PAIN MANAGEMENT AT THE ORTHOPAEDIC SPINE CLINIC LOCATED AT THE CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL.

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

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DECLARATION

I, Anne Wanjiru Maina, student number 02030118V, declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University

Anne Wanjiru Maina

12th March 2018 in Johannesburg

DEDICATION

To my husband Ricky and daughter Zoë

for their infinite patience, love and support.

To my parents, brothers, family and friends for

being the ‘giants’ on whose shoulders I stand on.

In memory of Rebecca Wanjiru Mwangi.

- Wanji

ABSTRACT

This study examined outpatient disability in chronic low back pain (cLBP), assessed whether patients received treatment, and clinicians' prescribing habits.

Methods and materials: This prospective, single-centre cross-sectional study was conducted from the 1st of July to the 31st of October 2016. An Oswestry Disability questionnaire (ODI) and medical records were surveyed in 279 participants.

Results: The median ODI was 48.9%. More than 50% of patients reported 'fairly severe' to 'very severe' pain that significantly limited walking distance and ability to lift objects. In contrast, standing, sitting, travel and social life were relatively unaffected. Paracetamol was readily available 23% of the time, non-steroidal anti-inflammatories 46%, and opioid-like drugs 7%.

Discussion: The above average ODI and its discrepant impact on Activities of Daily Living may be due to drug shortages with patients judiciously self-dosing for selected activities.

Conclusion: Pain significantly disabled participants. Essentially all drugs underwent shortages despite clinician compliance with evidence-based protocols.

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NOMENCLATURE

ACP	American College of Physicians
BMI	Body Mass Index
CHBAH	Chris Hani Baragwanath Academic Hospital
COX	Cyclo-ocygenase
cLBP	Chronic low back pain
CVS	Cardiovascular System
DoH	Department of Health
DVT	Deep Vein Thrombosis
EDL	Essential Drugs List
GIT	Gastrointestinal
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
IVD	Intervertebral Disc
ICF	International Classification of Functioning, Disability and Health
LBP	Low Back Pain
MIMS	Monthly Index of Medical Specialities Desk Reference
MSS	Musculoskeletal System
NCS	National Core Standards
NICE	National Institute for Health Care Excellence
NSAIDs	Non-Steroidal Anti-inflammatory Drugs
OPD	Outpatients Department
ODI	Oswestry Disability Index
"O/S"	Out of Stock
PI	Principal Investigator
REDCap™	Research Electronic Data Capture™
RCT	Randomised Control Trials
SA	South Africa
SNS	Sympathetic Nervous System
SSP	Stop Stock Outs Project
SSRI	Selective Serotonin Reuptake Inhibitors
SVS	Stock Visibility System
TCA	Tricyclic Antidepressants
TTO	To Take Out (re: medication)
UK	United Kingdom
WHO	World Health Organisation

1. CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1. General Introduction

The primary purpose of this study is to objectively analyse functional outcomes following treatment of chronic low back pain (cLBP) in patients attending the Chris Hani Baragwanath Academic Hospital (CHBAH) Orthopaedic Spine Outpatients Department (OPD) based in Soweto, South Africa (SA). The study also assesses whether patients receive medicines as prescribed to manage their cLBP.

The secondary aims of the study are to determine which specific drugs and drug classes are affected by problematic pharmacy supplies and evaluate the extent of these issues. The study also analyses orthopaedic clinicians' prescribing habits.

1.2. Definitions

(i) Low back

Anatomically, the 'low back' is the area in the posterior aspect of the body from the lower margin of the twelfth ribs to the lower gluteal folds[1].

(ii) Low back pain (LBP)

LBP is an "activity-limiting low back discomfort that may be referred into one or both lower limbs[2]."

(iii) Chronology of LBP

- Acute LBP lasts less than 4 weeks[3].
- Sub-acute LBP lasts 4 to 12 weeks[3].
- Chronic LBP (cLBP) implies ongoing symptoms of greater than 3 months' duration[4].

