



**THE PREVALENCE OF ABNORMAL URINE COMPONENTS AS DETECTED BY
ROUTINE DIPSTICK URINALYSIS: A SURVEY AT A PRIMARY HEALTH
CARE CLINIC IN MANKWENG HOSPITAL**

By

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DECLARATION

I, Malemolla Carl Tjale hereby declare that the work on which this research is based is original (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being or is to be submitted for another degree at this or any other university.

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ABSTRACT

Aim: To determine whether routine dipstick urinalysis adds value to the management of patients at Primary Health Care clinic (PHC) in Mankweng Hospital.

Objectives:

1. To determine the prevalence of urine abnormality in patients.
2. To determine components of urine (i.e. blood, protein, glucose etc.) that shows abnormality.
3. To determine the association of urine abnormality with regard to age and gender.
4. To estimate the cost of doing dipstick urinalysis.

Design: This was a cross-sectional, quantitative survey. A fresh urine sample collected from patients attending the clinic was tested for ten components using UriCHECK 10. The cost of the dipstick test was estimated.

Setting: A Primary Health Care clinic in Mankweng Hospital which is a tertiary institution for the province of Limpopo, RSA.

Results: A total of 227 patients participated in the study. Of these, 153(67%) were female and 74(33%) were male. Urine abnormality rate was 35%. The most (26%) abnormalities were found in the age group 20-24 years. The prevalence of abnormalities were 19% blood, 12% leukocytes, 4% protein, 11% ketones, 3% glucose, 3% nitrites and 0.4% urobilinogen. The total cost per 100 urine samples was R319.41.

Conclusions: The prevalence of initial urinary abnormality at primary care setting is high. There is no significant association between urine abnormality and age. Females are more likely to show urine abnormality. Routine dipstick urinalysis does not lead to significant additional cost and can add value to the management of patients at a Primary Health Care setting.

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CHAPTER 1: BACKGROUND OF THE STUDY

Introduction

Urine dipsticks are applied worldwide in various clinical settings (Mazouz B and Almagor M, 2003). Under many conditions, stick technology provides all that is required of it-quickly, conveniently and inexpensively. The only real obstacle to their more widespread use is the difficulty of maintaining the analytical standards when tests are performed outside the laboratory (Marks V, 1991).

A major question for renal medicine in developing countries is how to define strategies that can identify early enough those subjects who are at risk of developing a renal disease later in life. This will make it possible to design population-oriented preventive measures that will limit the need for dialysis and transplantation. The simplest and least expensive way of screening apparently healthy subjects is urinalysis and several studies have been made using reagent strips, documenting their effectiveness in detecting urinary abnormalities at relatively low cost (Plata R, 1998).

Early treatment of chronic kidney disease and its complications may delay or prevent the development of end-stage renal disease. Consequently, detection of chronic kidney disease should be a priority for family physicians. However, data from national screening programs suggest that chronic kidney disease often is not detected, even when patients have access to primary care. High-risk groups that should be screened for chronic kidney disease include patients who have a family history of the disease and patients who have diabetes, hypertension, recurrent urinary tract infections, urinary obstruction, or a systemic illness that affects the kidneys. A recent analysis suggested that screening all patients older than 60 years is cost-effective even when other risk factors for chronic kidney disease are absent; screening low-risk patients younger than 60 years does not appear to be cost-effective (Snyder S and Pendergraph B, 2005).

Microscopic examination of urine is the standard method used to detect pyuria. However, the dipstick test to measure urinary leukocyte esterase activity is quick,

inexpensive, and does not require technical expertise. This test is commonly used to identify pyuria in accident and emergency departments and in out-patient clinics in which a urine microscopy service is not available (Yuen SF, Ng FN and So LY, 2001). A urine dipstick pressed into a wet incontinence pad of an elderly nursing home resident may be an effective method to assess bacteriuria. This method would be easy, safe and inexpensive in the initial evaluation of a Urinary Tract Infection (Midthun SJ et al., 2003).

Asymptomatic dipstick haematuria in adults is a common finding (Mishriki SF, Nabi G and Cohen NP, 2008). Microscopic haematuria without proteinuria is often an incidental finding. Even with a thorough investigation, the source of the microscopic haematuria frequently is not found (Cohen RA and Brown RS, 2003). As with dipstick testing for bacteriuria, which has questionable value for screening adults, so the usefulness of testing for microhaematuria is now doubted (Malmstrong P, 2003).

The Study Problem

Primary Health Care clinic (PHC) at Mankweng hospital serves as a gateway for patients who are not booked. It does not provide all primary health care services which are normally provided at local clinics. The department of Family Medicine which runs the clinic and indeed the whole hospital is experiencing a severe shortage of both medical and nursing personnel. The clinic is run by three primary health care nurses, two medical practitioners and five lower rank nurses on any given day. It runs for seven days a week, except that doctors are not available on weekends. According to the statistics, an average of 2301 patients visits the clinic monthly. The highest number is 2777 so far. This means that just over 80 patients are seen at the clinic daily. One of the challenges is at the vital signs station where only two nurses are allocated. As a result thereof routine dipstick urinalysis has been replaced with urinalysis on a prescription basis. The reasoning behind this decision is that it takes time and needs more manpower. The question that arises is how much urinary abnormality do we miss by not doing dipstick urinalysis routinely?

In the past two years, the hospital overran its budget by a substantial amount. The provincial Department of Health did not allocate more funds to the institution to cover the budget. As a result of this, the hospital has instituted measures to try and save costs. Some of these measures include reducing the number of investigations and tests that are ordered and performed by health care professionals. The cost of doing dipstick urinalysis is both in terms of money and time.

Arguments from Literature

Routine urine dipstick may provide transient or false-positive results, generate unnecessary evaluation and should be eliminated. A positive nitrite or leukocyte esterase reaction and even positive urine culture in an asymptomatic patient are of questionable value and do not necessarily demand therapy. In haematuria, the dipstick neither localises the source of bleeding nor determines whether blood is from pigment or cells. Persistent significant proteinuria usually implies major underlying renal disease. A child can spill substantially more than nephrotic levels of protein and still have a negative dipstick for albumin. Much depends on the degree of urinary dilution. Occasionally, the dipstick protein fails to define orthostatic proteinuria, and a more careful quantitative assessment of urinary protein is required. This in addition to false-positive/transient results, the dipstick may be misleading (Linshaw MA and Gruskin AB, 1997).

The utility of screening urinalyses in asymptomatic paediatric patients has come into question based on data from multiple different studies. The most important problem with screening dipstick urinalysis is the high rate of either false-positive or transient abnormalities detected. The money expended on screening asymptomatic children for renal disease would be well spent if it improved the health of the children. Screening dipstick urinalysis can cause harm. Because of a high false-positive/transient abnormality rate and low prevalence of disease, it serves to cause anxiety and discomfort in many patients and their parents by submitting them to unnecessary evaluation. Many practitioners and researchers have concluded that there is no need for a screening urinalysis in asymptomatic paediatric patients. Interval screening dipstick

urinalysis in asymptomatic paediatric patients is a costly ritual which should be discontinued. In its place, a single, screening dipstick urinalysis should be obtained at school entry age, between 5 and 6 years old, in all asymptomatic children (Kaplan RE, Springate JE and Feld LG, 1997).

The routine nature of urinalysis may make physicians overlook substantial abnormalities; this is unfortunate and should be deplored because of the possible consequences of missing serious curable conditions. An abnormal result should alert physicians and prompt them to change their management lines. At the same time, overestimating the risk of an abnormal urinalysis should be avoided and serious decisions which could affect the patient's future should only be made after adequate investigation of the significance of the abnormalities, because, frequently, simple urinalysis is operator-dependent (Khallid NS and Haddad FH, 1999).

Motivation for the study

There are two issues that need to be addressed. First, it is the question of whether screening or routine dipstick urinalysis will add value to the management of patients who attend at Mankweng hospital's Primary Health Care clinic (PHC). Although there is extensive literature coverage of this topic, Mankweng hospital management needs to make a decision based on local research.

Secondly, the cost implications of such a programme need to be assessed in view of the tight budget alluded to earlier. It is these two issues that prompted me to undertake a survey to investigate the necessity of doing routine dipstick urinalysis at Mankweng Hospital's Primary Health Care clinic.

Research Question

Does screening or routine dipstick urinalysis add value to the management of patients who attend at Mankweng Hospital's Primary Health Care Clinic (PHC)?

Aim of the study

The main purpose of this study is to determine whether routine dipstick urinalysis adds value to the management of patients at Primary Health Care clinic in Mankweng Hospital.

Objectives of the study

1. To determine the prevalence of urine abnormality in patients.
2. To determine components of urine (i.e. blood, protein, glucose etc.) that shows abnormality.
3. To determine the association of urine abnormality with regard to age and gender.
4. To estimate the cost of doing dipstick urinalysis.

CHAPTER 2: LITERATURE REVIEW

Introduction

In this chapter, we attempt to do a comprehensive appraisal of literature which is pertinent to the problem outlined in chapter 1. The literature is mainly from reputable scientific journals worldwide. The search for articles was done on the internet using search engines such as Pubmed, ScienceDirect, Google and Google Scholar. The information is then synthesised and organised into various topics to cover the full spectrum of dipstick urinalysis.

Routine Dipstick Urinalysis: Is it worthwhile

A complete urinalysis includes physical, chemical and microscopic examinations. Midstream clean catch collection is acceptable in most situations, but the specimen should be examined within two hours of collection. Cloudy urine often is a result of precipitated phosphate crystals in alkaline urine, but pyuria also can be the cause. A strong odour may be the result of a concentrated specimen rather than a urinary tract infection. Dipstick urinalysis is convenient, but false-positive and false-negative results can occur. Specific gravity provides a reliable assessment of the patient's hydration status. Glomerular, renal and urologic causes of microhaematuria often can be differentiated by other elements of the urinalysis. Although transient proteinuria typically is a benign condition, persistent proteinuria requires further work-up. Uncomplicated urinary tract infections diagnosed by positive leukocyte esterase and nitrite tests can be treated without culture. (Simerville JA et al., 2005)

Urinalysis is an essential part of clinical assessment. An abnormal urinalysis, mainly proteinuria, has serious implications for a person and may lead to rejection from the armed forces, denial of life insurance or disqualification from a new job. In clinical practice, it is better to do urinalysis in all patients as a check against having missed a clue to relevant disease in the history or examination. The finding of an abnormality in routine urinalysis is of no importance if it does not lead to useful corrective treatment. The detection of proteinuria and/or haematuria is useful in selecting patients who

require long-term surveillance. In some patients, proteinuria may last for many years without other evidence of kidney damage, or it may be an insignificant and transient laboratory finding. Haematuria, after exclusion of serious urinary tract infection, renal calculi and malignancy may follow a benign course and have a good prognosis. Glycosuria is highly inducible and has significant correlation with blood glucose level. Pyuria is a common problem mainly in women; it has been reported that as many as a quarter may experience an acute dysuric episode each year (Khallid NS and Haddad FH, 1999).

