinical rotations such as Surgery, Internal Medicine, Paediatrics and Obstetrics and Gynaecology. Various new procedures are introduced to them in the clinical environment. They are required to perform basic procedures, such as drawing blood and setting up IV lines much more than other procedures. However this is not the case. If we look at the amount of clinical time spent during each year we find that the 3rd years spend 5 months per year, 4th years 5 months per year, 5th years 6.5 months per year, and 6th years on average 10 months per year attending clinical rotations. If we standardized the time spent in relation to the number of incidents and represent it all as 12 months for all of the years concerned (3rd, 4th, 5th, 6th), we would find the 3rd years would possibly have 132 incidents per year, 4th year 70 incidents a year, 5th years 126 incidents a year and 6th years 154 incidents per year. Based on this, the 3rd years would have 6 more incidents than the 5th years, which is not a large difference taking into consideration their relative inexperience and introduction to clinical medicine. This is explained further in Chapter 5: Cohort section, year of the undergraduate.

The 4th years have smaller clinical rotations with less time spent in the major rotations. Some of these rotations require fewer procedures to be performed by the student. They include amongst others: Forensic Medicine rotation, Dermatology, Radiology and Chemical Pathology. This explains the decrease in the number of exposure incidents in the 4th years compared to other years.

Midway through the 5th year all formal lecturing modules come to an end and for the next 1 ½ years, until the end of the 6th year, only clinical rotations take place. During the final year of the 6-year program, only clinical rotations take place and more months are spent in clinical rotation compared to other years. As such all students go through all surgical disciplines (ENT, Ophthalmology, Urology and Surgery), including Obstetrics and Gynaecology. More time is spent on activities like assisting in theatre. This is over and above existing activities of drawing blood and setting up IV lines.

This explains the findings in terms of the 6th year students that have higher numbers of exposure incidents over the 5 year period. Based on the standardized data on the time spent in clinical rotations, we find that there is a difference between 5th years and 6th years (28 incidents) and 6th years and 3rd years (22 incidents) and 4th years (84 incidents) (Other studies conducted in China found that the 4th and 5th years had the most incidents ⁽⁹⁾. A study conducted in the USA found the 4th years had most incidents ⁽¹¹⁾).

The training program details are lacking in the literature and although the studies may indicate that a particular year had the most incidents, there are both 5-year and 6-year undergraduate medical training programs internationally, where exposures during the 5th year might be equivalent to exposures during the 6th year in other instances.

Departments

Internal medicine was the department where most of the students had their exposure incidents over the 5 year period. This was followed by Surgery, Obstetrics and Gynaecology, Paediatrics, other departments, and the “not defined” category (missing information in medical records about the department). The “not defined” category was higher than the category of “other” and Psychiatry. Virtually all of Family Medicine training happens outside TAH. Within the ‘not defined’ category lies Family Medicine which is not accounted for as a separate category. When analysing records related to exposure incidents that occurred at other hospitals, it was difficult to categorise Family Medicine as it was not specifically mentioned.

Looking at the departments at TAH, Paediatrics was the department ranked number 3 and Obstetrics and Gynaecology number 4 in relation to exposure incidents. When the exposure incidents from other hospitals were combined with TAH data, Obstetrics and Gynaecology moved up to number 3 and Paediatrics down to number 4. The reason for this is that half of the Obstetrics and Gynaecology clinical undergraduate training happens outside the vicinity of TAH.

The aforementioned findings indicate the importance of the structure of the undergraduate training programs and the number of times the student goes through a clinical rotation in different years of undergraduate study. Surgical, Internal Medicine, Obstetrics and Gynaecology, Orthopaedics, and the Accidents and Emergency

disciplines are the top 5 disciplines amongst studies for sustaining exposure incidents amongst students ⁽⁹⁾⁽⁶⁾⁽²⁰⁾⁽²¹⁾⁽²²⁾

Anatomical location of injuries and activities

Besides taking a history and performing a medical examination on a patient, special investigations, such as taking blood, are also necessary in order to assist in making a diagnosis and guiding treatment of the patient. Setting up IV lines is also vital in the treatment of some patients. During clinical rotations, the medical undergraduate are required to draw blood on patients and site IV lines. They are also required to assist in the operating theatre. Taking into consideration these activities, this explains the findings related to the finger being the common anatomical location for injuries and then other exposure areas. Eye exposure incidents can be reduced by adhering to standard and universal precautions and by wearing Personal Protective Equipment (PPE), particularly eye protection, in high risk activities. Although recapping is not advised it accounted for 10 % (n=29) of the incidents. The Hazardous Biological Agents Regulations prohibit recapping of needles ⁽²⁹⁾, however, some students are still recapping. Exposure incidents related to recapping 10.4%,(n=29) disposals 7.9%, (n=22), and insertion of blood into sample tubes 4.3%, (n=12) are potentially preventable, amounting to 22.5 % (a total of 63 incidents) by adhering to standard and universal precautions.

