Catherine McAuley

School of Nursing and Midwifery

Brookfield Health Sciences Complex

University College Cork

Factors Associated with Forensic Clinical Examiners Offering HIV nPEP Treatment to Patients following Rape or Sexual Assault

Deborah Marshall

Higher Diploma Nursing (Sexual Assault Forensic Examination), Higher Diploma Nursing Studies (Oncology), BA (Addiction Studies), RNP, RGN

Supervisor: Professor Eileen Savage (Head of School)

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Declaration

This work is mine and does not contain unacknowledged work from other sources. This dissertation has been submitted in partial fulfilment of the requirements for an award of Masters in Nursing Studies. The examiners cannot be held responsible for the views expressed, nor the factual accuracy of the contents.

Deborah Marshall

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ABSTRACT

Factors Associated with Forensic Clinical Examiners Offering HIV nPEP Treatment to Patients following Rape or Sexual Assault

Background: Risk of HIV acquisition is higher for patients following rape or sexual assault with multiple factors identified. Patient assessment should be prompt and individualised, requiring knowledge of the factors associated with HIV transmission. Effective implementation of HIV nPEP (non occupational post exposure prophylaxis) treatment by forensic examiners is often protocol driven and may be dependent on the interpretation of risk assessment tools. However this treatment may be offered inconsistently to patients.

Aim: To determine factors associated with forensic clinical examiners offering HIV nPEP Treatment to patients following a rape or sexual assault.

Method: This study determined factors associated with the offer of HIV nPEP treatment to patients following a rape or sexual assault by forensic clinical examiners. A quantative, descriptive, correlation design was carried out. Retrospective chart review of a 3 year period yielded 276 charts. Statistical Package for Social Sciences (SPSS) was used for data analysis.

Results: Two hundred patients attended < 72hrs post rape/sexual assault and of these, 33(16.5%) were commenced on HIV nPEP treatment. Seventy one risk factors were identified. Bivariate analysis demonstrated an association between the offer of HIV nPEP treatment and assailant number (p<0.001), assailant /patient relationship (p=0.002), assailant race/ethnicity (p<0.001), assailant characteristics (p= 0.001), vaginal (p=0.019) anal penetration (p <0.001) and object penetration (p <0.012) . Twenty six per cent of charts had a risk assessment documented, associated with the offer of HIV nPEP treatment (p <0.001).Of the 25 patients who attended the HIV specialist service, 24 were continued on treatment. Six patients did not attend the HIV specialist service. Adherence to 28 days treatment was 56%. Reasons for not giving HIV nPEP treatment were noted in 24 charts.

Conclusions: Findings highlighted that HIV nPEP treatment was appropriately prescribed to this cohort of patients and that some patients experienced multiple risk

factors for HIV. Documented risk assessment is necessary for all patients, demonstrating decision making with each patient based on up to date risk assessment tools and protocols. Adding condom use to risk assessment tools is recommended. Treatment adherence was favourable when compared to other studies. Further research on the outcomes of patients not returning to the prescribing Sexual Assault Treatment Unit (SATU) for follow up is recommended.

General Introduction to the Study

The incidence of Human Immunodeficiency Virus (HIV) infection continues to be a global public health concern and "efforts to reduce the numbers of new infections are being redoubled" (Sultan *et al*. 2014). The fastest growing group of people contracting HIV are young men and women aged 18-25 years and this same group are most at risk for sexual assault (Draughon 2012). Globally, the prevalence of sexual violence amongst women is reported at 35% by the World Health Organisation (WHO 2014) and it is known that in Ireland, more than four in ten women (42%) and over a quarter of men (28%) have experienced some form of sexual abuse or assault in their lifetime (McGee *et al.* 2002).

HIV non occupational Post Exposure Prophylaxis (HIV nPEP) treatment is the provision of HIV antiretroviral treatment for 28 days to patients as a possible risk reduction strategy for acquisition of HIV, particularly sexual exposures. Evidence suggests that HIV nPEP treatment can decrease the amount of HIV in the bloodstream and possibly interrupt infection at the exposure site (Draughon *et al*. 2014).

The decision to initiate HIV nPEP treatment to patients who have experienced a rape or sexual assault within 72 hrs following assault has a role to play in preventative measures for HIV (Sultan *et al.* 2014) and such a decision making process requires case by case risk assessment, guidance and locally agreed protocols. Sexual assault when compared to consensual sexual activity may pose an increased risk for ano genital trauma and exposure to other sexually transmitted infections leading to an increased risk for HIV (Wieczorek, 2010). Such risk

assessments consider factors regarding the probability of HIV transmission following a rape or sexual assault, however the HIV status and risk factors of the assailant are rarely known post sexual assault (Loutfy *et al.* 2008), therefore limiting its use to high risk exposures (Draughon & Sheridan 2012).

Studies have been carried out to examine the availability of risk assessment tools, guidelines and protocols in the provision of HIV nPEP treatment to patients following a rape or sexual assault, the factors associated with HIV nPEP treatment offers and the challenges, inconsistencies and efficacy in offering such an intervention by forensic examiners. However, no studies have been carried out in the Irish context.

This study will determine the factors that influence the decision making of forensic clinical examiners on whether or not HIV nPEP treatment is offered to patients who have experienced a recent rape or sexual assault.

Structure of the Thesis

This thesis consists of four chapters as follows:

Chapter One Literature Review

Chapter Two Methods

Chapter Three Research Findings

Chapter Four Discussion of Research Findings

Chapter One

Literature Review

1.0 Introduction

The aim of this study is to determine the factors that are associated with forensic clinical examiners offering HIV nPEP (Non Occupational Post Exposure Prophylaxis) treatment to patients following rape or sexual assault in an Irish Sexual Assault Treatment Unit (SATU). As highlighted previously, little is known in the Irish context about what informs the forensic examiner assessment, decision making and prescribing of HIV nPEP treatment to male and female patients who have recently reported a rape or sexual assault. In this chapter, a review of the literature is presented in three main themes: HIV transmission risk following Sexual Assault, Guidelines for HIV nPEP Risk Assessments and Practitioner Adherence to Guidelines.

1.1 HIV transmission risk following Sexual Assault.

In relation to HIV transmission risk generally, it is understood that the probability of HIV transmission is dependent on the type of exposure and the likelihood that the source is HIV positive (Tolle *et al*. 2010). Guidance in establishing risk in relation to the type of sexual exposure by specific act is essential since some sexual acts are more risky than others. As clarified by Sultan *et al*. (2014, p 149) risks for sexual exposure range from "low for oral sex to 138 infections per 10,000 exposures for receptive anal intercourse". Establishing risk for HIV

transmission following rape or sexual assault is particularly challenging since the HIV status of the assailant is usually not known nor is it possible for the assailants HIV status risk to be determined rapidly, if at all. Additionally, multiple factors and mechanisms can amplify the risk for HIV transmission pertaining to a sexual assault or rape (Loutfy *et al*. 2008). These include genital injury, breaches in the mucosal barrier and bleeding (Wiebe *et al*. 2000, Sultan *et al.* 2014, Resnick *et al*. 2002, Draughon 2012, Du Mont *et al.* 2008). In Draughton (2012) literature review on sexual assault injuries and increased risk of HIV transmission, the unique ways in which HIV transmission is linked to sexual assault was explained. She suggests that the increased likelihood of broken skin following a violent assault indicated that a higher risk of HIV transmission should be associated with sexual assault rather than consensual intercourse. Benn *et al.* (2011) findings concurred, stating that the aggravated anal or vaginal intercourse experienced during a sexual assault increases the risk of HIV transmission.

Others suggest that more than one assailant or multiple sex acts (Loutfy *et al*. 2008, Du Mont *et al.* 2008), lack of condom use (Davis *et al.* 2008, Peterson *et al.* 2010),the presence of sexually transmitted infections (Sultan *et al.* 2014, Manfrin-Ledet & Porche 2003, El-Bassel *et al.* 2007, Giotakos *et al.* 2003), first intercourse (Benn *et al.* 2011) and uncertain exposure or unknown HIV status of the assailant (Merchant *et al.* 2004, Olshen *et al.* 2006,Draughon 2013, Schremmer *et al.* 2005) are important factors to consider.

Griffith (2010) suggested in a report "Sexual Assault: A Report on Human Immunodeficiency Virus Post exposure Prophylaxis" that the prevalence of HIV

amongst convicted sexual assault assailants may be twice that of the general male population which emphasises the higher risk of HIV exposure following sexual assault. This finding was linked to a report from Dallas County profile of HIV and AIDS (2008) which stated an increase in HIV prevalence county- wide. A thirteen year ban on condom distribution was rescinded by the Dallas County commissioners the same year. HIV was also known to be more prevalent in the prison population at this time (Pallas *et al*. 1999, Curtis & Edwards 1995 *in* Giotakos *et al.* 2003) when HIV treatment options, education, testing and harm minimisation / risk reduction strategies were less available.

Conversely, Giotakos *et al*. (2003) found that no prisoner was diagnosed with HIV in their prospective study of 194 male prisoners who were convicted for rape and child molestation. The prevalence of blood borne viruses (Hepatitis B and Hepatitis C) was higher than the general population. The participants were asked to sign an informed consent form for interview and also submit a blood sample for blood borne virus in the first two weeks of their prison admission. However, this sample group was not representative of the whole prison population as inclusion was voluntary and inmates that refused to participate were excluded from the study in addition to those with language problems or those due for early release.

It is also known that the incidence of HIV infection as a consequence of a rape or sexual assault is largely unknown, despite some cases documented in the USA (Draughon *et al.* 2014b). Draughon & Sheridan (2012) found in a review of 70 research articles that conflict existed around establishing exposure risk when it is unlikely that the source is HIV positive such as in industrialized low HIV

prevalence countries. They concluded that practitioners should take time in their determination of what treatment is offered based on a case by case, person by person basis with wide variations found in levels of provision, acceptance and adherence of patients to HIV nPEP treatment. Loutfy *et al.* (2008) suggested that the provision of HIV nPEP treatment is considered cost effective and necessary in populations with established high rates of HIV infection such as endemic countries or men who have sex with men (MSM) communities in low prevalence countries.

In an industrialized low HIV prevalence country such as Ireland, risk of HIV transmission remains unclear. It is thought that HIV nPEP treatment is offered more readily based on a history of rape or sexual assault and if "the assailant is perceived to be from a high prevalence group" (Benn *et al.* 2011, p 700). In Ireland , high prevalence groups are defined as individuals where there is a higher likelihood that the source or assailant in this context may be HIV positive such as men who have sex with men or an individual who has immigrated from an area of higher HIV prevalence, particularly sub-Saharan Africa.

In addition to these factors, the British Association of Sexual Health and HIV (BASHH) GUIDELINES (2011) on the Management of Adult and Adolescent Complainants of Sexual Assault and the SATU risk assessment tool for HIV & PEP from the Emergency Management of Injuries (EMI) toolkit (2012, updated 2014) advocate considering HIV nPEP treatment based on the presence of multiple risk factors.

Once risk of HIV acquisition has been assessed and categorised, the provision of HIV nPEP treatment, which is the use of short term antiretroviral therapy following a non occupational exposure risk, is prescribed. This is largely as a consequence of sexual exposure where the risk of acquisition of HIV is balanced with the potential for harm due to HIV nPEP treatment (Sultan *et al.* 2014). Prescribing of antiretroviral therapy at the time of exposure presents an opportunity to interrupt or prevent HIV viral replication. This therapy effectively allows a person's immune system prevent an exposure from becoming an established infection (Wieczorek 2009).

It is not feasible to carry out prospective randomised control studies on humans since withholding of potentially efficacious treatment such as HIV nPEP treatment is unethical and it would also prove difficult to recruit a high enough sample size for a study. Therefore, evidence for the efficacy of HIV nPEP treatment is limited to animal studies where it is suggested that such treatment is potentially effective with initiation time and duration of treatment important factors (Benn *et al*. 2011). These researchers assert that 'absence of evidence' does not equate to 'evidence of absence' and state that studies that have been carried out on not only occupation exposure to HIV and also on vertical transmission of HIV (mother to child) have shown that HIV nPEP treatment can be protective.

In relation to the provision of HIV nPEP treatment to patients following sexual assault, Sultan *et al.* (2014) and Garcia *et al* . (2005) agree that generally, there is a lack of data with no randomized controlled trials available. Additionally, sparse

data are available on the efficacy of HIV nPEP treatment for patients following a rape or sexual assault.

In a US study, Draughon *et al.* (2014a) electronically surveyed a cross-sectional convenience sample of 174 SANE (Sexual Assault Nurse Examiners) and FNE (Forensic Nurse Examiners). They stated that no estimates of the magnitude of decreased HIV infection associated with the offer of HIV nPEP treatment in patients following rape or sexual assault were available. They also highlighted that the risk of HIV transmission specific to rape and sexual assault had not been measured. Sultan *et al.* (2014) documented that the prescribing of HIV nPEP treatment at this time has a significant role to play in reducing the incidence of HIV and that the assessment process at this stage is crucial as a HIV prevention strategy. Decision making can be difficult particularly for forensic clinical examiners who are not HIV specialist practitioners and therefore to assist this decision making process, a simple equation can be used: risk of HIV transmission equals risk that the source is HIV positive multiplied by the risk of exposure. This equation is widely documented in the literature (Sultan *et al.* 2014, Benn *et al*. 2011, EMI toolkit 2012, updated 2014).

1.2 Guidelines for Risk Assessment

In the context of the lack of clarity about perceived HIV risk versus actual risk and lack of conclusive data about transmission risk generally, risk assessments, protocols and guidelines become invaluable tools with up to date, evidence based

information which is required to inform the decision making process in relation to the offer of HIV nPEP treatment. Informing forensic examiners who are not HIV or Infectious Disease specialists about the important factors to consider in relation to sexual assault e.g. assault /assailant characteristics and examination findings, decision making around offering HIV nPEP treatment or not can be made in a more comprehensive and informed way. Meeting the needs of patients who have been raped or sexually assaulted however is challenging and the World Health Organisation agree that the provision of HIV nPEP treatment to patients who have been recently raped or sexually assaulted poses "specific challenges to the wider use of post-exposure prophylaxis among people who have been sexually assaulted include integrating HIV risk assessment (and counselling specific to HIV and PEP) into a trauma context" (WHO 2007, p 48).

Griffith *et al.* (2010) conducted a retrospective chart review of 151 female patient charts over a thirteen month period who received HIV nPEP treatment following a reported rape or sexual assault. A collaborative protocol for Sexual Assault HIV nPEP treatment was written with multiple disciplines involved including Obstetrics and Gynaecology, Infectious Diseases, Patient Advocacy and Pharmacy with clear guidance on patient counselling, HIV nPEP treatment prescribing and follow up. Aside from advocating written protocols based on standardised guidelines, the authors in this study also stated that HIV nPEP treatment should be offered on an individualised basis since the provision of such treatment "remains an unproven clinical intervention" (Griffith *et al.* 2010, p 2). Others including Bennett and Johnson (2011) refer to the BASHH Guidelines for

the use of HIV nPEP treatment following sexual exposure (Fisher *et al.* 2006) and highlight the importance of guidance documentation to assist in the decision making around what factors indicate the need or not for HIV nPEP treatment.