Screening interval urinalyses have long been considered essential to paediatric well care. A urinalysis is recommended at four times: infancy, early childhood, late childhood and in adolescence. The utility of screening urinalyses in symptomatic paediatric patients has come into question based on data from multiple different studies. In the present health care environment, cost-benefit analysis is extremely important (Kaplan ER, Springate JE and Feld LG, 1997).

Although urinalysis for proteinuria and haematuria is a basic tool in the investigation of renal tract disease, the role of population-wide urine screening remains contentious. The justification for urine screening remains questionable given the relative rarity of renal disease and the lack of specific therapy. Existing data on screening focus on those aged over 35 years. There are few data regarding the value of urine screening in younger populations (Topham PS et al., 2004).

There is now unprecedented emphasis on reducing the number of medical tests and costs. Routine testing of infants is unnecessary and, thus, cost of bags, cultures, and urinalysis can be eliminated. The health screen including analyses of electrolytes, blood urea nitrogen, creatinine, albumin, total protein, and so forth, is unnecessary in cases of mild haematuria or minimal or orthostatic proteinuria. This will also reduce costs. A routine multidipstick screen using a first morning specimen should be obtained no later than at school entry, perhaps even as early as age 3 (when it becomes easier to obtain urine). Asymptomatic proteinuria and haematuria are often benign and nonprogressive and, therefore, extensive and repeated laboratory tests are not warranted. However,

when a dipstick reveals persistent proteinuria or haematuria, a meticulous evaluation of urine sediment should precede any additional laboratory evaluation (Linshaw MA and Gruskin AB, 1997).

Urine dipstick has been used successfully as a screening test for serum creatinine elevation in Emergency Department patients with severe hypertension. Specifically, proteinuria and haematuria on dipstick urinalysis correlate with impaired renal function. Proteinuria on urine dipstick correlates directly with significantly higher serum creatinine. Proteinuria plus haematuria on urine dipstick correlates even stronger and is sensitive for detecting elevated serum creatinine in Emergency Department patients (Firestone D et al., 2007).

The technological key to stick testing is dry chemistry. This typically comprises thin pads or films containing all the reagents required for performing an assay. The number of substances of clinical importance that can be measured by dry chemistry technology in urine has grown almost exponentially and shows no sign of diminishing. Many stick tests are performed on urine, mainly for analytes such as glucose and protein, but now that the technological difficulties of the measurements have been overcome, increasing attention is being given to their clinical usefulness and cost effectiveness. There is no limit to the number of analytes for which stick tests can be developed nor is the format restricted only to analytes of clinical interest. Tests for pregnancy and predicting ovulation are examples of over the counter tests currently available. When all cost elements are taken into account many of the single analyte stick tests are competitive with similar tests performed in a central laboratory and have the added advantage of timeliness (Marks V, 1991).

Accuracy and Reliability of Urine Dipstick

It is difficult to draw conclusions about the overall accuracy of dipstick tests given the heterogeneity between studies in some areas, and the lack of data in others (Whiting P et al., 2006).

Urinalysis, originally called uroscopy, was first described in the early eighteenth century. Urinalysis, especially the microscopic component of the analysis, remains a time-consuming and labour-intensive test done by the laboratory. Dipstick reagent strips are often used as a quick screening test but there is controversy surrounding their accuracy and appropriateness. There are some data to suggest that semi-automated reading is more accurate than visual reading of urine dipsticks. For the following components of urinalysis, red blood cell urinalysis, red blood cell microscopy, leukocyte esterase, and nitrite, there is a close agreement between the results obtained by the emergency physician and the laboratory. For white blood cell analysis, bacterial microscopy and measurement of proteinuria, there is poor agreement (Kerr S, Marshall C and Sinclair D, 1999). The combination of a positive test for both nitrite and leukocyte esterase was found to be most accurate for ruling in disease, and a negative test for both nitrite and leukocyte esterase was found to be most accurate for ruling out disease. A test for absence of urinary glucose was found to be considerably better than the other tests, for both ruling in and ruling out disease (Whiting P, 2006).

For screening purposes, in order not to miss a diagnosis, sensitivity is more important than specificity. A good screening test accepts false positives while minimizing false negatives. Sensitivities and specificities for dipstick analysis are similar to the 80% values reported by others studying paediatric patients, therefore supporting elimination of the microscopic portion of urinalysis, saving time and money for children 2 years of age and above (Craver RD and Abermanis JG, 1996).

Substituting a urine dipstick test for a hospital laboratory urinalysis may be less time-consuming and less expensive, but the dipstick may not be as accurate. Diagnostic accuracy of urine dipsticks is unclear because methodologies, such as definitions of a positive urine culture and thresholds for test positivity, vary among published studies. Consequently, some authors recommend confirmatory urinalyses if the urine dipstick results are negative, and others if results are positive (Lammers RL et al., 2001).

The value of Urine Screening

Any health screening programme is justified by its capacity to identify patients with significant treatable disease using a technique which is acceptable to the general population, has high specificity and sensitivity and is cost effective. In younger age groups (<30 years), the prevalence of persistent isolated microscopic haematuria is reported to be <2%. Since malignancy is very rare in young adults, the purpose of screening is to identify renal stones, structural renal tract abnormalities or parenchymal renal disease. The prevalence of persistent haematuria and proteinuria is <1% in all age groups. Nonetheless, the combination of haematuria and proteinuria is a powerful predictor of significant parenchymal disease (Topham PS et al., 2004).

The tradition of glycosuria screening at each prenatal visit dates back to an era when this was the principal method of diagnosing gestational diabetes and monitoring its treatment. However, the correlation between urine and blood glucose is poor in pregnancy. Women with dipsticks positive for glucose during the first two trimesters have a greater likelihood of having gestational diabetes diagnosed when they undergo blood glucose screening at 24-28 weeks. It has been shown that at least some women with gestational diabetes can be identified sooner than 24-28 weeks by doing earlier blood screening. Therefore, because glycosuria during the first two trimesters is more common in women who are later found to have gestational diabetes, it may be reasonable to use the presence of glycosuria as an indication for earlier blood screening. However, it is noted that only a minority of women diagnosed with gestational diabetes have glycosuria in the first two trimesters (Gribble RK, Meier PR and Berg RL, 1995).

Elders who are incontinent and confused pose a special challenge for determining the presence of a urinary tract infection. They may exhibit some urinary tract infection symptoms chronically and may not be able to communicate the presence of others, such as pain or temperature. A urine dipstick pressed into a wet incontinence pad of an elderly nursing home resident may be an effective method to assess bacteriuria (Midthun SJ et al., 2003). The leukocyte esterase and nitrite tests on dipstick products

are commonly used as preliminary evaluations of random urine specimens to support the diagnosis of urinary tract infections or to support the decision to analyse urine for microorganisms by culture techniques (Lyon ME, 2003).

Time and Cost

In this era of cost constraints, economic analyses are increasingly used to identify costs hidden in the simplest basic tests. This may be the case of urinalysis, a pivotal test in general practice and in nephrology, where it influences diagnostic and therapeutic procedures. Urinalysis is demanding and relatively expensive. Time is the major determinant of the costs; microscopic urinalysis is the most expensive and time-consuming item. Time ranges are wide: technician time 3.2 to over 10 minutes per sample; biologist-nephrologist time dedicated to the morphological reading, from 3 to 12 minutes per sample (Piccoli GB et al., 2002).

A fiscal assessment of testing is part of a good management programme. Before offering a new test, consider the level of reimbursement and factors that contribute to total test cost. These factors include:

- Tests kits or instruments, supplies not provided with the test, control and calibration materials, inventory requirements for anticipated test volume (including seasonal testing), and the shelf life of test components and supplies.
- Equipment maintenance, such as repairs or preventive maintenance contracts.
- Additional safety and biohazard equipment.
- Personnel training, competency assessment, and the potential need for additional personnel.
- Recordkeeping and information systems.
- Required supplemental/confirmatory testing.
- Regulatory compliance.
- Resource needs to manage public health reporting, if required nationally or by the state (Howerton D et al., 2005).

Specimen Collection

Types of urine specimens

Over the course of 24-hour period, the composition and the concentration of urine changes continuously. For this reason, various types of specimens may be collected including:

- First morning specimen
- Single random specimen
- Timed short-term specimen
- Timed long-term specimen: 12 or 24 hours
- Catheterised specimen or specimen from an indwelling catheter
- Double voided specimens (test for sugar and acetone)
- Clean-catch (midstream) specimen for urine culture and cytological analyses.

A midstream clean-catch technique usually is adequate in men and women. Although prior cleansing of the external genitalia is often recommended in women, it has no proven benefit. Urine must be refrigerated if it cannot be examined promptly; delays of more than two hours between collection and examination often cause unreliable results (Simerville JA et al., 2005).

The accurate diagnosis of a urinary tract infection is necessary to ensure appropriate therapy for infected children and to avoid unnecessary therapy and prevent hospital admission for additional evaluation in noninfected children. A urine culture result is considered the gold standard for diagnosis of a urinary tract infection, but difficulty in specimen collection and interpretation of inadequately collected specimens may contribute to its misdiagnosis in children. The clean-catch midstream technique is time-consuming to explain, frequently performed incorrectly, and associated with increased costs. Several studies in adults have reported no difference in contamination rates between midstream clean-catch and midstream non-clean-catch urine samples (Vaillancourt S et al., 2007).

Physical properties: Colour and Odour

Foods, medications, metabolic products and infection can cause abnormal urine colours. Cloudy urine often is a result of precipitated phosphate crystals in alkaline urine, but pyuria also can be the cause. The normal odour of urine is described as urinoid; this odour can be strong in concentrated specimens but does not imply infection. Diabetic ketoacidosis can cause urine to have a fruity or sweet odour, and alkaline fermentation can cause an ammoniacal odour after prolonged bladder retention. Persons with UTIs often have urine with a pungent smell. Gastro-intestinal fistulas are associated with a fecal smell and cystine decomposition is associated with a sulfuric smell. (Simerville JA et al., 2005).

