TITLE

THE LUNAR CYCLE AND INPATIENT SEDATION USAGE IN A PSYCHIATRIC SETTING

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

Master of Medicine in the branch of Psychiatry

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DECLARATION

I, Faeeza Mohamed, declare that this MMed is my own work. It is being submitted for the Degree of Master of Medicine in the branch of Psychiatry at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

Signature of candidate

---------- day of ---------- 20------- in----------

DEDICATION

In memory of my grandfather who set me on my academic path

Adul-Hai Cassim

1931-1995

ACKNOWLEDGEMENTS

I would like to acknowledge my family, friends and supervisor for their endless support through the process of completing this research.

ABSTRACT

Introduction:

This study aimed to investigate whether an association exists between the lunar cycle and the amount of sedation required by an inpatient psychiatric population.

Methods:

The study was a retrospective record review of psychiatric inpatient sedation usage at Chris Hani Baragwanath Academic Hospital, in Johannesburg, over 18 months. For each day in this period, data of the total amount of intramuscular sedation, the number of intramuscular injections administered and data of bed occupancy were collected and correlated with the days of the lunar cycle.

Results:

Outcomes included the amount (mg) of sedative administered and the number of intramuscular injections (per sedative and total) per bed occupied. There was no significant effect of any day of the lunar cycle on the amount of sedation dispensed or the number of intramuscular injections administered.

Conclusion:

Inpatient psychiatric illness severity, as measured by intramuscular sedation administered, is not exacerbated by the lunar cycle.

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Chapter 1:

1.1. Introduction

The term *lunatic* is derived from the Latin terms *Lunaticus* and *Luna*. It describes a person "affected by the kind of insanity that was supposed to have recurring periods dependant on the changes of the moon" (1). The Romans believed that the moon may have supernatural influences over humans, with the goddess Luna being associated with mental illness. The effect that the moon has on human physiology, psychology and behaviour has become known as the "Transylvanian Effect" (2). This term originated in the Middle Ages, in Europe, where madness was associated with human transformation into creatures such as werewolves and vampires at the time of a full moon (3).

The belief that health and behaviour is affected by lunar phases has persisted throughout history. Hippocrates documented that "No physician should be entrusted with the treatment of disease who was ignorant of the science of Astronomy" (4). In 1843, the Lancet journal published an article reporting on research linking the lunar cycle to fevers, cholera, epilepsy, birth and mental illness (5).

These beliefs are still prevalent amongst healthcare workers. Qualitative research done in the University of Pittsburgh in 2005 suggest that superstitious beliefs amongst healthcare practitioners persist, with 69% of perioperative nurses believing that the full moon worsens stress and workload (6). In a study of 325 people in Alabama (USA), 43% of participants believed that the lunar cycle influenced behaviour. It is further noted that mental health professionals held these beliefs more than other groups, with up to 81% believing that the full moon will affect behaviour (7).

The BILE (Belief in Lunar Effects) instrument, a 9-item scale introduced in 1985, found that 46% of 165 university students held suspicious lunar beliefs (8). Using this instrument in a 2011 thesis from the University of Minnesota (USA), Duluth studied the lunar effect beliefs of those

working in social service settings. This study also showed that these beliefs are still evident (9). However, there is a lack of research regarding such beliefs in a South African context.

1.1.1 The lunar cycle

The earth revolves around the sun every 365 days, 5 hours and 48 minutes. The moon is the earth's only satellite and rotates around the earth every 29 days, 12 hours and 44 minutes. This is referred to as the lunar month or synodic period (10). As the moon orbits around the earth, the angle between the earth and the moon varies, and results in the different phases of the moon. Depending on the position of the moon, earth and sun, the following phases are created; new moon (NM), full moon (FM), first quarter (FQ) and last quarter/third quarter (LQ) (10).

The lunar cycle can further be split into quarters. This includes the first quarter (between NM and FQ), second quarter (between FQ and FM), third quarter (between FM and LQ) and the last quarter (between LQ and NM). The waxing period of the moon is between NM and FM. The waning period is between FM and NM. The waxing crescent, waxing gibbous, waning gibbous and waning crescent are interphases that occur following NM, FQ, FM and LQ respectively (Figure 1.1)

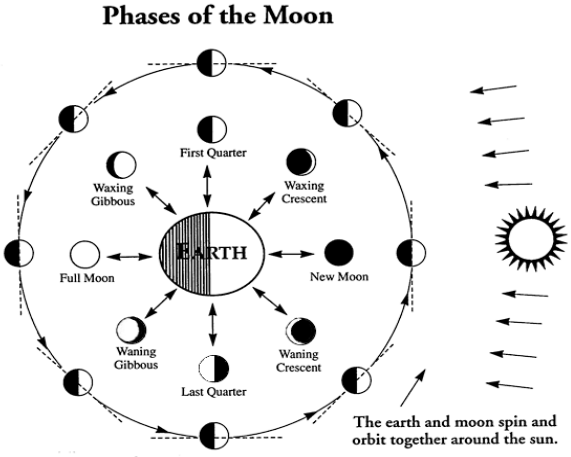

Figure 1.1. Phases of the lunar cycle (11)

When the moon is NM or FM the gravitational forces of the moon and sun are aligned, and high tides occur on these days due to the greater gravitational pull of the moon. These tides are known as spring high tides. Low tides occur when the gravitational force of the moon and sun are acting at right angles to the gravitational pull of the Earth. This occurs on the days of FQ and LQ (10).

1.1.2 The lunar cycle and its effect on human physiology

Theories around how the lunar phases influence biological function are based on the effect of the moon on gravitational forces. The belief is that the changes in gravitational forces caused by the lunar phases can affect fluid in the body - referred to as 'biological tide' - as well as disrupt electromagnetic fields, also thought to affect the body. As the human body is composed of 80% water, such physiological changes are proposed to affect autonomic function, cardiovascular function, reproduction and behaviour (10).

In contrast to the above belief that the lunar cycle disturbs human physiology, the effect of gravitational forces on smaller bodies of water are thought to be insignificant. For example, although the moon may affect tides in the ocean, it does not produce effects on lakes and dams. This refutes the biological tide theory (12).

The correlative historical perspective suggests that prior to domestic lighting, FM was associated with more social activity and decreased sleep. It is suggested that this is likely the cause of exacerbations in perceived mental illness and behavioural changes (12).

1.1.3 The context of this study

The belief that the lunar cycle affects human physiology is of longstanding duration, and the perceptions of many healthcare workers are consistent with this belief. This perspective offers the proposal that changes in external environment can disturb numerous biological systems.

Research in this field is extensive, and includes the effect of the lunar cycle on medical conditions, surgical conditions, crimes, human aggression, as well as psychiatric illness.

The literature review will focus on the findings in the field of psychiatry. This will include admissions and presentations to emergency departments, suicidal behaviour, patients in an outpatient setting, as well as other measures of psychiatric illness. Violence and crime will be explored briefly, as this can be related to mental illness. The literature review will then summarise findings in fields of medicine outside of psychiatry. Epilepsy, an illness treated by both physicians and psychiatrists, will be covered in this section. The presentations to a hospital setting due to violent or disruptive behaviour will also be incorporated, due to the possible link to psychiatric illness. Other studies affecting surgical illness, obstetrics and gynaecology, as well as general medical illness will be summarised to assess links between the lunar cycle and biological functioning. The literature review will be concluded with a review of the types of restraints, including sedation, to contextualise this study.

Such research in the psychiatric field has not been done in a South African context, and it would be of benefit to add a South African perspective to the current research. Research closer to home will allow healthcare professionals to address their own perceptions of psychiatric illness.

1.2 Literature Review:

1.2.1 Psychiatry and the lunar cycle

Research around the effects of the lunar cycle on people with psychiatric illness is conflicting, although most is in keeping with the hypothesis that psychiatric illness is not affected by the lunar cycle (2). Research in this area has not been done in a South African context.

1.2.1.1 Psychiatric admissions and presentations to emergency departments

Although earlier research published in the 1970s found an increase in mental health admissions on the days of FM (13, 14), newer research has shown predominately negative findings. The Naval Medical Centre in San Diego (USA) assessed 8 473 admissions over an eight-year period. No association was found between psychiatric admissions and the lunar cycle. Diagnoses of psychiatric illnesses were also found to be independent of the lunar cycle (15). Similarly, research done in Brighton (USA) showed no association between the lunar phases and four variables selected to measure psychiatric morbidity. These variables included presentation to emergency departments due to self-harm, psychiatric admissions, psychological problems, and referrals to the mental health trust (16). Further studies in emergency settings also observed no findings of note (17 - 19). Moreover, no significant effects of the lunar cycle were determined in anxiety and mood disorder cases consulting in the emergency department (20).

When the lunar cycle is assessed in different ways, significant results appear to emerge using different models. A Canadian study assessed emergency psychiatric presentations using three different full moon models. These included the 12-hour model (6 hours before and after FM), the 24-hour model (12 hours before and after FM) and the 3-day model (24 hours before and after the day of FM). The 12-hour and 24-hour models showed fewer presentations of patients with anxiety disorders, while the 24-hour model showed more presentations of patients with personality disorders and higher triage scores of presenting patients. A study such as this provides contradictory findings which may demonstrates the confusion found in lunar research. The authors of this study have discussed the significant weakness in lunar research, regarding the

different methodologies used, and therefore the need for standardised definitions of the lunar cycle is highlighted (21).

A study conducted in Iran assessed the lunar cycle in models defined by day instead of traditional quarters, namely two 15-day sections, three 10-day sections, and six 5-day sections. These models were correlated with emergency visits, gender, aggression, admissions, legal referrals, and need for involuntary chemical restraint. Most of the measured outcomes in this study did not reveal positive correlations. However, an increased frequency of admissions was shown in the first and last part of the three part model as well as in the first and last parts of the six part model. The reasons for these positive findings are not fully explored and remain unclear. The study also explored the trend of increased emergency room visits at the FM, however the number of aggressive patients, patients needing admission and those needing chemical restraint are decreased at this time. These opposing trends suggest conflicting findings. The possible physiological effects of the lunar cycle on the human body was explored but many confounding factors are also highlighted. These factors include the availability of finances and the effect of the weather on the presentation to a hospital. There is also a recognised trend of intoxication, aggression and relapses of psychiatric illness when substances are used. This usage is increased when funds are available which may correlate with a monthly cycle (22).

1.2.1.2 Suicidal Behaviour

In a review of 20 studies assessing suicidal behaviour and the lunar cycle, 11 studies assessed completed suicide. In 10 out of these 11 studies, no relationship between the lunar cycle and suicide was established (23). The single, older study with a positive finding assessed 928 suicides in Ohio (USA) between 1972 and 1975, and noted an increase in suicide rate at the time of NM (24). This finding has not been replicated (2).

Further studies in the area included a population-based study assessing age, gender, and method of suicide in Middle Franconia between 1998 and 2003 (3,504 suicides). No significant

relationship was found with the lunar cycle. However, an association was made between NM and non-violent suicide in young adult men. This association is documented as weak and the article concludes no evidence to associate the lunar cycle with suicide rates (25). A study in Madrid, assessing method and timing of suicide in a sample of 897, reached no significant findings (26).

1.2.1.3 Psychiatric illness and the lunar cycle in an outpatient setting

Some studies opted to assess psychiatric illness in community settings, and contrary results were found in the different studies (27 - 29).

Psychiatric community-based services in Italy found no relationship between the lunar cycle and frequency of contact with community services (27). In a study assessing presentations to an outpatient department, both the number of new patients seen in the outpatient department of a tertiary psychiatric hospital in Goa (India) and their diagnoses were evaluated over two years. Non-affective psychosis was found to be increased on days of visible lunar eclipse and FM days. Affective psychosis as well as admission rates were not affected. When assessing the results of the lunar phases and the eclipse days in relation to the distance between the earth and moon, this study suggests that the effect of gravitational pull on the human body is less likely to be of significant influence. The study proposes that the electromagnetic effect of the lunar phases on human physiology may explain the higher incidence of affective psychosis (28).

Barr studied the lunar cycle (using weeks in the cycle) and quality of life of mentally ill people who lived in the community, in the United Kingdom (UK). One hundred community service mental healthcare users were randomly selected. Four different interviews were done with each participant using the BPRS (Brief Psychiatric Rating Scale) and the LQOLP (Lancashire Quality of Life Profile). Deterioration was observed in patients with schizophrenia at the time of FM. This was shown in three subscales of the BPRS (signs and symptoms of acute schizophrenia, hostility, and total scores). The mood disorder subgroup of the study did not display significant findings. The limitation of this study is that the confounding factors were not assessed. The study

was based on the re-analysis of data which was collected for a different study with a different methodology, which did not address factors affecting level of functioning (29).

1.2.1.4 Other measures of severity of psychiatric illness in relation to the lunar cycle

From the above study describing quality of life, it can be seen that psychiatric illness can be assessed in ways other than analysing admission rates in emergency settings and presentations to healthcare providers.

Mason used seclusion as a measure of aggression and violence in psychiatric illness. He did not find any correlation between the days of FM and the use of seclusion (30). In Spain, a study over a one-year period showed no relationship between the moon phases and characteristics of psychiatric admissions or emergencies. However, there was a correlation with the brightness of the moon and the number of beds occupied, as well as the quantity of administered hypnotics. The brighter the moon, the greater the occupancy rate, and the greater the quantity of hypnotics that were administered. It has been proposed that the moon brightness at the time of full moon may affect sleep cycles and this could have resulted in the increased hypnotic usage (19).

Prospective research in an inpatient psychiatric setting used a rating scale, known as the Morrison's hierarchy of violence and aggression, to rate behaviour in five psychiatric hospitals in Australia over 105 weeks. No significant relationship was found between violence and aggression at any phase of the moon (31).

In Tennessee (USA), the behaviours of institutionalised, developmentally-delayed women were found to deteriorate at the time of FM and in the three days prior to FM (32). However, in a more recent study that assessed the behaviour of individuals with intellectual disability, Smith showed no relationship between worsening behaviour and the days of FM (33).

1.2.1.5 Difficulty in comparing studies

It is evident that the lunar cycle has been determined in different ways in separate studies. Most surveys assessed individual days (FM, NM, FQ, LQ), (15 - 18, 20, 32, 33) while others measured all the days of the lunar cycle (27, 28). Further research investigators broadened their definitions to surrounding days (20, 21, 30, 32), splitting the lunar cycle into weeks (29), quarters (15, 31), and even hours around the time of FM (18, 21). Some research used other models (22); and in some, it is unclear as to how the lunar cycle had been gauged (19).