The findings related to exposure incidents of drawing blood confirms the findings of 4 other studies where the most common incidents are exposure incidents related to drawing of blood ⁽¹¹⁾⁽¹⁸⁾⁽²⁰⁾⁽²¹⁾. There were 4 studies that found that suturing was the most common cause of exposure incidents ⁽¹⁰⁾⁽²²⁾⁽²³⁾⁽²⁴⁾, which is contrary to our findings. We do not know the specific details about the duration and activities of time spent in these studies, as this may have influenced the number of incidents related to suturing.

PEP visits

It is evident from the results that 91% (n=96) attended the 6 week consultation, with a sharp decline to 48% (n=51) at 3 months and further decline to 35% (n=37) for the 6 month visit. Low risk injuries accounted for 62.14 % (n=174); and 37.86% (n=106) were high risk exposure incidents. Medical undergraduates who sustained high risk exposure

incidents subsequently went on to use PEP. The percentage of incidents that required PEP was 37.86%.

These findings illustrate better retention for follow up consultations compared to other studies. We should note the other results are based where students formed part of the healthcare worker group ⁽³⁾. An alternative study found that student representation was 2% in the two study groups and no further details specifically relating to students follow up were mentioned. Follow up results were based on 2 groups of healthcare workers as an entire group and represented as adherence, partial adherence and loss to follow up which was 56%, 26% and 18% for the one group and 53%, 33 % and 14 % for the second group⁽³⁾. Another study based on healthcare workers in Taiwan reported a 56.4% follow up for seroconversion testing⁽⁴⁾. This study therefore shows better adherence to follow up visits. This is further evaluated in the cross sectional component of the study.

CHAPTER 4: CROSS SECTIONAL ANALYTICAL COMPONENT**4.1 Results****Table 4.1: Variables analysed for association**

	Number (%)	OR (95% CI)	p-value (Chi)
<i>Association with sharps injuries</i>			
Drawing blood	91 (34.6)	8.04 (3.51 - 18.42)	<0.01
<i>Association with mucocutaneous injuries/splash</i>			
Assisting in surgery	35 (13.31)	8.68 (3.91 - 19.25)	<0.01
Setting up iv line	22 (8.37)	5.05 (2.02 - 12.62)	<0.01
Obstetrics and Gynaecology Department	44 (18.18)	3.04 (1.55 - 5.96)	<0.01
<i>Association with afterhours injuries</i>			
Other hospitals	15 (5.95)	3.93 (1.3 - 11.87)	<0.01
<i>Association with work hours injuries</i>			
Paediatrics Department	36 (16.36)	3.44 (1.36 - 8.67)	<0.01
<i>Association with drawing blood incidents</i>			
Paediatrics Department	42 (18.1)	2.57 (1.3 - 5.07)	<0.01
<i>Association with eye injury</i>			
6th year	79 (40.93)	2 (1.08 - 3.69)	<0.03
Obstetrics and Gynaecology Department	26 (15.76)	3.62 (1.53 - 8.59)	<0.01
<i>Association with finger injuries</i>			
3rd year	47 (24.35)	2.38 (1.21 - 4.66)	<0.01

PEP follow up visit comparison**Table 4. 2: Adherence of medical undergraduates who attended PEP follow-up visits**

Cases in spreadsheet	106		
Cases with missing values	0		
Cases included in the analysis	106		
Frequencies			
Variable	Value		Proportion (%)
	0	1	
PEP 6 th week follow up visit	10	96	90.57
PEP 3 rd month follow up visit	55	51	48.11
PEP 6 th month follow up visit	69	37	34.91
Cochran's Q test			
n	106		
Cochran's Q	87.7231		
DF	2		
Significance	<0.001		
Multiple comparisons			
Variable	Different (P<0.05) from variable nr		
(1) PEP 6th week follow up visit	(2) (3)		
(2) PEP 3rd month follow up visit	-1		
(3) PEP 6th month follow up visit	-1		
Minimum required difference (%): 14.8671			

4.2 Discussion

Paediatrics Department

The turnover of patients in the Paediatrics Department is high. Special investigations like drawing blood are also relied on for diagnosis and further management. There are much more students during the day, compared to the few who do after hours work (after hours work is until 11pm). Medical undergraduates have clinical rotations in Paediatrics (including Neonatology) in their 3rd, 4th, 5th and 6th years of study. This explains the association with drawing blood incidents and association with working hour injuries.