(iv) Oswestry Disability Index (ODI)

The ODI was developed over several years by O'Brien et al. in 1980[5]. It is a condition-specific, validated tool used to measure patient outcomes in spine disease, and is based on self-reported symptoms representing the impact of spine disease in up to ten aspects of their lives[5].

The ODI is used in acute, subacute and chronic spine disease, and is considered the 'gold standard' in assessing functional capacity as well as measures outcomes of therapy in LBP[5]. All ten questions follow a similar format and all have six possible answers. The first question, for example, specifically analyses the participant's subjective experience of pain. Participants are required to describe their pain as either: 'non-existent', 'mild', 'moderate', 'severe', 'very severe' and 'the worst imaginable'. Each response in the ODI is allocated an individual score between zero and five. Increased severity is denoted by incrementally higher scores allocated to progressively worsening responses to each question.

Additional questions in the ODI analyse patient personal care, ease of lifting items, walking, sitting, standing, sleeping, sex life (an optional question), social life and ability to travel. At completion, each question's response is scored, and the final score tallied and divided by 50 (or 45 if the patient omits optional question 8 on their sex life). This total is then multiplied by 100 to obtain a percentage.

This percentage may fall into five possible categories of disability, ranging from 'mild disability' (0 - 20%), 'moderate disability' (21 - 40%), 'severe disability' (41 - 60%), 'crippled' (61 - 80%) and 'bed-bound' (81 - 100%)[5].

(v) Disability

The International Classification of Functioning, Disability and Health (ICF) manual prescribes disability as a broad description of a dynamic limitation to function - relative to potential capacity - within each patient's environment[6, 7].

(vi) Drug stock outs, shortages and substitutions

A 'stock out' implies complete unavailability of medication. A 'shortage' occurs when a drug is available in smaller than adequate drug volumes to meet predicted demand. In response, pharmacists may ration all quantities of medication dispensed - giving patients fewer doses than what is prescribed by the clinician – in a bid to ensure wider distribution of the same[8]. Should a pharmacist dispense an alternative drug in the same class - in lieu of a clinician-prescribed drug that is out of stock - a drug 'substitution' is noted.

(vii) Patient records

The patient's record is his/her individual medical file. In the Spine OPD at CHBAH, patient records are manually maintained with handwritten entries in chronological order. These records include medically relevant data, including the patient's prescribed medications to take home (T.T.O.) and volumes of drugs dispensed.

1.3. Background

1.3.1. Economic Impact of Low Back Pain

Chronic LBP contributes significantly to the global burden of disease as one of the top two reasons for medical consultation[9, 10]. Pain's debilitating nature cannot be overstated. It is the world's principal precipitant for activity limitation, work absences and the greatest contributor to disability globally[9].

Although cLBP's wide scale economic impact in SA has not been fully explored, it has been estimated to run into the millions per annum[11]. Developed nations, such as the United Kingdom (UK), estimate that up to 20% of their annual health care budget is disbursed in the management of cLBP. Chronic LBP has a larger effect on their economy than most other medical conditions - exceeding costs attributed to most other illnesses within the UK[12-15].

Eighty five percent (85%) of the cost to global economies from cLBP is predominantly due to indirect costs, such as lost productivity from incapacity, absenteeism and the affected individuals potentially leaving the labour market prematurely. LBP's direct costs are linked to the investigation and treatment of the condition[12, 16].

LBP beleaguers individuals across socioeconomic classes and political confines[13] and demonstrates a high incidence and prevalence in all populations[2, 17]. If anything, LBP has an increased incidence in low and middle-income countries, with a prevalence predicted to increase 'substantially' in these nations within the next few years[10, 14, 18, 19]. Chronic LBP is both common and recurrent, with an adult prevalence up to 84%, peaking at around 80 years of age[20].

1.3.2. Consequences and Dilemmas in Pain Management

The impact of pain on livelihoods is so significant, that its treatment has been upheld in the Universal Declaration of Human Rights, as a fundamental human right[21].

In failing to have symptoms of pain adequately managed by health care professionals, both patient satisfaction and their health-seeking behaviour is negatively impacted[22]. Patients generate maladaptive health seeking patterns and become increasingly reluctant to attend to their pain and other health problems[22].