Krause *et al.* (2014) retrospectively reviewed the charts over a four year period of 138 female patients who presented to an emergency department following a sexual assault. They found this emergency department "highly compliant" to guidelines for HIV nPEP treatment sexual assault prescribing. These guidelines were based on the US Centres for Disease Control and Prevention (CDC) Guidelines (2005) in addition to updated guidelines for Sexually Transmitted Disease Treatment (2006 and 2010) which all support provision of HIV nPEP treatment to sexual assault patients. Data collection included factors such as demographic information, assault details (type of assault, number of assailants, condom use, if the patient knew her assailant or not) and timeframe from assault to Emergency Department presentation. The researchers acknowledged that their study was limited to the population and practice of just one department and that it demonstrated a higher proportion of HIV nPEP treatment offers to patients following a rape or sexual assault (100% of eligible patients offered HIV nPEP) than others. For example, the best available percentage in the literature is documented by Linden *et al.* (2005) when 49% of eligible patients were offered HIV nPEP treatment. However, Krause *et al.* (2014) stated that they did have a protocol in place since 1999 with a dedicated quality assurance team for sexual assault.

Some authors (e.g. Merchant *et al.* 2004, Olshen *et al.* 2006) carried out retrospective chart reviews on the adolescent patients attending their Emergency Departments following a rape or sexual assault and suggested that previous practice and attitudes were varied on the provision of HIV nPEP treatment to patients following a rape or sexual assault in the absence of uniform guidelines.

In a retrospective chart review by Linden *et al.* (2005), 299 patients attending an Emergency Department following a rape or sexual assault. 181 patients were eligible for HIV nPEP treatment of which only 89 (49%) were offered HIV nPEP treatment and few completed treatment. Linden *et al.* (2005) agreed that protocols were limited in their availability and it was established that more definitive protocols for prescribing of HIV nPEP treatment were necessary. Despite Emergency Department and Sexual Assault Nurse Examiner (SANE) guidelines " the standard of care for non occupational HIV exposure was in flux" (Linden *et al.* 2005, p 645) .

Three years later, Loutfy *et al.* (2008) conducted an 18 month prospective cohort study assessing universal HIV counselling for patients following sexual assault presenting to 18 Ontario Sexual Assault Treatment Centres. They stated that few Canadian jurisdictions had developed guidelines for the provision of HIV nPEP treatment for sexual assault in a large prospective cohort study of over 1000 patients, citing that the decision to offer HIV nPEP treatment to a patient who had recently experienced a rape or sexual assault was left to the discretion of the individual physician/team. The outcome of this study was a province wide standardised programme for universal HIV counselling and offering of HIV nPEP

treatment to all patients following a rape or sexual assault with frequent follow up which was deemed feasible and implemented successfully. More recently, Draughon et al. (2014a) found that 26% of the SANE/ Forensic Nurse Examiner US/Canadian programmes surveyed in their study did not have an existing protocol for HIV post-sexual assault nPEP in place.

Some researchers using the common approaches of retrospective chart review, prospective chart review and study reviews of guidelines incorporating literature review found that when protocols and guidelines were in existence, they were inconsistent in their recommendations (Draughon *et al.* 2014b, Wiebe *et al.* 2000, Sultan *et al.* 2014, Tolle & Schwarzwald 2010). For example, Sultan *et al.* (2014) in their review of "Current perspectives in HIV post –exposure prophylaxis", found that New York state guidelines were advocating maximum time to start HIV nPEP treatment of no more than 36 hours after exposure which differed from the majority of international guidelines of no later than 72 hours.

In the Republic of Ireland, provision of free, holistic, responsive and patient focused care to women and men who have experienced a sexual crime is the aim of the SATU services (National SATU Guidelines Development Group 2014). Such care demands staffing and availability "around the clock to allow prompt provision of medical and supportive care and collection of forensic evidence" (National SATU Guidelines Development Group 2014, p 36). Typically, SATU visits involve a head to toe physical examination, ano genital examination, assessment and documentation of injuries, evidence collection and offer of

medication including emergency contraception and STI prophylaxis. Provision of such medical care incorporates the prompt and timely risk assessment necessary for administration of HIV nPEP treatment. More often than not, such assessments occur at night and during weekends due to the nature of the service, when guidance is sought. A number of widely available resources are available to inform this decision making including Recent Rape /Sexual Assault: National Guidelines on Referral and Forensic Clinical Examination in Ireland (National SATU Guidelines Development Group 2014), BASHH Guideline for the use of post-exposure prophylaxis for HIV following sexual exposure (Benn *et al.* 2011), WHO clinical guidelines and policy for responding to intimate partner violence and sexual violence against women (WHO 2013) and the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) in addition to localised site specific protocols.

The SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) was adapted by SATU staff for use nationally in 2013 to reflect the unique factors associated with HIV nPEP treatment and sexual assault. It is known through quarterly national and regional SATU peer review and input from the National SATU GUIDELINES Group that this toolkit (Appendix 1) gives very clear guidance on not only assessment of HIV risk, but also choice of HIV nPEP treatment and follow up responsibilities. In addition to the Recent Rape /Sexual Assault National Guidelines SATU guidelines (2010 and 2014), these guideline documents and tools are standardised across all of the current SATUs operational in the Republic of Ireland.

1.3 Practitioner Adherence to Guidelines

From this literature review, there is evidence that health care practitioners adherence to guidelines and protocols following risk assessment vary, with HIV nPEP treatment offered inconsistently to patients following rape or sexual assault. Cross sectional studies indicated disparity for a variety of reasons; lack of knowledge by HIV nPEP treatment providers or counselling; timing of HIV nPEP treatment; cost or availability of HIV nPEP treatment; patient or provider uncertainty about exposure; perceived poor adherence to the treatment; unstable living conditions; barriers to follow up; medical concerns or patients appearing unconcerned about HIV (Sultan *et al.* 2014, Draughon *et al.* 2014b, Draughon & Sheridan 2012, Draughon 2012, Du Mont *et al.* 2011, Griffith *et al.* 2010, Chin 2010, Tolle & Schwarzwald 2010, Wieczorek 2010, Du Mont *et al.* 2008, Merchant *et al.* 2004, Wiebe *et al.* 2000).

Draughon (2012) highlighted in her report on sexual assault injuries and increased risk of HIV transmission that accurate assessment and documentation were vital in determining a patient's risk for HIV following a rape or sexual assault. However, Wieczorek (2010) reported that most healthcare providers lack the specialised knowledge to address the issue of a potential HIV transmission exposure following sexual assault in an expeditious manner and in their retrospective chart review, Merchant *et al.* (2004) concluded that Emergency Department practitioners needed to be educated on the proper use of HIV nPEP treatment.

Tolle & Schwarzwald (2010) stated that physicians do not completely understand or implement the recommendations around HIV nPEP treatment. Du Mont *et al.* (2011) identified insufficiently trained and knowledgeable staff as a possible barrier to the sustainability of a HIV nPEP programme when they surveyed 132 experienced health care providers in sexual assault provision services based in Ontario. This finding was supported by others who acknowledge the complexity and confusion around the process of implementation of HIV nPEP treatment in their study on "Factors Associated with Forensic Nurses Offering HIV nPEP Status Post Sexual Assault" (Draughon *et al.* 2014b). They discussed the importance of practitioners keeping up to date with site specific protocols and HIV risk assessment algorithms impacting very much on whether a patient was offered HIV nPEP treatment or not. The point was emphasised that treatment modalities and literature around HIV transmission are constantly changing and so to ensure that patients are being given consistent evidence –based care, treatment programmes and clinicians need to keep abreast of latest developments (Draughon *et al.* 2014b).

In a literature review incorporating 22 retrospective chart reviews on HIV nPEP treatment in low prevalence for HIV industrialised countries, Draughon & Sheridan (2012) stated that patients were more likely to accept HIV nPEP treatment if they were positively encouraged by the health care provider, a fact they suggested should be considered in conversations with patients. The prospective analysis study of 386 female adolescents by Du Mont *et al.* (2008) was included in the literature review by Draughon & Sheridan (2012). They

expanded further the concept that provider encouragement around HIV nPEP treatment influenced higher acceptance and completion rates and they advocated that this encouragement should come from those consistently trained to offer and administer HIV nPEP treatment to all of the patients who meet the established risk criteria.

Griffith *et al.* (2010) in their retrospective chart review of 150 women who were sexually assaulted and prescribed HIV nPEP treatment by protocol found that counselling was important on many levels; the protocol was necessary to provide Non Infectious Diseases specialists clear assistance in patient counselling, counselling was integral to initiating any medical intervention such as HIV nPEP treatment which had side effects or toxicities yet has no clear proven benefit and patient follow up for counselling was an identified barrier . Wiebe *et al.* (2000) in their retrospective chart review of 258 patients highlighted the concern that service providers experienced difficulty in offering information about HIV nPEP treatment to patients recently traumatised.

Timing of HIV nPEP treatment has also been considered important to acknowledge by many (Sultan *et al.* 2014, Tolle & Schwarzwald 2010, Chin 2010, Griffith *et al.* 2010, Olshen *et al.* 2006 & Merchant *et al.* 2004). Benn *et al.* (2011) cautioned that delays experienced in commencing HIV nPEP treatment could adversely affect its efficacy. Their UK guideline for the use of post exposure prophylaxis for HIV following sexual exposure suggested that it was not recommended to initiate HIV nPEP treatment after 72 hours of exposure when it was thought to be ineffective or less efficacious. The rationale for this is clearly

documented by Sultan *et al.* (2014) who advise that HIV can take up to 72 hrs to be detected in regional lymph nodes, 5 days in blood and 8 days in cerebrospinal fluid. If HIV nPEP treatment is started early, it is thought that the acquisition of HIV infection is prevented by inhibiting the viral replication process or preventing dissemination of infection at this window of opportunity (Sultan *et al.* 2014). Chin (2010) also stated that HIV nPEP treatment should be initiated as soon as possible as the efficacy of treatment may be highly time dependant.

However, long delays from sexual assault to Emergency Department presentation were noted by Merchant *et al.* (2004) with additional delays acknowledged in ordering the HIV nPEP treatment and the patient receiving it. Griffith *et al.* (2010) found that immediate medication accessibility was important if timely provision of prophylaxis is to be achieved and Olshen *et al*. (2006) identified 24 patients who were excluded from their study which examined the use of HIV nPEP treatment in adolescent sexual assault victims as they received the HIV nPEP treatment outside of the 72 hr time frame. Tolle and Schwarzwald (2010) agree, stating that regimens started more than seventy two hours after exposure and continued for less than four weeks were deemed less effective.

Cost of the drugs or drug availability was suggested as a factor for inconsistent adherence to HIV nPEP treatment guidelines following sexual assault (Draughon *et al.* 2014a, Du Mont *et al.* 2011, Griffith *et al.* 2010, Linden *et al.* 2005, Schremmer *et al.* 2005, Merchant *et al.* 2004) with Linden *et al.* (2005) concluding that HIV nPEP treatment was offered to less than half of sexual assault patients. Her study found that HIV nPEP treatment was more likely to be

offered if health insurance was in place, a statistically significant finding (p=0.018).

Olsen *et al*. (2006) suggested that patient uncertainty about exposure highlighted difficulties in administering HIV nPEP treatment to adolescents after sexual assault in relation to specific details in relation to the assault. Amongst the 110 patients in their retrospective chart review, over half were unsure if ejaculation had occurred and over a quarter were unsure if a condom was used. A further 21% reported a black out during the assault (Olsen *et al.* 2006). These difficulties inevitably make guideline adherence an issue and case by case assessments remain crucial in such circumstances.

Draughon *et al.* (2014b) suggests that it is likely that factors are assessed by individual clinicians and that HIV risk assessments are operationalized and documented differently. Some clinicians possibly take additional factors into account which influence their decision making as to whether or not HIV nPEP treatment is offered and such factors may not always be indicated on a HIV risk assessment form. Such factors have been reported as perceived poor patient adherence (Draughon 2013,Chako *et al.* 2012, Draughon & Sheridan 2011, Linden *et al.* 2005), and barriers to follow up (Draughon *et al.* 2014a, Draughon & Sheridan 2012, Griffith *et al.* 2010, Olshen *et al.* 2006, , Reeves *et al.* 2004). Two studies in particular conducted by Loutfy *et al.* (2008) and Du Mont *et al.* (2008) included patients living in unstable situations, patients unconcerned about HIV and medical concerns (e.g. another illness or taking medications

contraindicated with HIV nPEP treatment) as reasons for not offering HIV nPEP treatment.

The provision of HIV nPEP treatment remains an important tool in the ongoing efforts to reduce the incidence of HIV infection, particularly among risk groups (Sultan *et al.* 2014) but a significant psychological role for the patient also exists. In Canada, Du Mont *et al.* (2008) asserts "that patients deserve the choice to try to reduce their chance of HIV transmission after a sexual assault" (Du Mont *et al.* 2008, p 973). Some researchers have raised concerns that patients following a rape or sexual assault are not been given the option to make informed healthcare choices if it was assumed by practitioners that poor follow up for the patient was a problematic barrier (Draughon *et al.* 2014a). Fear and concern about HIV following rape or sexual assault was found to be high in a small study (n=62) by Resnick et al. (2002) when 82% of recent rape victims attending a six weeks post rape medical treatment clinics wished they had more information about HIV risk at the time of the post rape exam. Patients who responded that they were extremely fearful or concerned about contracting HIV were more likely to have been raped by a stranger. Du Mont e*t al.* (2008) agrees that studies have found that significant numbers of patients worry about HIV transmission and that there is a demand for preventative HIV treatment post rape or sexual assault when appropriate. Wieczorek (2010) suggests that a risk assessment should be made *with* each patient and not *for* each patient when she examined a forensic nursing protocol for initiating HIV nPEP treatment following sexual assault.

With other factors influencing practitioner decision making which were not evident in their protocols, "appropriate assessment and documentation are vital during risk assessment for HIV transmission" (Draughon 2012, p 4) with further research recommended to examine these decision making mechanisms (Draughon *et al.* 2014).

1.4 Conclusion

In this chapter, the literature has been reviewed in relation to what is known about the provision of HIV nPEP treatment to patients who have experienced a recent rape or sexual assault in countries where the prevalence of HIV is low. Study settings were limited to Emergency Departments mostly and to a lesser extent, specialised sexual assault treatment facilities in Canada, USA and the UK. Inconsistencies and challenges existed in the decision making and administration of such treatment despite protocols, internationally recognised guidelines and algorithms available in some circumstances. No studies were carried out in an Irish setting and little is known about the factors that influence decision making on whether or not HIV nPEP treatment is offered to patients who have experienced a recent rape or sexual assault attending an Irish SATU. Therefore a gap in the literature exists. The factors associated with forensic clinical examiners offering HIV nPEP treatment to patients following a rape or sexual assault and adherence to HIV risk assessments, guidelines and protocols available in one Irish SATU will be determined through a retrospective chart review.

This literature review has demonstrated that retrospective chart reviews are a common methodological approach used in this patient cohort and this study will adopt a similar approach.

Chapter Two

Methods

2.0 Introduction

This chapter will outline the research methods selected for this study and the rationale to support this approach. The study aims and objectives are presented in addition to details relating to the study sample used. This chapter will describe the research design and research instrument proposed. It will also outline the method of data collection utilised and details relating to the data analysis procedure. Ethical considerations and study limitations encountered in this study will also be addressed.

2.1.1 Aim of the study:

The broad aim of this study is to identify the factors associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault.

2.1.2 Objectives of the study:

1) Determine the patient and assailant characteristics that are associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault.

2) Identify the assault characteristics that are associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault.

3) Describe the examination findings that are associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault.

4) Examine other factors of note associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault or not.