Activities relating to type of injuries

Besides taking a history and performing a medical examination, special investigations such as taking blood is vital in order to assist in making a diagnosis and treatment of the patient. Setting up IV lines is also vital in the treatment of some patients. During clinical rotations, the medical undergraduates are required to draw blood on patients, establish IV lines and also assist in theatre. These fundamental activities form the core of most clinical rotations and it also explains the association found in this study.

Of special interest are the eye splashes that occurred in the operating theatre. The medical undergraduate spends more time in the operating theatre during this clinical rotation (surgery) compared to other clinical rotations. These splash incidents are potentially preventable and are indicative of a possible lack of availability of personal protective equipment (PPE) for eyes (i.e. goggles) or lack of usage thereof. Further reasons as to why students do not wear goggles (if available) need to be assessed in a separate study.

A study conducted in the U.S.A found that most injuries amongst 4th year students was associated with the student rotating through the clinical department of surgery, while assisting in theatre ⁽²²⁾. These injuries were associated with suturing ⁽²²⁾⁽²³⁾. However our study found an association with eye splashes.

Obstetrics and Gynaecology Department

Exposure to blood and body fluids (e.g. amniotic fluid) is increased while in the Obstetrics and Gynaecology department. Over and above taking blood samples from patients and setting up IV lines there is an increased risk of exposure to blood and bodily fluids while assisting with delivery (baby covered with blood, umbilical cord, placenta, etc.), including during assistance with caesarean sections. This explains the significance of the eye being the anatomical location for exposure incidents, as well as the association with mucosal splash incidents. This association can be reduced by making PPE (eyewear) available to the students. Various aspects of PPE need to be investigated in a separate study.

Year of the undergraduate

The 6th year

The 6th year undergraduates spend all their time in various clinical rotations including all surgical disciplines. They are required to assist in theatre for all the surgical disciplines and perform various procedures such as setting up IV lines and drawing of blood. This would then explain the eye being a common anatomical association with exposures amongst the 6th years.

The 3rd year

The 3rd years are relatively inexperienced and they start off with major clinical rotations such as Surgery, Internal Medicine, Paediatrics and Obstetrics and Gynaecology. Various new procedures are introduced to them in the clinical environment. They are required to perform basic procedures, such as drawing blood and setting up IV lines much more than other procedures and thus we find the association with finger injuries amongst the 3rd years.

Post exposure follow up consultation attendance

The primary objective of the study was to determine whether the medical undergraduates attended their follow up consultations (including testing for HIV) following exposure incidents that required PEP. It is clear from the results that there was poor adherence at 3

months and 6 month as 91 % (n=96) attended the 6 week consultation, with a sharp decline to 48% (n=51) at 3 months and further decline to 35 % (n=37) for the 6 month visit. There was a significant statistical difference between the expected follow up consultation times in relation to those who attended and those who did not. Students are told about the visit when they received full PEP as well. The underlying factors can be postulated, but they require a separate study to be conducted to establish the precise reasons for noncompliance.

Amongst the postulated reasons are:

- Individual factors:
The student forgot; wrong perception or thoughts about follow up consultations i.e. lack of knowledge; Concerns about the cost of the follow up consultation.
- The student may have qualified from 6th year and the rest of the consultations took place outside the Health Science campus.
- The student (irrespective of the year of study) had the follow up consultations with his or her own General Practitioner.
- The student is placed outside the vicinity of Tygerberg Hospital for a clinical rotation. He/she then follows up at the site where they have been placed.

CHAPTER 5: COHORT COMPONENT**5.1 Results****Table 5.1: Annual cumulative risk of incidents stratified by year of study period**

Annual cumulative risk	Risk	95 % Confidence Interval
2007	0.07	0.05 to 0.09
2008	0.09	0.07 to 0.11
2009	0.07	0.05 to 0.09
2010	0.06	0.04 to 0.08
2011	0.10	0.08 to 0.12
Average annual cumulative risk Over the 5 year period	0.08	0.07 to 0.09

Table 5.2: Annual cumulative risk of exposure incident stratified by gender per year of study period

Annual cumulative risk	Males		Females	
	Risk	95 % CI	Risk	95 % CI
2007	0.05	0.03 to 0.09	0.08	0.05 to 0.11
2008	0.06	0.03 to 0.09	0.11	0.08 to 0.14
2009	0.06	0.03 to 0.09	0.07	0.05 to 0.10
2010	0.07	0.04 to 0.11	0.05	0.03 to 0.08
2011	0.08	0.05 to 0.12	0.11	0.08 to 0.14
Annual average cumulative risk Over the 5 year period	0.06	0.05 to 0.08	0.08	0.07 to 0.01
Annual Average relative risk of females vs. males	1.29	(1.0 to 1.61)		