Such differences in the classification of the lunar cycle highlight the difficulties in comparing lunar studies adequately. An example of this would be the study evaluating emergency psychiatric presentations using the 3 different full moon models, in which the 12-hour, 24-hour, and 3-day models each showed varied results (21).

Research finding positive associations between the lunar cycle and a psychiatric context appears to be older, published mainly in the 1970s (14, 15, 24). Where positive associations were found in later research, two out of three investigations were of small sample sizes (28, 29, 32). Studies that uncovered both positive and negative associations include those where the lunar cycle was defined by elaborate models (21, 22), or which did not indicate a clear description of how the lunar cycle had been assessed (19).

The above discrepancies in study methodology make comparisons questionable, and all results must be assessed with caution.

1.2.2. Violence and crime in relation to the lunar cycle:

Between 1978 and 1982, a study in India in three different areas (rural, urban, and industrial) observed that the incidence of crime reporting increased at FM (34), although more recent research in the USA does not replicate this finding (35). Some research shows that the incidence

of homicides and assaults increases around the time of FM (36, 37), whereas other studies found no such correlation (38, 39). In Germany, aggravated assaults between 1999 and 2005 were not related to any specific phase of the lunar cycle (40); nor has any association been found with increased domestic violence (41).

1.2.3. The effects of the lunar cycle on medical fields outside of psychiatry

When assessing the possible relationship between epilepsy and the lunar cycle, recorded seizures over a 3-year period in an epilepsy monitoring unit in Tampa Hospital (Florida, USA) revealed an increase in epileptic seizures in LQ and an increase in non-epileptic seizures at FM. This study classifies non-epileptic seizures under psychiatric illness and does not explore the causes further. It does however suggest that patients with psychiatric illness and non-epileptic seizures may be more interested in the lunar phases and horoscopes (42).

Admission to the intensive care unit for *status epilepticus*, as well as seizure occurrence, has been associated with the lunar cycle (43, 44). Status epilepticus with intensive care unit admissions were associated with environmental factors such as diurnal, weekly and lunar cycles as well as weather variables. This study assists us in considering that the lunar cycle is only one variable that may affect human physiology and the impact of numerous other environmental factors need to considered (43).

Increased seizure frequency around the full moon was demonstrated in an emergency unit setting in Greece. This study looks into how seizure threshold may be affected by the lunar cycle. It considers how both direct influences (physiological) and indirect influences (change in activities especially at night) may play a role in affecting seizure threshold (44). Research studies into sudden unexpected death due to epilepsy have shown conflicting results (45, 46). Other findings suggest that the frequency of episodes of epilepsy is related to the brightness of the night and atmospheric conditions, rather than the lunar cycle (47), which is in keeping with the trends suggested in the research above.

In the emergency room setting, an observational study at Calvary Mater Newcastle Hospital (Australia) showed that violent and behaviourally-disturbed patients presented more frequently at the time of NM over a one year period. This study showed that alcohol and illicit substance usage was evident in these violent patients. This highlights the need for assessing confounding factors such as substance usage (48). Further studies assessing emergency room visits, including presentations of victims of violence as a measure of increased violent behaviour, have not shown any correlation to the lunar cycle (49 - 51).

In obstetrics and gynaecology, research focuses on both the menstrual cycle and the onset of the birth process. The relationship between the lunar cycle and ovulation was shown in some studies (52, 53). Conversely, more recent studies are of the opinion that the lunar phases do not affect the menstruation cycle (54, 55). Research in a natural-fertility population similarly found no association between the lunar phases and the menstrual cycle (56).

An association between the lunar cycle and births was established in certain studies (57, 58). In contrast to these studies, research in Arizona (USA) that assessed birth records of full-term vaginal deliveries between 1995 and 2000 (n = 167,956) showed no correlation between the lunar phase and the birth rate (59). Similarly, a retrospective cohort of 564,039 births from North Carolina between 1997 and 2001 concluded that the lunar cycle had no influence on either deliveries or obstetric complications (60).

The incidence of acute coronary events and admissions in the departments of emergency medicine and cardiology were studied between 1999 and 2001 in India, in which a statistical analysis revealed a notable increase in admission rates on the days of NM (61). Times of weak gravitation of the moon were associated with an increase in the number of acute myocardial infarcts (62). A study of atrial fibrillation and the lunar cycle found a decrease in the frequency of episodes at FM (63). Cardiovascular mortality has also been found to have a biphasic pattern of increased frequency during FQ and LQ (64). However, a retrospective analysis of emergency department visits in northern New Jersey (USA) found no significant difference in the

occurrence of cardiopulmonary resuscitations during times of FM and NM (65). It is evident that the results of studies concerning the times of cardiovascular incidents in relation to the lunar cycle vary in their findings.

In a study of 447 patients over a period of two years, an increase in the number of admissions related to gastrointestinal haemorrhage was described during FM, especially in male patients (66). The incidence of abdominal aneurysm rupture was shown to be higher during the waxing period of the moon (67). Although occurrences of aneurysmal subarachnoid haemorrhage showed a peak at NM (68), these positive findings were not replicated during another study (69). The rates of surgically-related haemorrhage or epistaxis have not been shown to be associated with the lunar cycle (70-74). Research around renal colic, urinary retention and urological emergencies have shown contradictory findings (75-79).

A small but statistically significant association between general practice consultation rates and the lunar cycle was noted in a study in the UK after assessing the number of consultations in 60 practices (80). Also appointments for both new and follow-up consultations at an outpatient thyroid clinic in Vienna showed an increase in requests for appointments around the time of FM (81).

It appears that research assessing medical and surgical illnesses outside of psychiatry show conflicting evidence regarding the effect of the lunar cycle. Even studies within the same speciality appear to show contradictory findings in relation to the phases of the lunar cycle.

1.2.4. Methods of restraint for uncontained mental healthcare users

The effect of the lunar cycle on psychiatric illness and behaviour has been researched extensively in various ways. Some studies have measured admission rates and contact with mental health services within different settings, such as community-based, outpatient, and emergency unit settings; while others have assessed the severity of illness by looking at quality of life, aggression, seclusion, and chemical restraint. In the context of this study, where chemical restraint is being assessed in an inpatient population, the concepts and types of restraint will be explored. The different forms of chemical restraint will also be discussed to understand the sedatives used in this study.

Restraints are used to ensure the safety of patients and others should verbal intervention and routine medication fail. These are classified into categories of environmental, chemical, and physical. Environmental restraint involves limiting a patient's movement, physical restraint requires the use of devices to reduce or inhibit movement, and chemical restraint is the use of pharmaceutical agents to reduce or limit problematic behaviours such as aggression (82).

1.2.5. Sedation as a means of chemical restraint used in an inpatient psychiatric setting

Chemical restraints usually involve three classes of medication; namely, first generation antipsychotics, second generation antipsychotics, and benzodiazepines (83).

First generation antipsychotics are D2 antagonists. Butyrophenone derivatives such as haloperidol have a high risk of inducing extrapyramidal side effects, but are effective for containment when used as an intramuscular preparation. Phenothiazine derivatives such as chlorpromazine require higher doses for treatment efficacy and have greater anticholinergic, antihistaminic, and alpha 1 antagonist effects. Phenothiazine derivatives are less frequently used for containment. Dibenzothiazepine derivatives, such as clothiapine, have considerable potential to cause extrapyramidal side effects, but do have significant sedative properties that assist in containment (83 - 85).

Second generation antipsychotic agents are D2 antagonists as well as 5HT2A antagonists. Most trials with regards to second generation antipsychotics have not been administered in acute emergency settings. Olanzapine, ziprasidone, and aripiprazole are available in intramuscular preparations (83).

Benzodiazepines such as diazepam, lorazepam, and clonazepam influence GABA receptors. GABA is the predominant inhibitory neurotransmitter in the brain. Benzodiazepine usage is common for acute containment (83).

1.3. The motivation for conducting this study

This study was conducted at Chris Hani Baragwanath Academic Hospital (CHBAH). CHBAH is a tertiary hospital, servicing areas in the south of Johannesburg (South Africa). It has a psychiatric department of 150 inpatient beds.

A general perception amongst healthcare providers is that the lunar cycle affects mental health, and suspicions persist that the workload increases at specific times of the lunar cycle. Since research regarding the lunar cycle and psychiatric illness has not been undertaken in a South African setting, the aim of this study is to present an objective assessment of the influence of the lunar cycle in a psychiatric inpatient setting. Such research, if no correlation is found, could dispel these misgivings, and encourage more insight among the healthcare providers. Alternatively, should positive findings be established, further research would be warranted to afford a better understanding of psychiatric illness in our population; and further resources could be allocated to assist with the associated increased workload.

1.4. Hypothesis

Intramuscular sedation usage varies related to the lunar cycle, indicating that severity of behavioural disturbance due to psychiatric illness is influenced by the lunar cycle.

1.5. Null Hypothesis

Intramuscular sedation usage does not vary related to the lunar cycle.

1.6. Aim of the study

To assess intramuscular sedation usage in a psychiatric inpatient setting in relation to the days of the lunar cycle.

1.7. Study objectives

1) To document the daily usage of intramuscular sedation for an 18-month period, in male and female inpatients.
2) To relate intramuscular sedation usage to the lunar cycle.

Chapter 2

Methods

2.1. Study Population

CHBAH has separate male and female psychiatric wards, with a total bed capacity of 150 psychiatric beds. Admissions to the unit cover all psychiatric illnesses with the exception of eating disorders. This study assessed the adult psychiatric inpatient population. Records from one male ward and one female ward were used in this study as a representation of admitted patients. Since patients are randomly assigned to wards, no difference in the pathology or severity of illness is expected between wards. All ward records were assessed and there was no exclusion criterion.

2.2. Study design

This study was a retrospective record review of psychiatric sedation usage in psychiatric inpatients at CHBAH over an 18-month period between 1 July 2014 and 31 December 2015.

Although it is noted that ways to assess the severity of psychiatric illness include the evaluation of the patient on either their admission to hospital or their arrival at an emergency or outpatient setting, in this population admissions and presentations for assessment would be confounded by variables. These could include inaccessibility of transport for the patient which would prevent them from reaching a medical setting; or their choice not to present for treatment when their symptoms first occur. Therefore, a patient's initial presentation to psychiatry would not necessarily indicate the onset of psychiatric symptoms. In addition, as resources are limited in this setting, severity of illness may not be gauged merely by a patient's admission, as some patients who would warrant inpatient care are discharged with close follow-up, due to the non-availability of hospital beds.

Thus, this research methodology elected to assess severity of illness only in an inpatient setting, and using intramuscular injection (IMI) sedation as an indicator of severity of illness. In the setting of this study, routine medication is prescribed as fixed doses, and medication needed for containment is prescribed on the basis of need. The staff supervising the patients has flexibility regarding the dose and route of sedation administration, and these decisions would be based on clinical factors such as agitation, aggression and/or distress.

The initial choice of sedation in this setting is benzodiazepines. The benzodiazepines most frequently used are clonazepam and lorazepam, which are available in oral and intramuscular preparations. Intramuscular route of administration is used for acute containment of particularly unwell patients, whereas oral sedation may be used for containment as well as being a routine hypnotic. Data were collected for intramuscular sedation.

The two first generation antipsychotics assessed were haloperidol and clothiapine. Haloperidol is available in oral and intramuscular preparations. The intramuscular route of administration can be used for acute containment, whereas oral administration is used for routine treatment of psychosis. Data were collected for intramuscular usage. In this setting, clothiapine is only available in intramuscular preparation and can be used for containment. Data for intramuscular clothiapine administration were collected.

It must be noted that the intramuscular route of sedation is not routinely used, and is thus an indication that the patient is refusing oral medication or is extremely uncontained and requires immediate chemical restraint for their own safety and the safety of others. Therefore, the administration of intramuscular sedation is sporadic and not routine.

The chosen drugs are classified as Schedule 5 drugs and so all usage must be recorded (date, time, dosage, and route of administration) according to legal requirements. Therefore, due to their common usage and the availability of accurate records, the four drugs mentioned above

administered via IMI were employed for this study. The unit does not use second generation intramuscular preparations for acute containment.

Each ward records daily statistics, which include the number of patients in the ward on a particular day. Calculations of intramuscular sedation thus factor in the number of patients to determine the amount of sedation per bed occupied. Since records are documented in the morning prior to discharges or new admissions, they indicate the number of patients in the ward on the previous day.

Information regarding the lunar cycle was obtained from the Johannesburg planetarium. Although the dates of NM, FM, FQ and LQ were documented for the period between 01 July 2014 and 31 December 2015, for this study the lunar cycle was assessed in days (1-30), and data collected each day. This allowed for the assessment of trends on all days of the lunar cycle.

2.3. Data collection

Data were collected in an Excel spreadsheet. For each day in the study period, the following data were recorded (Appendix A):

- Ward (male or female)
- Date
- Public Holiday indicator (weekday vs. weekend/holiday)
- Day of the lunar cycle (1st day of the lunar cycle being the day of NM)
- Indicator if the day corresponds to a particular phase (NM, FM, FQ, LQ)
- Bed occupancy
- Total dosage of IMIs in mg of each sedative administered on each day: lorazepam, clonazepam, haloperidol, clothiapine.
- Total number of IMIs of each sedative administered on each day: lorazepam, clonazepam, haloperidol, clothiapine.
- Medication out of stock on the day

It must be noted that the unit of observation here was the DAY, rather than the patients as in most studies. The ward was assessed as a unit, and the outcomes encapsulate multiple patients with uncontained episodes, as well as multiple episodes per patient.

2.4. Data analysis

2.4.1. Sample size calculation

A sample size calculation was based on a one-way Analysis of Variance (ANOVA) with the lunar day as the independent variable, and the milligrams (mg) of sedative per occupied bed and the number of IMIs as the outcome variables. At the 5% significance level, and 80% power, the detection of a small/medium/large between-group (between-lunar day) difference requires a sample size of 2,460 / 420 / 180 days, respectively. To detect at least a medium effect size, should it exist, a sample size of 420 days (1.15 years) was required. This was rounded up to 1.5 years (18 months). Sample size calculations were carried out in G*Power (86).