2.2 Research Design

To achieve the aim and objectives of this study, a quantative research design was utilised. This design was chosen since "it consists of stating, in advance, the research questions or hypotheses, operationalising the concepts and devising or selecting in advance, the methods of data collection and analysis...findings are presented in numerical and/or statistical language" (Parahoo 2014, p 42).

The study is descriptive in nature since it aims to "provide an accurate account of characteristics of particular individual, situations or groups" (Kerlinger & Lee, 2000 cited in Burns & Grove, 2011 p 34). Descriptive studies assist researchers to describe what already exists, determine frequency of occurrences, discover new meanings and categorize the information obtained. Burns & Grove (2011) and Parahoo (2014) agree that descriptive studies are useful in describing phenomena of which little is known and that research outcomes include the identification of concepts, the possible relationships between the concepts and the generation of future hypotheses as a basis for future research. Additionally, Parahoo (2014) defines descriptive studies as studies where emerging trends or patterns are

identified with possible links between variables observed, however the emphasis is very much on describing the phenomena (Parahoo 2014).

A retrospective, cross-sectional chart review took place where the "data are collected at one point in time" (Polit & Beck, 2014, p 725). This research design has been advocated by some who suggest that "retrospective chart review is an important methodology with distinct advantages and has the potential to provide us with valuable research opportunities" (Gearing *et al,* 2006 p 131). Advantages such as allowing the study of sensitive patient circumstances (e.g. patients who have experienced a rape or sexual assault) have been described. This approach enables clinicians to effectively conduct research with rich, readily accessible existing data that can inform and add to their practice. Others also agree of the importance for researchers of health care records since the information and documentation contained are regarded as medically and legally accurate and reliable (VonKoss Krowchuk *et al,* 1995). Some authors have cautioned that retrospective chart reviews as research are limited due to incomplete documentation, information unrecorded or unrecoverable and the use of jargon (Gearing *et al,* 2006). However forensic examiner SATU documentation and charts are routinely completed in such ways that leave little ambiguity with minimal use of jargon and minimal incomplete documentation. The charts are uniform in format and are a contemporaneous record and necessary tool for preparation of medical legal reports and so concerns about inaccuracy of research data are minimised.

This chart review looked back at the forensic examiner documentation of the patient demographic characteristics, assault characteristics and examination findings at the patient's initial visit to the SATU within seventy two hours of a reported rape or sexual assault. Documentation around the decision making process which determines if HIV nPEP treatment is offered or not and subsequent follow up care arising from an initial visit decision if HIV nPEP treatment was offered was also examined.

This study design best suits the sexual assault patient cohort involved as this patient group for the most part, have just a brief yet therapeutic interaction with the SATU and some choose to not engage with the service any further after the initial examination visit. Hess (2004) agrees, stating that retrospective chart reviews are advantageous by allowing the study of "rare occurrences". This design ensured that no contact was made with any SATU patient to achieve the study aims and objectives which could potentially have a negative consequence for them.

2.3 Setting and Context

The setting for this study is a Sexual Assault Treatment Unit (SATU) located in an acute general hospital in the Republic of Ireland. The unit is one of six regional specialised services currently available in the Irish Republic and offers a range of specialist multi-agency responses following rape/sexual assault to male and female patients age fourteen years and older. The Clinical Nurse Specialist

(Sexual Assault Forensic Examination) or CNS (SAFE) who works full time in the unit ,is one of six forensic clinical examiners who provides a round the clock, on call range of examination options to patients following a rape or sexual assault. This service is provided in partnership with on call assisting nurses and psychological support workers from the Rape Crisis Centre. Additionally, the CNS (SAFE) facilitates a nurse led follow up STI clinic. Typically, the unit receives referrals from 15 different counties each year and since the unit opened in 2009, over 530 patients have been seen at the study location.

2.4 Data Collection and Research Instrument

Data collection was facilitated by a 33 itemed questionnaire (Appendix 2) for the retrospective chart review. The questionnaire as a data abstraction instrument was developed in an organised, simple and clear fashion so that data collection could be uniform and "organised in a logical order" (Gearing *et al.* 2006, p 128). Each item was considered so that the response involved a simple, unambiguous answer and as advocated by Gearing *et al.* (2006), the flow of information in the questionnaire was parallel with the patient chart. The questionnaire consists of predetermined, standardised and structured questions; some questions are two way questions, some questions are multiple choice and some are checklists. Three questions required additional information to a two way question. If only one option was required, the questionnaire indicated this. Closed questions were used where possible since they yield comparative data so all responses will be in the

same format, making pre coding and analysis easier. The questionnaire was devised by the researcher and is subdivided into six sections as follows; Section A (General Information) five questions; Section B (Assault and Assailant Characteristics) ten questions; Section C (Patient Demographics) three questions; Section D (Examination Findings) seven questions; Section E (Decision to Treat) three questions; Section F (Documentation of Follow Up Care) five questions.

This data collection method was chosen since it offers anonymity (Polit & Beck 2014). This consideration was essential for patients in obtaining the sensitive data involved for this particular study.

A coding manual was devised which listed each item so that the data could be abstracted from the chart and inputted electronically into a database based using Statistical Package for Social Sciences (SPSS). Missing data were coded as *not documented*. The questionnaire was completed with data abstracted from the SATU charts which are stored confidentially on site in the SATU, looking back over a specific timeframe of three years.

Once approval was granted, advantages for choosing this data collection method included a minimal risk for delay in collecting the data since the charts are readily available and easily accessible in the SATU. The researcher reviewed, coded and inputted 100% of the charts with a second reviewer independently coding 10% of the charts. There was greater than 95% concordance between the two reviewer's coders. In cases of discrepancy, the database was amended accordingly. The researcher was also very familiar with the charts used for the study which adds to the validity of the study with consistent and accurate data obtained which are

important considerations. Burns & Grove (2011) agree when discussing data collection tasks, asserting that "the key to accurate data collection in any study is consistency" (Burns & Grove 2011, p 363).

Each SATU chart is a confidential, contemporaneous, patient record which contains medical and forensic relevant details about the alleged assault and care given. Such details include patient demographics, assault and assailant characteristics, examination findings, treatment given including medication and follow up/discharge care. The SATU chart does not address legal aspects of the case or confirm whether a rape or sexual assault has occurred. This study collected data solely from the information available in the SATU chart.

2.5 Reliability, Validity, Pilot Study

2.5.1 Reliability

Reliability, a precondition for validity, refers to the accuracy of the data in terms of their stability and repeatability. (Carter & Porter, 2000). Questionnaire stability was ensured in that when the charts are reviewed on different occasions periodically, similar results will be obtained. This reliability depends largely on the wording and structure of the questionnaire and so as much as possible, the questionnaire reflected the wording on the SATU chart. Double barrelled, leading, double negative and hypothetical questions were avoided as advocated by Parahoo (2014). A test –retest of the questionnaire was also carried out on the first ten charts with the second reviewer on two occasions, following a one week interval.

With responses unchanged over that one week interval, this contributed to the overall reliability and accuracy of the process involved.

2.5.2 Validity

A quantative questionnaire should be valid in that "it should measure what it is supposed to measure" (Polit & Beck 2014). Validity cannot be supported if the questionnaire fails to demonstrate reliability; however a questionnaire can be reliable yet not valid. For the purposes of this study and content validity, variables theoretically relevant to HIV risk were abstracted by a review of the HIV nPEP risk assessments and SATU charts in use so that all of risk factors which influence decision making for HIV treatment were included in the questionnaire (BASHH GUIDEINES 2011, Benn *et al.* 2011, SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014), National SATU GUIDELINES 2010, WHO GUIDELINES 2003). The questionnaire items also match the terminology and pro-formas used in the SATU chart which ensure the validity of the study and its ability to address the research question. Contrasting groups of patients can then be evaluated which can add to the instruments validity by obtaining contrasting results.

Patients who did receive HIV nPEP treatment will be identified to determine the factors that influenced the decision making of the forensic examiners and their adherence to guidelines including follow up care. In addition, the charts of all patients that did not receive HIV nPEP treatment within the same timeframe of three years will be reviewed to determine the factors which influenced the

decision making of forensic examiners if they presented to the unit within seventy two hours following a rape or sexual assault. If any patients attended the SATU and fulfilled eligibility criteria for HIV nPEP treatment as per guidelines but were not offered HIV nPEP treatment, this decision making if documented will be identified.

2.5.3 Pilot Study

To demonstrate reliability, a pilot study was undertaken in advance of the data collection process. This generally recognised guideline for reliability in retrospective chart reviews suggest that pilot studies should target ten percent of the overall sample (Gearing *et al.* 2006). Pilot studies have many advantages and provide the researcher an opportunity to assess the study feasibility, determine the adequacy of the questionnaire, and demonstrate in advance any methodological pitfalls in the data collection strategy. Moreover, pilot studies assist in the evaluation of the data abstraction sheet for reliability, clarify protocols for data abstraction, determine the frequency of not documented responses as missing data and evaluate any sampling concerns such as inclusion or exclusion criteria (Gearing *et al.* 2006). Due to the small sample size of this study, ten charts were selected randomly, five from each of the study cohort i.e. charts where a clear prescription of HIV nPEP treatment was recorded and charts where a prescription for HIV nPEP treatment was not recorded and a pilot exercise was carried out.

2.6 Sampling

The retrospective chart review examined the charts of female and male patients attending a SATU within seventy two hours following a rape or sexual assault who were administered HIV nPEP treatment (n=33). Patients who attended over the same period of time and did not receive HIV nPEP treatment within seventy two hours following a rape or sexual assault were also included in the study (n= 167). These patients were selected by consecutive sampling which "involves recruiting all of the people from an accessible population who meet the eligibility criteria over a specific time interval or for a specified sample size" (Polit & Beck 2011, p 278). Both groups were selected if they presented within the same three year period i.e. May 1st 2011- July 31st 2014 inclusive. This time period was chosen since it is known from a previous audit on HIV nPEP treatment use in the SATU by the researcher that 33 patients in total were prescribed HIV nPEP treatment during that time.

The sample size is a convenience sample where the most conveniently available people are included as participants (Polit & Beck 2012). This sample can be viewed also as the recruitment sample. This study utilised the accessible sample population with data abstracted from one of the six regional SATU in Ireland; each of the six SATU are similar in terms of the adult patient population who access the service (i.e. patients age 14 years and older). Although site specific protocols may exist , the six units are uniform in their standardised use of National SATU Guidelines (2010) and SATU specific risk assessment tool for HIV and PEP (EMI toolkit (2012 (updated 2014) in addition to other International

HIV nPEP Treatment Guidelines. The inclusion and exclusion criteria for the study are as follows:

2.6.1 Inclusion Criteria

- First examination (initial visit) of all patients age 14 years or older attending one Irish SATU.
- Attendance recorded as less than seventy two hours following a rape or sexual assault.
- Attendance within the time frame of May 1st 2011-July 31st 2014.

2.6.2 Exclusion Criteria

- All patients who present presented outside of the recommended timeframe for administration of HIV nPEP treatment of seventy two hours as per National and International guidelines (Sultan *et al.* 2014, Benn *et al.* 2011, SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) .
- All patients whose initial first SATU visit did not occur within the three year time frame of May 1st 2011- July 31st 2014.
- All patients whose initial visit occurred at a different SATU or other location.
- All patients administered HIV nPEP treatment at a different prescribing location.
- All patients who presented to the SATU for follow up care only.

2.7 Access

In order to gain access to the charts and conduct the study, permission was sought and granted from the local ethics committee (Appendix 3), the Medical Director of the SATU (Appendix 4) and the Director of Nursing of the hospital (Appendix 5) where the study was taking place. For the purpose of this study, within SATU service provision in the Irish Republic, the study setting is defined as an adult SATU where patients aged 14 years or older are eligible to attend. As per the National SATU Guidelines Development Group (2014), "for a person under the age of 18 years, the statutory requirements of Children First: National Guidance and Withholding of Information Act should be followed...the age in relation to consent for a Forensic Clinical Examination is governed by different elements of the law." (National SATU Guidelines Development Group, 2014 p 45-6).

2.8 Data analysis

Data were analysed using descriptive and inferential statistics. According to Parahoo (2014), descriptive questions use statistical analysis to identify relationships whilst correlational and causal relationships use inferential statistics to explore such relationships. Descriptive analysis was achieved by stating frequencies. This study adopted both methods of analysis to determine the factors that are associated with forensic clinical examiners offering HIV nPEP treatment to patients following a rape or sexual assault.

Decision making and guidance is sought and influenced from factors which are stated in the guidelines available on offering HIV nPEP treatment in the SATU

but other less explicit factors such as patient socioeconomic or psychological issues may influence a forensic clinical examiners decision making around the offer of HIV nPEP treatment which are not present in the guidelines. Draughon *et al.* (2014b) examined in their retrospective chart review, the factors associated with forensic nurses offering HIV nPEP post sexual assault in their retrospective chart review and data were analysed by bivariate associations which analyses the relationship between multiple independent variables and a nominal outcome (Polit & Beck 2014). This study adopted similar methods to examine the correlational elements of the study between the factors identified and the offer of HIV nPEP treatment or not.

For the purpose of this study, independent variables such as number of assailants or vaginal injury were measured with the dependant variable of offer of HIV nPEP treatment (the primary outcome). Bivariate analysis was conducted with Pearson's chi square test or Fisher exact test at $p < 0.05$. Measurement using the index (Cramer's *V)* was carried out to describe the magnitude of the relationships between the nominal data since the contingency tables used were larger than 2 x 2. Variable abstraction took place using the SATU chart in addition to the SATU specific EMI toolkit (2012 (updated 2014) which was the principal risk tool used. Any other variables theoretically relevant to HIV risk for questionnaire inclusion were abstracted from other risk assessment and guideline information available for reference and consultation in 2011 (BASHH GUIDEINES 2011, Benn *et al.* 2011, National SATU GUIDELINES 2010, WHO GUIDELINES 2003).

2.9 Ethical principles and considerations

Ethics can be defined as the moral principles providing the framework for conducting research studies (Parahoo 2014). Applied to this study, all data obtained from the chart review are confidential and anonymous with respect to the patient group involved so that not even the researcher can identify a patient by name. This is important since the sample size is small and because rich descriptive data will be presented (Polit & Beck, 2014) .This practice and culture of confidentiality and anonymity is a common, routine practice in the SATU where patient names are rarely used and patient records are substituted by numbers. The setting of the study will be non identifiable by name or location.

The study approach was selected particularly with the principle of beneficence (protection from discomfort and harm) in mind so that no patient was contacted by the SATU months or years after a reported rape or sexual assault. This strategy was implemented with regard to the concept of opening up of old wounds in relation to memories of a traumatic event and where there was a concern established that the patient may have been at an increased risk of HIV transmission at that time. The researcher was mindful of the vulnerable population described by this study and so particular attention was paid to the study approach so that the risk of unintended effects was minimised.

Fairness was ensured by selecting patients only on the basis that they fulfilled the criteria of the accessible sample rather than any undisclosed benefits to the patient or the researcher. Ethical approval was granted by the local ethics committee, the

clinical director of the unit who is the gatekeeper of the charts and the director of nursing where the study took place.

2.10 Limitations of the study

Limitations of the study include the following; sample size and the study location which was restricted to one clinical site. However the sample size was the whole accessible population available to that SATU and the population attending the study location are representative of the SATU patient population nationally. This assertion is clarified with reference to the National Annual SATU report (2013) which categorizes such information.

Risk of researcher bias as the sole data collector for the study is balanced by the pilot analysis of the questionnaire and adaptation of this data abstraction instrument to ensure the reliability and validity of the data collected.