Historically, urine examination involved assessment of the appearance, smell and taste of urine, and physicians, known as Pisse Prophets, carved out lucrative careers based on urine examination (uroscopy) and its interpretation (uromancy). The macroscopic appearance of urine can, occasionally, be useful. The urine of patients presenting with acute porphyria is dark reddish-brown (urinary porphobilinogen), and this becomes more pronounced if the urine is left standing. Chyluria is also characteristic, with the urine having 'milky' appearance due to the presence of lipids, especially triglycerides, in the urine (Barrat J, 2007).

Dipstick Urinalysis

False-positive and false-negative results are not unusual in dipstick urinalysis. (Simerville JA et al., 2005).

Specific gravity

Urinary specific gravity (USG) correlates with urine osmolality and gives important insight into the patient's hydration. It also reflects the concentrating ability of the kidneys. Normal USG can range from 1.003 to 1.030, a value of less than 1.010 indicates relative hydration, and a value of greater than 1.020 indicates relative dehydration. (Simerville JA et al., 2005). A low specific gravity can be seen in intrinsic renal disease and a high specific gravity in patients with dehydration, fever, vomiting

and diarrhoea. Assuming a thorough history and examination have been undertaken, the urine specific gravity rarely adds to the assessment of the patient (Barrat J, 2007).

Urinary pH

Urinary pH can range from 4.5 to 8 but normally is slightly acidic (5.5 to 6.5) because of metabolic activity. Urinary pH generally reflects the serum pH, except in patients with renal tubular acidosis (Simerville JA et al., 2005).

In isolation, urine pH cannot be reliably interpreted and therefore should be used only in assessing the patient in specific circumstances (for example, renal tubular acidosis). If a urine sample is strongly alkaline one should, however, consider a UTI with a urease-producing bacteria (urease catalyses the conversion of urea to ammonia) (Barrat J, 2007).

Haematuria

The dipstick test for blood detects the peroxidase activity of erythrocytes. However, myoglobin and hemoglobin also will catalyse this reaction, so a positive test result may indicate haematuria, myoglobinuria or hemoglobinuria. (Simerville JA et al., 2005). Microscopic haematuria is defined as the excretion of more than three red blood cells per high-power field in a centrifuged urine specimen. Because the degree of haematuria bears no relation to the seriousness of the underlying cause, haematuria should be considered a symptom of serious disease until proved otherwise. The prevalence of asymptomatic microscopic haematuria in adult men and postmenopausal women has been reported to range from 10 percent to as high as 20 percent. A spotted pattern to the dipstick indicates the presence of free hemoglobin. Dipstick testing has been shown to be 91 to 100 percent sensitive and 65-99 percent specific for the detection of hemoglobin (Thaller TR and Wang LP, 1999). Haematuria has been classified into four categories: life-threatening; significant, requiring treatment; significant, requiring observation; and insignificant (Grossfeld GD et al., 2001).

Persistent or intermittent haematuria is an alarming symptom for the patient and his doctor. Haematuria can be caused by a number of conditions, including infections and stone disease of the urinary tract, malignant disorders, coagulation disorders and

intrinsic renal disease(for example glomerulonephritis). Woolhandler and co-workers reviewed five population-based studies, and mention a prevalence of asymptomatic haematuria of 0.19 to 16.1%. Mohr and co-workers found a prevalence of 13% in a population that consisted of men older than 35 years of age and postmenopausal women. Briton reported the presence of occult haematuria in 20.1% of men over 60 years of age undergoing screening for bladder cancer using dipstick tests. Various studies have shown that the prevalence of asymptomatic haematuria increases with age, whereas others found no correlation between advanced age and the prevalence of occult haematuria. Myoglobinuria, poorly washed glassware, the presence of oxidizing agents in the urine (e.g. povidine) and bacterial contamination are common causes of a false-positive dipstick test, whereas urinary samples that contain ascorbic acid or formaldehyde, or have low pH (<5.1), can lead to a false-negative dipstick test (Huussen J,Koene RAP and Hilbrands LB, 2004).

Because reagent strips for urine hemoglobin cannot be used to distinguish readily between the presence of erythrocytes and free hemoglobin or myoglobin, the positive results of a dipstick test must be confirmed by microscopic examination. Women may be susceptible to contamination of the urine by blood from menses or lesions of the reproductive tract, thus, these sources of blood loss must be considered in the history, the physical examination and in the timing of follow-up testing. Failure to confirm haematuria on repeat testing is reassuring, although some sources have recommended repeated tests over the following year to reduce the likelihood of occult disease (House AA and Cattran DC, 2002).

Haematuria can be measured quantitatively by any of the following:(1) determination of the number of red blood cells per milliliter of urine excreted (chamber count), (2) direct examination of the centrifuged urinary sediment(sediment count) or (3) indirect examination of the urine dipstick(the simplest way to detect microscopic haematuria). Patients with asymptomatic microscopic haematuria who are at risk for urologic disease or primary renal disease should undergo an appropriate evaluation. In patients at low risk for disease, some components of the evaluation may be deferred (Grossfeld GD et al., 2001).

Microscopic haematuria without proteinuria is often an incidental finding. Even with a thorough investigation, the source of the microscopic haematuria frequently is not found (Cohen RA and Brown RS, 2003). No additional clinical investigations are required during pregnancy in women found to have dipstick-positive haematuria in the absence of urinary tract infection (Brown MA et al., 2005).

Microscopic haematuria may be associated with urologic malignancy in up to 10 percent of adults. The aetiologies of microscopic haematuria are numerous and range from clinically insignificant causes to potentially life-threatening neoplastic lesions. Evaluation of the upper urinary tract followed by cystoscopy fails to identify the source of microscopic haematuria in 19 to 68 percent of patients. The younger the patient, the less likely it is the aetiology will be identified. Transient microscopic haematuria can be caused by rigorous exercise, sexual intercourse, trauma, digital rectal prostate examination, or menstrual contamination. If transient microscopic haematuria is suspected, follow-up urine studies should demonstrate resolution 48 hours after the discontinuation of these activities. It should be noted, however, that renal cell carcinoma and urothelial tumours also may present with transient microscopic haematuria. Screening asymptomatic patients is not generally recommended (McDonald MM, Swagerty D and Wetzel L, 2006).

Proteinuria

Proteinuria is defined as urinary protein excretion of more than 150 mg per day and is the hallmark of renal disease. Microalbuminuria is defined as the excretion of 30 to 50 mg of protein per day and is a sign of early renal disease. Asymptomatic proteinuria is associated with significant renal disease in less than 1.5 percent of patients. Proteinuria can be classified as transient or persistent (Simerville JA et al., 2005). Proteinuria on initial dipstick urinalysis is found in as much as 17 percent of selected populations. Although a wide variety of conditions, ranging from benign to lethal, can cause proteinuria, fewer than 2 percent of patients whose urine dipstick test is positive for protein have serious and treatable urinary tract disorder. Proteins cross to the tubular fluid in inverse proportion to their size and negative charge. Proteins with a molecular weight of less than 20 000 Daltons pass easily across the glomerular capillary wall.

Conversely, albumin, with a molecular weight of 65 000 Daltons and a negative charge, is restricted under normal conditions. The smaller proteins are largely reabsorbed at the proximal tubule, and only small amounts are excreted. The pathophysiologic mechanisms of proteinuria can be classified as glomerular, tubular or overflow (Carroll MF and Temte JL, 2000).

Growing evidence indicates that the presence of relatively low levels of urine protein can be an early marker of increased risk of progressive kidney disease, poor cardiovascular outcomes, and death. Dipstick urinalysis has imperfect accuracy in the diagnosis of persistent proteinuria, but it is an inexpensive test that can be performed in most medical settings. It is not clear whether screening of the entire adult population by physicians is warranted. Annual screening to detect proteinuria is not cost-effective. However, based on the best available evidence to date, selective annual testing focusing on high-risk groups is highly cost-effective (Boulware L et al., 2003).

Abnormal urine proteins and their concentrations are highly variable; they usually point to glomerular disease if the excretion is primarily albumin and other high-molecular-weight proteins and to tubular disorders if primarily low-molecular-weight proteins are increased (Pugia M et al., 2002). Microalbuminuria is used clinically to monitor incipient diabetic nephropathy, but it is known also to be a non-specific marker of inflammation both systemic and local and appears to be useful as predictor of outcome in several clinical situations (Evans G and Greaves I, 1999).

Proteinuria can be a major clue to underlying renal disease or transient finding in normal children. It is likely to be much more significant if associated with haematuria. Urinary sticks for ward testing are quite sensitive for proteinuria. False-positive results may be obtained with concentrated or alkaline urine, and false-negative results may be obtained with dilute or markedly acidic urine. Suspected proteinuria should always be sent for laboratory quantification. Proteinuria may occur in febrile children or in the context of disease states such as cardiac failure. It may also occur after strenuous exercise. Before further investigations are carried out, there must be documented proteinuria on at least two occasions. In some, there may be intermittent proteinuria. Orthostatic

proteinuria is commonly transient but may persist. It should be remembered that proteinuria with a pathological basis will also frequently have an orthostatic component. Urine protein excretion increases with activity and upright posture, and so the protein content of urine passed late in the day will always be greater than that passed first thing in the morning. This is not usually detectable on dipstick testing but the physiological increase is exaggerated occasionally (Christian MT and Watson AR, 2004).

According to the National Kidney Foundation guidelines, dipstick protein evaluation is sufficient for routine screening of proteinuria. If dipstick protein results show 1+ or greater on two occasions temporally separated by at least 1 week, it should trigger quantification of proteinuria (Agarwal R, Panesar A and Lewis RR, 2002). Dipstick positive proteinuria of more than or equal to 1+ can substitute for an albumin: creatinine ratio (Davidson MB and Smiley JF, 1999).

Glycosuria

Glycosuria occurs when the filtered load of glucose exceeds the ability of the tubules to reabsorb. Etiologies include diabetes mellitus, Cushing's syndrome, liver and pancreatic disease. (Simerville JA et al., 2005). Testing for glucose is most commonly used to confirm a diagnosis of diabetes mellitus and/or monitor the effectiveness of diabetic control. Glycosuria is not necessarily abnormal and further testing must always be performed to establish a diagnosis of diabetes mellitus (Barrat J, 2007).