2.4.2. Statistical analysis

Descriptive analyses of the data were carried out as follows. Categorical variables were summarised by frequency and percentage tabulation. Continuous variables were summarised by the mean, standard deviation, median and interquartile range.

Outcomes:

1. To calculate the amount (mg) of sedative administered per bed occupied, in both male and female wards.
2. To calculate the number of IMIs (per sedative and total) per bed occupied, in both male and female wards.

Each outcome was analysed by a negative binomial regression with the outcome as the dependent variable, and the lunar day as the independent variable, controlling both for day type (weekday vs. weekend/holiday), and whether or not other drug/s were out of stock. A negative binomial regression was chosen to account for the type of data (rate data; bounded at 0) and its distribution (very positively skewed).

Analyses were carried out separately for the data collected for the male ward and the female ward. Post-hoc tests were conducted with the Tukey-Kramer adjustment for unequal group sizes. Data analysis was carried out using SAS version 9.4 for Windows. The 5% significance level was used.

2.5. Ethics

This study was approved by the University of the Witwatersrand's Human Research Ethics Committee (HREC) (Appendix B). Authorisation to conduct the study was obtained from the CEO of CHBAH (Appendix C).

This study is a retrospective review, and patients remained anonymous when data was collected. The data was collected from drug registries and not from patients' files. Data collection was done in the hospital. The data collected did not have any identifying criteria. Names, file numbers, and dates of birth were not documented. Due to the nature of the retrospective data collection, patient consent was not needed for this study.

Chapter 3

Results:

3.1. Descriptive analysis of the study group

The data set covered 549 days (Table 3.1.)

Table 3.1. Description of day type in data set

Variable	Category	N (days)	%
Day Type	WEEKEND/PUBLIC HOLIDAY	170	31,0
	WEEKDAY	379	69,0

The median male bed occupancy was 43 beds (interquartile range (IQR) 41-46; range 30-49 beds). The bed capacity of the ward at the time of this study was 47 beds. The range of occupancy shows a maximum bed occupancy of 49. This could be accounted for by patients who were awaiting discharge while new admissions had already been allocated to the ward, but may also represent wards functioning above capacity. As expected, the distribution of the data was highly skewed as bed occupancy is usually high (Table 3.2). The median female bed occupancy was 27 beds (interquartile range (IQR) 24-28; range 15-30 beds). The bed occupancy above capacity as well as the distribution of data are similar to that of the male findings above (Table 3.2).

Table 3.2. Bed occupancy over study period

Variable	N (days)	Median	Interquartile range		Minimum	Maximum
Male bed occupancy	549	43	41	46	30	49
Female bed occupancy	549	27	24	28	15	30

In the male ward, one or more of the four drugs was out of stock on 49.4% of the study days. In the female ward, one or more of the four drugs was out of stock on 55.9% of the study days (Table 3.3.)

Table 3.3. Medication out of stock over the study period

Variable	Category	n (days)	% (study period)
Medication out of stock (Male ward)	No medication out of stock	278	50,6
	Medication out of stock	271	49,4
	Haloperidol out of stock	*163*	*29,7*
	Lorazepam out of stock	*108*	*19,7*
Medication out of stock (Female ward)	No medication out of stock	242	44,1
	Medication out of stock	307	55,9
	Haloperidol out of stock	*159*	*29,0*
	Lorazepam out of stock	*160*	*29,1*

3.2. Overview for Result interpretation

The results of individual drugs for both male and female wards are depicted in tables and figures. The figures are depicted as box-and-whisker plot diagrams categorised by the lunar day, while the tables represent the results of the negative binomial regression analysis. The tables assess DF (Degrees of freedom i.e. number of categories), chi-square and p-value, hence assessing the association between each outcome and the days of the lunar cycle, controlling for both day type and whether or not other drug/s were out of stock.

Since there was no significant effect of the day of the lunar cycle on the mg of sedation dispensed, or on the number of IMIs per bed occupied for all four sedatives, or on the total amount of IMIs dispensed, both the male and female results are summarised in collated tables. Only the graphs and tables for Haloperidol (male) are displayed. The other graphs and tables are included in Appendix D.

The following key is to be used when assessing box and whisker plot graphs:

Symbol	meaning	symbol	meaning
◊	**Mean**		**Interquartile Range (IQR)** **Extended Whisker (1.5x IQR)**
○	**Outlier Value**	-	**Median**

3.3. Male ward outcomes

For all four sedatives, there was no significant effect of day of the lunar cycle on the mg of sedation dispensed, or on the number of IMIs per bed occupied. The table below uses p values to represent significant effects. A significant p value is noted to be < 0.05. (Table 3.4).

Table 3.4. Male Collated results - effect of the day of the lunar cycle on amount of sedation and number of IMIs dispensed (haloperidol, clothiapine, clonazepam, lorazepam)

Drug:	**Effect of the day of the lunar cycle on the amount of sedation per bed occupied (mg) – P value**	**Effect of the day of the lunar cycle on the number of IMIs per bed occupied – P value**
Haloperidol	0.91	0.54
Clothiapine	>0.99	0.37
Clonazepam	0.69	0.59
Lorazepam	0.99	0.45

Haloperidol

There was no significant effect of the day of the lunar cycle on the mg of Haloperidol dispensed, or on the number of IMIs, per bed occupied (Table 3.5, Table, 3.6, Figure 3.1 and Figure 3.2).

n=385; 1 outlier removed

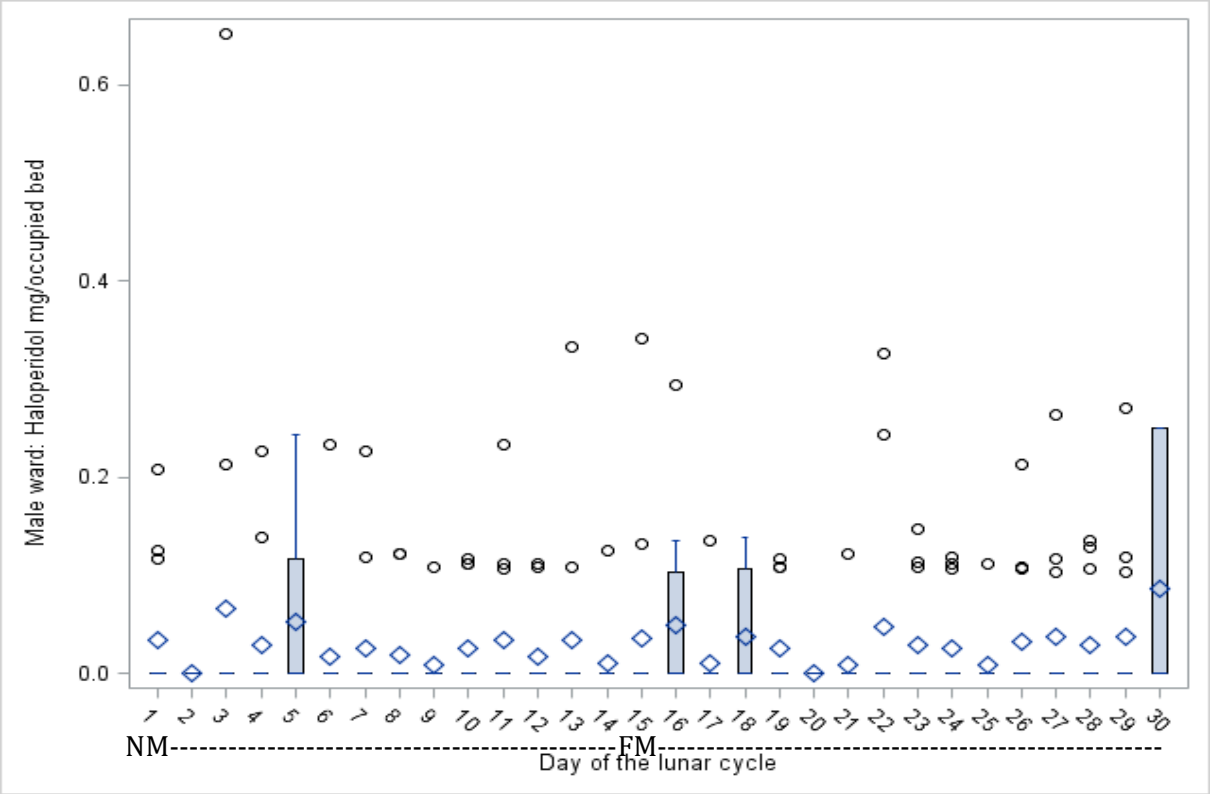

Figure 3.1. Haloperidol (male): mg per bed occupied

Table 3.5. Haloperidol (male): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	19,37	0,91
Day Type	1	0,11	0,74
Any medication out of stock	1	0.87	0.35

n=385; 1 outlier removed

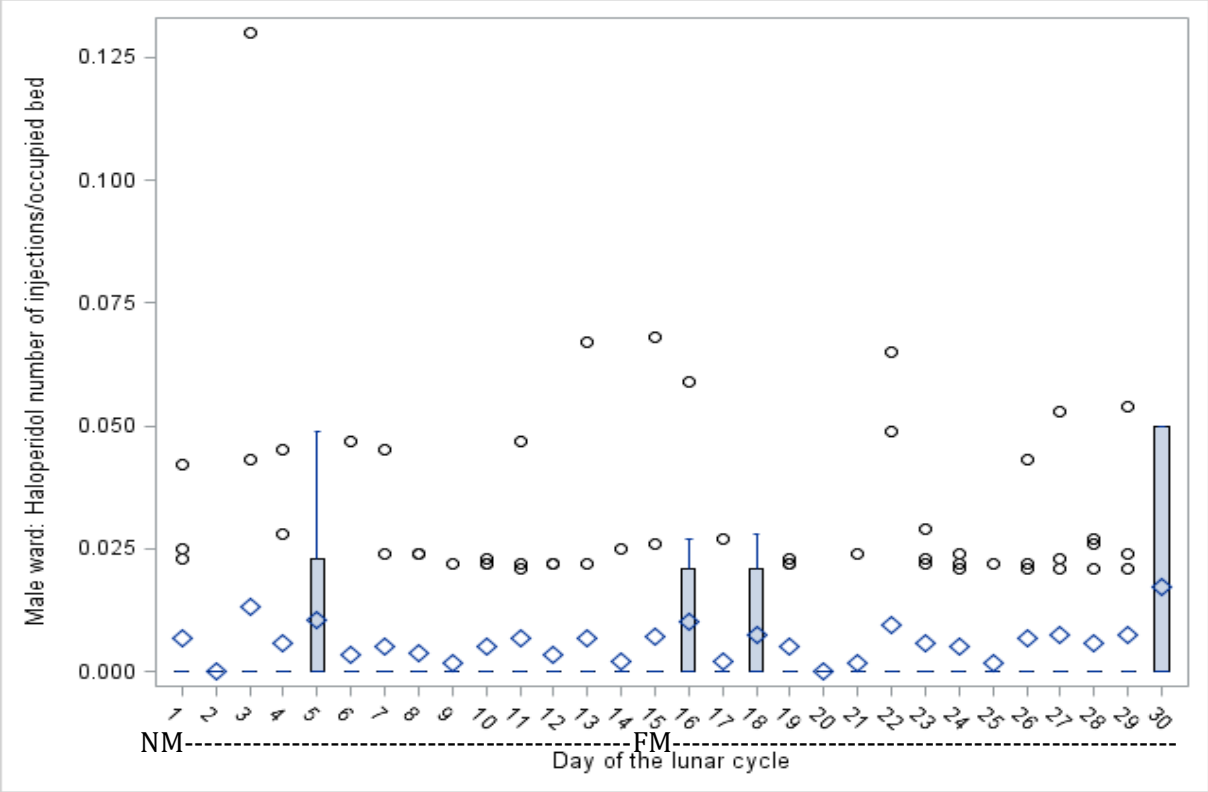

Figure 3.2. Haloperidol (male): number of IMIs per bed occupied

Table 3.6. Haloperidol (male): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	27,68	0,54
Day Type	1	0,04	0,84
Any medication out of stock	1	0,75	0,39

Clothiapine

There was no significant effect of the day of the lunar cycle on the mg of Clothiapine dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.7, Table 3.8, Figure 3.3 and Figure 3.4).

Clonazepam and Lorazepam

There was no significant effect of day of the lunar cycle on the mg of clonazepam/lorazepam dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.9, Table 3.10, 3.11, 3.12, Figure 3.5, 3.6, 3.7, 3.8).

Incidentally, the estimated rate of administration of Clonazepam in mg/bed occupied when any other medication was out of stock was 2.9 (95% CI: 1.3-6.6) times higher than when no other medication was out of stock (p=0.0059). Similarly, the estimated rate of administration of IMIs of clonazepam/bed occupied when any other medication was out of stock was 2.9 (95% CI: 1.5-5.4) times higher than when no other medication was out of stock (p=0.0009).

Similar to clonazepam, the estimated rate of administration of IMIs of lorazepam per bed occupied when any other medication was out of stock was 1.4 (95% CI: 1.1-1.9) times higher than when no other medication was out of stock (p=0.016).

Total number of IMIs

There was no significant effect of day of the lunar cycle on the total number of IMIs per bed occupied (Appendix D: Table 3.13, Figure 3.9).

3.4. Female ward outcomes

Results were similar to the male outcomes for all four sedatives, with no significant effect of the day of the lunar cycle on the mg of sedation dispensed, or on the number of IMIs per bed occupied (Table 3.14).

Table 3.14. Collated results female - effect of the day of the lunar cycle on amount of sedation and number of IMIs dispensed (haloperidol, clothiapine, clonazepam, lorazepam)

Drug:	**Effect of the day of the lunar cycle on the amount of sedation per bed occupied (mg) – P value**	**Effect of the day of the lunar cycle on the number of IMIs per bed occupied – P value**
Haloperidol	0.31	0.36
Clothiapine	0.93	0.91
Clonazepam	0.044 (post hoc tests showed no significant difference between any lunar day)	0.032 (post hoc tests showed no significant difference between any lunar day)
Lorazepam	0.75	0.051

Haloperidol

There was no significant effect of day of the lunar cycle on the mg of Haloperidol dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.15., Table, 3.16, Figure 3.10 and Figure 3.11)

Clothiapine

There was no significant effect of day of the lunar cycle on the mg of Clothiapine dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.17 and 3.18, Figure 3.12 and 3.13).