By limiting the study inclusion criteria to < 72 hours following a rape or sexual assault (which is the recommended time frame for administration of HIV nPEP treatment), it is unknown if any patients were administered HIV nPEP treatment outside of this recommended time frame.

A further study limitation could be viewed by some as the retrospective nature of the chart review. Difficulties may exist in unrecoverable or unrecordable data, variance in the quality of recorded information by the forensic examiners and problematic verification of information (Gearing *et al*, 2006). However, this approach allows the readily accessible rich data available from a vulnerable

speciality such as patients post rape or sexual assault to be researched in a safe, reliable and valid way. The generation of a hypothesis that can be tested prospectively at a later date will contribute to what little information is currently known about post rape and sexual assault care in Ireland.

2.11 Conclusion

This chapter has outlined the research methodology used for the study. The aims and objectives of this study were presented and the research design described. Justification has been given for the sample chosen and the data collection procedure has been explained. Data analysis for this study was stated and limitations of the study were addressed. Ethical considerations were discussed with particular reference to the vulnerable patient sample chosen for this research study.

The next chapter will present the findings of the study.

Chapter Three

Research Findings

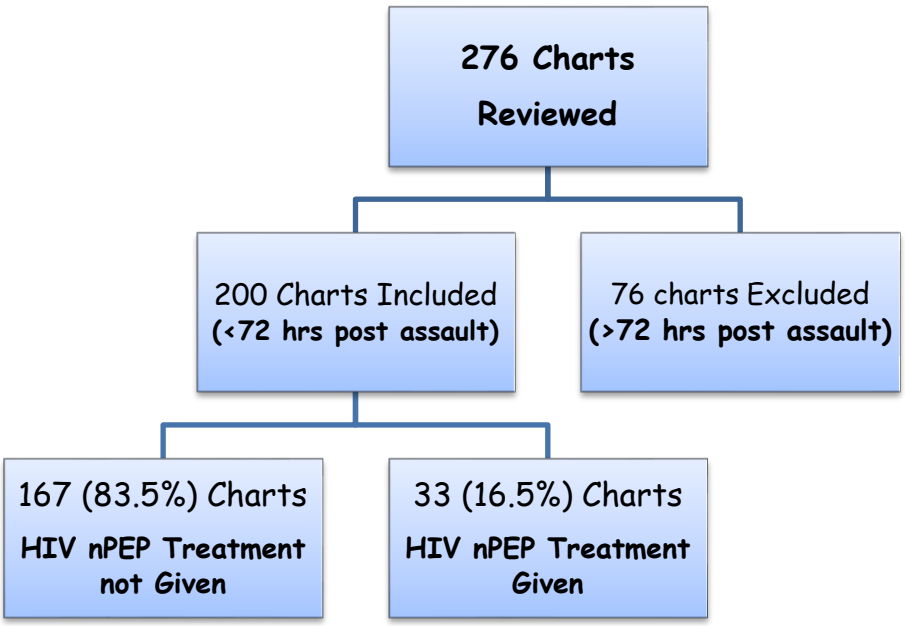
3.0 Introduction

This chapter presents the findings of a quantative, descriptive, correlation study which identifies the factors associated with forensic examiners offering HIV nPEP treatment to patients following a rape or sexual assault. Data collection by retrospective chart review was carried out to elicit the aim of the study. The results of the retrospective chart review are presented as descriptive statistics. Bivariate analyses was conducted which explored the relationship between offer of HIV nPEP treatment independently with each of the demographic variables relating to timing of initial visit to SATU, assault and assailant characteristics, patient demographics, examination findings, decision to treat and follow up care. All bivariate analyses were conducted with Pearson's chi square test or Fisher exact test at $p<0.05$. This retrospective chart review revealed numerous factors which were associated with the offer of HIV nPEP treatment to patients following a rape or sexual assault including number of assailants, assailant race/ethnicity and relationship to the patient, assailant characteristics, vaginal and anal penetration and documented risk assessment. The research findings will now be presented.

3.1 Cases included in Retrospective Chart Review

This study is based on a retrospective chart review of 276 patients who presented to the SATU for an examination over a three year period from May 1st 2011- 31st July 2014. In total, 200 patients fulfilled the inclusion criteria for this study of which, 33 patients (16.5%) was administered HIV nPEP treatment in the SATU at their initial visit (Figure 1).

Figure 1: Chart abstraction based on Inclusion / Exclusion Criteria



3.2 General Information

Section A (General Information) asked about the date and time (during office hours or not) of the initial examination and also confirmed that the patient

attended the unit <72 hrs post rape or sexual assault. This section also included the dependant variable where the offer of HIV nPEP treatment was determined by chart documentation or not.

Of the 200 charts included in the study, 159 (79.9%) patients attended the SATU out of office hours for an examination. The remaining 41 (20.5%) patients attended the unit for an examination during office hours, defined as Monday – Friday 0900hrs-1700hrs. There was no significant difference in the offer of HIV nPEP treatment vs. time of patient's examination (p=0.405)

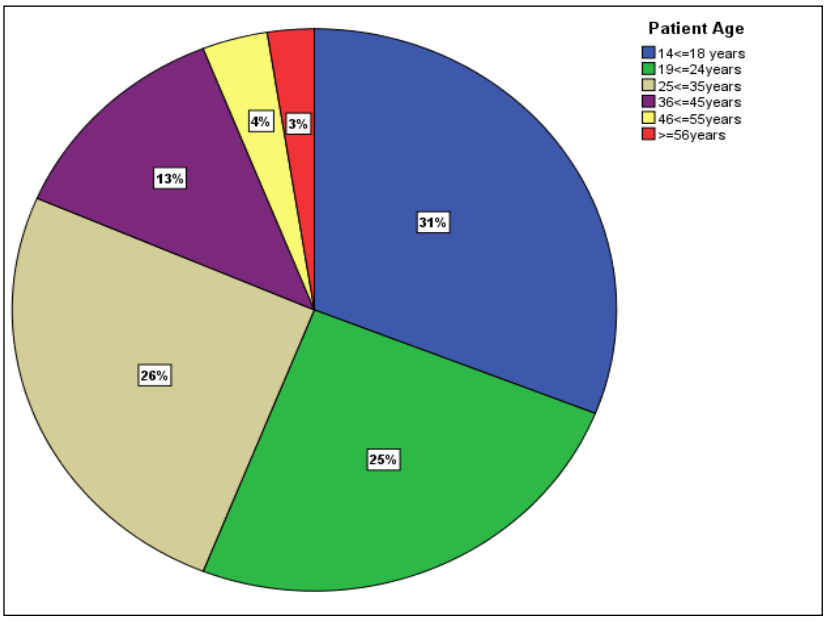
In total, 29 (14.5%) patients had a clear prescription for HIV nPEP treatment recorded in their charts. This treatment was documented as Truvada® (Tenofovir, Emtricitabine) and Kaletra® (Lopinavir, Ritonavir) which was the recommended HIV nPEP treatment during the study period (National SATU GUIDELINES 2010). In addition, 4 patients did not have clear prescriptions or documentation of HIV nPEP treatment in their SATU charts yet these patients were offered and commenced on HIV nPEP treatment by SATU examiners at their initial SATU visit. These patients were included in the study as patients who were offered HIV nPEP treatment.

3.3 Patient Demographics

Section C (Patient Demographics) documented the patient gender, age and race/ethnicity. Almost all of the patients seen were female 195 (97.5%) and nearly one third, 62 (31%) were aged 14 ≤ 18 years at the time of their SATU visit. Of the 33 patients who were administered HIV nPEP treatment, 31 (94%) were

female and 2 (6%) were male. Due to the small number of male cases seen (n= 5), patient gender was not dichotomised further to male or female as a variable in the bivariate analyses. Half of the total numbers of the patients seen were distributed between two age ranges with 50 (25%) patients aged 19 ≤ 24 years and 51 (25.5%) patients aged 25≤ 35 years. Twenty five (12.5%) patients were older at 36 ≤ 45 years and 7 (3.5%) patients were aged 46 ≤ 55 years (Figure 2).

Figure 2: Patient Age



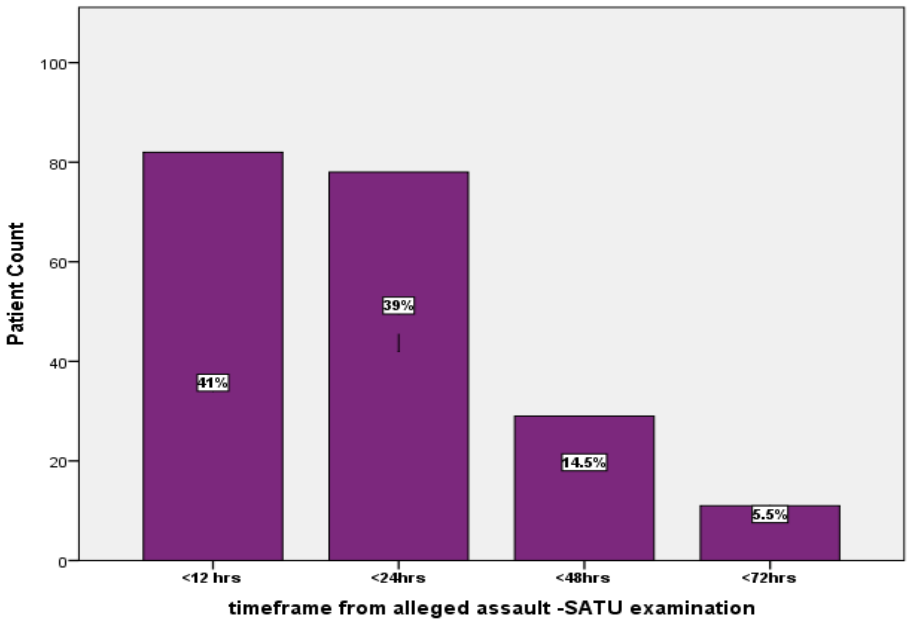
The majority (n=161, 81%) patients were Irish with the race/ethnicity of 33 (16.5%) patients not documented. Four patients stated they were from the European Union (EU) with a further 2 patients recorded as "Other" where the race/ethnicity prevalence was low in this sample size. On bivariate analysis, there was no association between offering HIV nPEP treatment and the following patient demographic factors a) patient gender (p=0.191), b) patient age (p=0.166) and c) patient race /ethnicity (p=0.193).

3.4 Assault and Assailant Characteristics

Section B (Assault and Assailant Characteristics) asks more specifically about the timeframe from the incident to the examination, if the incident was reported to An Garda Síochána, assailant gender, number and characteristics, race/ethnicity of the assailant and the assailant relationship to the patient. This section of the questionnaire also asked about the site specific acts documented, if a condom was used or if ejaculation occurred.

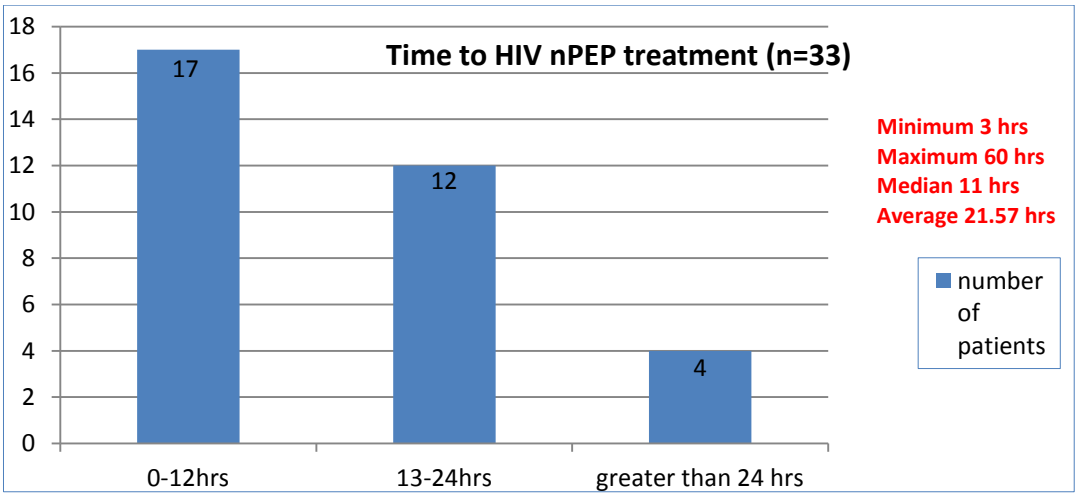
In relation to timeframe from alleged assault to SATU attendance, 41% (n=82) of patients attended <12hrs post assault with a further 39% (n=78) of patients attending <24 hrs post assault. Twenty nine (14.5 %) patients attended the unit < 48 hrs post assault with the remaining 11% (5.5%) patients attending <72 hours for an examination (Figure 3).

Figure 3: Timeframe from alleged assault- SATU examination



Of the 33 patients who were administered HIV nPEP treatment by the SATU forensic examiners, 51.5% patients attended the unit within 12 hrs following a rape or sexual assault. A further 12 (36.5%) patients attended within 24 hrs with the remaining 4 (12%) patients attending within 25-72 hrs (range 3-60 hrs) for an examination (Figure 4).

Figure 4: Time to HIV nPEP treatment.

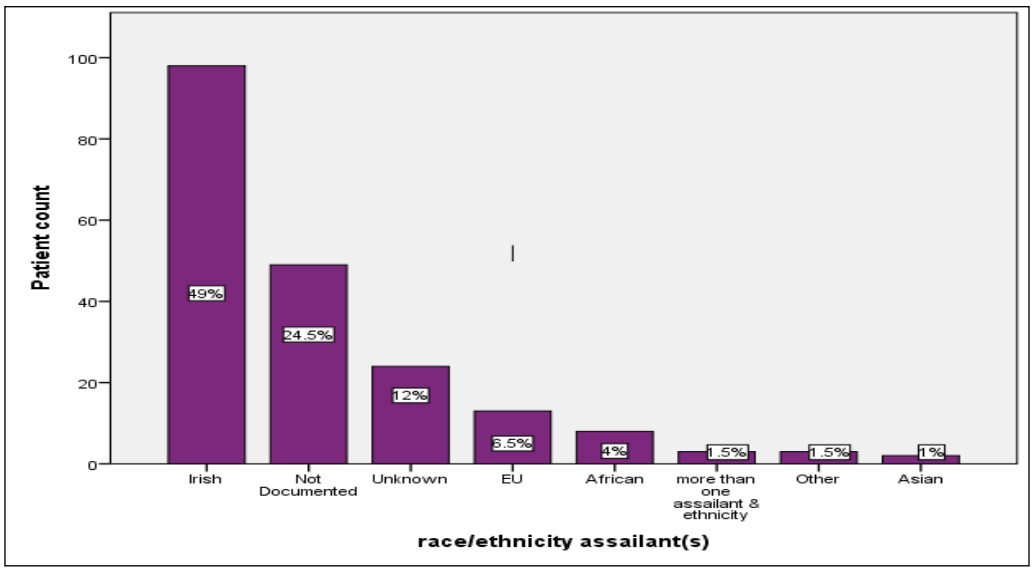


The majority, (n= 183, 92 %) of patients reported the alleged assault to An Garda Síochána with 17 (8 %) patients recorded as not reporting.

Assailant gender was documented for most cases as "Male" with 178 (89%) cases whilst 20 (10%) cases were evenly distributed between "Unknown" or "Not documented". The remaining 2 patients stated that the assailant was "Female".