Ketonuria

Ketones are not normally found in urine. Ketonuria most commonly is associated with uncontrolled diabetes, but it also can occur during pregnancy, carbohydrate-free diets and starvation (Simerville JA et al., 2005). Each of these underlying causes should be readily apparent on clinical assessment of the patient, and therefore ketonuria rarely requires independent evaluation (Barrat J, 2007).

Nitrites and Leukocyte Esterase

Nitrites are not found in urine but result when bacteria reduce urinary nitrates to nitrites. This test is specific but not highly sensitive. Thus a positive result is helpful, but a negative result does not rule out Urinary Tract Infection (Simerville JA et al., 2005).

Not all urinary pathogens produce nitrites. Previous studies report a wide variation in the sensitivity and specificity of the components of dipstick urinalysis in detecting Urinary Tract Infection (UTI). Dipstick urinalysis significantly augments clinical assessment in diagnosing UTI in symptomatic patients (Sultana RV et al., 2001). A positive nitrite test indicates that nitrite has been produced from the reduction of nitrate by enteric bacteria, most commonly by genera of the Enterobacteriaceae family. The decreased sensitivity of urine dipstick tests in detecting lower colony counts limits the utility of this method in diagnosing uncomplicated urinary tract infections in women (Semeniuk H and Church D, 1999). The gold standard for diagnosing UTI remains clean-catch, midstream urine that is spun and examined under a microscope (Roberts RG and Hartlaub PP, 1999). A clinical useful screening test for UTI should be simple, rapid, inexpensive, and most importantly, accurate (Gorelick MH and Shaw KN, 1999).

Leukocyte Esterase is produced by neutrophils and may signal pyuria associated with UTI (Simerville JA et al., 2005). The diagnostic sensitivity of leukocyte esterase to detect urinary tract infection is 67 to 94% with specificity of 64 to 92%. It is assumed that WBCs are present in the urinary tract because of invading bacteria. However, leukocyturia can arise from parasitic diseases (ie bilharziosis), infections with yeast, fungi or viruses as well as glomerular diseases or urinary obstruction. The package insert supplied with the Bayer Multistix 8SG reagent strips indicates that elevated glucose concentrations (166 mmol/l) or high specific gravity may decrease the leukocyte esterase test results (Lyon ME et al., 2003). Evidence from emergency settings suggests that dipsticks may be particularly helpful where clinical assessment indicates a moderate probability of infection (Little P et al., 2006).

If clinicians and laboratory staff can be satisfied that a strip test is a suitable screening test for infection for all urines this would reduce patients waiting times and be cost effective. If leukocyte esterase and nitrite markers are absent there is a negative predictive value for infection of over 98%. If all three markers (leukocyte esterase, nitrite and protein) are absent, there is a 100% negative predictive value. If both leukocyte esterase and nitrites are negative no further investigations for infection are needed. Children wait 3-5 minutes for the results of the dipstick test compared with 15-60

minutes when tested in the laboratory and less urine samples are sent to the laboratory for further analysis, thus allowing that service to be used more efficiently (Molyneux EM and Robson WJ, 1995).

The leukocyte esterase and nitrite tests often are used in primary care settings to evaluate urinary symptoms; however, they are not useful for diagnosing UTI in an asymptomatic patient. Limitations of the dipstick nitrite test in diagnosing bacteriuria include: infection with non-nitrite-producing pathogens; delays between obtaining and testing the sample; and insufficient time since the last void for nitrites to appear at detectable levels. Combining the leukocyte esterase and nitrite tests results in higher specificity than using either test alone (Colgan R et al., 2006). In today's office practice, the dipstick test for nitrite is used as a surrogate marker for bacteriuria. It should be noted that not all uropathogens reduce nitrates to nitrite. For example, enterococci, *S. saprophyticus* and *Acinetobacter* species do not and therefore give false-negative results (Orenstein R, 1999). Sensitivity for nitrite is usually only about 30 percent. This is secondary to the six-hour incubation time needed. Sensitivity increases to 60 percent with first-voided morning urine samples (Kurowski K, 1998).

By screening for and aggressively treating pregnant women with asymptomatic bacteriuria, it is possible to significantly decrease the annual incidence of pyelonephritis during pregnancy. In randomised controlled trials, treatment of pregnant women with asymptomatic bacteriuria has been shown to decrease the incidence of preterm birth and low-birth-weight infants (Delzell JE and Lefevre ML, 2000). A dipstick urinalysis positive for leukocyte esterase and/or nitrites in a midstream-void specimen reinforces the clinical diagnosis of Urinary Tract Infection (Mehnert-Kay SA, 2005). Culture has the disadvantage of taking at least 48 hours to give a result. More rapid methods of Urinary Tract Infection diagnosis are therefore desirable. Dipstick tests have the advantage of being quick and easy to perform and can be carried out in primary care giving an immediate result (Whiting P et al., 2005).

Bilirubin and Urobilinogen

Urine normally does not contain detectable amounts of bilirubin. Unconjugated bilirubin is water insoluble and cannot pass through the glomerulus; conjugated bilirubin is water soluble and indicates further evaluation for liver dysfunction and biliary obstruction when it is detected in urine (Simerville JA et al., 2005). Urinary bilirubin excretion will reach significant levels in any disease process that increases the amount of conjugated bilirubin in the bloodstream (e.g. intrahepatic or extrahepatic biliary obstruction). Similarly, urinary urobilinogen excretion increases in liver diseases where there is reduced removal of reabsorbed urobilinogen from the portal circulation. Urinary urobilinogen excretion may also increase when there is significant destruction of red blood cells (e.g. haemolytic anaemia and malaria) (Barrat J, 2007).

Results of Studies

A cohort study by Topham et al. (2004) screened 3808 young adults in a student health center and found that 1% had persistent abnormalities. 0.45 % had persistent proteinuria, 0.39 % had persistent haematuria and 0.23 % had persistent proteinuria and haematuria. No glycosuria was detected. Khallid and Haddad (1999), investigated abnormalities in urine analysis in 247 University candidates. 8.1 % had pyuria, 6.1 % had haematuria and 4.8 % had albuminuria. No glycosuria was found. One or more abnormality in urinalysis was found in 10.5% of females and in 7.3% of males, but there was no statistical difference between the sexes. In the study of 2000 asymptomatic paediatric patients, Kaplan et al. (1997) found a dipstick urinalysis abnormality rate of 1.5% The calculated rate of false-positive/transient abnormality was 84 % (Simerville JA et al., 2005)

CHAPTER 3: METHODOLOGY

Introduction

The methods on how the study was conducted are outlined in this chapter. These include the setting of the study; study design; study population and sampling as well as the procedure for data collection and analysis. Other issues which are addressed include reliability, validity, bias and ethical considerations.

Setting

Mankweng hospital is part of Polokwane/Mankweng hospital complex. It is situated in the township of Mankweng, 30 km to the East of Polokwane city in the province of Limpopo, RSA. It was established by the then homeland government of Lebowa in 1988 to service a huge need that existed in the surrounding area which hosts several chieftainships and predominantly rural communities. With the advent of the new political dispensation since 1994, Mankweng hospital was amalgamated with the then Pietersburg hospital which is situated in the city of Polokwane, to become Pietersburg/Mankweng hospital complex. The name Pietersburg changed to Polokwane when the city was renamed Polokwane. The aim of the amalgamation was to share resources between the two hospitals.

Mankweng hospital is a tertiary and teaching institution for the province of Limpopo and the University of Limpopo. It is a departmentalized institution where each department has a joint head of department for the hospital complex. One of the departments is Family Medicine where I am working. The vision of the institution is to be a tertiary health institution of excellence, contributing to a better life for all.

The mission of Polokwane/Mankweng hospital complex is commitment to providing holistic, secondary and tertiary health care services and to promote community-orientated training and research for the people it serves. As part of the strategic plan, the complex renders both secondary and tertiary care services. It supports the regional hospitals through the outreach programmes in different clinical departments. It is also in

charge of certain tertiary services that are decentralized to district hospitals such as Elim hospital, Jane Furse hospital, Shiluvana hospital, Thabamooopo hospital and others.

The department of Family Medicine traditionally takes care of four units which are: General Outpatient Department, Primary Health Care clinic (PHC), HIV clinic and an Outreach programme to outside clinics serviced by the hospital. All patients coming into the hospital except maternity patients and those visiting the eye clinic go through Primary Health Care clinic which is situated at the entrance of the hospital. Another unit in the form of staff clinic has been added since 2007. The study was conducted at the Primary Health Care clinic.

Study Design

The study was applied research in the form of quantitative survey. It was a cross-sectional study where patients' urine was analysed using a dipstick strip as they visited the Primary Health Care clinic at Mankweng hospital.

Study Population and Sample

The study population included all patients aged five years and above who attended Mankweng hospital's Primary Health Care clinic on a daily basis. The age group was chosen on the basis of ability to produce urine voluntarily.

Systematic random sampling was used to select the study participants. This method was employed as this was the most appropriate method for sampling from a queue where the total population was not known. Patients were allocated numbered cards as they registered at the clinic. The study sample's cards were coloured blue, while other cards were white for easy identification by the research team. The third patient and every subsequent third patient thereafter were included in the sample on a daily basis. No patient was excluded on the basis of failure to produce urine, as all patients who agreed to take part in the study managed to produce urine. Repeat patients within the period of the study were excluded in order to avoid duplication. Data collection was completed within nine days.

The sample size of the study was calculated based on the following formula:

$n = \frac{Z^2 p(1-p)}{e^2}$ where p is the prevalence (i.e. we used p=18%, Khallid and Haddad, 1999), e is the sampling error (5%) and Z is the confidence interval (95% CI). The sample size required for the study was 227.

Materials, Apparatus and Instruments

The following instruments were used to collect the data for the study:

- Urine collecting glass jars
- Urine dipstick strips
- Data collection forms
- Patient identification cards
- Black pens
- Urine specimen bottles

Data Collection

A fresh random urine sample was obtained from patients in the study group at the Primary Health Care clinic. Clean jars were used to collect urine. The urine was then transferred into specimen bottles. UriCHECK 10, which is a dipstick test for ten components of urine, was used, because that was the test which was used at Mankweng hospital at the time of the study. The components that were tested included: blood, protein, glucose, ketones, nitrites, leukocytes, urobilinogen, bilirubin, specific gravity and pH. The urine was tested immediately by the researcher with the assistance of two specially trained Enrolled Nursing Assistants. The total number of dipstick strips used were counted and recorded. The price of the dipstick strips was obtained from the hospital pharmacy. The price of the urine specimen jars was obtained from the National Health Laboratory Service (NHLS). The duration of the test was estimated using a wrist watch. The reading of the test was done according to the recommended times on the test container. The Laboratory Technician time and the Pharmacist time were estimations by the Technician and the Pharmacist respectively. The salaries of the

Nursing Assistant and the Pharmacist were obtained from Human Resource Management of the hospital. The salary of the Technician was obtained from NHLS.