The estimated rate of administration of clothiapine in mg/occupied bed when any other medication was out of stock was 7.2 (95% CI: 1.3-41.5) times higher than when no other medication was out of stock (p=0,017). Similarly, the estimated rate of administration of clothiapine IMIs/occupied bed when any other medication was out of stock was 3.8 (95% CI: 1.1-13.1) times higher than when no other medication was out of stock (p=0.027).

Clonazepam

There was no significant effect of day of the lunar cycle on the mg of Clonazepam dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.19, Table 3.20, Figure 3.14 and Figure 3.15).

The effect of the day of the lunar cycle on the mg of clonazepam dispensed (p=0.044) and the number of IMIs (p=0.032) per bed occupied appeared to have significance. However, despite the overall p-value being <0.05, post-hoc tests showed no significant difference between any lunar days. Thus, there was no effect of lunar day on the outcome under consideration.

The estimated rate of administration of clonazepam in mg per bed occupied when any other medication was out of stock was 7.0 (95% CI: 2.9-16.9) times higher than when no other medication was out of stock ($p<0.0001$). Similarly, the estimated rate of administration of clonazepam IMIs per bed occupied when any other medication was out of stock was 5.9 (95% CI: 2.4-14.2) times higher than when no other medication was out of stock ($p<0.0001$)

Lorazepam

There was no significant effect of day of the lunar cycle on the mg of sedation dispensed, or on the number of IMIs, per bed occupied (Appendix D: Table 3.21, Table 3.22, Figure 3.16 and Figure 3.17).

Total number of IMIs

There were no significant results regarding the effect of the lunar day on the number of IMIs administered. However, the estimated rate of administration of drugs when any medication was out of stock was 0.74 (95% CI: 0.58-0.93) times lower than when no medication was out of stock ($p=0.011$) (Appendix D: Table 3.23, Figure 3.18).

Chapter 4

Discussion:

4.1. Summary of Results

This study was undertaken to evaluate the impact of the days of the lunar cycle on severity of illness of psychiatric inpatients by using the administration of intramuscular sedation as an indicator. This study assessed the total amount of intramuscular sedation used per bed occupied (haloperidol, clothiapine, clonazepam and lorazepam), as well as the number of IMIs administered (per sedative and the total number of IMIs of all measured sedatives). No association between the use of intramuscular sedation and any day of the lunar cycle was established by this research.

Medication that was out of stock was significant in this study. In the male ward, one or more of the four drugs was out of stock on 49.4% of the study days. In the female ward, one or more of the four drugs was out of stock on 55.9% of the study days (Table 3.2.) For some outcomes - including clonazepam (male) (Appendix D: Table 3.9, Table 3.10, Figure 3.5 and Figure 3.6), lorazepam (male) (Appendix D: Table 3.12 and Figure 3.8), clothiapine (female) (Appendix D: Table 3.17, Table 3.18, Figure 3.12 and Figure 3.13), clonazepam (female) (Appendix D: Table 3.19, Table 3.20, Figure 3.14 and Figure 3.15) and the total number of IMIs (female) (Appendix D: Table 3.23 and Figure 3.18) - there was a significant effect relating to whether or not other medication/s were out of stock. This was not of primary interest, but the effect has been quantified. The potential impact of out of stock medication on patient care will be discussed further.

However, these findings contribute to the validity of the data collected, in that the effect is seen in the assumed direction. Increased usage of different types of sedation were observed when other drugs were out of stock. The total amount of female IMI usage decreased when drugs were out of stock. This is to be expected, as decreased availability generally leads to decreased usage.

4.2. Discussion of Results

The lunar cycle and its effects on human behaviour is an area of interest to healthcare workers and the general population. However, it becomes a concern when such beliefs have an impact on how mental illness is perceived, diagnosed and treated. Seeing psychiatric illness as a medical condition requires research into aetiology, but also needs an extended amount of research into the myths associated with it. Personal perceptions about psychiatric illness must be addressed so as to further educate the general population and mental healthcare providers.

The results of this study will be assessed within the context of the study's setting - i.e. an urban, tertiary hospital in South Africa - and compared to the findings of other studies in similar settings. The discussion aims to explore reasons both for the findings in this study and the persistence of the erroneous belief that the lunar cycle has an impact on mental health.

4.2.1 Older research vs newer research

Now that newer research relating to the lunar cycle and psychiatric illness is emerging, positive findings are becoming less frequent. As this study will be incorporated into the category of newer research, it seems appropriate that the findings would not show an association between worsening psychiatric symptoms and the lunar cycle.

As was discussed in the literature review, most research showing positive findings between the lunar cycle and measures of psychiatric illness tends to be from earlier studies undertaken in the 1970s (13,14,24). Regarding studies done after 2000, this research study is in keeping with the majority of data that finds no association between the lunar cycle and psychiatric illness (15-18, 20, 25). Thus it would appear that newer research (including this study) refute the belief that the lunar cycle has an impact on mental illness.

In an attempt to understand this trend, the hypothesis proposing that changes in behaviour are related to increased activity and decreased sleep at the time of increased natural light at FM, rather than the moon phase itself, must be considered, since prior to community lighting, stronger natural lunar light would have coincided with FM (12). As newer studies emerge, the hypothesis that mental illness is not affected by the lunar cycle is strengthened, as with the advent of more available electrical lighting, human behaviour is no longer restricted by the variations in natural lunar light. Therefore, electric community lighting could account for the progression in study results, where older research showed more associations between the lunar cycle and psychiatric illness in comparison to newer studies. This specific study population live in an urban area with available community electric lighting, and so its findings would be in keeping with the above hypothesis.

4.2.2. Developed vs developing settings

The development status of a country is assessed by economic parameters. Since developing countries are thought to be more orientated towards tradition and culture, then such traditional and cultural perceptions around human behaviour and the lunar cycle should be considered when assessing research. Research undertaken outside of South Africa strongly suggests that the perceptions of healthcare workers continue to be consistent with suspicious beliefs around the lunar cycle and its effect on psychiatric illness, despite ongoing research that proves otherwise.

Should community members and/or staff members hold strong beliefs around the lunar cycle and its effect on human behaviour, this may result in a lower threshold of reporting symptoms or diagnosis at certain times of the lunar cycle. Traditional beliefs would then be a confounding factor to be taken into consideration.

Looking at the sources of psychiatric lunar research from an economic perspective, studies done in developing countries with strong traditional and cultural beliefs, such as India and Iran, have shown positive findings when associating the lunar cycle with mental illness (21, 27). However, these research studies do not explore their positive findings further within their context of traditional and cultural lunar perceptions.

Although this study population does not show results in keeping with the developing world, it must be stated that South Africa is classified as a country with features of both a developing and developed country. This study was also conducted in an urban, tertiary hospital setting, which may make comparisons with a developed setting more accurate.

However, in a South African setting where traditional beliefs are more prominent, correlating suspicious lunar beliefs with the results of lunar study outcomes may be an area of interest. Research such as this study will assist in altering traditional perceptions of patients' behaviour, allowing for a more evidence-based approach to psychiatric practice.

4.2.3. Studies with comparative study methodology – inpatient psychiatric population

When considering this research paper in the context of other studies that have assessed an inpatient psychiatric population, the majority of studies have shown that the lunar cycle does not have an effect on the severity of psychiatric illness (30, 31, 33). This is in keeping with the findings of this study. However, it is noted that a previous study in Spain had found a correlation between the brightness of the moon and the quantity of hypnotics administered in an inpatient psychiatric setting, although its methodology did not give a clear definition of how the lunar cycle was evaluated, or how the brightness of the moon was ascertained. The administration of hypnotics (type and method of administration) was also not clearly described (19). Despite these factors, this study is similar in that both studies assessed sedation usage in an inpatient

psychiatric population on all days of the lunar cycle, though this study does not replicate the positive associations found in the Spanish study.

4.2.4. Incidental finding of medication shortages

Despite the fact that the availability of medication was not the primary focus of this study, it was noted that medication was out of stock for significant intervals during the study period. This highlights a concern regarding the availability of medication in this setting. This particular finding may be used as motivation for a more adequate medication supply in the unit.

When the routine medication used for containment is not available, other methods of containment may have been employed. In the setting of this study, mechanical restraints, seclusion, and transfers to specialised units, may have been used to assist with containment. These methods of restraint and patients' transfers were not assessed in this study.

The impact of medication shortages on the patient population is of great concern. A lack of intramuscular sedation will most likely influence patient care, as well as increase the workload of staff members managing uncontained patients. This would result in long-lasting effects. The patient's perceptions of their illness and admission would be adversely shaped should their management not be optimal; an uncontained patient poses a physical risk to themselves, to others, and to their own reputation; and the impressions of family members around psychiatric illness and the treatment of other patients would be negatively affected by patients who are not adequately contained.

4.2.5. Considerations for further studies in the field

Research related to the lunar cycle is complicated by the differing methodologies employed by different studies. Existing research is difficult to assess due to multiple variations in the definition of the lunar cycle. It would be of benefit if fixed definitions for the lunar cycle be established for future articles. This will allow for the results of such a study to be comparable, and hence of more value.

4.2.6 The implications of this study

The majority of data in this area of research is in keeping with the findings of this study, in that no association has been found between psychiatric illness and the lunar cycle. Thus, clinical management and planning should be undertaken with the awareness that psychiatric illness is not affected by the lunar cycle. This study will serve as a platform to educate mental healthcare providers and address underlying suspicious lunar beliefs, should they be present.

4.3. Limitations

4.3.1 Study design

As this study was a retrospective record review, the accuracy of the data collected was dependant on the quality of record keeping. Ward occupation numbers are recorded by ward clerks and medication administration is recorded by nursing staff. It is noted that the measured sedatives are scheduled drugs, and that their usage must be strictly recorded and controlled.

Intramuscular sedation was used to indicate containment of the ward. The rationale to support this is that patients who are uncontained and not responding to verbal de-escalation or oral medication would receive intramuscular sedation. However, it must be noted that this is an indirect measure of containment in the ward. The ward was assessed as a unit, measuring

intramuscular sedation per bed occupied as an indicator of the ward's containment on the day. Therefore, the outcomes encapsulate multiple patients with uncontained episodes and multiple episodes per patient.

This study has assessed the lunar cycle in days, with specific days of the lunar phases (FM, NM, FQ, LQ) being documented for correlation, had any specific day of the lunar cycle shown positive associations. The lunar cycle was not split into quarters, and the time of the day was not considered.

4.3.2 Staff Factors

Since this study used an indirect measure to assess patient containment in a ward setting, staff factors will confound these results. The experience of staff members as well as staff shortages may affect the ability of staff members to contain patients' behaviour. This would have an impact on the amount of intramuscular sedation issued. Different staff members may also have different levels of tolerance regarding patients' behaviour, which would again affect the amount of intramuscular sedation issued.

As mentioned above, the nature of the staff's perceptions around the lunar cycle and psychiatric illness may also play a role. Should staff members expect behavioural changes at certain times of the lunar cycle, they may have a lower threshold to issue medication at these times.

4.3.3 Patient factors

The profile of ward illness was not assessed - the admission process at CHBAH does not admit patients to specific wards based on diagnosis. This would be a confounding factor, as different types of psychiatric illness present with different levels of aggression. However, this does ensure that the ward sample covered the general psychiatric inpatient population.

Patients who are admitted to the ward are also kept for different durations of time. Newly admitted patients may be expected to require more sedation than chronic patients. Further research in this setting can be done in a prospective manner, where data can be recorded around the circumstances of sedation in the context of diagnosis, hence yielding fewer limitations.

4.3.4 Medication Shortages

In the study period, there were significant periods of time when one or more sedatives were out of stock. This was unforeseen and was controlled for in the data analysis. When commonly used medications are not available, clinicians will prescribe alternative medications in an attempt to compensate for these shortages. This may result in differences from general prescription practices in the ward. This has probably had an impact on the results of this study. Other means of patient containment such as physical restraints, seclusion and transfers may have been instituted. These are also indirect measures of patient containment and have not been quantified in the context of medication shortages.

Chapter 5

Conclusion:

There has been a longstanding belief that the lunar cycle has an effect on human behaviour. This study aimed to investigate whether an association exists between the lunar cycle and the amount of intramuscular sedation required by an inpatient psychiatric population. The results of this study have concluded that inpatient psychiatric disruptive symptoms, when assessed by measuring the quantity and type of intramuscular sedation used, is not exacerbated or influenced by any particular day of the lunar cycle. This proves the null hypothesis.

This research will be of benefit to address and educate healthcare providers regarding possible suspicious beliefs around the lunar cycle affecting mental illness, and serves as a basis for further research in this area within a South African setting.