In relation to the race/ethnicity of the assailant, almost half (n=98,) of assailants were documented as "Irish" with a further 49 cases "Not documented". Thirteen (6.5%) assailant's were from the "EU" with a further 8 (4%) assailants recorded as "African". Twenty four (12%) patients stated the assailant race/ethnicity was "Unknown". The remaining 8 assailants (4%) were recorded as "Asian", "Other" where race /ethnicity prevalence were low in this sample or "More than one assailant/ethnicity" where more than one assailant and race/ethnicity was involved (Figure 5).

Figure 5: Race /Ethnicity of the Assailant

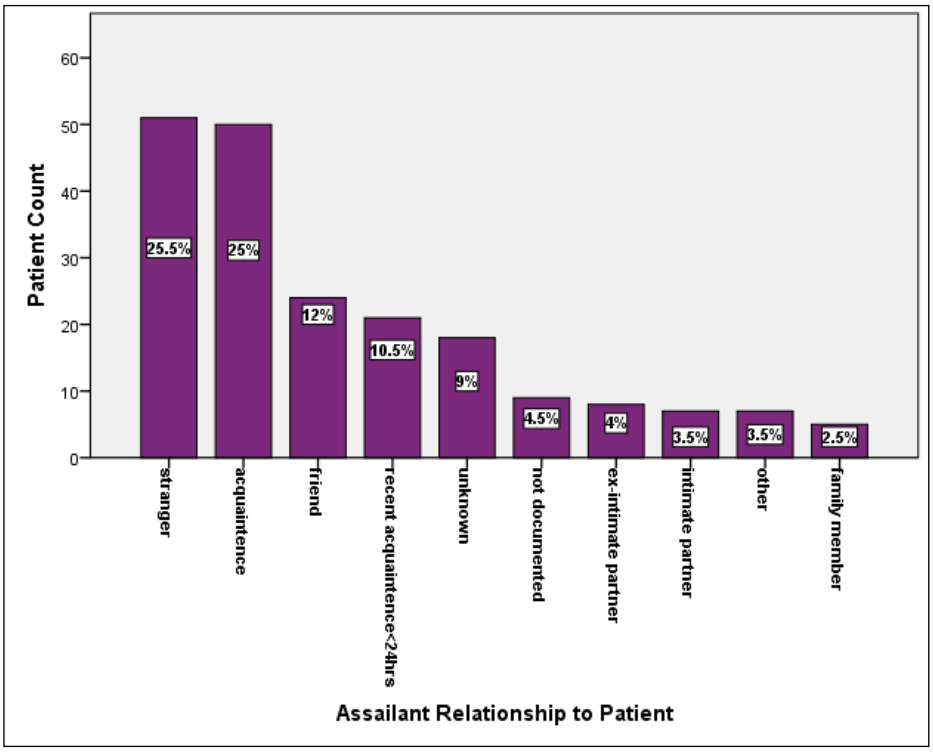


Offering HIV nPEP treatment was associated with assailant race /ethnicity (Cramer's V =0.466, p <0.001).

Number of assailant (s) for 159 (79.5%) cases was documented as "One" with 13 (6.5%) patients recalling "More than one assailant". In the remaining 28 cases, 10 (5%) patients said the number of assailants was "Unknown" and in 18 (9%) cases, the number of assailants was "Not documented". A relationship was noted between the offer of HIV nPEP treatment and the number of assailants (Cramer's V =0.292, p < 0.001).

A relationship was also noted between the offer of HIV nPEP treatment and the assailant relationship to the patient (Cramer's V =0.264, p = 0.022) with over one quarter (n= 51) of patients assaulted by a "Stranger". An additional 25% of patients were assaulted by an "Acquaintance". The assailant was documented as a "Friend" in 24 (12%) cases. "Recent Acquaintance" <24 hrs is defined as an assailant only known to the patient in the twenty four hours preceding the rape or sexual assault and accounted for 21 (10.5%) cases. "Ex intimate partner" and "Intimate partner" were documented as assailants in 8 cases and 7 cases respectively. In 18 (9%) cases, the assailant was documented as "Unknown" and in a further 5 cases, the assailant was a "Family member". Patient assailant was recorded as "Other" in 7 cases and in 9 cases, the patients assailant was "Not documented" (Figure 6).

Figure 6: Assailant Relationship to the Patient



With regard to assailant characteristics, 5 cases were documented as an Intravenous Drug User (IVDU) and in 3 cases, Men who have sex with Men (MSM) was a documented risk factor in the chart. These assailant characteristics were not documented in the remaining 192 (96%) charts, however the offer of HIV nPEP treatment was more likely if the assailant was documented as an IVDU or MSM (Cramer's V =0.324, $p < 0.001$).

Questions 13 and 14 asked if ejaculation occurred and if a condom was used. Almost half (n=95) of patients stated that a condom was not used with a further 69 patients saying they were unsure. Ninety five (47.5%) patients also responded unsure to the question relating to ejaculation. Condoms were used in 13 (6.5%) cases and ejaculation occurred in 24 (12%) cases. Ejaculation did not occur in 62

(31%) cases. Condom use and ejaculation were not documented in 23 (11.5%) and 19 (9.5%) cases respectively.

Responses to Question 15 in relation to the site specific acts documented are presented in Table 1 as follows.

Table 1 SITE SPECIFIC ACTS

M-F (Male to Female) M-M (Male to Male)	Yes	No	Unsure	N/A	Not Documented	Other info- site of penetration (if Yes)
Penile/Oral Penetration M-F	30 (15%)	106 (53%)	47(23.5%)	10(5%)	7 (3.5%)	-
Penis / mouth complainant M-M	2(1%)	2(1%)	1(0.5%)	195 (97.5%)	-	-
Penis /mouth suspect M-M	1 (0.5%)	3(1.5%)	1(0.5%)	195 (97.5%)	-	-
Penile/Vaginal Penetration	95 (47.5%)	27(13.5%)	62 (31%)	10 (5%)	6 (3%)	-
Penile/Anal Penetration	21 (10.5%)	27 (13.5%)	50 (25%)	4 (2%)	8 (4%)	-
Digital Penetration	55 (27.5%)	64 (32.5%)	69 (34.5%)	2(1%)	9(4.5%)	20 Vaginal 2 Anal 2 Vaginal/Anal
Object Penetration	4(2%)	126 (63%)	53(26.5%)	-	17(8.5%)	1 Anal 1 Vaginal

Bivariate analysis demonstrated an association between the offer of HIV nPEP treatment and the following factors documented as site specific acts ; Penile /Vaginal penetration (Cramer's $V = 0.224$, $p = 0.019$), Penile /Anal penetration

(Cramer's V = 0.358, p <0.001) and Object penetration (Cramer's V = 0.249, p =0.021).

There was no statistically significant relationship between the offer of HIV nPEP treatment and the following variables: a) timeframe from alleged assault to SATU attendance (p=0.55) , b) reporting to An Garda Síochána (p=0.491), c) assailant gender (p=0.179), d) ejaculation (p=0.634), e) condom used (p=0.332), f) site specific acts of penile /oral penetration M-F (p=0.801), penile /oral penetration patient M-M (p=0.424), penile /oral penetration assailant M-M (p=0.210) and digital penetration (p=0.600).

3.5 Examination Findings

Section D (Examination Findings) questioned the disclosure or clinical evidence of a Sexually Transmitted Infection (STI) on patient examination or the presence of site specific injuries. For the purposes of this study, an STI is defined as evidence of broken skin on visual inspection but STI results were not known to the forensic examiner at the time of the examination. The majority 197 (98.5%) patients did not disclose an STI and in the remaining 3 patients, disclosure of an STI was not documented in the chart as part of the patient medical history. In 186 (93%) patients, no clinical evidence of an STI (break of skin integrity) was reported. This examination finding was documented however in 5 patients. In a further 7 patients, clinical evidence of an STI was not documented and in 2 patients, not applicable where consent for an examination may not have been given.

The remaining five questions of this section asked about genital and non genital injuries noted on patent examination. Genital injuries for the purposes of this chart review are defined as abrasions, lacerations, bleeding or bleeding aside from menstruation and bruising. Genital swelling, erythema or tenderness were not included in our definition. Extra genital injuries were all body injuries documented aside from the ano-genital area including biting and aside from oral injury, were not body part specific.

These responses are presented in Table 2.

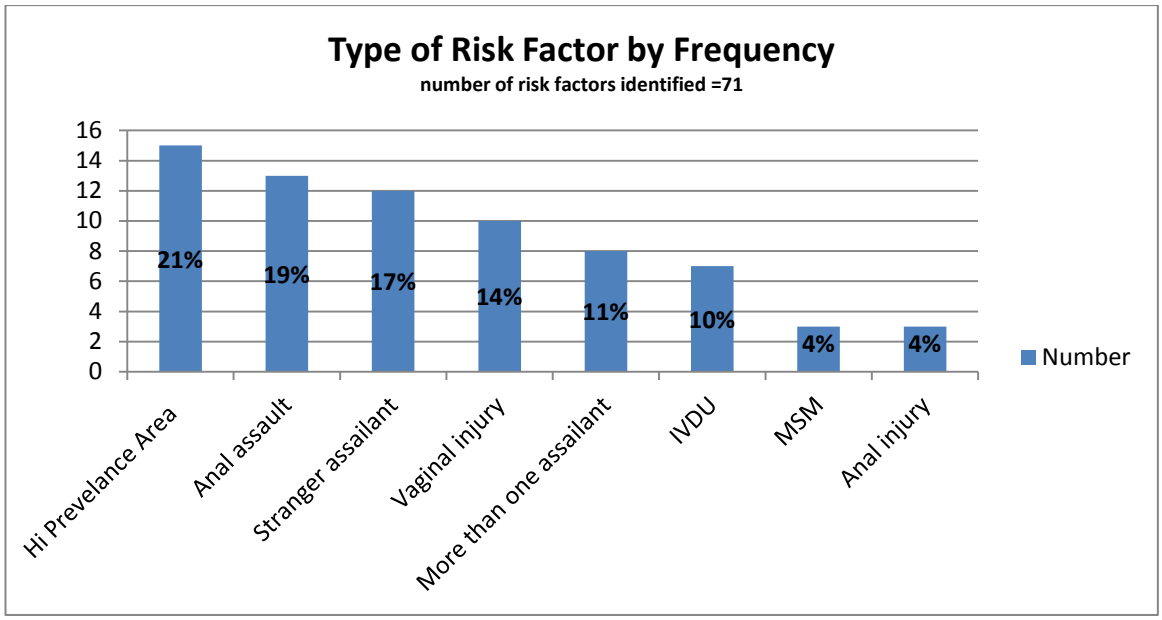
Table 2 INJURIES DOCUMENTED

	Yes	No	N/A	Not Documented
Vaginal Injury	46 (23%)	128 (64%)	16 (8%)	10 (5%)
Penile Injury	-	3 (1.5%)	193 (96.5%)	4 (2%)
Oral Injury	3 (1.5%)	125 (62.5%)	65 (32.5%)	7 (3.5%)
Anal injury	16 (8%)	125 (62.5%)	43 (21.5%)	16 (8%)
Extra Genital Injury	125 (62.5%)	64 (32%)	3 (1.5%)	8 (4%)

On bivariate analysis, there was no association between the offer of HIV nPEP treatment and a) vaginal injury (p= 0.482), b) penile injury (p= 0.698), c) oral injury (p= 0.207), d) anal injury (p= 0.191), e) extra genital injury (p= 0.180), f) disclosure of an STI (p= 1.000) or g) clinical evidence of an STI (p= 0.154).

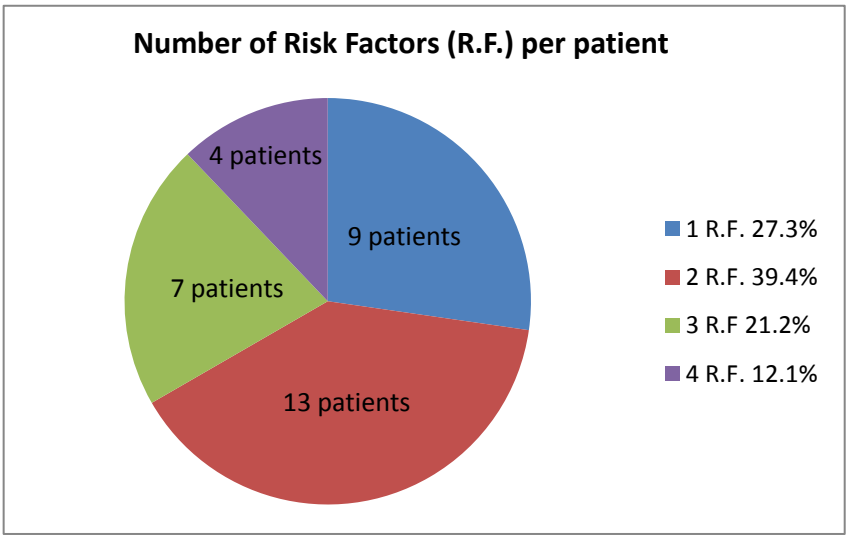
In relation to the 33 patients who received HIV nPEP treatment in the SATU, 71 risk factors were identified in the SATU charts which influenced the decision making of the forensic clinical examiner in their offer HIV nPEP treatment. These risk factors are illustrated (Figure 7).

Figure 7: Risk factors identified in those patients that received HIV nPEP treatment



Of the patients that received HIV nPEP treatment (n=33), almost three quarters (73 %) patients had more than one risk factor identified in their SATU chart (Figure 8).

Figure 8: Multiple Risk Factors per patient



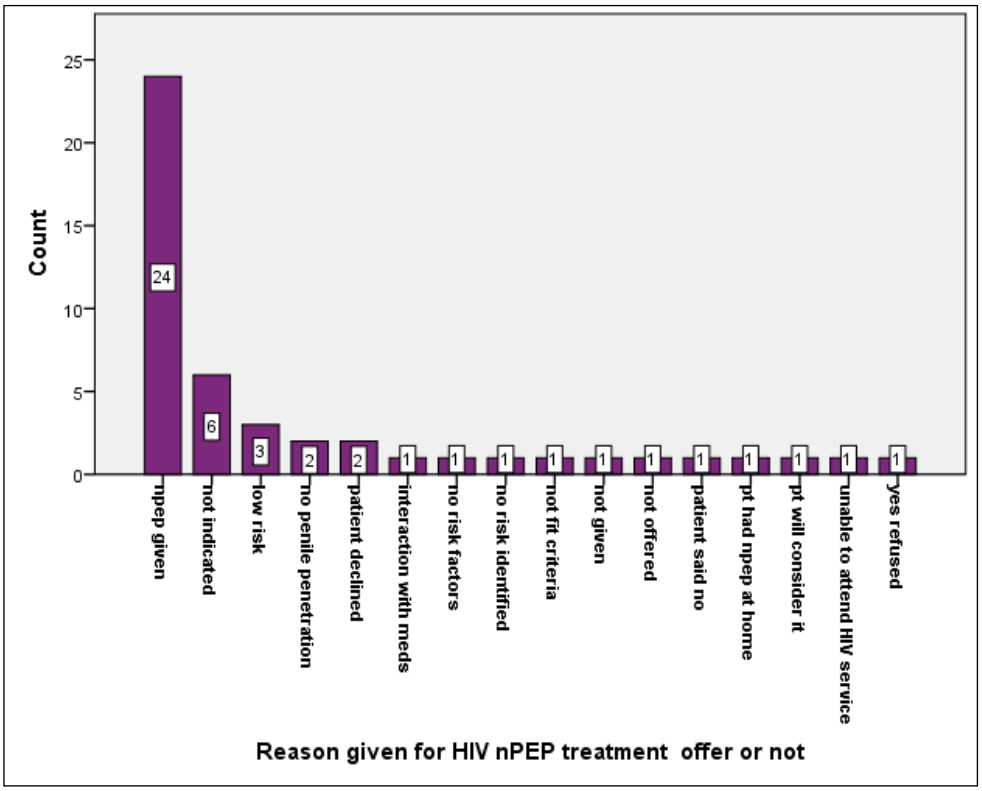
3.6 Decision to treat

Section E (Decision to Treat) captures independent variables or factors which may be associated with the offer of HIV nPEP treatment or not such as use of a risk assessment, reasons given for offer of HIV nPEP treatment or not and if a patient declined such an offer , was a reason documented for this patient decision.