Data Analysis

The data for the study were captured and analysed using EpiInfo 2002. The categorical data were interpreted using percentages, and continuous variables by mean \pm standard deviation. Chi-squared test was used to determine the association between categorical variables. Student t-test was used for association of continuous variables. The p-value of less than or equal to 0.05 was considered significant.

Reliability, Validity and Bias of the Study

Reliability

To ascertain accuracy and consistency of the results, the two nurses were trained specifically for the purpose of reading the test strips and they were the only ones used throughout the data collection. The researcher was on hand to verify and record the results immediately.

Validity

The results of the study could only be generalisable to the population from the catchment area of Mankweng hospital since other areas might have had different disease profiles. Participants who could not produce urine were given one or two glasses of water until they could produce urine to avoid the problem of attrition. In addition, the sampling continued until the required number of participants was reached. The dipstick strips used were at least one year away from expiry date to ascertain good working condition.

Bias

Dipstick urinalysis test involves matching colours on the dipstick strip with those on the container according to specified time frames. Two types of bias could have occurred which were colour error and timing error. This was overcome by involving the two trained nurses during the testing.

Ethical Considerations

All patients participating in the study were asked to sign an informed consent form. In the case of minors, this was done by their guardians. The participants' confidentiality was guaranteed by not revealing their names on any form or document. The urine specimen was discarded as soon as it was used. Permission to conduct the study was obtained from the manager of the institution. Approval was also obtained from the Research, Ethics and Publications Committee (REPC) of the University of Limpopo for the research project. We also obtained approval from the Provincial Research Committee of Limpopo Province.

CHAPTER 4: THE STUDY RESULTS

Introduction:

In the previous chapter, the methodology of the study was outlined. In this chapter, the findings and the interpretation of the results are presented. This chapter is divided into the following subheadings: demographic information of the study participants, prevalence of urine abnormality in the study participants, the relationship between urine abnormality and selected demographics, abnormality in the urine components, and cost analysis of dipstick urinalysis.

Demographic Information of the study participants

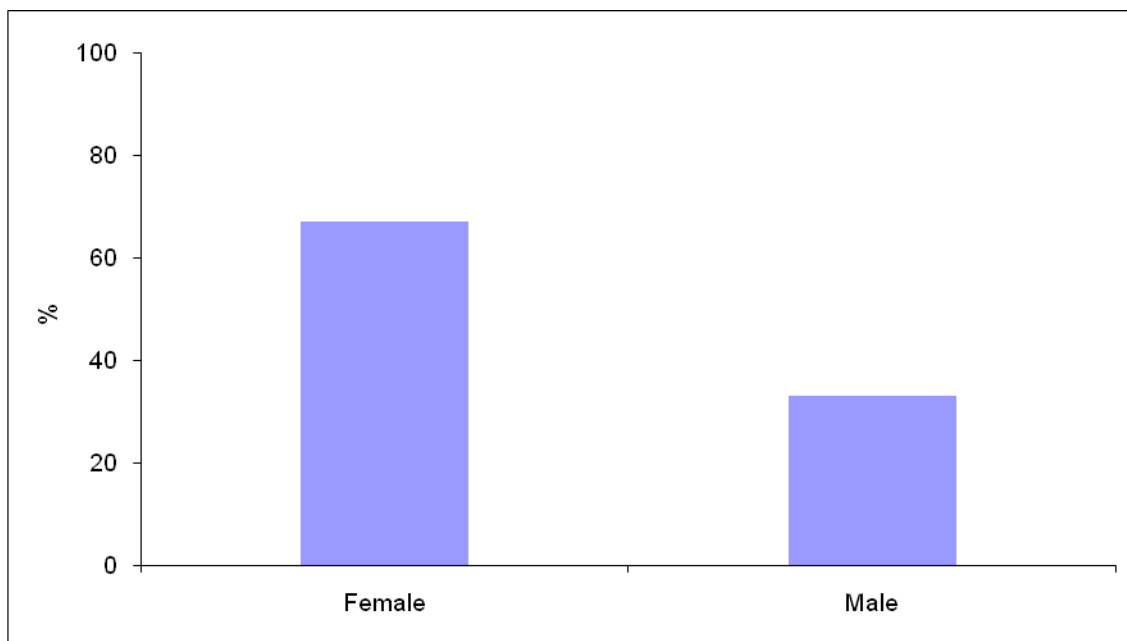


Figure 1: Distribution of Gender

A total of 227 patients participated in the study. Of these, 153(67%) were female and 74(33%) were male (**Figure 1**).

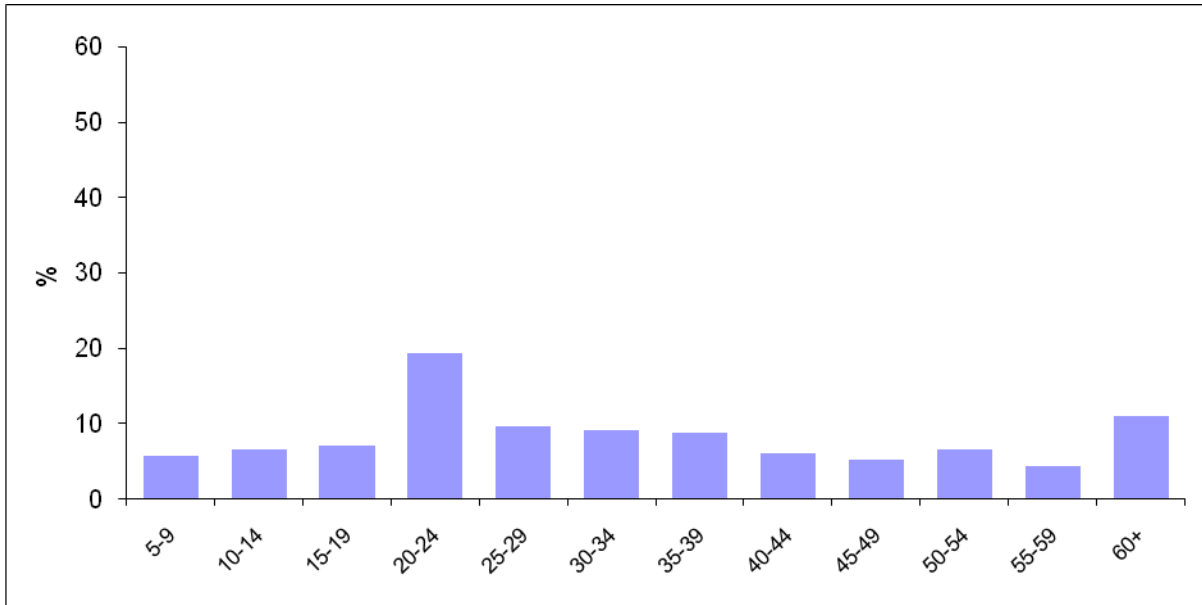


Figure 2: Distribution of Age (yrs)

Figure 2 illustrates the distribution of the participant's age. The majority 44(19%) were in the age group 20-24 years, followed by 25(11%) patients in the age group 60 years and above. The mean age was 33 years ranged from 5 to 84 years.

Prevalence of Urine Abnormality

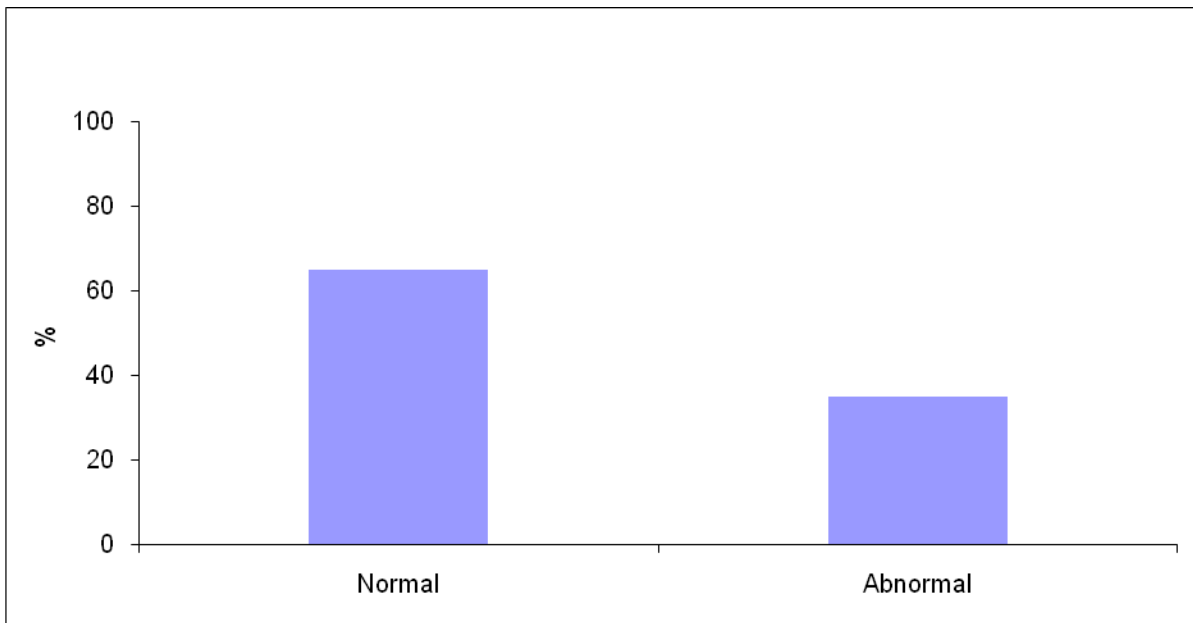


Figure 3: Proportion of patients with abnormality in the urine

Figure 3 indicated the proportion of patients with urine abnormality. Of the 227 patients who participated in the study, 80(35%) had urine abnormality.