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Appendix A. Data Collection Sheet

Ward:

Month and Year:

Date	Day	PH Indicator	Day of Lunar Cycle	Moon phase Indicator	Bed occupancy	haloperidol		clothiapine		clonazepam		lorazepam	
						Total mg	#IMI	Total mg	#IMI	Total mg	#IMI	Total mg	#IMI
1													
2													
3													

Appendix B. Ethics Clearance by the Human Research Ethics Committee of the University of the Witwatersrand

R14/49 Dr Faeeza Mohamed

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160634

NAME: (Principal Investigator)	Dr Faeeza Mohamed
DEPARTMENT:	Psychiatry Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Lunar Cycle and Inpatient Sedation Usage in a Psychiatric Setting
DATE CONSIDERED:	24/06/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Wendy Friedlander

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 27/06/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

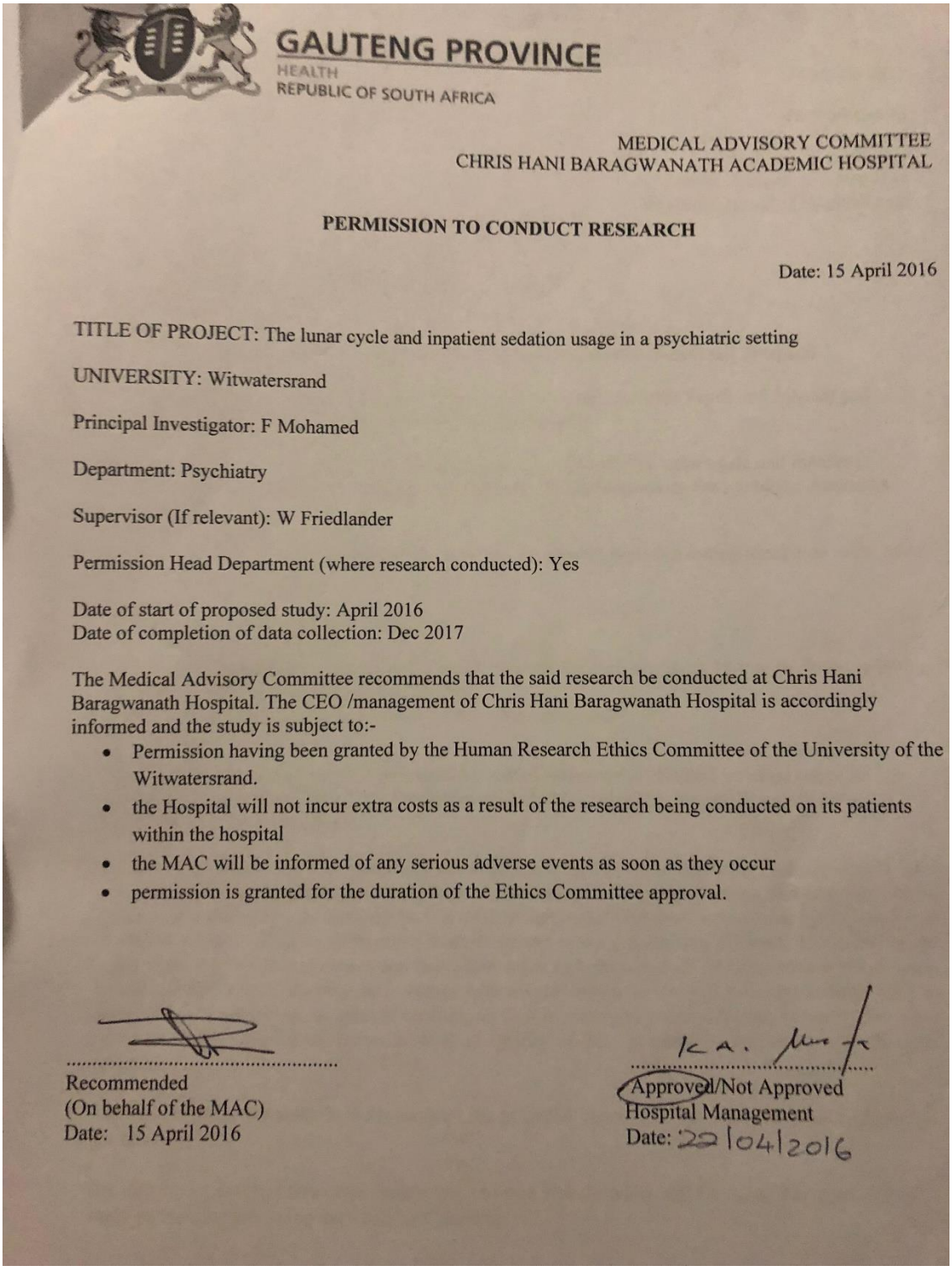
To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in June and will therefore be due in the month of June each year.

Principal Investigator Signature

Date 10/7/16

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C. Letter from CEO of Chris Hani Baragwanath Academic Hospital granting permission to conduct study



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 15 April 2016

TITLE OF PROJECT: The lunar cycle and inpatient sedation usage in a psychiatric setting

UNIVERSITY: Witwatersrand

Principal Investigator: F Mohamed

Department: Psychiatry

Supervisor (If relevant): W Friedlander

Permission Head Department (where research conducted): Yes

Date of start of proposed study: April 2016
Date of completion of data collection: Dec 2017

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 15 April 2016

.....
Approved/Not Approved
Hospital Management
Date: 22/04/2016

Appendix D.

n=549

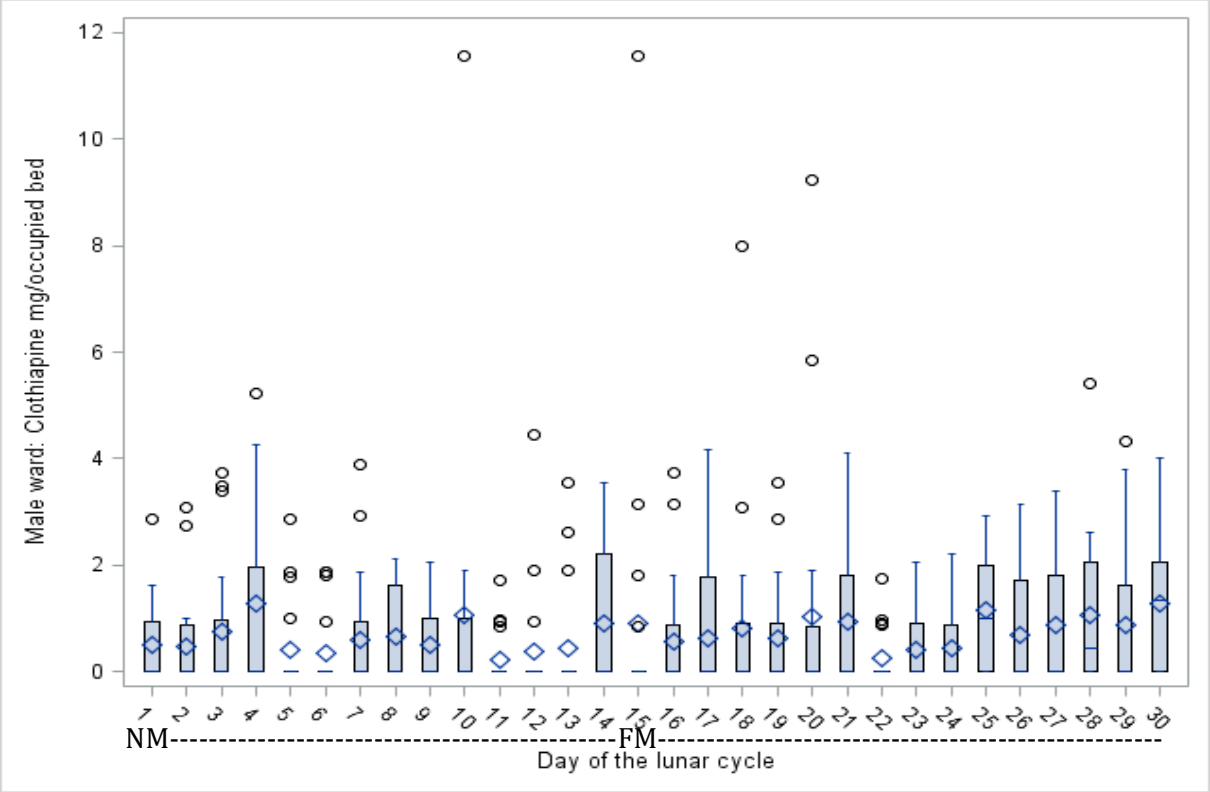


Figure 3.3. Clothiapine (male): mg per bed occupied

Table 3.7. Clothiapine (male): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	30,93	0,37
Day Type	1	0,44	0,51
Any medication out of stock	1	1,35	0,25

n=549

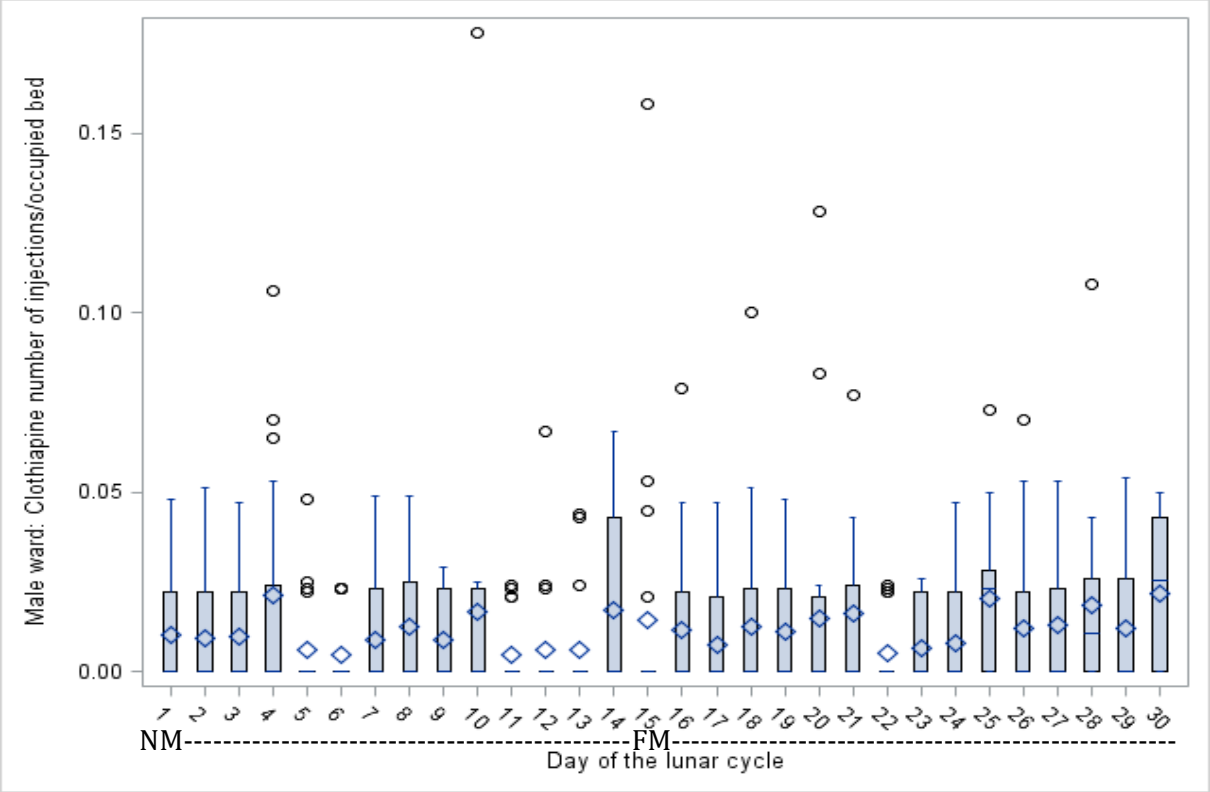


Figure 3.4 Clothiapine (male): number of IMIs per bed occupied

Table 3.8. Clothiapine (male): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	30,93	0,37
Day Type	1	0,44	0,51
Any medication out of stock	1	1,35	0,25

n=549

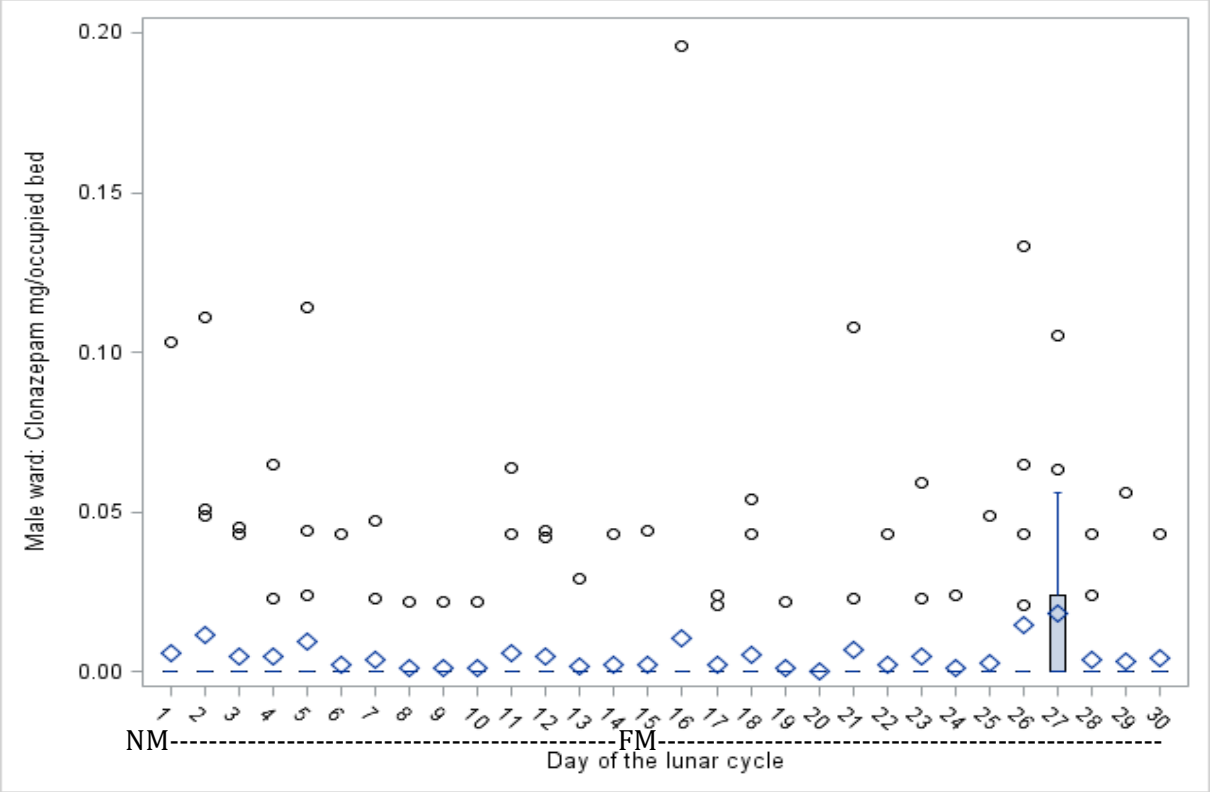


Figure 3.5. Clonazepam (male): mg per bed occupied

Table 3.9. Clonazepam (male): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	24,69	0,69
Day Type	1	0,00	0,97
Any medication out of stock	1	7,57	0,0059