Additionally, clinicians and hospitals, both earn a poor reputation, with medical professionals on the receiving end of successful litigation for poor management of pain in their patients[23]. Partly responsible for this situation is the wanting undergraduate clinician training that has historically been sorely lacking in comprehensive instruction relating to the pathophysiology and management of pain[24].

Several studies around pain management in cancer patients within SA have demonstrated 'relatively good' analgesic availability, when pitted against most nations on the continent, and globally[25, 26], while, locally CHBAH has been reported, according to the Gauteng Member of the Executive Committee, to have attained 96% of the National Core Standards (NCS)[27, 28]. This suggests outstanding service with respect to patient's Rights to access well-managed pain[29] and health care[30].

In spite of this promising information, several anecdotal word-of-mouth reports at CHBAH (and other SA medical centres), have suggested that patients frequently experience difficulty in receiving their prescribed T.T.O.'s[31-33]. Spurred on to improve service delivery, the Department of Health (DoH) in South Africa has tackled these hurdles with the implementation of several novel approaches to avert inadequate drug supplies[34-36].

1.4. Regional anatomy and pathoanatomy of LBP

1.4.1. Degenerative Changes in the Spine

The lower back consists of the 5 lumbar vertebrae, which transmit the spinal cord, conus medullaris and nerve roots. Unique to this region of the spine is its flexibility - a distinction that allows movement of the spine in several planes. To accommodate this particular capacity, the lumbar vertebrae are connected by strong ligaments: the

anterior longitudinal ligament, posterior longitudinal ligament and ligamentum flavum.

In addition, facet joints and intervertebral discs (IVD) between the vertebrae contribute to stability, dissipate stresses on the spine and permit movement. The IVDs consist of a peripheral ring of lamellar collagen called the annulus fibrosus (AF) that surrounds a proteoglycan rich nucleus pulposus. The AF is peripherally innervated by a meningeal branch of the relevant spinal nerve at each vertebral level[20, 37]. IVDs and facet joints are both potential sources of LBP. Degeneration of IVDs leads to instability of the spine, hypermobility of the same, disc herniation, hypertrophy of the ligamentum flavum, facet hypertrophy, and subsequent generation of osteophytes, causing back pain and functional limitation[38].

1.4.2. Patho-mechanics of Low Back Pain

(i) LBP, Aging and Body Habitus

In the general population, LBP may be caused by myriad factors, alone, or in combination, such as poor muscle tone, inactivity/overexertion or muscle sprain, malignancy, fracture of the vertebra(e), radiculopathy, pain secondary to spinal surgery, myofascial pain syndromes, or as a result of referred pain – (from the kidneys, sacroiliac joint) among others.

With age, patients undergo sarcopaenia – a condition wherein muscle mass is progressively replaced by adipose tissue. They ultimately lose muscle strength and struggle with mobility[39]. With an increase in - or exacerbation of - co-morbidities, the subsequent weakness predisposes patients to an increased risk of injury, both within and without the musculoskeletal system (MSS) [39, 40]. Repetitive MSS micro-trauma in older adults generates an increase in inflammatory mediators – mediators that have been associated with poor function[41].

On the other hand, lifestyles in modern, developed cities have become increasingly, and irrevocably, paired with sedentary lifestyles. Urbanites spend a significant portion of their time sitting at work, in travel and in leisure. This sedentary lifestyle is to blame, in part, for the obesity epidemic currently sweeping the globe. Obesity values, determined using Body Mass Indices (BMI), suggest that women in SA are particularly vulnerable. With up to 59.4% of women estimated to be overweight or

obese[42], this increased mechanical loading on the spine ramps up South African women's risk of LBP[43-45].

(ii) Posture

Sitting may ameliorate LBP by relatively widening the spinal canal. Similarly, leaning forward (manoeuvres such as the "shopping cart sign") improves LBP symptoms through the mechanics of spine flexion, hip flexion and anterior pelvic flexion. A posture that stretches the ligamentum flavum and enlarges the foramina[46].

LBP may, conversely, also be provoked by prolonged sitting. Through prolonged flexion of the lower back, this posture places strain on the posterior elements of the spine, and causes sustained low level muscle strain resulting in muscle fatigue and pain[47].