The relationship between urine abnormality and selected demographics

Table 1: Association between gender and urine abnormality

	Female		Male		p-value
	No	%	No	%	
Normal	88	58	59	80	0.001
Abnormal	65	43	15	20	

Table 1 shows the association between gender and urine abnormality. The results illustrate a significant relationship between gender and abnormality ($p < 0.001$). About 65(43%) of female had abnormality and only 15(20%) of male had abnormality.

Table 2: Effect of gender on abnormality

Odds Ratio	Std Err	95% Conf Interval	
2.91	0.952	1.515	5.572

Wald Test: $P < 0.001$

The simple logistics regression model is shown in **Table 2**. The result indicated that female are 2.91 more likely to show urine abnormality compared to male.

Table 3: Association between age and urine abnormality

	N	Mean	Std Dev	p-value
Normal	147	34.6	18.7	0.4860
Abnormal	80	32.9	16.1	

The relationship between age and abnormality is shown in **Table 3**. The mean age was 34.6 years in the normal patients ranged from 5 to 84 years, while the mean in the abnormal group was 32.9 years ranged from 7 to 81 years. There was no significant difference between normal and abnormal group with regard to age ($p = 0.4860$).

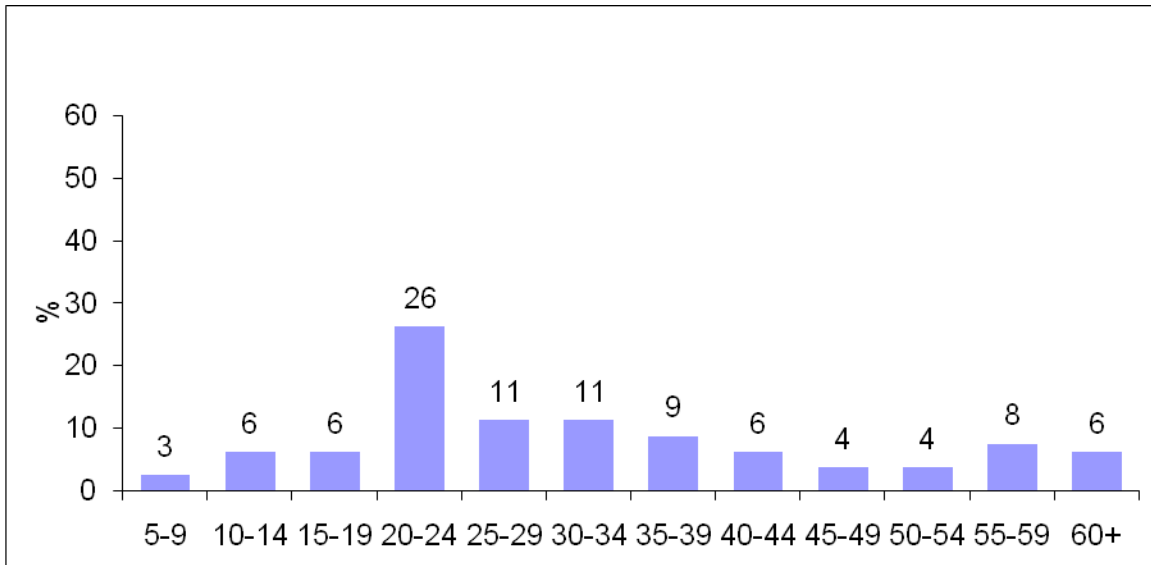


Figure 4: Age distribution of patients with abnormality in urine

Even though the result has shown non-significant difference among normal and abnormal groups with regard to age, the majority 21(26%) of the patients in the age group 20-24 years had shown abnormality (**Figure 4**).

Abnormality in the urine components

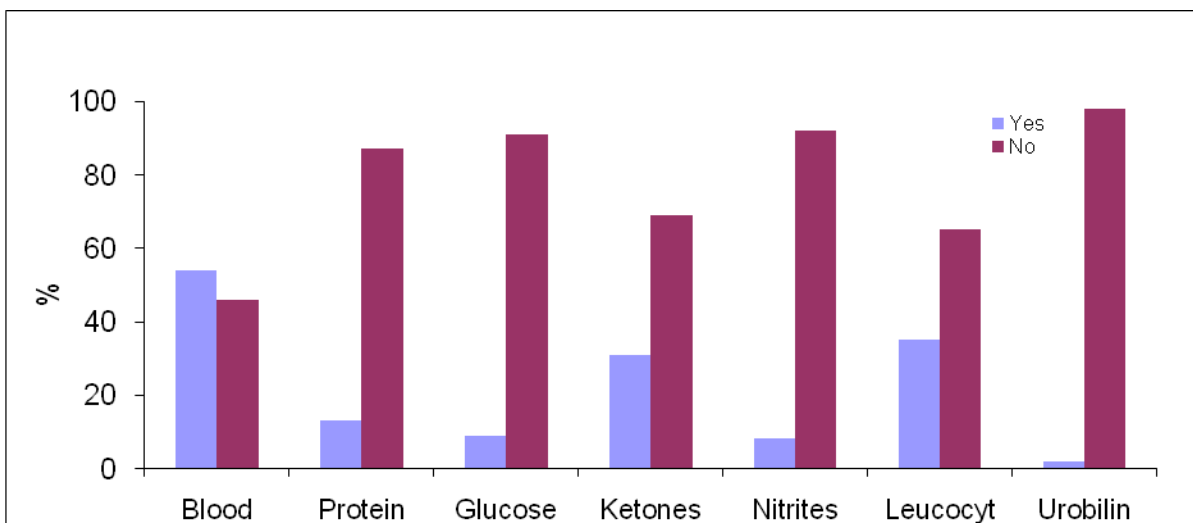


Figure 5: Urine components which indicated abnormal results, n=80

Figure 5 illustrates proportion of individuals with abnormality in blood, protein, glucose, ketones, nitrites, etc. Forty-three (53%) of the patients had abnormality in blood, and only 10(13%) participants showed abnormality in protein. About 25(31%) showed abnormality in ketones, 7(9%) in glucose, 6(8%) in nitrites, 28(35%) in leucocytes, and 1(1%) in urobilinogen. There was no bilirubin detected. Thirteen (16%) of patients with blood in urine were menstruating (**Appendix 9**).

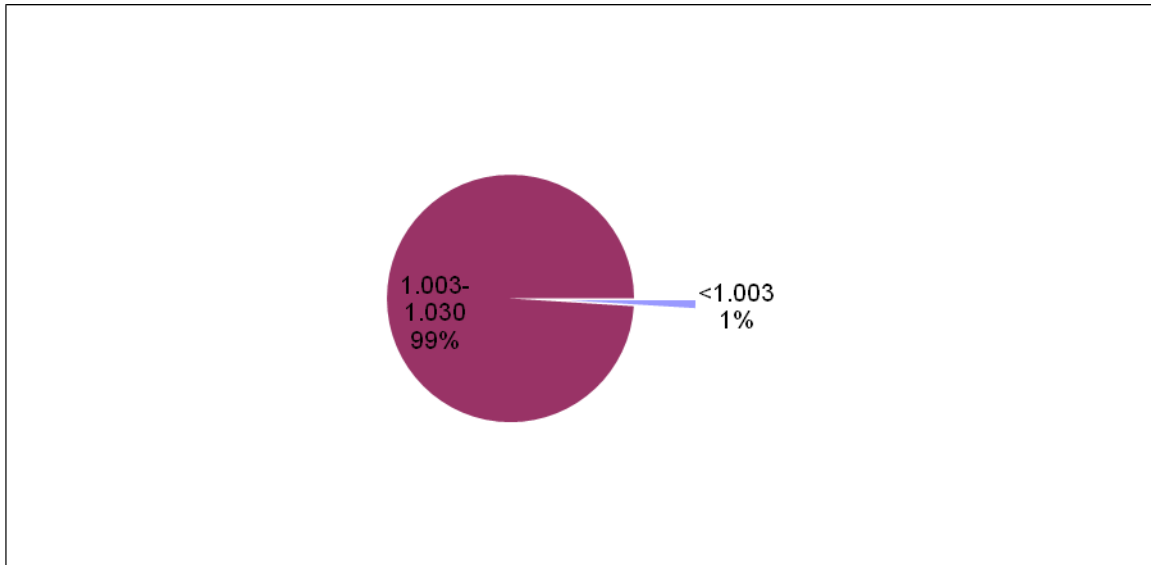


Figure 6: Distribution of Specific Gravity

The majority 226 (99%) of the participants had specific gravity of 1.003 to 1.030 (**Figure 6**). The mean for specific gravity was 1.021 ranging from 1.000 to 1.030.

Table 4: Association between specific gravity and urine abnormality

	N	Mean	Std Dev	p-value
Normal	147	1.021	0.008	0.1989
Abnormal	80	1.022	0.008	

Table 4 shows the relationship between specific gravity and abnormality. There was no significant difference between normal and abnormal group with regard to specific gravity (p=0.1989).

Table 5: Association between pH and urine abnormality

	N	Mean	Std Dev	p-value
Normal	147	5.299	0.645	0.3900
Abnormal	80	5.225	0.573	

The mean for pH was 5.27 ranging from 5 to 8. **Table 5** shows the association between pH and abnormality. There was no significant difference between normal and abnormal group with regard to pH ($p=0.3900$).

Cost Analysis of Dipstick Urinalysis

Table 6: Cost analysis of dipstick urinalysis

	Item	Quantity	Price
Reagents	Urine Strips	100	R 26.62
	Delivery (1% of Cost)		R 0.27
Disposables	1 x 40ml specimen jar	100	R 64.00
Lab Technician	Ordering of specimen jars	100	R 13.28
	Dispensing of specimen jars		
Enrolled Nursing Assistant	Testing strips	100	R 108.14
	Reading strips		
	Recording strips		
Pharmacist	Ordering strips	100	R 107.10
	Receiving strips		
	Dispensing strips		
Total cost per 100			R 319.41

Table 6 shows the cost of the different components in the process of dipstick urinalysis. The cost is expressed per 100 for easy evaluation.