n=549

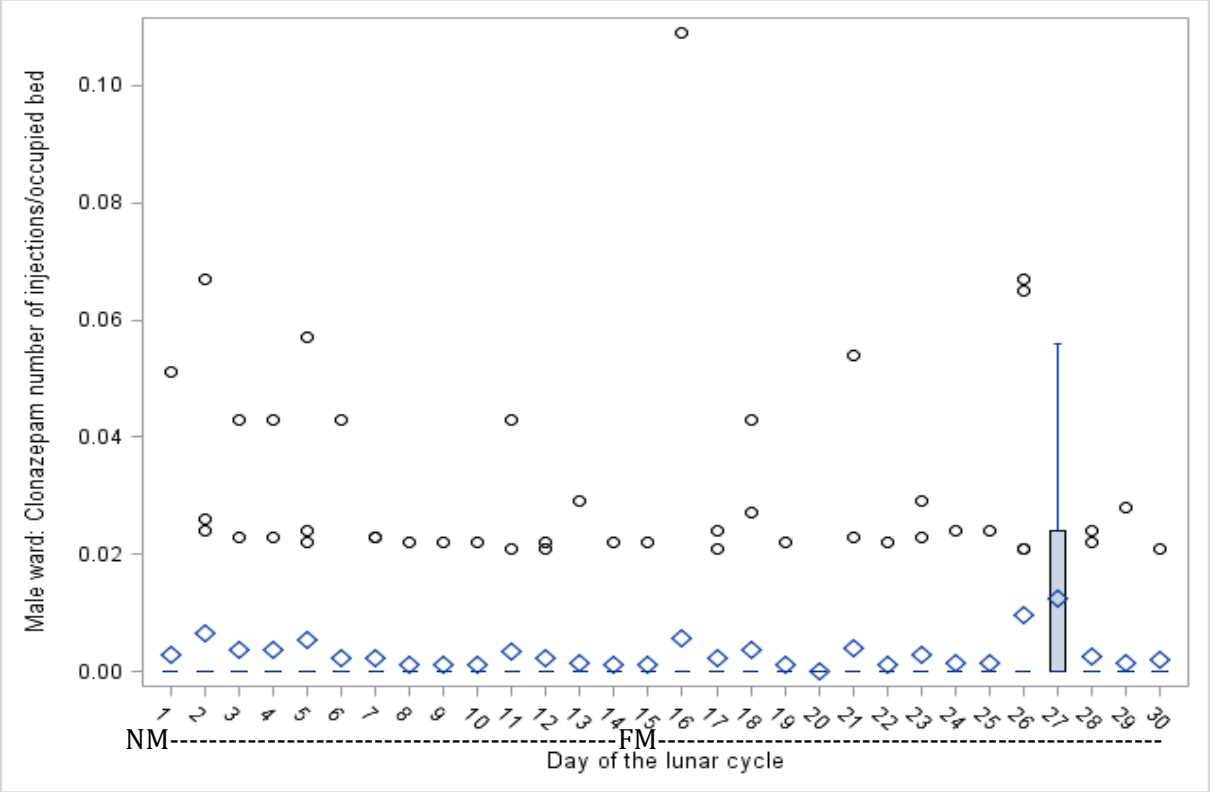


Figure 3.6.Clonazepam (male): number of IMIs per bed occupied

Table 3.10. Clonazepam (male): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	26,67	0,59
Day Type	1	0,15	0,69
Any medication out of stock	1	10,94	0,0009

n=440; 1 outlier removed

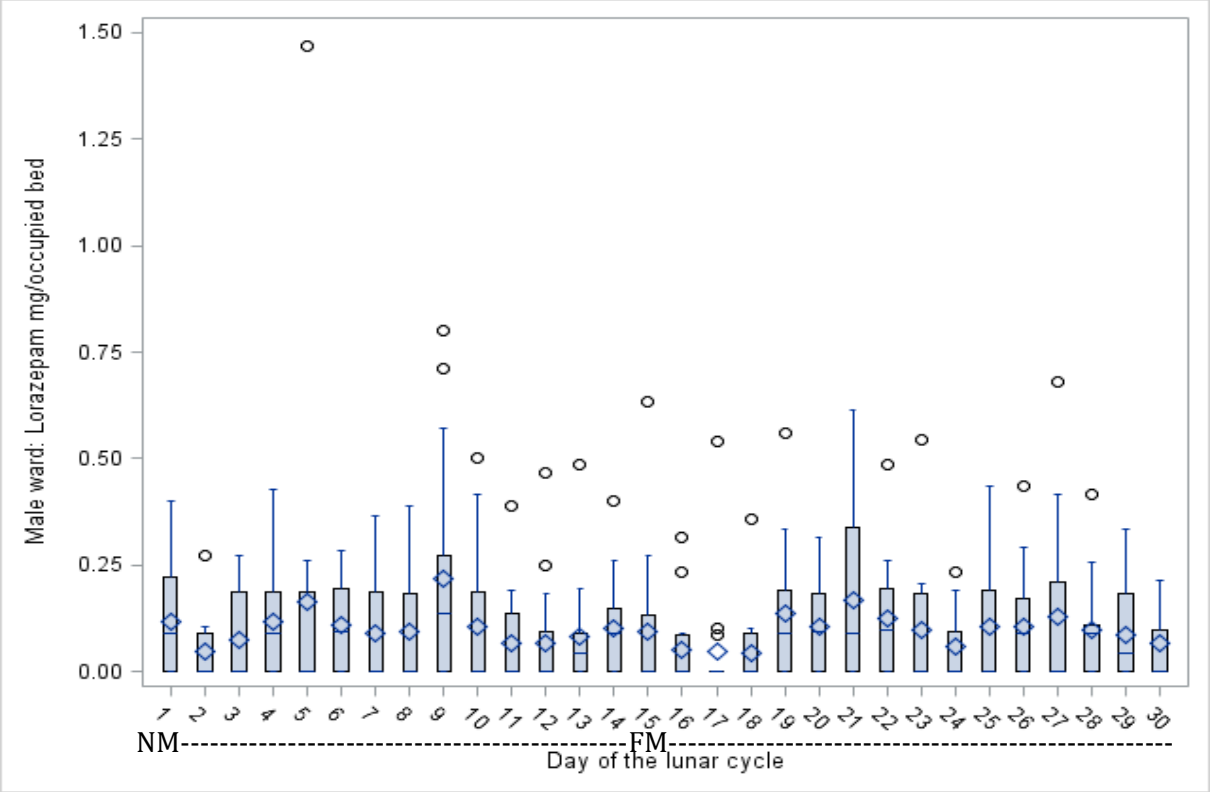


Figure3.7. Lorazepam (male): mg per bed occupied

Table 3.11. Lorazepam (male): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	10,85	0,99
Day Type	1	0,12	0,72
Any medication out of stock	1	0,05	0,83

n=441

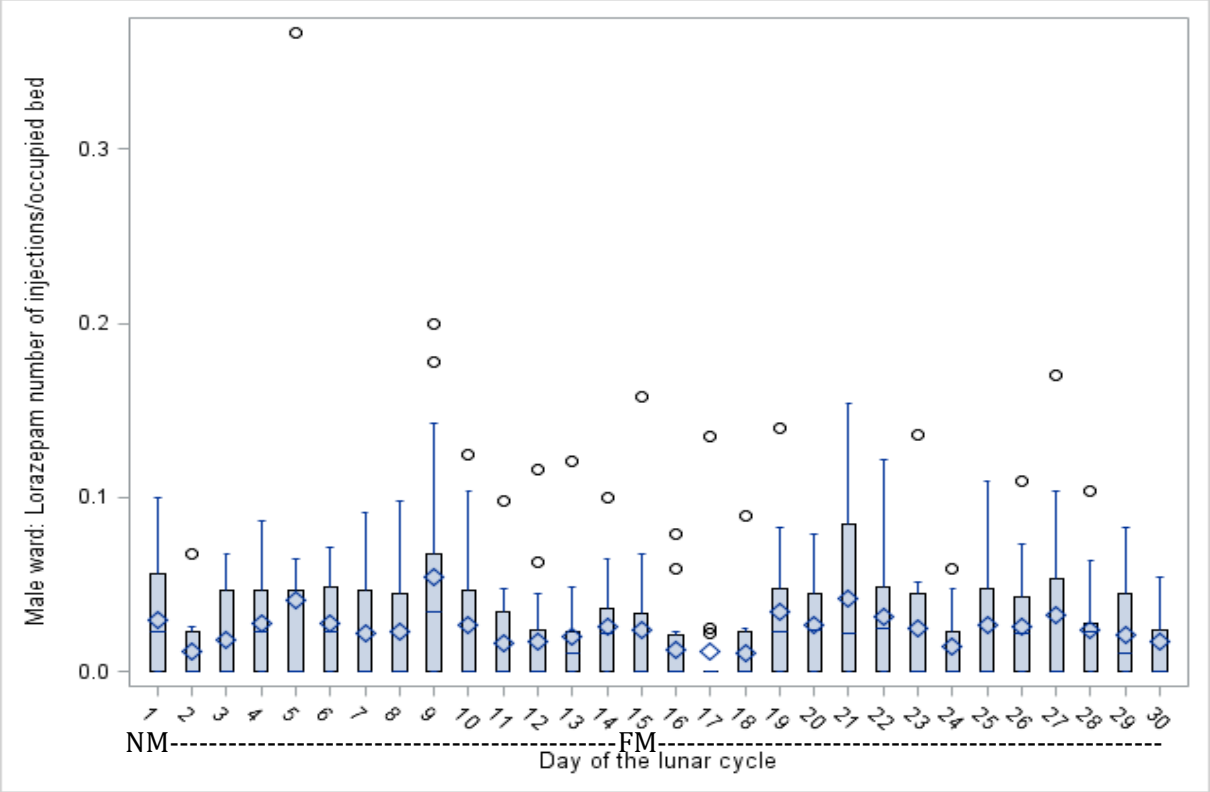


Figure 3.8. Lorazepam (male): number of IMIs per bed occupied

Table 3.12. Lorazepam (male): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	29,22	0,45
Day Type	1	1,08	0,30
Any medication out of stock	1	5,77	0,016

n=549

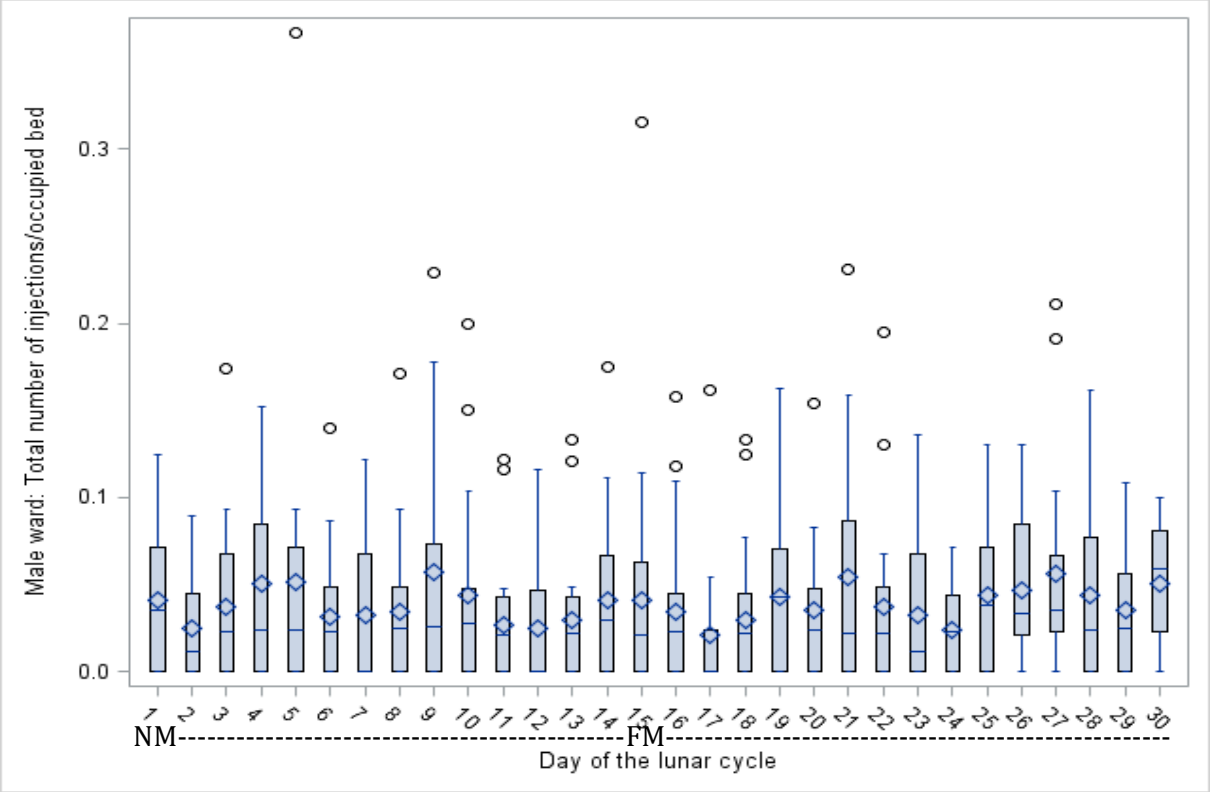


Figure 3.9. Total number of IMIs per bed occupied (male)

Table 3.13. Total number of IMIs per bed occupied (male)

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	23,03	0,78
Day Type	1	0,04	0,84
Any medication out of stock	1	0,49	0,49

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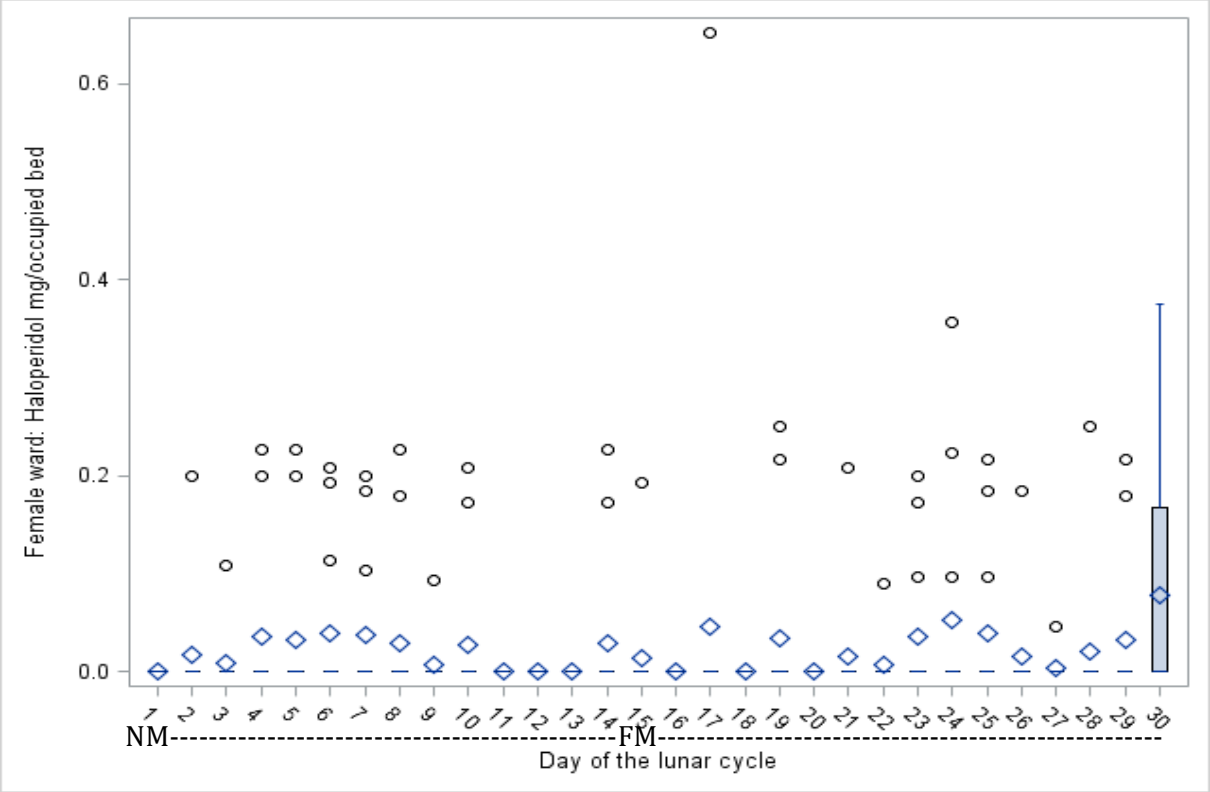