When standing, the sagittal alignment of the lumbar spinal cord is lordotic, and - if already narrowed by degenerative changes - further diminishes in size. This is in line with Penning's Rule of Progressive Narrowing[48]. In this manner, standing may exacerbate LBP.

Walking is a dynamic movement that has a variable effect on low back pain depending on several variables, including arm swing, walking cadence, gait pattern, presence of pathology in lower limbs and/or spine, ground inclination and others[48, 49].

Patients with LBP typically walk at a slower pace[50]. Kinematics studies reveal that slow gait exacerbates low back pain through decreased lumbar spine flexion/extension, twisting or lateral bending. This reduced movement results in constant and increased spine loading[49]. In contrast, fast gait may improve low back pain through relative lumbar spine flexion, increased movement of the spine and increased activation of trunk muscles[49].

Lying supine removes mechanical loading from the lumbar spine - hence the relief of pain symptoms. When a patient lifts an object, a variable burden (dependent on the weight of the object, among other factors) is placed on the spinal column. This

additional pressure increases spinal loading, invariably narrowing the lateral recesses, eliciting pain in predisposed patients[48, 51].

1.5. Current Concepts in the Pathophysiology of Pain

Pain is considered by some as a disease process in its own right. Inadequate management may result in several systemic adverse outcomes in response to pain symptoms[52-61]:

- The endocrine system releases several catabolic enzymes (cortisol, glucagon, growth hormone, catecholamines, etc.) that affect carbohydrate, protein and fat metabolism via the hypothalamic-pituitary-adrenal axis.
- Sympathetic Nervous System (SNS) activity is ramped up with a knock-on effect on the cardiovascular system (CVS) evidenced by tachycardia, raised peripheral vascular resistance and blood pressure rendering the heart prone to ischemia and infarction.
- The lungs have a decreased vital capacity as the patient suffers diaphragmatic dysfunction resulting in impaired ventilation, weak cough reflexes, atelectasis, infections, hypoxia and hypercarbia.
- Intestinal secretions and sphincter tone increases, generating nausea, vomiting, impaired gastrointestinal tract (GIT) function and ileus through decreased intestinal motility.
- The urinary system is affected by the increased sphincter tone, urine retention and oliguria.
- Coagulation pathways are affected: there is increased platelet aggregation, venostasis and a subsequent increased risk of deep vein thrombosis (DVT) and thromboemboli.
- MSS weakness, fatigue, muscle atrophy and reduced range of movement lead to atelectasis, and decubitus ulcers.
- Psychologically, pain induces anxiety, anger, depression, fear and even suicidal tendency.

Lastly, Human Immunodeficiency Virus (HIV) may exacerbate the incidence of LBP through HIV Associated Neuropathy (HIVAN)[62, 63]. The SA population is burdened with the highest global burden of HIV - an estimated 7 million people live within our borders with the virus[64]. HIV Associated Neuropathy is associated with the use of

Highly Active Antiretroviral Therapy (HAART), in particular, regimens including stavudine[24].

1.6. Guidelines and Medications in the Treatment of cLBP

1.6.1. Current Literature

Previously, the World Health Organisation's (WHO) Ladder of Pain Control proposal in 1986[65] laid the foundation for the general principles of pain management [66].

The latest guidelines (November 2016) from the National Institute for Health Care Excellence (NICE) recommend initial screening of patients to exclude 'specific' causes of LBP such as malignancy, infection, trauma and other 'Red Flags'[67]. Baseline assessment of disability is conducted at first contact to stratify patient care. Selective use of radiographic investigations is made if likely to change treatment and psychoeducation is administered.

On physical therapies, physical training and manipulation of the spine are suggested[3, 68], while medical management consists of oral Nonsteroidal Anti-inflammatory Drugs (NSAIDS) - with respect to pre-existing patient co-morbidities and potential complications. If NSAIDS are intolerable or contraindicated, weak opioids may be administered[68].