Table 5.3: Annual average relative risk of exposure incidents of working hours vs. after hours

	Average relative risk	Risk (95 % CI)
Working hours vs. afterhours	1.77	1.37 to 2.27

Table 5.4: Annual average cumulative risk and relative risk of exposure incidents stratified by medical activities

Activities	Cumulative Risk (95 % CI)
Drawing blood	0.02 (0.021 to 0.031) per year
Assisting in surgery	0.01 (0.006 to 0.013) per year
Recapping needle	0.01 (0.005 to 0.011) per year
Setting up IV line	0.01 (0.004 to 0.009) per year
	Relative Risk (95 % CI)
Drawing blood vs. assisting in surgery	2.6 (1.74 to 3.77)
Drawing blood vs. recapping needle	3.14 (2.04 to 4.67)
Drawing blood vs. assisting in setting up iv line	4.14 (2.55 to 6.45)
Assisting in surgery vs. recapping needle	1.21 (0.74 to 1.97)

Table 5.5: Annual average cumulative risk and relative risk of exposure incidents stratified by anatomical location over the 5 year period

	Cumulative Risk (95 % CI)
Eye	0.017 (0.01 to 0.02) per year
Finger	0.024 (0.01 to 0.03) per year
	Relative Risk (95%CI)
Finger vs. eye	1.44 (1.04 to 1.98)

Table 5.6: Annual risk stratified by the year of undergraduate study

Year	Annual Risk (95 % CI)	
	3rd year	5th year
2007	0.03 (0.001 to 0.06)	0.09 (0.05 to 0.15)
2008	0.06 (0.03 to 0.11)	0.10 (0.06 to 0.16)
2009	0.05 (0.02 to 0.09)	0.06 (0.03 to 0.11)
2010	0.03 (0.01 to 0.06)	0.05 (0.02 to 0.10)
2011	0.11 (0.07 to 0.17)	0.09 (0.05 to 0.15)
	4th year	6th year
2007	0.04 (0.02 to 0.09)	0.12 (0.07 to 0.18)
2008	0.02 (0.003 to 0.052)	0.17 (0.12 to 0.24)
2009	0.02 (0.01 to 0.06)	0.13 (0.09 to 0.19)
2010	0.03 (0.01 to 0.07)	0.12 (0.07 to 0.17)
2011	0.04 (0.02 to 0.09)	0.14 (0.09 to 0.20)

Table 5.7 Annual average cumulative risk vs. Standardised cumulative risk

	Annual average cumulative risk over the 5-year period (95% CI)	Annual average cumulative risk based on proportions of clinical time spent expressed as 12 months (95%CI)
3 rd	0.06 (0.04 to 0.07)	0.137 (0.11 to 0.16)
4 th	0.03 (0.02 to 0.05)	0.078 (0.06 to 0.098)
5 th	0.08 (0.06 to 0.10)	0.144 (0.12 to 0.17)
6 th	0.13 (0.11 to 0.169)	0.162(0.14 to 0.19)

Table 5.8 Annual average relative risk vs. Standardised annual relative risk based on the proportions of actual time spent expressed as 12 months

Annual average relative risk			Standardised relative risk based on proportions of clinical time spent expressed as 12 months		
Year of Study	Relative Risk	95% Confidence interval	Year of Study	Relative Risk	95% Confidence interval
3 rd vs. 4 th	1.72	(1.11 to 2.68)	3 rd vs. 4 th	1.66	(1.26 to 2.19)
3 rd vs. 5 th	0.73	(0.53 to 1.05)	3 rd vs. 5 th	0.95	(0.75 to 1.19)
3 rd vs. 6 th	0.45	(0.33 to 0.61)	3 rd vs. 6 th	0.86	(0.69 to 1.08)
4 th vs. 3 rd	0.57	(0.37 to 0.90)	4 th vs. 3 rd	0.60	(0.45 to 0.79)
4 th vs. 5 th	0.41	(0.28 to 0.66)	4 th vs. 5 th	0.57	(0.41 to 0.76)
4 th vs. 6 th	0.26	(0.17 to 0.39)	4 th vs. 6 th	0.52	(0.39 to 0.68)
5 th vs. 3 rd	1.36	(0.95 to 1.89)	5 th vs. 3 rd	1.05	(0.83 to 1.32)