A risk assessment for HIV and nPEP treatment was documented in 26% (n= 52) of cases and this variable was associated with the offer of HIV nPEP treatment (Cramer's $V = 0.474$, $p<0.001$). No evidence of risk assessment was available for the remaining 148 cases.

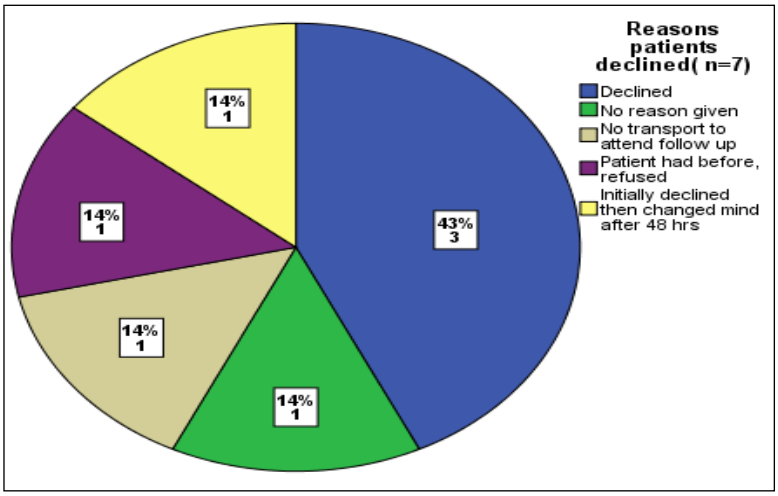
Question 27 asked if the forensic clinical examiner documented a reason for their decision to offer HIV nPEP treatment or not and in the vast majority 148 (74%) charts, no reason was given. Four charts had the "Not applicable" option ticked and in the remaining 48 (24%) cases, the "Other" option was ticked indicating that a reason was documented. Of these 48 reasons documented, HIV nPEP treatment was documented as given in 24 (50%) cases. A further 6 charts documented that HIV nPEP treatment was "Not indicated" and an additional 3 cases were deemed "Low risk". Additional responses are illustrated in Figure 9.

Figure 9: Reasons given for HIV nPEP treatment offer or not



In total, 7 (3.5%) patients refused the offer of HIV nPEP treatment (Cramer's V=0.231, $p < 0.002$), these reasons are captured in Figure 10.

Figure 10: Reasons patients declined offer of HIV nPEP treatment.

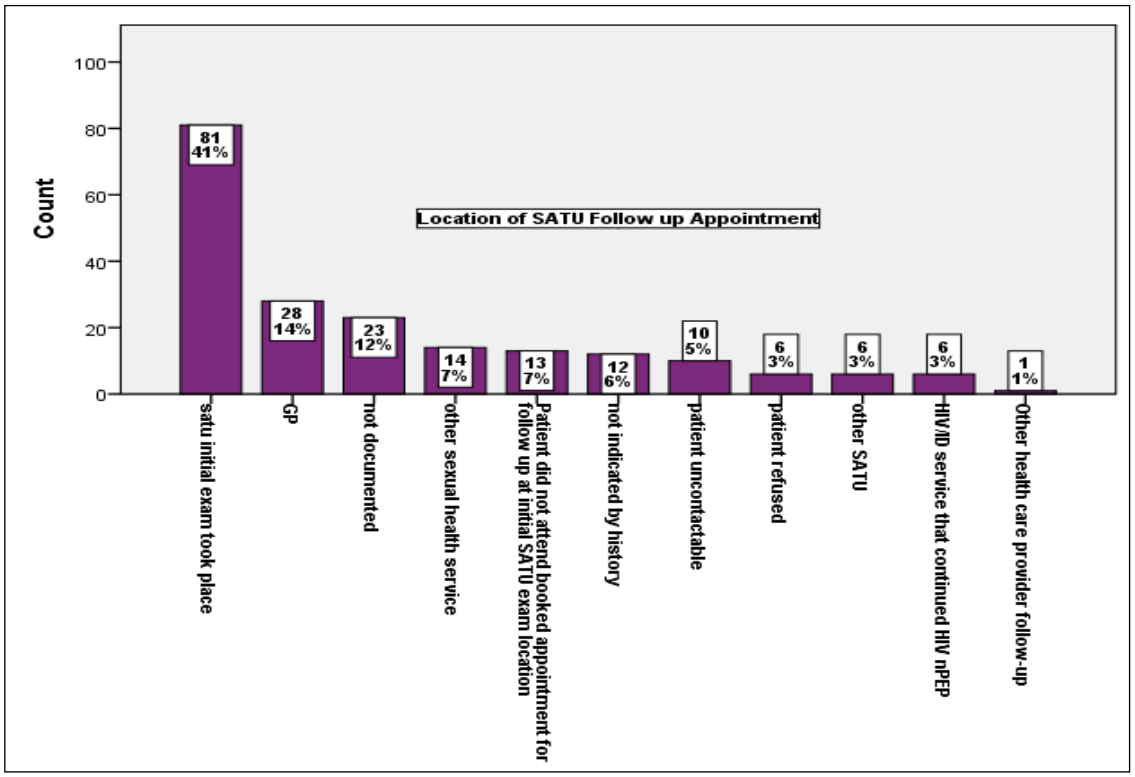


3.7 Documentation of Follow up care

Section F (Documentation of Follow up Care) determined patient outcomes and referral pathways for those patients who were prescribed HIV nPEP treatment and those that were not. This section revealed information on follow up location, continuation of HIV nPEP treatment by the specialist HIV service and reasons given by the patient for discontinuation of the HIV nPEP treatment. Finally, the questionnaire asked if the patient has a HIV negative test documented in the chart if the follow up appointment took place at the initial visit SATU.

Eighty one (40.5%) patients chose to return to the SATU where the initial examination took place for follow up where sexual health screening, completion of vaccination schedule and health surveillance in relation to HIV nPEP treatment were carried out. All 81 patients tested negative for HIV with documentation available in their charts to show their sero - negative status. The HIV status of the remaining 119 (59.5%) patients remains unknown including 13 (6.5%) patients who did not attend a booked follow up appointment at the SATU where the initial exam took place, 28 (14%) patients who were referred to their GP's for follow up and an additional 10 (5%) patients who remained uncontactable for follow up. 10 (6%) patients did not require STI screening, possibly related to a lower risk for STI transmission such as digital assault. Other locations of documented follow up are included in Figure 11.

Figure 11: Location of SATU follow up Appointment



Of the 33 (16.5%) patients who were commenced HIV nPEP treatment in the SATU, all were referred to a specialist HIV service for follow-up assessment and review. Twenty five patients (76%) were continued HIV nPEP treatment for a further 23 days, one patient was discontinued the treatment by the HIV specialist service and in one patient, the outcome was documented as unknown. The remaining 6 (18%) patients did not attend follow up at the specialist HIV service which included one patient who discontinued their HIV nPEP treatment on day 4 due to nausea and vomiting.

The final question of the study related to the 25 patients who were assessed by the specialist HIV service to continue HIV nPEP treatment and asked if they

completed the treatment for the prescribed 28 days. In total, 14 (56%) patients completed the treatment to day 28 with 3 patients in this group switched from a three drug regime to a two drug regime (Truvada monotherapy) to minimise side effects and aid drug adherence to treatment completion. Reasons given for the switch included nausea and vomiting, high blood sugar and no reason was known for the third patient. A further 5 (20%) patients stopped taking the HIV nPEP treatment, with nausea and vomiting the main reason given for discontinuation. One patient within the discontinued group also disclosed additional information in relation to the perpetrator at a later date which minimised the risk for HIV transmission (Table 3).

Table 3 REASONS FOR NOT COMPLETING HIV nPEP treatment

	Reason for Stopping HIV nPEP treatment
Patient 1	Nausea and Vomiting +++
Patient 2	Nausea and Vomiting stopped Day 14
Patient 3	Nausea and Vomiting stopped Day 17
Patient 4	Truvada Monotherapy stopped Day 17 reason unknown
Patient 5	Nausea and Vomiting plus additional assailant information received which reduced HIV transmission risk.

In 6 cases, the outcome of treatment completion is documented as unknown with 3 patients documented as not attending booked follow up appointments and 1 patient documented as uncontactable within this group.

3.8 Conclusion

In total, 200 charts were included in the study of which 33 patients were offered HIV nPEP treatment. The majority of patients in the study were female, Irish, reported the alleged assault to An Garda Siochana and attended the SATU at night and weekends, 80% patients < 24 hrs after the alleged assault. One third were aged 14 to 18 years. Extra genital injury was the most common injury documented. These findings were not associated with the offer of HIV nPEP treatment. Assailants were more likely to be male, Irish, singular and either not known or a stranger to the patient. Assailant race, multiple assailants, the relationship between the assailant and patient and the characteristics of MSM or IVDU were factors associated with the offer of HIV nPEP treatment. Mode of penetration and multiple risk factors were also associated with the offer of HIV nPEP treatment.

Additionally, 26% of charts had a risk assessment documented and this factor was also associated with the offer of HIV nPEP treatment. Reasons for not giving HIV nPEP treatment to patients were noted in 24 charts.

Of the 33 patients who were administered HIV nPEP treatment by the SATU, 25 were prescribed a further 23 day course and 14 finished the 28 day regime. Nausea and vomiting was the principal side effect responsible for discontinuation of HIV nPEP treatment. In total, 81 patients choose to be followed up at the initial visit SATU for STI screening and all patients were documented HIV negative following the alleged assault.

These findings will now be discussed further in Chapter Four.

Chapter Four

Discussion of Research Findings

4.0 Introduction

A discussion of the main study findings will be presented in this chapter. Additionally, any similarities or differences revealed will be compared to the findings of the literature review. There is a paucity of research on the offer of HIV nPEP treatment to patients following a rape or sexual assault, particularly in the Irish context and so in presenting the discussion, the researcher will critically analyze this study's findings and outline recommendations for research and clinical practice.

4.1 Cases included in the Retrospective Chart Review

In this study, the retrospective chart review of 276 patients who presented to the SATU for an examination following a rape or sexual assault abstracted 200 charts suitable for the study once inclusion and exclusion criteria were applied. This sample size compared favourably with other retrospective chart reviews included in the literature review such as Draughon *et al.* (2014b) 270 charts reviewed with 182 retained for inclusion, Olsen et al. (2006) 177 charts reviewed with 145 retained for inclusion, Linden *et al.* (2005) 229 charts reviewed with 181 retained for inclusion and Krause *et al.* (2014) 179 charts reviewed with 162 retained for inclusion.

4.2 General Information

In this study, 80% cases took place at night and weekends (out of office hours) and this is not an unexpected finding given the nature of the round the clock service activity. Of the 33 cases who were offered HIV nPEP treatment within the 72 hour time frame advocated, the majority of patients commenced HIV nPEP treatment within 24 hours following a rape or sexual assault (median 11 hrs, mean 21.5hrs). This finding reassuringly reflects prompt and timely risk assessment and accessibility to free HIV nPEP treatment available immediately in the SATU drug stock, a concern expressed in previous studies reviewed (Wieczorek 2010, Merchant *et al.* 2004).

Four patients were commenced on HIV nPEP treatment and had no clear prescription in their chart; all four attended the SATU in 2012 and 2013 when an earlier version of the SATU chart was in use. This chart has since been updated with a clear prescription page now available.

4.3 Patient Demographics

Predominantly, patients were female and Irish, an expected finding which reflects the national profile of patients reporting rape and sexual assault currently in Ireland (National SATU report 2013). Two of the five men included in the study identified more than one risk factor on HIV risk assessment and received HIV nPEP treatment. These cases often present a higher risk of exposure (Reeves *et al.* 2004). In contrast to Linden *et al.* (2005), this study found that patients of younger age were no more likely to be offered HIV nPEP treatment.

4.4 Assault and Assailant Characteristics

Similar to Draughton *et al.* (2014b), no association was demonstrated in this study between the offer of HIV nPEP treatment and the number of hours between the alleged assault and the SATU visit. It is known that in Ireland, rape and sexual assault crimes are frequently unrecorded and underreported (McGee *at al.* 2002) yet this study demonstrated a higher level of reporting (91.5%, n=183) to An Garda Síochána than other studies of similar sample numbers (85%, n=155) in Draughton *et al.* 2014b). Whilst the inclusion timeframe of <72 hours for this study is also the most optimal time for collection of timely forensic evidence if present when Garda accompaniment to the unit is more likely, this finding is encouraging.

In the 33 patients who were administered HIV nPEP treatment in the SATU, an assailant from a high prevalence area for HIV featured as a risk factor in nearly half (n=15) of the cases, a finding advocated by Wieczorek (2010) who suggested that " consideration should be given to HIV prevalence rates in specific geographical areas". High prevalence areas for HIV include parts of Sub Saharan Africa where nearly 1 in 20 persons aged 15-49 years in 2013 were living with HIV (WHO 2013b). This study finding contrasts with Draughon *et al*. (2014b) who revealed a concerning trend of counterintuitive HIV nPEP treatment offers to patients based on the assailant race/ ethnicity, with their sample less likely to receive HIV nPEP treatment if their assailant was documented as Black or Other where the incidence of HIV infection is deemed higher. They concluded that more

research was warranted to investigate this association and that it was possible that assailant race was a proxy for patient race in their sample.

Overall, 13 (6.5%) patients stated that they were assaulted by more than one person, a percentage lower than other studies. Draughon (2012) referred to a study of 1000 cases of sexual assault where 20% of that cohort were assaulted by multiple assailants. Additional findings in this study sample were 10 patients who stated the number of assailants as unknown. These patients could have been assaulted by more than one person, however Draughon (2012) suggests that patients find the number of assailants much easier to recall in comparison to other details such as whether or not a condom was used. A further 9% of this sample did not have the number of assailants documented; this is related to an earlier version of the SATU chart where this information was not explicitly requested.

Of the 33 patients who received HIV nPEP treatment, 21% (n=8) recalled more than one assailant. With the offer of HIV nPEP treatment strongly associated with assailant race /ethnicity and number of assailants documented ($p < 0.001$) respectively in this study, these associations concur with recommendations from not only the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) but also international best practice BASHH GUIDELINES (2011), Benn *et al.* (2011), Sultan *et al.* (2014), WHO (2013).