Opioids are to be avoided, as is paracetamol alone. Potential additional therapies include epidural blocks and local anaesthesia, surgical decompression and denervation. After one year, if symptoms persist, these patients are to be down referred to primary care facilities as well as a pain clinic where warranted[67].

In the presence of sciatica, antiepileptic medication may be prescribed and epidural injections and/or surgical decompression may be performed.

American College of Physicians (ACP) guidelines, released in April 2017 provides similar guidelines, endorsing paracetamol (in combination with other drugs)[68], NSAIDS, weak opioids[3] as first line therapy as well as physical therapies and muscle relaxants[68], but did not consider radiculopathy and surgery in their guidelines. Second line therapy included tramadol and duloxetine while opioids could be considered if first and second line therapies had failed and the benefits outweigh the risk[3, 69].

1.6.2. Drugs

(i) Paracetamol

Paracetamol is commonly prescribed as first line therapy for pain as recommended in the Essential Drugs List (EDL) of SA and the WHO's analgesic ladder[70]. More recently, several studies have shown that it may not be as effective as once thought in both acute and cLBP. In addition to paracetamol's questionable efficacy are concerns about the safety of paracetamol when consumed by patients at optimal doses. Side effects such as hepatotoxicity, renal dysfunction, increased risk of myocardial infarction and high blood pressure have been documented[70-72].

(ii) NSAIDS

By inhibiting the crucial cyclooxygenase (COX) enzymes through the administration of NSAIDS, inflammation and pain are prevented by the inhibition of prostaglandins. There are two types of NSAIDS: selective (COX-1 enzyme inhibitors) and non-selective (COX-1 and COX-2 inhibitors)[73]. While the literature on NSAID efficacy has been contradictory, a recent meta-analysis of 13 Randomised Control Trials (RCTs), all NSAIDs showed a slight improvement in pain and disability symptoms[73]. However, NSAIDs' potentially lethal side effects (cardiovascular risk and GIT[73]), must be borne in mind when prescribing NSAIDs[73].

(iii) Opioids

Weak opioids occupy the second step in the WHO analgesic ladder. Codeine is a weak opioid used for the management of chronic pain, however its effectiveness is controversial and studies, to date, have not been of sufficient quality to indicate, or dissuade against, its use[74, 75]. There is the accompanying potential for opioid abuse and dependency, among other side effects such as nausea, constipation, sedation - increasing the risk of falls[76].

(iv) Opioid-like drugs

With a mechanism of action similar to opioids, drugs within this class - such as tramadol - have been shown to have a better side effect profile than opioids with reduced pain and improved functional outcomes[74, 76]. Tramadol is a synthetic opioid whose mechanism of action involves activity at μ (mu) receptors as well as inhibiting the reuptake of serotonin and noradrenalin[77].

Tramadol is also the only drug that has been found in clinical trials to unequivocally improve fibromyalgia symptoms at doses of 200-300mg per day[78] with these improvements replicated in cLBP studies[79]. Tramadol, however, reduces the seizure threshold – particularly in combination with the use of neuroleptics and antidepressants and its addictive potential[80].

(v) Combinations

This class is a miscellaneous collection of various drug combinations of various ratios including paracetamol, NSAIDS, opioids and opioid-like drugs.

(vi) Muscle relaxants

Although this class of drugs has been used in the management of LBP [3, 81] – its use remains controversial due to a paucity of data on long-term outcomes and a poor evidence base supporting its use[81].

(vii) Topical analgesics

These drugs were developed for use in patients in whom oral therapies would compromise their clinical condition. Methyl salicylate – known locally as 'rub rub' or 'wintergreen' - is closely related to acetylsalicylic acid. Theoretically 'rub rub' increases the risk of distal mucosal bleeding, but these side effects have not been pronounced in literature[82].

Rubefacients provide relief through a counter-irritant effect effecting either a cooling or warming effect on overlying skin[82], but there is limited evidence supporting their widespread use for clinical indications outside of soft tissue injuries and chronic joint-related conditions[83].

(viii) Antiepileptics

Despite the paucity of literature, topiramate has been shown in several studies to improve symptoms in LBP effecting stable moods and weight loss alongside its direct effects on central pain pathways[84].