5 th vs. 4 th	2.41	(1.51 to 3.54)	5 th vs. 4 th	1.74	(1.32 to 2.30)
5 th vs. 6 th	0.61	(0.46 to 0.80)	5 th vs. 6 th	0.92	(0.73 to 1.13)
6 th vs. 3 rd	2.20	(1.62 to 2.98)	6 th vs. 3 rd	1.15	(0.93to 1.43)
6 th vs. 4 th	3.81	(2.55 to 5.62)	6 th vs. 4 th	1.9	(1.47 to 2.52)
6 th vs. 5 th	1.63	(1.23 to 2.16)	6 th vs. 5 th	1.10	(0.89 to 1.37)

5.2 Discussion

The annual risk was decreasing up until 2010, however it was noted that there was a rise in annual risk in 2011.

Males vs. females

If the two populations of males and females are considered as separate population groups, females seem to have a higher 5 year average risk compared to males. However, the relative risk did not have a statistically significant difference. Female undergraduate percentage representation ranged from 59.56% to 60.52% per year in the undergraduate class. This was determined from information obtained from the administration department of Stellenbosch University.

If we hypothetically define a standard medical undergraduate population to represent equal proportions of 50% males and 50% females in the class, males would be more at risk than females and the annual risk for 2007, 2008, 2009, 2010 and 2011 for males would be higher than the females. Regarding the standardization process, as mentioned above, the concern would be how we define the standard medical undergraduate class, based on gender. Males are prone to take more risk and females have motherly caring, nurturing behaviour that may be risk averting, with better fine motor skills. This has been established in literature ⁽³⁰⁾ ⁽³¹⁾.

The risk of having an exposure incident during working hours was higher compared to working after hours. The reasons included that fewer students worked after hours

and in 2010 a decision was taken by the university that (for safety reasons) after hours work for medical students in most disciplines would be until 11pm.

Year of the undergraduate study

The annual cumulative risk for each year is noted in the table above. Of particular importance is the increase in annual cumulative risk between 2010 and 2011. Although other year groups also contributed to the increase in risk, the most noticeable increases in risk were noted amongst the 3rd and 5th years between 2010 and 2011. Reasons for the large increase in these particular year groups need to be explored in further studies.

There were limited changes in the training program for the past 6-7 years. Students still receive training in the skills laboratory before they start clinical rotations, so the massive rise in 2011 needs to be explored and compared with 2012 in a separate study.

Annual average cumulative risk and relative risk

The annual average cumulative risk and relative risk for the years of the undergraduate was standardised to 12 months in accordance with the clinical time spent in each year when the incidents occurred.

After standardization, the annual average cumulative risk was similar across the 3rd, 5th, and 6th year students. The relative risk between the groups also did not have a statistically significant difference.

The 4th years had the lowest standardized cumulative risk and this group was the only group to show a statistically significant decrease in risk compared to the 3rd, 5th, and 6th years. The 4th years have smaller clinical rotations with less time spent in the major rotations. Some of these rotations require fewer procedures to be performed by the student. These include (amongst others): Forensic Medicine, Dermatology, Radiology and Chemical Pathology rotations. Rotation through these “low risk”

clinical specialities (as far as exposure incidents are concerned) may explain the risk difference compared to other years.

Activities and anatomical location

The only statistically significant results found, were the relative risk of “drawing blood” incidents compared to “setting up an IV line” incidents, “recapping needle” incidents, and “assisting in theatre” incidents. In all 3 instances the relative risk ranged from 2.6 (compared to assisting in theatre) and 4.1 (compared to recapping a needle). One reason for this may be that drawing blood samples is a core component of most disciplines and the frequency of the activity results in students being more at risk of having an exposure incident compared to other activities like assisting in theatre and setting up an IV line.

Common anatomical locations of incidents can be related to the activities that were performed by the student, e.g. the finger being a common injury location due to high number of “drawing blood” exposure incidents and the eye another common injury location due to mucocutaneous splashes related to various activities ranging from drawing blood, to setting up IV lines and assisting in theatre. The relative risk is slightly higher (1.44) for finger compared to the eye. Although the difference is statistically significant, the confidence interval is extremely close to one. This should be interpreted with caution, taking into consideration the bigger picture with interpretation of hand as an anatomical location.