The price of urine test strips was R26.62 for a pack of 100 strips. The price of 40ml specimen jars was R320.00 for a pack of 500 jars. Both prices were vat-inclusive. The annual entry level salary of an Enrolled Nursing Assistant was R54879.00. The annual entry level salary of a Pharmacist was R117501.00. The annual entry level salary of a Laboratory Technician was R117670.00. The estimated time spent by different professionals was as follows: Laboratory Technician- ordering of specimen jars +-10 minutes; dispensing of specimen jars +-3 minutes; total=13 minutes. Enrolled Nursing Assistant- testing +-2minutes 6 seconds; reading test strip +-5 seconds; recording results +- 5 seconds; total=2minutes 16 seconds. Pharmacist- ordering of test strips +-30minutes; receiving delivery from supplier +-60minutes; dispensing test strips +-15minutes;total=105 minutes. The time was estimated by the relevant professional, except the time for Enrolled Nursing Assistant which was estimated by the researcher during the testing.

CHAPTER 5: DISCUSSION

Introduction

In chapter 4, we presented and interpreted the results of the study. In this chapter, the findings of the study are discussed and compared with other studies. This chapter is sub-divided into the following sub-heading: Demographic characteristics of the study subjects, The relationship between Urine Abnormality and selected Demographics, Prevalence of Urine Abnormality, Abnormality in the urine components, and Cost Analysis of Dipstick Urinalysis.

Demographic information of the study participants

A total of two hundred and twenty seven patients participated in this study. Craver and Abermanis (1996) in their study on 'Dipstick urinalysis screen for the paediatric emergency room' reported 236 participations. Kaplan et al. (1997) did a study in a cohort of 2000 asymptomatic paediatric patients in a primary care setting to determine the minimal cost of screening dipstick urinalysis. In a study to compare the emergency physician and laboratory technician on dipstick urinalysis by Kerr et al. (1999) 41 patients were included. A total of 98 residents were included in a study to evaluate a new method (dipstick/pad=dipstick pressed onto a recently wet incontinence pad) of initial on-site evaluation of bacteriuria in an incontinent nursing home population (Midthun et al., 2003). A total of 247 students were examined with urine analysis as part of a medical check-up for students enrolling in the University of Al-Bayt in Mafrqa, northern Jordan (Kallid and Haddad, 1999). Topham et al. (2004) studied a cohort of 3808 young adults to identify the prevalence of persistent urine abnormalities and to establish the added value of screening for both haematuria and proteinuria. Brown et al. (2005) did a study to determine the prevalence of dipstick microscopic haematuria in pregnancy which included 902 women. Sultana et al. (2001) studied 400 urine specimens to determine whether dipstick urinalysis significantly augmented the accuracy of clinical assessment in the diagnosis of Urinary Tract Infection (UTI) in symptomatic patients. The observation from the above studies is that the size of the study sample varies depending on the size of the study population.

Of the 227 participants in this study, (67%) were female and 33% were male. A study by Midthun et al. (2003), reported eighty-four percent of Nursing Home residents were female.

In the study by Craver and Abermanis (1996), out of the 236 children studied, 136(58%) were girls. In a study by Arinzon et al. (2008) to determine the validity of Multistix 10 SG compared with standard urinalysis for the early detection of Urinary Tract Infection in elderly patients, most of them were female (78%). Of the 247 students studied 150 (61%) were males and 97(39%) were females (Khallid and Haddad, 1999). In the Topham et al. (2004) study, 52% were female. A study to evaluate the interaction between urine specific gravity and leukocyte esterase results, by Lyon et al. (2003) found that 55% were females. We can see that females are in the majority in most studies.

In the study by Kerr et al. (1999) the age ranged from 17 to 94 years with a mean age of 50 years. The students in the study by Khallid and Haddad (1999) had a mean age of 20.08 years (18-38 years). This is understandable since most university students would be expected to be young adults. The mean age in the study by Topham et al. (2004) was 21.8 years with a range of 18-59 years. These were university students in a student health centre and a university hospital nephrology unit.

In our study the age was classified into intervals of 5 years for the purpose of easy interpretation. In total, there were 12 classes. The mean age was 33 years with a wide range of 5-84 years. The majority (19%) of patients who attended Primary Health Care clinic were in the age group 20-24 years, followed by age group 60 years and above. These two groups appear to be the ones who have time during week days to come to the clinic, either because they are not working, not attending school or they are pensioners. The wide interval for age group 60 years and above could also account for the increased number in this age group.

Prevalence of Urine Abnormality

Nine percent of paediatric patients were calculated to have an abnormal initial urinalysis. Upon retesting, only 1.5% of the patients were calculated to have a persistent

abnormality (Kaplan et al., 1997). An overall abnormal urine analysis was found in 15.4% of University candidates (Khallid and Haddad, 1999). The urinalysis in these candidates was part of a routine medical check-up. In our study, we found urine abnormality rate of 35%. This appears to be significantly high, but if one considers the calculated rate of false positive/transient abnormality of 84% by Kaplan et al. (1997), the persistent abnormality rate could be much lower. Dipstick urinalysis was positive in 30% of patients (Sultana et al., 2001). This is closer to findings in our study. It is apparent that the prevalence of urine abnormality is varied from one study to the other.

The relationship between urine abnormality and selected demographics

Females were found to be more likely to show abnormality in urine than males (Odds ratio 2.91). There was no significant association between age and urine abnormality ($p=0.4860$). Even though there was no significant association between age and urine abnormality, the results of this study indicated more abnormalities among participants in the age group 20-24 years. This suggests that if routine dipstick urinalysis was to be done, it would have to include mainly this younger age group.

Abnormality in the urine components

The most frequent urine abnormality was blood (53%) followed by leukocytes (35%), then ketones (31%). The other abnormalities were very few, ranging from 0% (bilirubin) to 13% (protein). All females with blood abnormality were assessed for menstruation, and 13 (16%) were found to be menstruating. This means that actual blood abnormality prevalence was 37% of the total abnormalities ($n=80$). In order to get a sense of the prevalence of the different abnormalities in the population, the percentages had to be calculated out of the total sample number of 227. The prevalence was then found to be 43 (19%) for blood; 10 (4%) for protein; 25(11%) for ketones; 7(3%) for glucose; 6(3%) for nitrites; 28(12%) for leukocytes; and 1(0.4%) for urobilinogen. If we subtract those who were menstruating, the prevalence of blood would come down to 30(13%).

Khallid and Haddad (1999), in their study of University candidates found the prevalence to be 8.1% pyuria; 6.1% haematuria; 4.8% proteinuria and they concluded that these

values were significant to warrant routine urinalysis. Urine specimens testing positive for bacteriuria were found in 27.6% of the sample (Midthun et al., 2003). The study by Topham et al. (2004) revealed 3.8% proteinuria and 1.7% haematuria. In general, results of urine components from most studies show low values, but these could be clinically significant in individual patients. Our values are higher, probably because our participants were patients and not normal subjects. We therefore think that routine dipstick urinalysis is more likely to yield positive results in patients than in normal people.

The majority (99%) of participants had a specific gravity within normal limits (1.003 to 1.030). This means that most patients were well hydrated. There was, however, no association between specific gravity and urine abnormality. All urine samples had a normal pH ranging from 5 to 8 with no significant association between pH and urine abnormality ($p=0.3900$).

Cost Analysis of Dipstick Urinalysis

Piccoli et al. (2002) analysed the cost of urinalysis by breaking it down into cost of reagents; cost of disposables; Technician time and Biologist-nephrologist time. Although this was a laboratory microscopic urinalysis, we found that this approach was useful in our study. Our analysis looked at the cost of urine strips and urine specimen jars. The cost of the Laboratory Technician, Pharmacist and Enrolled Nursing Assistant was calculated by multiplying the estimated time by the salary of the respective professional per minute. Some cost was direct and some was indirect. The total cost per 100 urine samples was significant (R319.41). Most of the time was spent by the Pharmacist, especially when receiving stock from the supplier (Table 6). If one considers that the cost of Technician, Nurse and Pharmacist was incurred by the hospital in any case, we can estimate that the real additional cost of dipstick urinalysis would be R90.89 (R26.89+ R64.00) per 100. The time that these employees spend would not increase since this would be part of their regular work. For example, it was observed that the time taken while waiting to read the dipstick (2 minutes) was the time needed to do other vital

signs. So, the only additional time was for opening containers, reading and recording results (+- 16 seconds) per participant.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

Introduction

On the basis of the findings of our study and literature appraisal, we have reached certain conclusions which will be outlined in this chapter. Following on our conclusions, we make recommendations to Mankweng Hospital Management for practical implementation. We also comment on the limitations of the study.

Conclusions

Our conclusion is that the prevalence of initial urinary abnormality as detected by dipstick urinalysis is significantly high in Primary Care setting. The most prevalent abnormalities are blood and leukocytes. There is no significant association between the presence of urine abnormality and age. Females are more likely to show urine abnormality compared to males. Routine dipstick urinalysis does not lead to significant additional cost in terms of time and money to an established Health Care institution. We therefore think that routine dipstick urinalysis can add value to the management of patients at a Primary Health Care setting.

Limitations of the Study

One of the limitations of the study is that the urine was tested once; therefore we do not know the effect of false/transient abnormalities. The other limitation is on costing. The time for the Pharmacist and the Laboratory Technician were estimations, with the result that our findings are at best, estimated and not calculated values.

Recommendations

- All new patients to Mankweng Hospital should have routine dipstick urinalysis done.
- Follow-up patients at Mankweng Hospital should have dipstick urinalysis done only on request by the doctor.

- To save costs, other more expensive tests ordered by doctors should be reviewed, rather than dipstick urinalysis.

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APPENDIX 1: CONSENT FORM

MEDUNSA CONSENT FORM

Statement concerning participation in a clinical trial/Research Project*.

Name of Project / Study /I*

The Prevalence of Abnormal Urine Components As Detected By Routine Dipstick Urinalysis: A Survey At A Primary Health Care Clinic In Mankweng Hospital.

I have read the information on */heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Clinical Trial / Study / Project* is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Trial/ Study / Project* has been approved by the Research, Ethics and Publications Committee of Medunsa. I am fully aware that the results of this Trial /Study / Project* will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Trial /Study/ Project*.

.....
Name of patient/volunteer

.....
Signature of patient or guardian.

.....

Place

Date

Witness

Statement by the Researcher

I provided verbal and / or written* information regarding this Trial /Study/ Project*.

I agree to answer any future questions concerning the Trial /Study/ Project* as best as I am able.

I will adhere to the approved protocol.