Figure 3.10. Haloperidol (female): mg per bed occupied

Table 3.15. haloperidol (female): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	32,30	0,31
Day Type	1	0,08	0,78
Any medication out of stock	1	0,53	0,46

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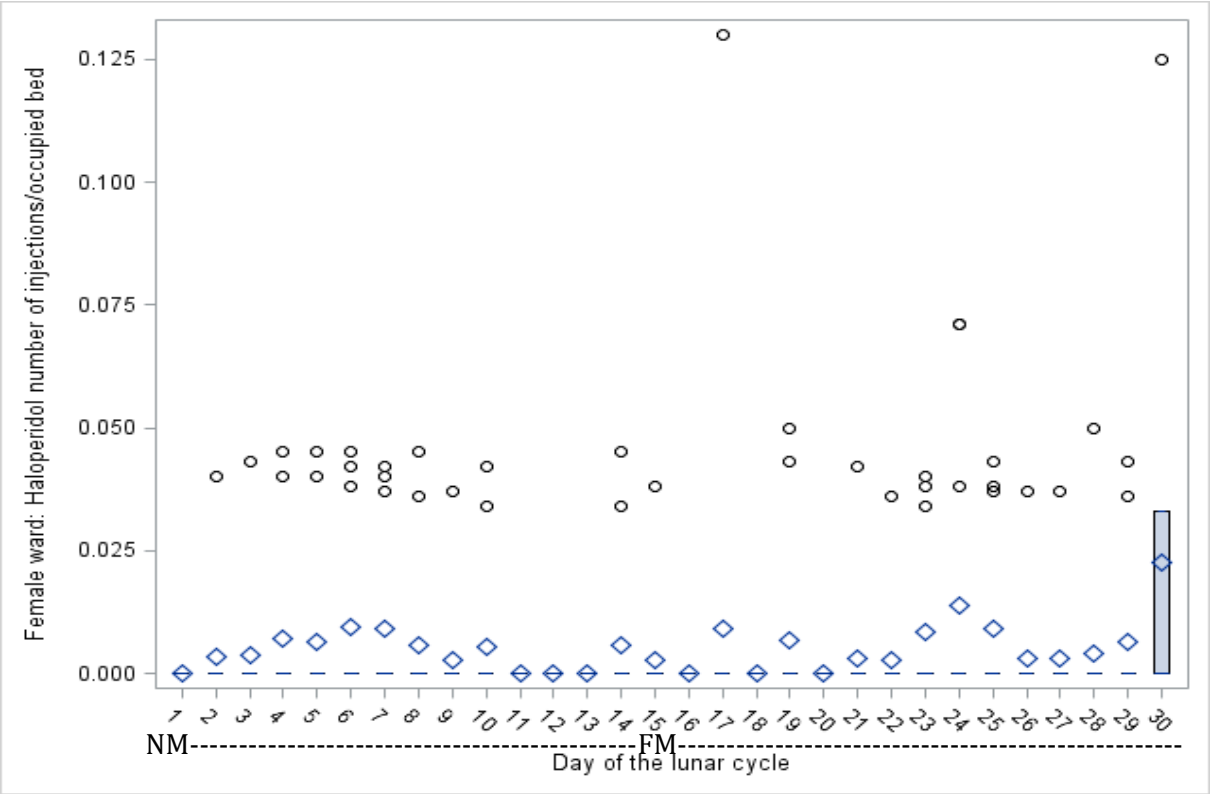

Figure 3.11. Haloperidol (female): number of IMIs per bed occupied

Table 3.16. Haloperidol (female): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	31,06	0,36
Day Type	1	0,05	0,82
Any medication out of stock	1	0,37	0,55

n=549

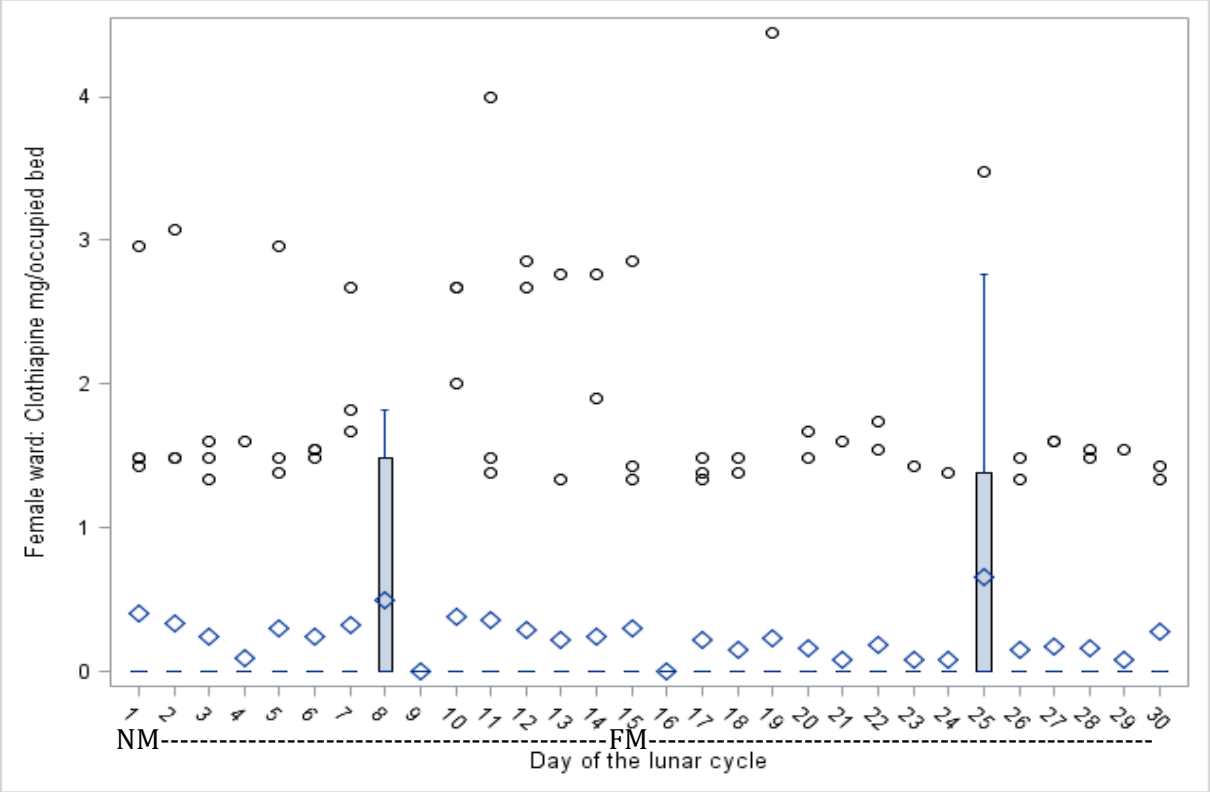

Figure 3.12. Clothiapine (female): mg per bed occupied

Table 3.17. Clothiapine (female): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	18,44	0,93
Day Type	1	2,59	0,11
Any medication out of stock	1	5,66	0,017

n=549

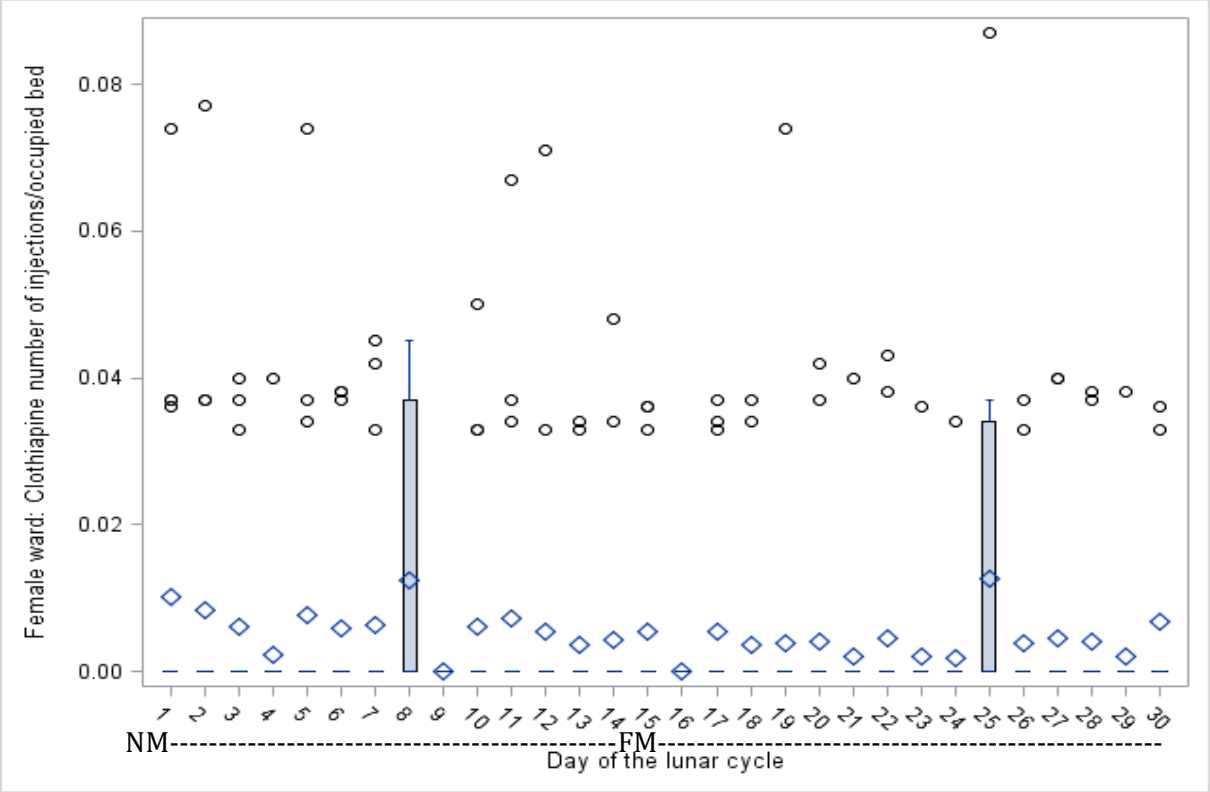

Figure 3.13. Clothiapine (female): number of IMIs per bed occupied

Table 3.18. Clothiapine (female): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	19,32	0,91
Day Type	1	2,99	0,084
Any medication out of stock	1	4,88	0,027

n=548; 1 outlier removed

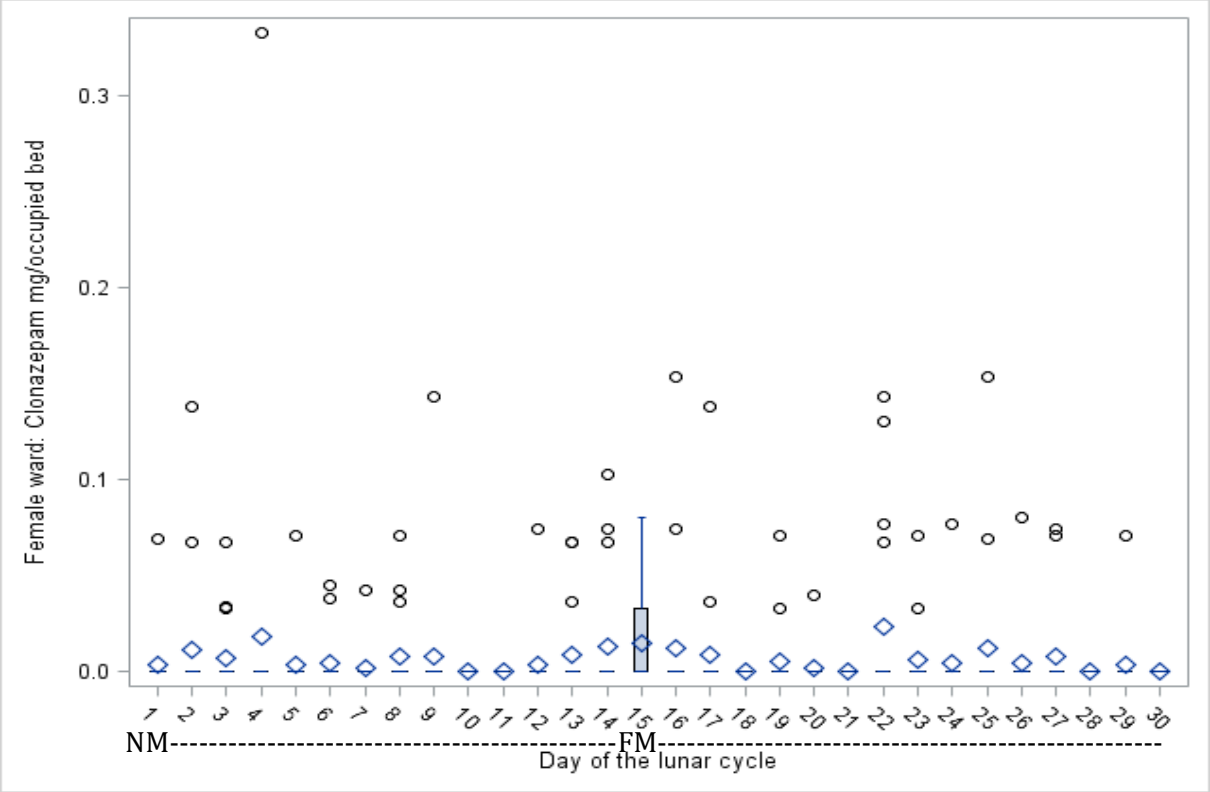

Figure 3.14. Clonazepam (female): mg per bed occupied

Table 3.19. Clonazepam (female): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	43,19	0,044
Day Type	1	0,01	0,92
Any medication out of stock	1	25,24	<.0001