5.3 Career Cohort Groups

5.3.1 Results

Table 5.9: Cohort student groups of 2007 and 2008

	Annual Average cumulative risk over the 4 year period	95% Confidence Interval
Student cohort group 1 (2007 group)	0.057	0.04 to 0.08
Student cohort group 2 (2008 group)	0.068	0.05 to 0.09

Cohort groups

For cohort group 1, entrance into study was on 1st of January 2007 as a 3rd year. This cohort was retrospectively followed until 31st December 2011 as a 6th year. The annual average cumulative risk calculated over the 4 year period for an exposure incident for cohort group 1 was 0.058 (5.8%).

Entrance into study for cohort group 2 was on 1st of January 2008 as a 3rd year student, and followed retrospectively until 31st December 2011 as a 6th year. The annual average cumulative risk calculated over the 4 year period for an exposure incident for cohort group 2 was 0.068 (6.8%). Group 2's annual average cumulative risk difference compared to group 1 was 0.01(1%).

5.3.2 Discussion

Medical students are in the front lines at the academic hospital. This places the medical student at risk (amongst others) for HIV and hepatitis. The medical school should continually consider whether enough is done to protect students who are, in this case, the least skilled "workers". Policies exist and training takes place from the 2nd academic year. The initial training takes place in the skills laboratory under ideal conditions, which may be different to conditions in reality. Following initial training in the skills lab, further training needs to be considered in the real-world setting, i.e. on patients, under supervision. There is a gap between what is written in policies and

what actually gets done on the ground. This gap needs to be bridged. It requires more focus to be placed on primordial and primary prevention. The application of standard precautions needs to be re enforced in order to reduce the number of exposure incidents. An in-depth study needs to be conducted to critically identify the multiple factors that play a role amongst exposure incidents and strategies should be developed from here.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

It is evident from this study that those students who have taken PEP for high risk exposure incidents do not adhere to the PEP 3 month and 6 month follow up consultations. However, the majority are compliant at the 6-week visit. A holistic approach needs to be taken in order to address the noncompliance in relation to follow up visits. A further survey needs to be done to identify issues that lead to non-compliance and address those that can be resolved.

Important factors have been identified in relation to exposure incidents. These factors can be addressed. There is room for improvement to further reduce exposure incidents across all years of study. Typical examples would be the incidents related to the activities of recapping needles, disposal of sharps, and inserting blood in a sample tube. These incidents can be reduced by enforcing standard precautions and adhering to proper techniques. Eye protection can also be provided in the operating theatre, which should decrease the number of potential incidents even further.

Other factors also play a role on exposure incidents, but the magnitude of its effects on the incidents needs to be determined. Some (like the patient characteristics) may play a significant role in certain incidents. Other relevant factors may include information on whether the patient moved or turned when the student was drawing blood or setting up an IV line. Such actions by the patient may play a role in the student sustaining an exposure incident.

The 4th year students were least at risk compared to the other years of study. The 2 cohort groups provide an indication of the annual average cumulative risk over the 4 year period of clinical exposure time which forms part of the entire 6 year training program.

As mentioned before, the medical undergraduate training programs in various countries differ. With the Stellenbosch University medical undergraduate training program, exposure to some disciplines may come earlier or later in the medical undergraduate curriculum compared to training programs from other universities. Therefore, some average annual cumulative risks, relating to the year of

undergraduate compared to that of other countries will differ. A comparison with a similar training program (in a similar teaching environment to that of the Stellenbosch University medical undergraduate training program) would be useful.

6.2. Recommendations

Reducing the number of incidents related to blood and body fluid exposure

Extensive investigations to look at reducing the number of incidents were not dealt with in this particular study. However, with existing data it was noted that 21.4% of exposure incidents were related to eye splashes, mostly attributed to assisting in theatre and there were incidents which were related to students not adhering to standard work requirements, in this case not wearing closed shoes. Both non-compliances caused a number of preventable incidents. Other incidents can also be reduced, which include: incidents related to recapping, disposal of needles, and insertion of blood into sample tubes. For repeated injuries involving the same individual, remedial action should take place. This was not specifically looked at in the data.

Other factors that play a role are beyond the scope of this study, i.e.

- Environment resources (equipment, needles, syringes, gloves), and
- Patient characteristics. In what way did the patient contribute to the incident?
- For incidents relating to drawing blood and recapping, the current training program for the medical undergraduates also needs to be reviewed in this regard.

All students should wear closed shoes and this should be enforced. Eye protection must be compulsory while assisting in theatre. The reasons for not wearing eye protection should be explored in detail. Stellenbosch University and the Department of Health should provide reasonable measures to protect not only employees but also those “individuals other than employees”, as mentioned in the Occupational Health and Safety Act ⁽¹⁾. Therefore, the students should be provided with eye protection - supplied either by the Stellenbosch University or the Department of Health. Emphasis needs to be placed during training that recapping is not allowed,

the importance of proper techniques of disposal and insertion of blood into sample tubes and students should be retrained on a regular basis if necessary. Whichever measure is implemented, the effectiveness thereof needs to be re-evaluated as well.