In this sample, 51 patients were assaulted by a stranger and a relationship between the offer of HIV nPEP treatment and the assailants relationship to the patient ($p=0.022$) was found. Of the 33 patients who were given HIV nPEP treatment, 12 were assaulted by strangers with an additional 3 patients given HIV nPEP

treatment with the relationship to the assailant unknown. This finding reflects Linden e*t al.* (2005) who found that HIV nPEP treatment was offered more frequently to patients with unknown assailants. However, it is difficult to determine retrospectively from the charts if the term 'unknown' meant that the patient could not recall anything about the assault or if the assailant was unknown or a stranger to the patient. Draughon *et al.* (2014) agree that assessment for HIV in such unknown circumstances is challenging in applying best practice to categorising patients to measurable risk vs. low risk when exposure uncertainties exist (Olshen *et al.* 2006).

Assailant characteristics of IVDU or MSM were associated in this study with the offer of HIV nPEP treatment (p <0.001) and both characteristics are considered to present a higher risk for HIV transmission (Wieczorek, 2010, Reeves *et al.* 2004). These characteristics were not documented in the majority of the charts and this is due possibly to an earlier version of the chart where such questioning about assailant characteristics was not prompted, the absence of risk assessment tools which became available at a later date or such details just not known by the patient.

Condom use decreases HIV transmission by 80% (Draughon 2012) and in nearly half of this study cohort (n=95), a condom was not used. Sixty nine patients were unsure if a condom was used and condom use was not associated with the offer of HIV nPEP treatment (p=0.332). In just 24 cases, ejaculation occurred with 95 patient unsure to the occurrence of ejaculation. No relationship was identified between ejaculation and the offer of HIV nPEP treatment. These findings

highlight the difficulty in risk assessing patients where such details are unsure. The findings are in contrast with Draughon et al (2014b), who found lack of condom use significantly associated with the offer of HIV nPEP treatment on bivariate analysis but this relationship disappeared when combined with penile penetration, possibly due to the number of patients who could not recall if a condom had been used. Use of a condom or the presence of ejaculation are not factors included on the SATU specific risk assessment tool.

In relation to site specific acts, an association between the offer of HIV nPEP treatment and the penile /vaginal penetration and penile /anal penetration was found which reflects the findings of others. Draughon & Sheridan (2012) found in their review that high risk exposures (anal penetration) were positively associated with offering HIV nPEP treatment. Of the 33 patients offered HIV nPEP treatment in this study, 13 (39.5%) patients were anally assaulted which is known as a high risk exposure.

In the 4 patients where object penetration occurred, 1 patient was assaulted anally and in 1 patient the assault was vaginal. A relationship between the offer of HIV nPEP treatment and object penetration was identified (p=0.021). It is difficult to comment following retrospective chart review why patients were offered HIV nPEP treatment following an activity deemed low risk for HIV transmission. Other risk factors were identified in this four patient group however no vaginal or anal injuries were documented.

4.5 Examination Findings

This study revealed no significant relationship between the offer of HIV nPEP treatment and documented examination findings such as genital injury, extra genital injury or the disclosure / evidence of a STI.

Our findings in relation to anal injuries (8%, n=16) and vaginal injuries (23%, n=46) are consistent with Linden *et al.* (2005) and Draughon *et al.* (2014b) where no association was found. Use of the variable 'any kind of anal or genital injury' was evident in both studies. However it is important to note some variations in injury definitions between the studies. An additional no significance relationship was found between the offer of HIV nPEP treatment and the presence of genital bleeding (Linden *et al.* 2005) however Draughon *et al.* (2014b) defined open injury to anus or genitalia further which they stated was a significant factor in offering HIV nPEP treatment. For this study, vaginal injury (abrasion, laceration, bleeding not from menstruation) and anal injury (abrasion, laceration, bleeding) matched closest to the 'open injury' definition in Draughon *et al.* (2014b) with bruising added to this study for both anatomical sites. Also, examination findings were noted on visual inspection only in this study where as Draughon *et al.* (2004b) used the techniques of visual inspection, staining and colposcopy in their study where injury identification rates are thought to be higher (39%, n=69). Of the 33 patients who received HIV nPEP treatment, 10 had a vaginal injury and 3 had an anal injury. It is interesting to note here that the patients who received HIV nPEP treatment in the SATU were found to have 71 risk factors identified and that almost three quarters (n=24) of patients had more than one risk factor identified in

their SATU chart . Multiple risk factors are flagged as a consideration for HIV nPEP treatment in the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) and 4 patients who received HIV nPEP treatment had four risk factors identified following risk assessment in this study. Extra genital injuries were the most prevalent injuries reported in this study (62.5%) and this finding which is not associated with increased risk of HIV is similar to those reported (60%) by Draughon (2012) who reviewed sexual assault injuries and increased risk of HIV transmission.

4.6 Decision to treat

Fifty two (26%) charts had a documented risk assessment for HIV nPEP treatment in the chart and this practice was associated with the offer of HIV nPEP treatment (p <0.001). Draughon *et al.* (2014a) also reported a relationship between the offer of HIV treatment and having a protocol in place. Other similar studies however have reported higher rates of documented risk assessment including Draughon et al. (2014b) where almost 126 (70%) charts had a documented HIV risk assessment. The lower rates of risk assessment for HIV in this study may be explained by the development of our service documentation during the timeframe of this chart review. In 2011, an early version of the SATU chart was in use, and the EMI toolkit 2012 (updated 2014) in addition to the SATU specific risk assessment tool for HIV and PEP (EMI toolkit updated 2014) were yet to be implemented. Additionally, HIV nPEP treatment was not readily accessible within the SATU unit. However other resources were available to forensic clinical

examiners at that time (BASHH GUIDEINES 2011, Benn *et al.* 2011, National SATU GUIDELINES 2010, WHO GUIDELINES 2003). An updated, improved version of the SATU chart which was developed by the National SATU Documentation Group (2014) of which the researcher is a member, is due for local implementation imminently. This chart will have the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) integrated within the chart.

This study revealed that when HIV risk assessment was performed, the documentation demonstrated that such assessments were mostly carried out in an informed way with some responses such as 'not given' or 'not offered' warranting further clarification. This outcome is widely reported in other studies (Draughon *et al.* 2014b, Linden *et al.* 2005, Loutfy *et al.* 2008, Du Mont *et al.* 2008) where it is reported that other factors not explicitly documented in the chart may inform the forensic examiners decision to not offer HIV nPEP treatment. Encouragingly, some HIV risk assessments demonstrated not only patient involvement in the decision to decline treatment such as 'no transport for follow up ' or 'had before' but also demonstrated collaborative decision making with patients to allow them to change their mind with responses such as ' initially declined then accepted after 48 hrs' seen. This strategy of patient involvement and decision making *with* rather than *for* patients is very much advocated by others (Wieczorek 2010).

4.7 Documentation of Follow up care

The study unit typically receive referrals from a large geographical area yearly and the broad range of follow up care locations for sexual health screening, completion of vaccination schedule and HIV nPEP treatment health surveillance are captured in the study findings. Onward referral for STI follow up, HIV nPEP treatment review and local follow up, adherence support and STI screening are facilitated by the forensic nurse examiner who carried out this study. These locations demonstrate follow up referral pathways with patient choice, accessibility and geographical /economic considerations in mind. Of the patients who returned to the study unit for follow up, all 81 tested negative for HIV including 19 (58%) of the patients who received HIV nPEP treatment (n=33). Determining the outcomes of patients who chose to access follow up care elsewhere regardless of whether they were prescribed HIV nPEP treatment or not is a time consuming but necessary part of the CNS (SATU) role. Plotting the outcomes of patients who are referred elsewhere becomes even more challenging if the patient becomes uncontactable, particularly if proper patient monitoring is required whilst on HIV nPEP treatment.

All patients (n=33) who started HIV nPEP treatment in the SATU were referred to a specialist HIV service for follow-up assessment and review, a practice advocated by Wieczorek (2010) and advocated in the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) . In contrast with Wiebe *et al*. (2000) who found that 59% (n=42) patients given a 5 day HIV nPEP treatment supply did not attend this first follow up appointment, only 18%

(n=6) patients in our study did not attend the initial first appointment at the specialist HIV service. One patient within this group did not attend the specialist HIV service due to nausea and vomiting, however the outcomes of the others are unknown. This finding reflects not only the difficulties and challenges with patient follow up as previously described but also the difficulties and challenges faced by forensic clinical examiners in assessing patient suitability for HIV nPEP treatment from not just a clinical HIV risk reduction strategy but also from an adherence point of view and ability to attend follow up. Frequently, these decisions are made during unsocial hours with vulnerable patients after just meeting them for the first time maybe one hour previously. Encouragingly, HIV nPEP treatment completion rates to 28 days in this study were 56% (n=14) which compares with completion rates of 0%-63% in 19 articles on HIV nPEP treatment completion/adherence (Draughon & Sheridan 2011). Du Mont *et al.* (2008) and Loutfy *et al* .(2008) reported lower adherence rates of 30%.

The study findings of 56% as a flexible, nurse led follow up SATU service compares favourably with Chacko *et al.* (2012) who reported adherence rates for similar nurse led models of 20%-58%. Drug adherence in this study was positively linked to switching HIV nPEP treatment drugs from a three drug regime to two drug regime (n=3) and negatively linked to nausea and vomiting (n=5). These drug adherence findings are commonly reported in the literature (Draughon & Sheridan 2014) and Draughon (2013) suggest that clinicians should consider factors that may affect patient adherence when considering decision to treat. Since July 2014, the study unit has switched the content of the HIV nPEP

treatment 5 days packs stocked in the SATU from Kaletra to Isentress ® (Raltegravir). This strategy is made in line with best practice (Sultan *et al.* 2014, National SATU Guidelines Development Group, 2014) with more favourable tolerability, potency and reduced pill burden in mind. Other considerations include fewer side effects and fewer drug –drug interactions in addition to improved metabolic profiles.

Conclusions and Recommendations

4.8 Conclusion

The purpose of this study was to determine the factors associated with forensic examiners offering HIV nPEP treatment to patients following rape or sexual assault. This study was undertaken following a literature review which demonstrated a gap in the literature in the Irish context.

This study revealed that 31% of patients were aged 14 to 18 years. One hundred and twenty five patients reported an extra genital injury, more prevalent than ano-genital injury. One quarter of patients stated they were assaulted by a stranger. Patients in this study more likely to offered HIV nPEP treatment based on site specific acts and assailant factors. Condoms were not used in half of the cases and a further 69 patients were unsure, yet this factor was not associated with the offer of HIV nPEP treatment. Individually, patients who were offered HIV nPEP treatment had multiple risk factors for HIV documented, particularly in relation to the assailant or assailants involved.

This study demonstrates that free, easily accessible HIV nPEP treatment was offered promptly when required and that the clearly defined referral pathways to HIV specialist services were utilised on all occasions. The barriers of inaccessible, costly HIV nPEP treatment suggested in other studies was not a factor associated with the offer of HIV nPEP treatment in this study. The majority of cases took place out of office hours when guidance is most sought and the study demonstrated the importance of up to date SATU specific HIV risk assessment

tools and guidelines in addition to site specific protocols which were associated positively with the offer of HIV nPEP treatment.

Of the 26 patients who attended the specialist HIV service, 25 were continued HIV nPEP treatment by HIV specialists, supporting the forensic examiner assessment and decision to offer HIV nPEP treatment. A nurse driven follow up STI programme in the SATU has demonstrated equitable and in some cases, improved levels of adherence to HIV nPEP treatment compared to other studies. This documented follow up and support for all patients, ensured that where possible patient outcomes are known from initial SATU visit to HIV testing in the months to follow. These outcomes, feed back to the SATU team may have influenced forensic examiner decision making through reflective practice.

Six patients who were given HIV nPEP treatment did not attend follow up. This finding reflects the challenge of assessing the HIV risk and adherence ability of a vulnerable patient on first encounter. Additionally, where HIV nPEP treatment may have been considered and not given, these reasons on occasion were documented with evidence showing that these reasons were often patient led as well as practitioner led. It is likely that the process of HIV risk assessment is utilized differently by each forensic clinical examiner and those factors not explicitly documented in the chart may have influenced the decision on whether or not to offer HIV nPEP treatment.

Limitations of the study include the retrospective nature of the study and the small sample size which limits the generalisability on the study. Furthermore, this study was carried out at one setting only.

4.9 Recommendations

The following recommendations are divided in two separate categories; recommendations for research and recommendations for clinical practice.

4.9.1 Recommendations for Clinical Practice

- Including condom use in the SATU specific risk assessment tool for HIV and PEP (EMI toolkit 2012 (updated 2014) as a factor to consider may be a useful addition to future adaptations of this tool.
- Forensic Examiners to document a HIV nPEP risk assessment on all patients who attend the SATU within the recommended time frame of <72hrs following a rape or sexual assault.
- Address the issue of determining the outcomes of those patients who were referred elsewhere for follow up through improved communication and liaison with consent from the patients involved.
- Planned audit of charts and findings with relation to the recent change in HIV nPEP treatment and implementation of the new national SATU chart, such findings to be fed back locally and nationally at quarterly peer review meetings.

4.9.2 Recommendations for Research

Addressing a gap in the literature has been the main strength of this study. No other Irish study determined the factors associated with forensic examiners

offering HIV nPEP treatment to patients following a rape or sexual assault. Statistically significant associations were identified by retrospective chart review.

In the future, following the implementation of the new SATU chart with integrated HIV risk assessment tool and in the era of a HIV nPEP treatment regime change, a prospective multi centred, national study with a larger cohort of patients may yield some different results, in particular, why practitioners do not offer HIV nPEP treatment to patients following a recent rape or sexual assault.