n=549

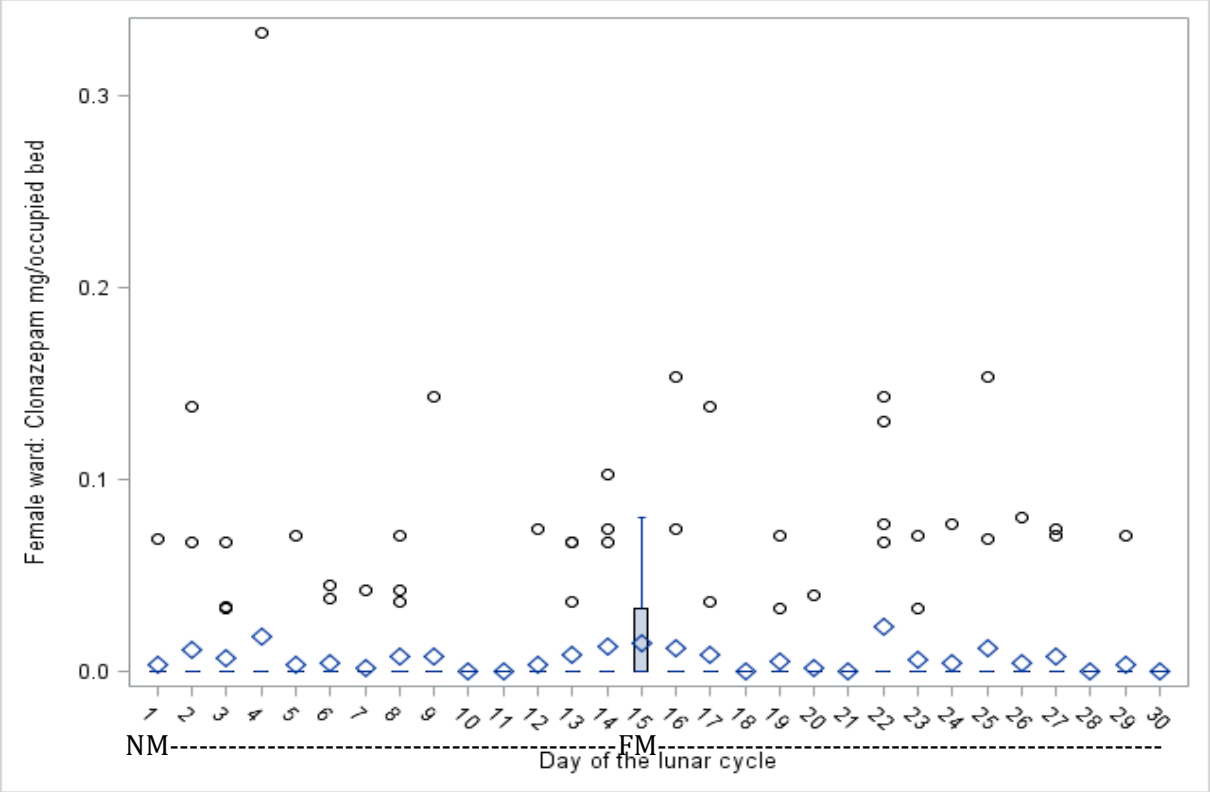

Figure 3.15. Clonazepam (female): number of IMIs per bed occupied

Table 3.20. Clonazepam (female): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	44,67	0,032
Day Type	1	0,00	0,98
Any medication out of stock	1	25,26	<.0001

n=388; 1 outlier removed

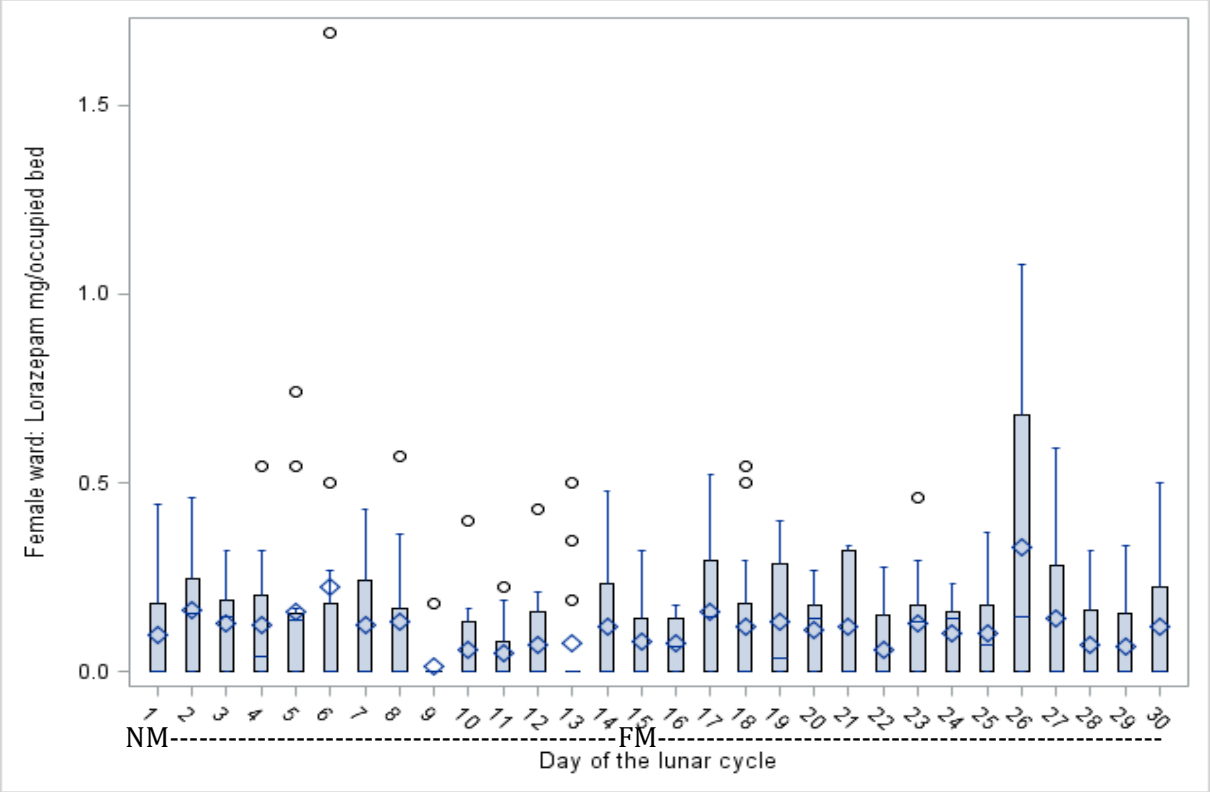

Figure 3.16. Lorazepam (female): mg per bed occupied

Table 3.21. Lorazepam (female): mg per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	23,66	0,75
Day Type	1	0,02	0,90
Any medication out of stock	1	0,02	0,90

n=388; 1 outlier removed

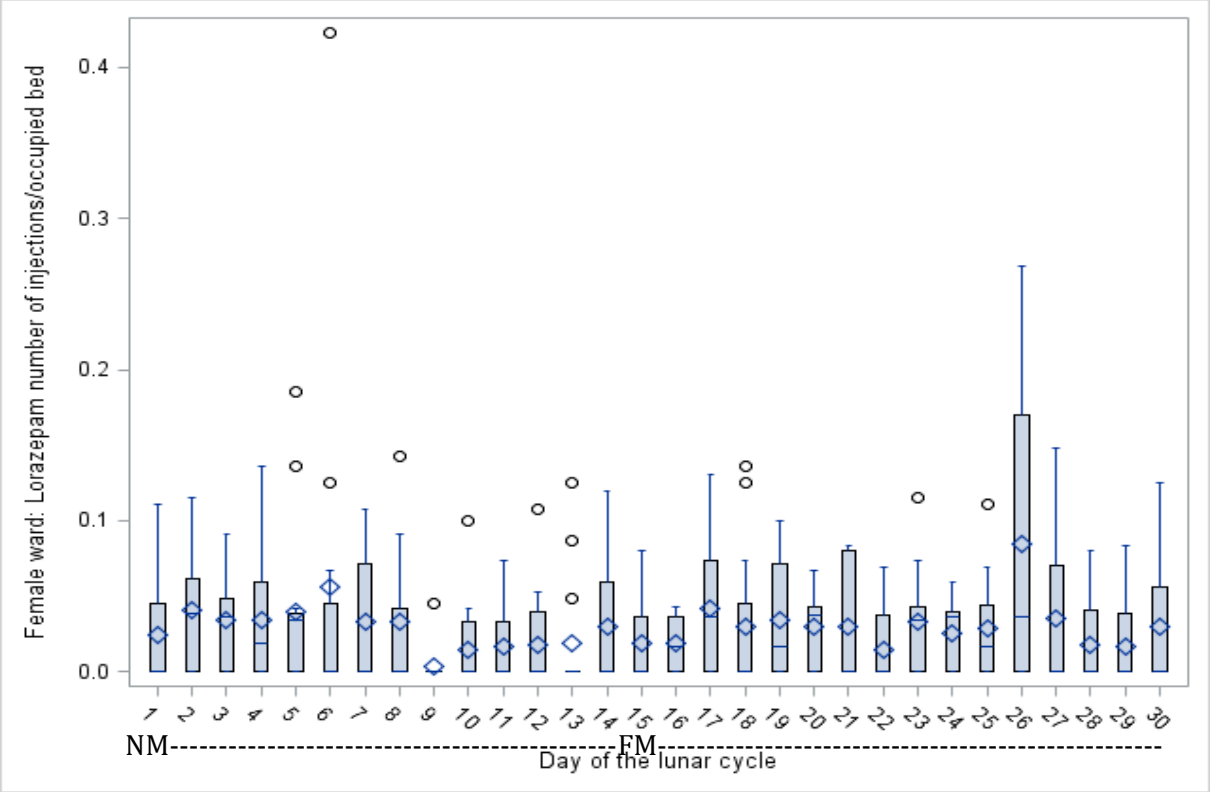

Figure 3.17. Lorazepam (female): number of IMIs per bed occupied

Table 3.22. Lorazepam (female): number of IMIs per bed occupied

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	42,48	0,051
Day Type	1	0,12	0,73
Any medication out of stock	1	0,09	0,76

n=548; 1 outlier removed

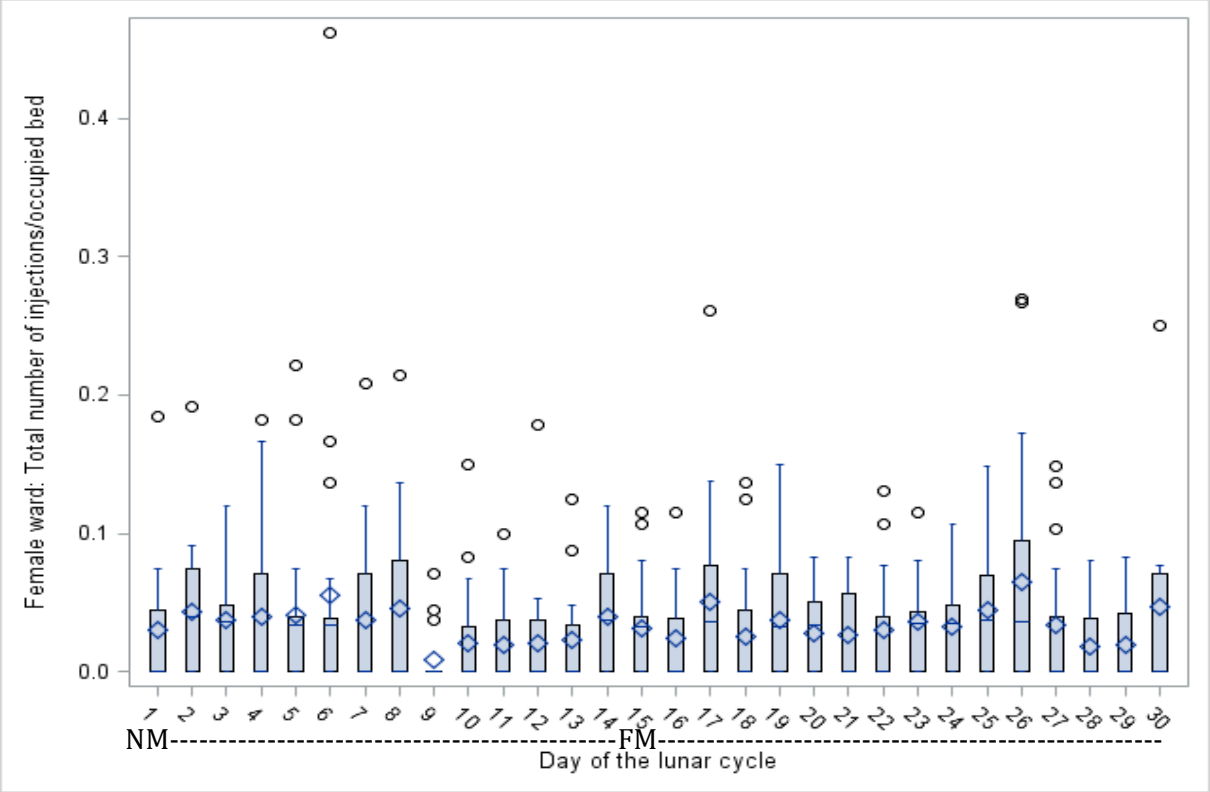

Figure 3.18. Total number of IMIs per bed occupied (female)

Table 3.23. Total number of IMIs per bed occupied (female)

Variable	DF	Chi-Square	p-value
Day of the lunar cycle	29	39,15	0,10
Day Type	1	0,16	0,69
Any medication out of stock	1	6,50	0,011