Adherence to PEP

Adherence to PEP follow-up visits is clearly lacking. The majority of individuals don't attend their 3- and 6-month visits.

The following reasons are put forward as possible causes:

Individual reasons

- May have forgotten about the follow up visit.
- Lack of knowledge regarding follow ups.
- Might be a 6th year that finishes or student that dropped out.
- Decided to see their private General Practitioner

Environmental reasons

- Due to finishing the final year the student is placed for internship elsewhere.
- The student is currently partaking in clinical rotations outside the vicinity of TAH as part of their undergraduate training.

The reasons for not attending follow up appointments need to be explored in more detail in a separate study.

The following proposals are put forward in order to improve compliance:

- A central office should be established to coordinate the follow-up of students with any work-related injury or illness. This should preferably be within an environment with occupational health knowledge and experience.
- Agreements should be put in place with other training hospitals to allow rotating students to have follow-up visits on their sites, with feedback given to the central office
- Automated SMS and email generation a week before expected follow up consultation dates to remind the student could be used. These dates are programmed once the student reports to the Campus Health clinic after the initial incident.

Reducing the number of incidents is a priority and various aspects need to be looked at, related to the incidents, which range from the individual, environment to patient characteristics.

Retraining

The current undergraduate training program for procedures can be reviewed and if necessary, adjustments can be made. An example would be that a short refresher training practical can be introduced in 5th year, in order to reinforce proper techniques. Teaching the student to apply standard precautions at all times would be ideal after investigation regarding the current knowledge and application as other studies have found this to be lacking ⁽³²⁾⁽³³⁾. The effect of non-device interventions has proved to facilitate the reduction of needlestick injuries ⁽³⁴⁾. If a student is also found to have repeated exposure incidents they need to be retrained.

All Incidents to be reported

Some incidents go unreported, as students:

- Knowing the status of the patient, the student decides not to go to Campus Health clinic (patient being negative) as they manage the process themselves and subsequently don't report it.
- Those that are exposed to blood and bodily fluids decide to see their own medical practitioner and receive their PEP outside. They attend follow up consultations with a medical practitioner of their choice.

The following proposals are put forward:

- Designing and enforcing a standard work procedure, relating to the exposure to blood and body fluids incidents, which will be applicable to all students. This procedure is introduced to the medical students in their 2nd year when they receive training on drawing bloods and setting up IV lines. This includes the appropriate protocol to follow if blood and body fluid exposure occurs.
- Implementation and operation of a database to allow accurate up-to-date capture of information should also be explored. This will increase the

probability of incidents being reported and will provide more comprehensive information that can be utilised for planning purposes.

- An agreement with training sites outside TAH to transfer information relating to blood and body fluid exposure incidents amongst Stellenbosch University medical undergraduates to the Campus Health clinic for further capturing.
- A non-reporting-of-incidents study should be conducted.

Investigations of all incidents

All incidents should be investigated. Investigations should encompass all role players including the individual involved. Recommendations need to be communicated with the individual and all other relevant role players. If the recommendation involves other role players, the other role players need to ensure that the recommendations are implemented. Subsequently they also need to be re-evaluated. (E.g. ensuring protective eyewear is available to the students at operating theatres)

Recommendations implemented

Up-to-date and accurate data capturing so that all incidents are reported

A preformatted data collection form was designed relating to exposure to blood and body fluids incidents with Google forms. It contains all the possible answers from ward to age, and type of activity, when the incident occurred. It involves just clicking with the mouse to choose the correct answer and does not include personal details of the student. This capturing procedure is done during the consultation and takes less than 2 minutes. This happens after the student consents to it that his /her details are for use for statistical purposes only.

This form takes the hassle out of capturing individual data in excel as it automatically sorts the data in excel and provides brief descriptive statistics with graphs. This up to date live statistics would be available to the clinic manager. He or she can then forward any important issues arising from this data to the Undergraduate Committee, where they can analyse it further and address the issues (e.g. by making recommendations, or by discussing issues with hospital management about incidents in a particular ward and take steps to remedy them). The new data

capturing system ensures all data to be captured correctly before allowing the user to submit to excel.

CHAPTER 7: SHORTCOMINGS AND WEAKNESSES OF THE STUDY

Investigation into noncompliance with follow up consultations needs to be investigated. An in depth investigation would have been ideal, however due to time constraints and the inability to track medical students who had qualified and left, it was subsequently omitted from the study.