.....
Name of researcher

.....
Signature

.....
Date

.....
Place

APPENDIX 2: STATISTICAL ANALYSIS

STATISTICAL ANALYSES

The chairperson,
Research, Ethics and Publications Committee,
Faculty of Health Sciences
Box _____

MEDUNSA

Dear Sir/Madam

STATISTICAL ANALYSES

I have studied research protocol of Dr Malemolla Carl Tjale
Titled: The Prevalence of Abnormal Urine Components As Detected By Routine Dipstick Urinalysis: A Survey At A Primary Health Care Clinic In Mankweng Hospital

And I agree/do not agree * to assist with the statistical analyses.

Yours sincerely,

Signature: Statistician

SAM NTULI

Name in block letters

28/08/07

Date

APPENDIX 3: DATA COLLECTION FORM

PATIENT DETAILS

1. GENDER

MALE	
FEMALE	

2. AGE (IN YEARS): _____

DATE OF BIRTH: _____

3. RACE

AFRICAN	
WHITE	
INDIAN	
COLOURED	

4

ABNORMAL URINE COMPONENT	PRESENT	
	YES	NO
Blood		
Protein		
Glucose		
Ketones		
Nitrites		
Leukocytes		
Urobilinogen		
Bilirubin		

5 Specific Gravity		< 1.003	1.003 – 1.030	>1.030

6 pH		<4.5	4.5 - 8	>8
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APPENDIX 4: LETTER OF PERMISSION TO THE MANAGER OF THE INSTITUTION

To: The Chief Executive Officer
Mankweng Hospital
Private Bag x 1117
SOVENGA
0727

Date: 07 March 2008

Dear Sir /Madam

PERMISSION TO CONDUCT RESEARCH

I hereby apply for permission to conduct research, as part of the requirements for my M.MED (Family Medicine) Degree with the University of Limpopo in your institution. The aim of this study is to investigate the necessity of doing routine dipstick urinalysis at Mankweng Hospital's general outpatient department. The research work plan and other details about the study are contained in the research protocol herewith included .This protocol received permission from the Research, Ethics and Publications Committee of Medunsa.

For further information please contact me at 072 308 7276

Yours sincerely

M.C Tjale

APPENDIX 5: LETTER OF PERMISSION TO THE PROVINCIAL AUTHORITY

Provincial ethics committee
Limpopo Government
Department of Health and Social Welfare

Date: 07 March 2008

The Chairperson
Research and Ethics Committee

Dear Sir/Madam

APPLICATION FOR PERMISSION TO CONDUCT RESEARCH

I hereby apply for permission to conduct research, as part of the requirements for my M.MED (Family Medicine) Degree with the University of Limpopo in Mankweng Hospital. The aim of this study is to investigate the necessity of doing routine dipstick urinalysis at Mankweng Hospital's general outpatient department. The research working plan and other details about the study are contained in the research protocol herewith included. This protocol received permission from the Research, Ethics and Publications Committee of Medunsa.

For further information please contact me at 072 308 7276

Yours sincerely

M.C Tjale

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX

MANKWENG CAMPUS

PRIMARY HEALTH CARE

MONTHLY STATISTICS: JUNE, 2006

CONDITION	TOTAL
RESPIRATORY	1054
ENT	172
STI	45
STI CONTACT	12
PENILE DISCHARGES	2
OPHTHALMOLOGY	0
MALNUTRITION	1
GASTRO INTESTINAL	163
MUSCULO SKELETAL	179
UTI	36
DERMATOLOGY	127
GYNAECOLOGY	148
MENTAL ILLNESS	9
ANC	14
CARDIO VASCULAR	59
VCT	28
TOTAL	2777
REF: OPD	56
REF: CASUALTY	73
REF: GYNAE CLINIC	113
UNDER FIVE	679
URTI UNDER FIVE	444
PNEUMONIA UNDER FIVE	12
DIARRHOEA WITH DEHYDRATION	5
DIARRHOEA WITHOUT DEHYDRATION	95
UNATTENDED	1
OTHERS	80
SEEN BY DOCTOR	503
REF: EYE CLINIC	0

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX

MANKWENG CAMPUS

PRIMARY HEALTH CARE

MONTHLY STATISTICS: MAY, 2006

CONDITION	TOTAL
RESPIRATORY	622
ENT	219
STI	60
STI CONTACT	7
PENILE DISCHARGES	10
OPHTHALMOLOGY	0
MALNUTRITION	1
GASTRO INTESTINAL	187
MUSCULO SKELETAL	187
UTI	27
DERMATOLOGY	163
GYNAECOLOGY	225
MENTAL ILLNESS	7
ANC	16
CARDIO VASCULAR	78
VCT	32
TOTAL	2585
REF: OPD	40
REF: CASUALTY	54
REF: GYNAE CLINIC	103
UNDER FIVE	532
URTI UNDER FIVE	306
PNEUMONIA UNDER FIVE	8
DIARRHOEA WITH DEHYDRATION	9
DIARRHOEA WITHOUT DEHYDRATION	80
UNATTENDED	1
OTHERS	60
SEEN BY DOCTOR	338
REF: EYE CLINIC	0

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX

MANKWENG CAMPUS

PRIMARY HEALTH CARE

MONTHLY STATISTICS: APRIL, 2006

CONDITION	TOTAL
RESPIRATORY	534
ENT	168
STI	71
STI CONTACT	19
PENILE DISCHARGES	10
OPHTHALMOLOGY	0
MALNUTRITION	11
GASTRO INTESTINAL	75
MUSCULO SKELETAL	134
UTI	31
DERMATOLOGY	168
GYNAECOLOGY	165
MENTAL ILLNESS	4
ANC	18
CARDIO VASCULAR	37
VCT	20
TOTAL	2007
REF: OPD	75
REF: CASUALTY	38
REF: GYNAE CLINIC	102
UNDER FIVE	322
URTI UNDER FIVE	179
PNEUMONIA UNDER FIVE	5
DIARRHOEA WITH DEHYDRATION	8
DIARRHOEA WITHOUT DEHYDRATION	71
UNATTENDED	0
OTHERS	65
SEEN BY DOCTOR	91
REF: EYE CLINIC	0

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX

MANKWENG CAMPUS

PRIMARY HEALTH CARE

MONTHLY STATISTICS: MARCH, 2006

CONDITION	TOTAL
RESPIRATORY	588
ENT	204
STI	57
STI CONTACT	4
PENILE DISCHARGES	7
OPHTHALMOLOGY	0
MALNUTRITION	7
GASTRO INTESTINAL	235
MUSCULO SKELETAL	239
UTI	50
DERMATOLOGY	165
GYNAECOLOGY	189
MENTAL ILLNESS	7
ANC	25
CARDIO VASCULAR	54
VCT	49
TOTAL	2159
REF: OPD	123
REF: CASUALTY	62
REF: GYNAE CLINIC	82
UNDER FIVE	564
URTI UNDER FIVE	345
PNEUMONIA UNDER FIVE	32
DIARRHOEA WITH DEHYDRATION	10
DIARRHOEA WITHOUT DEHYDRATION	148
UNATTENDED	0
OTHERS	44
SEEN BY DOCTOR	123
REF: EYE CLINIC	0

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX

MANKWENG CAMPUS

PRIMARY HEALTH CARE

MONTHLY STATISTICS: FEBRUARY, 2006

CONDITION	TOTAL
RESPIRATORY	435
ENT	167
STI	85
STI CONTACT	7
PENILE DISCHARGES	7
OPHTHALMOLOGY	1
MALNUTRITION	8
GASTRO INTESTINAL	194
MUSCULO SKELETAL	155
UTI	38
DERMATOLOGY	85
GYNAECOLOGY	229
MENTAL ILLNESS	1
ANC	31
CARDIO VASCULAR	47
VCT	50
TOTAL	2296
REF: OPD	110
REF: CASUALTY	42
REF: GYNAE CLINIC	162
UNDER FIVE	648
URTI UNDER FIVE	185
PNEUMONIA UNDER FIVE	6
DIARRHOEA WITH DEHYDRATION	10
DIARRHOEA WITHOUT DEHYDRATION	163
UNATTENDED	0
OTHERS	85
SEEN BY DOCTOR	221
REF: EYE CLINIC	0

APPENDIX 6: PRIMARY HEALTH CARE CLINIC MONTHLY STATISTICS

POLOKWANE/MANKWENG HOSPITAL COMPLEX
MANKWENG CAMPUS
PRIMARY HEALTH CARE
MONTHLY STATISTICS: JANUARY, 2006

CONDITION	TOTAL
RESPIRATORY	294
ENT	161
STI	61
STI CONTACT	2
PENILE DISCHARGES	4
OPHTHALMOLOGY	0
MALNUTRITION	8
GASTRO INTESTINAL	156
MUSCULO SKELETAL	199
UTI	30
DERMATOLOGY	148
GYNAECOLOGY	186
MENTAL ILLNESS	0
ANC	20
CARDIO VASCULAR	49
VCT	67
TOTAL	1980
REF: OPD	39
REF: CASUALTY	49
REF: GYNAE CLINIC	132
UNDER FIVE	314
URTI UNDER FIVE	125
PNEUMONIA UNDER FIVE	9
DIARRHOEA WITH DEHYDRATION	15
DIARRHOEA WITHOUT DEHYDRATION	100
UNATTENDED	2
OTHERS	146
SEEN BY DOCTOR	225
REF: EYE CLINIC	11

**APPENDIX 7: CLEARANCE
CERTIFICATE**

UNIVERSITY OF LIMPOPO

Medunsa Campus



MEDUNSA CAMPUS RESEARCH & ETHICS COMMITTEE

FACULTY OF HEALTH SCIENCES

CLEARANCE CERTIFICATE

P O Medunsa
Medunsa
0204
SOUTH AFRICA

Tel: 012 - 521 4000

Fax: 012 - 560 0086

MEETING: 06/2007

PROJECT NUMBER: MCREC/M/110/2007: PG

PROJECT

Title:

The prevalence of abnormal urine components as detected by routine dipstick urinalysis: A survey at a Primary Health Care Clinic in Mankweng Hospital

Researcher:

Dr. M.C. Tjale

Supervisor:

Dr. G. Marjowitz

Hospital Superintendent:

LL Sangweni-Ramokgonami
(Mankweng Hospital)

Department:

Family Medicine & Primary Health Care

School:

Medicine

Degree:

M Med (Family Medicine)

DATE CONSIDERED:

November 22, 2007

DECISION OF THE COMMITTEE:

REPC approved the project.

DATE:

December 03, 2007



PROF. GA OGUNBANJO
DIRECTOR: RESEARCH & CHAIRPERSON

- Note:**
- i) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.
 - ii) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

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