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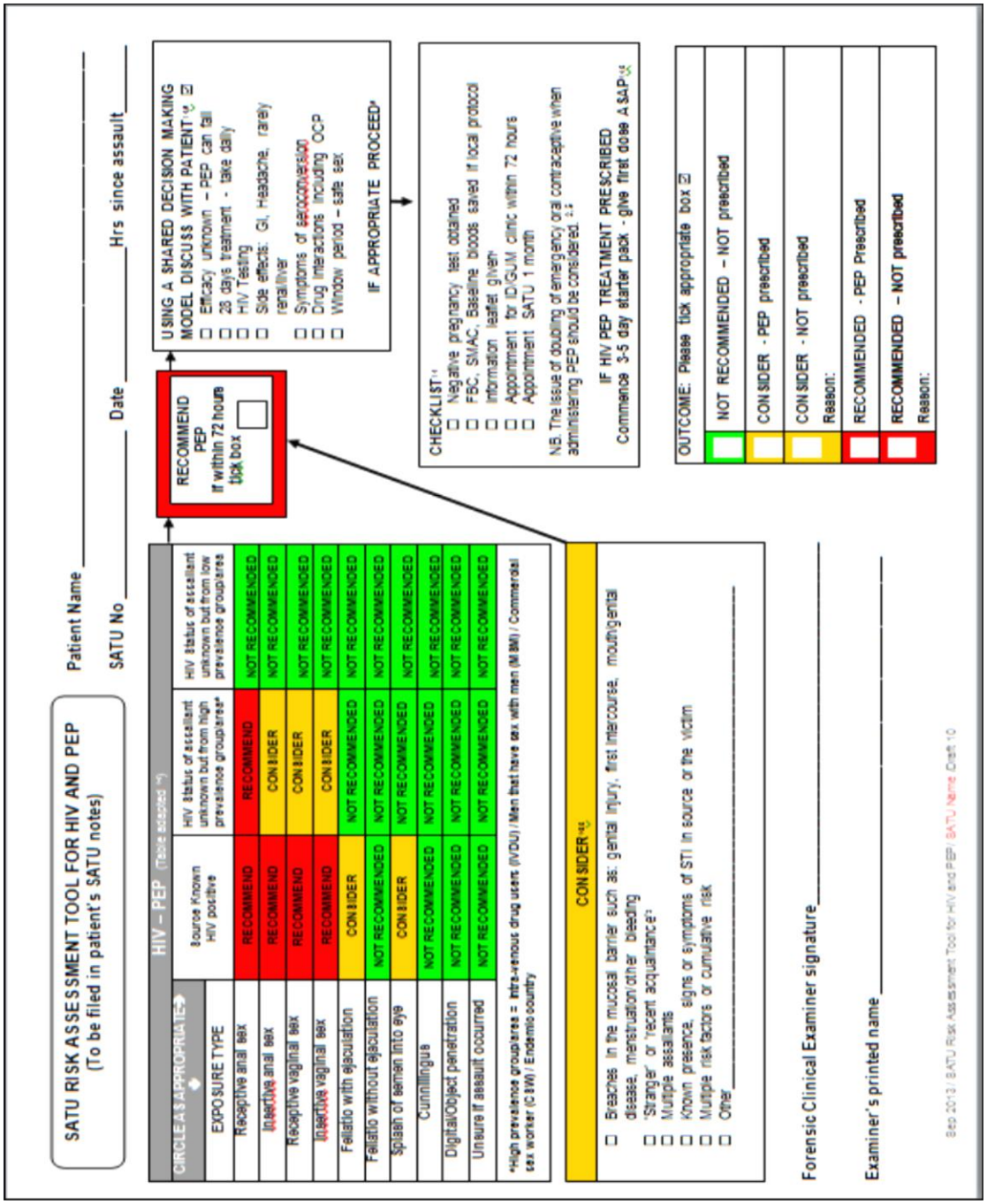
Appendix 1

SATU risk assessment tool for HIV and PEP from the Emergency Management of Injuries (EMI) toolkit (2012, updated 2014)



Appendix 2 QUESTIONNAIRE

Questionnaire for Chart Review

Section A: General

1 Did the patient attend the SATU ≤ 72 hours post rape or sexual assault? Yes ☐ No ☐

2 Patient SATU Number ☐

3 Date of initial visit to the SATU ☐

4 Did the patient attend the SATU during office hours? Yes ☐ No ☐

5 **Is HIV n PEP treatment clearly documented in the SATU chart?**

Tick one option **Yes** ☐ **No** ☐

Section B: Assault and Assailant

6 What was the timeframe from alleged assault to SATU attendance? *Tick one option*

<12 hrs ☐ < 24 hrs ☐ < 48hrs ☐ <72 hrs ☐

7 Was the alleged assault reported to An Garda Siochana? Yes ☐ No ☐

8 What was the reported number of assailants? *Tick one option*

One ☐ More than one assailant ☐ Unknown ☐ Not documented ☐

9 What was the gender of the assailant (s)? *Tick one option*

Male ☐ Female ☐ Unknown ☐ Not documented ☐

10 What was the race/ethnicity of the assailant (s)? *Tick one option* Irish ☐

EU ☐ African ☐ Asian ☐ Other ☐ Unknown ☐ Not documented ☐

11 What was the assailant relationship to the patient? *Tick one option* Stranger ☐

Intimate Partner ☐ Ex Intimate Partner ☐ Family member ☐ Friend ☐

Acquaintance ☐ Recent Acquaintance < 24 hrs ☐ Unknown ☐ Not documented ☐

12 Were any of the following assailant characteristics documented? *Tick one option*

Not documented ☐ MSM (men who have sex with men) ☐ IVDU (intravenous drug user) ☐

13 Did ejaculation occur? *Tick one option* Yes ☐ No ☐ Unsure ☐ Not documented ☐

14 Was a condom used? *Tick one option* Yes ☐ No ☐ Unsure ☐ Not documented ☐

15 What were the site specific acts documented? *Tick any option that applies*

Penile / Oral penetration (male to female)	Yes ☐	No ☐	Unsure ☐	N/A ☐	
Penis in mouth of complainant (male to male)	Yes ☐	No ☐	Unsure ☐	N/A ☐	
Penis in mouth of suspect (male to male)	Yes ☐	No ☐	Unsure ☐	N/A ☐	
Penile / Vaginal Penetration	Yes ☐	No ☐	Unsure ☐	N/A ☐	
Penile / Anal penetration	Yes ☐	No ☐	Unsure ☐	N/A ☐	
Digital Penetration	Yes ☐	No ☐	Unsure ☐	N/A ☐	*if yes, specify site* ☐
Object Penetration	Yes ☐	No ☐	Unsure ☐	N/A ☐	*if yes, specify object* ☐

Section C: Patient

16 What was the gender of the patient? *Tick one option* Male ☐ Female ☐

17 What was the age of the patient? *Tick one option* 14 ≤ 18 years ☐ 19 ≤ 24 years ☐ 25≤ 35 years ☐ 36 ≤ 45 years ☐ 46 ≤ 55 years ☐ 56 years > ☐

18 What was the race/ethnicity of the patient? *Tick one option* Irish ☐ EU ☐ Black African ☐ Asian ☐ Other ☐ Not documented ☐

Section D:

19 Did the patient disclose evidence of an STI at the examination? *Tick one option*

Yes ☐ No ☐ Not documented ☐

20 Was there clinical evidence of an STI on patient examination e.g. break of skin integrity at mouth, vagina, penis, anus? *Tick one option* Yes ☐ No ☐ Not documented ☐

21 Was a vaginal injury (abrasion, laceration, bleeding aside from menstruation, bruising) noted on patient examination? *Tick one option* Yes ☐ No ☐ Not documented ☐ N/A ☐

22 Was a penile injury (abrasion, laceration, bleeding, bruising) noted on patient examination? *Tick one option* Yes ☐ No ☐ Not documented ☐ N/A ☐

23 Was an oral injury (abrasion, laceration, bleeding, bruising) noted on patient examination? *Tick one option* Yes ☐ No ☐ Not documented ☐ N/A ☐

24 Was an anal injury (abrasion, laceration, bleeding, bruising) noted on patient examination? *Tick one option* Yes ☐ No ☐ Not documented ☐ N/A ☐

25 Was an extra genital injury including biting noted on patient examination? *Tick one option* Yes ☐ No ☐ Not documented ☐ N/A ☐

Section E: Decision to

26 Is documentation present in the chart to demonstrate risk assessment by examiner (use of tool or rationale given)? *Tick one option* Yes ☐ No ☐

27 If there is no clear prescription in chart, did the forensic examiner state the reason why they did not offer HIV n PEP treatment? *Tick one option* No ☐ Yes ☐

If yes, state reason ☐

28 Did the patient decline HIV n PEP treatment offered? *Tick one option*

Not documented ☐ Yes ☐ No ☐ if yes, state reason ☐

Section F: Documentation of

29 What was the location of the SATU follow up? *Tick any option that applies*

SATU where initial exam took place	☐	Other sexual health service	☐
HIV/I.D. service that continued the HIV n PEP	☐	Patient uncontactable	☐
Other SATU service	☐	GP	☐
Other health care providers follow up	☐	Refused	☐
Patient did not attend initial SATU for follow up	☐	Not documented	☐

30 Does the patient have a negative HIV test documented in the chart if follow up was at the SATU where the initial exam took place? Yes ☐ No ☐ Not documented ☐ N/A ☐

For Completion If Given HIV nPEP Treatment

31 Was the patient referred to a specialist HIV/Infectious Diseases service for review? *Tick one option* Yes ☐ No ☐ Not documented ☐

32 Was the patient prescribed HIV n PEP treatment for a further 23 days by the specialist HIV service? *Tick one option* Yes ☐ No ☐ Patient did not attend the service ☐ Unknown ☐

33 Did the patient complete HIV n PEP treatment to 28 days? *Tick one option*

Yes ☐ No ☐ Unknown ☐ if no, state reason if documented ☐

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Appendix 3 ETHICS

Research Ethics Committee
HSE – xxx
HSE Area Offices
Xxxxxx
Co. xxxxxx

Telephone: xxxxx Fax: xxxxxxxx

5th February 2015 Ref: 041215DM

Ms. Deborah Marshall
Forensic Examiner & Clinical Nurse Specialist
xxxxxx
Co. Xxxxxx

Re: Guideline adherence to risk assessment for HIV post exposure prophylaxis (PEP) treatment in an Irish Sexual Assault Treatment Unit (SATU)

Dear Ms. Marshall,

The above proposal came before the Research Ethics Committee (REC) on the 4th of February 2015.

While this project is described as a retrospective case control study, it does not meet the definition of research; i.e. it does not generate new knowledge that is generalisable outside its setting.

It does however meet the definition of audit, '*a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'.* While all clinical audit must be conducted within an ethical framework this project does not require research ethics review.

The REC had one further comment. In section D7, it is explained that there is no benefit from receiving medication now for a client who perhaps should have been offered post exposure prophylaxis for HIV at the time of presentation. However, before commencing the audit, the team should have a clear policy on whether or not the client is informed of such a situation should it arise. This may not be relevant or may well already be covered in the counselling of the client at the time.

Best wishes with your audit.

Yours Sincerely,

_____

Paul Marsden
Secretary – Research Ethics Committee
On behalf of
Dr. Una Fallon MCRN 014313
Chairperson – Research Ethics Committee

A favourable ethics review from the Research Ethics Committee (REC) is not the same as permission from the relevant HSE manager to proceed with the study. Authorisation from HSE management must be sought separately

Please note that the REC submits details of all reviewed research to LENUS – the Irish Health Repository www.lenus.ie

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Address:

Tel:

2nd June 2015.

Dear Paul,

Re: Ethics submission for Deborah Marshall- dated 4th Feb 2015

Thank you so much for the feedback in relation to my Ethics Submission to carry out a retrospective chart review. Please be advised that the title of the study has now changed to

FACTORS ASSOCIATED WITH FORENSIC EXAMINERS OFFERING HIV nPEP TREATMENT TO PATIENTS FOLLOWING RAPE OR SEXUAL ASSAULT.

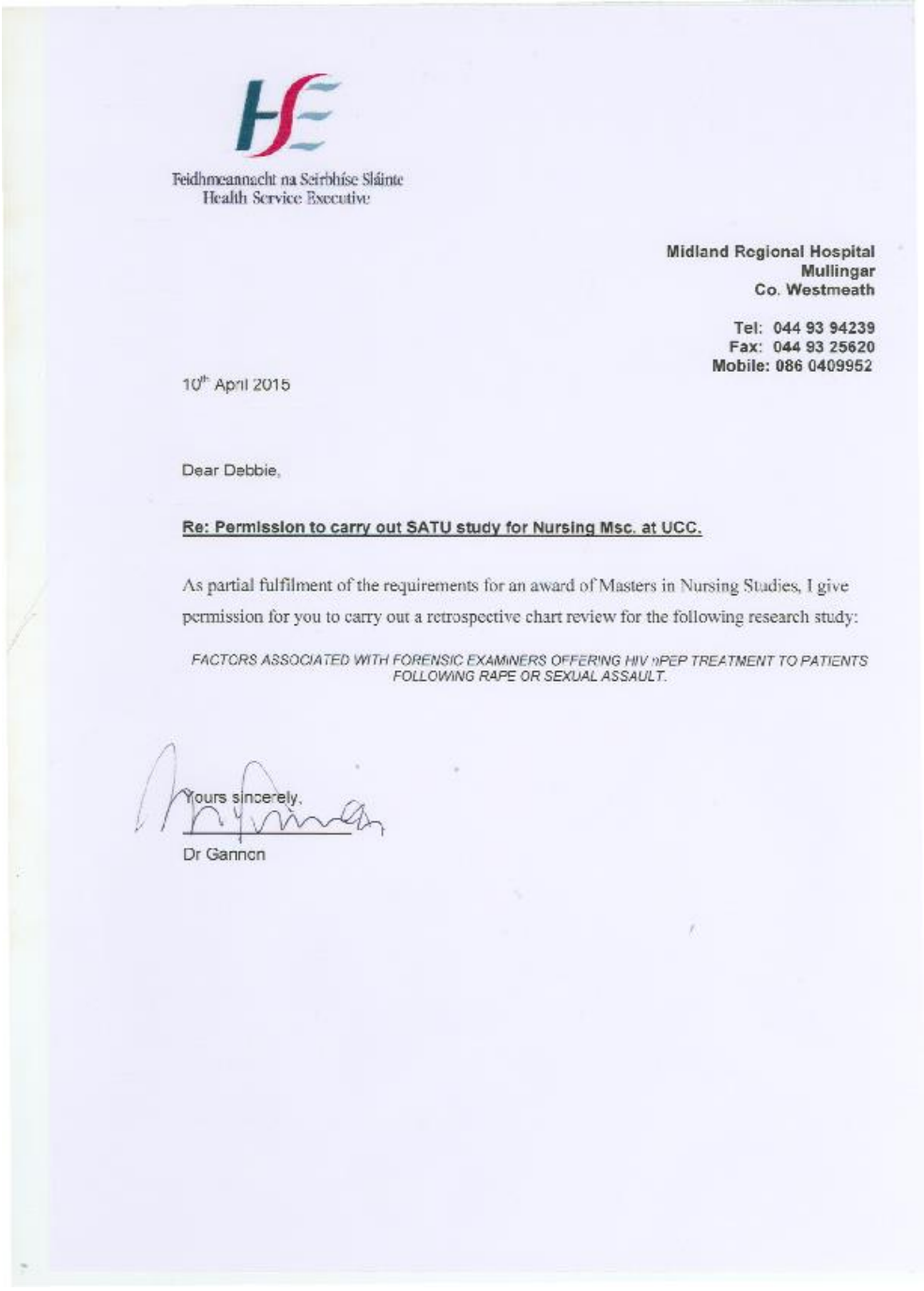
This amendment to the original title is the only change to the study; all other elements including the study cohort remain the same, however 200 charts have been reviewed.

Yours sincerely,
Debbie Marshall

_____

Debbie Marshall,
CNS (Sexual Assault Forensic Examination)

Appendix 4 Permission from Medical Director



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Midland Regional Hospital
Mullingar
Co. Westmeath

Tel: 044 93 94239
Fax: 044 93 25620
Mobile: 086 0409952

10th April 2015

Dear Debbie,

Re: Permission to carry out SATU study for Nursing Msc. at UCC.

As partial fulfilment of the requirements for an award of Masters in Nursing Studies, I give permission for you to carry out a retrospective chart review for the following research study:

FACTORS ASSOCIATED WITH FORENSIC EXAMINERS OFFERING HIV nPEP TREATMENT TO PATIENTS FOLLOWING RAPE OR SEXUAL ASSAULT.

Yours sincerely,

Dr Gannon

Appendix 5 Permission from Director of Nursing

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Health Service Executive
Limistéar Lár Tire
Midland Area
Nursing Administration
Midland Regional Hospital Mullingar
Mullingar
Co. Westmeath

Telephone: 044-9394550
Administration Fax. 044-9394556

3rd March 2015

Ms. Deborah Marshall,
Rhencullen House,
Monadarragh,
Mostrim,
Co Longford.

RE: Permission to Carry Out SATU Study for Nursing Msc. at UCC.

Dear Ms. Marshall,

As partial fulfilment of the requirements for an award of Masters in Nursing Studies, I give permission for you to carry out a retrospective chart review for the following research study:

FACTORS ASSOCIATED WITH FORENSIC EXAMINERS OFFERING HIV nPEP TREATMENT TO PATIENTS FOLLOWING RAPE OR SEXUAL ASSAULT.

Yours sincerely,

Anne Kelly.
Director of Nursing & Midwifery.