This was a retrospective record review and data was captured from clinical records. Important information was lacking in some of the clinical records. The treating medical personnel need to be informed of the importance of collecting complete comprehensive information regarding the incident. The missing information may have influenced the objectives. The amount and effect size of missing information was not evaluated in the study. The extent of the following missing information is unknown and it could be significant.

- When the medical student did not report the incident, or
- When the medical student decided to manage herself/himself, if he had known that the source patient was negative
- If the medical student decided to be treated by a personal medical practitioner, the reporting of the incident would not take place.
- Another situation is when the incident is reported, however the follow up PEP visits take place outside the Campus Health clinic by a private medical practitioner.
- Missing information pertaining to the lack of information transfer if an incident took place at other hospitals and clinics, and subsequently follow up visits were done there.

The missing information as discussed above may have influenced the study objectives. The above shortcomings and weaknesses can be addressed with a well-designed prospective cohort study.

Logistic regression analysis was not looked at specifically in this study, but it would have been ideal. Family Medicine is a major rotation that was not listed under the clinical departments. All Family Medicine rotations take place outside TAH. It was captured as “not defined” in the cluster of data due to lack of information from clinical

records. Those incidents that happened outside TAH contain Family Medicine incidents. The actual number of Family Medicine related exposure incidents is unknown. The effect of family medicine missing information is unknown in the category of incidents related to the departments labelled as “other”.

The loss to follow up between the 2 cohort groups occurred when the student in the 2007 group failed and was kept back in the same year of study, however the student then fell into group 2 of the study (2008 group). The addition of the students to group 2 (2008 group) may have had a statistically significant effect but the impact on the cumulative risk is unknown. Further loss to follow up could occur when the student decided not to continue with his medical undergraduate studies. Addition to the group from outside the 2 defined groups may have also occurred e.g. if a student was readmitted to the particular year after a period of absence.

Some students may have had more than one incident in the same year and in further undergraduate years; it may even involve the same anatomical location, and activity or alternative anatomical location and activity. Although they have been accounted for as separate exposure incidents this may not necessarily mean it's a new student having an exposure incident in the collected data. The extent and statistical significance of this missing data is unknown. This can be solved by having a well-designed prospective cohort study.

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ADDENDA



UNIVERSITEIT-SELLENBOSCH-UNIVERSITY
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Approved with Stipulations New Application

15-Jan-2013
ESSOP, Ziyaad Hoosain

Ethics Reference #: S12/11/288

Title: Post Exposure Prophylaxis use Secondary to Occupational Exposure to blood and body fluids in Undergraduate Medical students over a period of 5 years : A Cross- Sectional Study.

Dear Dr Ziyaad ESSOP,

The New Application received on 12-Nov-2012, was reviewed by members of Health Research Ethics Committee 1 via Expedited review procedures on 15-Jan-2013.

Please note the following information about your approved research protocol:

Protocol Approval Period: 15-Jan-2013 -15-Jan-2014

The Stipulations of your ethics approval are as follows:

The researcher should provide a letter of support form the Institutional Research and Planning Division of Stellenbosch University.

Please remember to use your protocol number (S12/11/288) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389657.

Included Documents:

Application Form
Checklist
Synopsis
Consent Form
Investigators declaration



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01 February 2013

Dr Ziyaad Essop
Department of Defence (SANDF)
2 Military Hospital
Wynberg
7800

Dear Dr Essop

Re: Post Exposure Prophylaxis use Secondary to Occupational Exposure to Blood and Body Fluids in Undergraduate Medical Students over a period of 5 years: A Cross-Sectional Study

The researcher has institutional permission to extract data from the database of the Stellenbosch University Campus Health Clinic (Tygerberg Campus) and the Tygerberg Hospital Occupational Health Unit, specific to incidents of exposure to blood and body fluids, amongst Stellenbosch University undergraduate medical students registered between 2007 and 2011, while performing their clinical duties at Tygerberg Hospital during the same period. This data may only be used for the purpose of this study as indicated in the research proposal. Based on the reasons provided in the research protocol, the researcher may proceed without the consent of the participants.

With this permission the researcher must adhere to the conditions stipulated as follows:

- The identities of participants may not be revealed in the analysis of the data.
- The identities of participants may not be revealed in the dissemination of the results of the study.
- All data that is extracted for the purpose of this study must be adequately secured and may only be accessed by the primary researcher himself.
- The researcher must treat the data that is collected with utmost sensitivity and complete confidentiality.
- The privacy and anonymity of participants may not be compromised.

Best wishes,



Jan Botha
Senior Director: Institutional Research and Planning