(ix) Antidepressants

Although the quality of studies and type of antidepressant assessed has varied, several placebo-controlled RCTs on duloxetine (Cymbalta) have shown a statistically significant improvement in symptoms[85]. Tricyclic antidepressants (TCA's) and Selective Serotonin Reuptake Inhibitors (SSRI's) are the two antidepressant classes typically used to supplement first- and second-line medical management of cLBP.

Antidepressants are believed to act centrally by inhibiting the reuptake of neurotransmitters (noradrenaline and/or serotonin)[86]. Through these pathways they modulate central as well as peripheral nociception, neural transmission and sensitisation to pain[86]. TCA's (the category to which amitriptyline belongs) are the more effective class of the two antidepressants[87]. Amitriptyline works at doses much lower (25 - 50mg) than those used in treating major depressive disorders (100 - 300mg) without inducing its mood-altering effects and avoiding side effects[88].

(x) Antipsychotics

Although studies of antipsychotics as add-on therapy for management of acute and chronic pain support their benefits, extrapyramidal and sedating side effects are major concerns in their use[89].

1.7. Measurement and Interpretation of Outcomes

The ODI is a popular outcome measure used by clinicians in patients suffering from back pain to assess a baseline at the commencement of therapy and monitor response to intervention.

The average ODI in 'normal' patients is 10.19[5]. Serial ODI tests should be done on LBP patients to assess improvement. The minimum clinically meaningful response to therapy is a decreased score of at least 30% or 10 points[15, 90].

1.8. Healthcare Standards and Challenges

With regards to the provision of quality healthcare, the NCS has set measures against which standards are upheld within SA public hospitals[27, 28, 30]. Comprised of several aspects, the domain of 'Patient Rights' upholds citizens' right to access healthcare[30], 'Patient Care' upholds protocol-directed management of medical

conditions and ‘Clinical Support Services’ encompassing pharmaceutical services (procurement, stock control, and dispensing medication)[28, 30, 66].

In response to this inefficient ‘Clinical Support’, repeated drug supply chain failures have occurred. To ameliorate this, ‘Operational Management’ tools and surveillance programs have been instituted by the DoH recently, namely[30, 34-36, 91]:

- Pipeline Analysis (PAI): launched in 2015 is a world first. Designed to allow provincial health departments’ direct access to information on drug availability, it aids in projecting delays in supply and acts as an early warning system triggered by potential shortfalls in drug supply.
- Stock Visibility System (SVS): alerts central databases of drug shortages or overstock
- Rx Solution: stock management software

Reports compiled by surveillance organisations - such as the Stop Stock Outs Project (SSP) and several mainstream media outlets have documented concerns that several essential medicines are being found perpetually unavailable in adequate quantities or completely inaccessible[36 30, 34-36, 91]. SSP has verified and published these reported, countrywide shortages at various medical facilities, documenting supply issues spanning several months at a time - or, in some instances - several times in a year[8].

Criticism of these shortages - despite the tools in place to mitigate these events as indicated earlier in this study - points the finger at several domains, suggesting financial and logistical mismanagement through unpaid suppliers, incorrect deliveries and poor forecasting of drug demand[36].

1.9. Research Questions

i. What is the disability status of patients treated at the orthopaedic spine outpatient department at CHBAH for cLBP?
ii. What is the pain intensity experienced by cLBP patients managed at CHBAH?
iii. What is the availability of prescribed medication for outpatients managed at CHBAH and what are the treating clinicians’s prescribing habits?

1.10. Research Objectives

i. To perform a cross sectional analysis of impairment in patients suffering from cLBP through their responses to the Oswestry Disability Index questionnaire. By summing their overall score, to allow their classification into various classes of disability.

ii. To individually assess various activities of daily living and their correlation to age, gender, pain and disability.

iii. To analyse how readily available analgesia is at the CHBAH pharmacy once it has been prescribed by clinicians.

iv. To analyse what drugs and their quantities are dispensed to determine access to medication and clinicians prescribing habits.

2. CHAPTER TWO – METHODS AND MATERIALS

2.1. Ethics

The study was approved by the Human Research Ethics Committee (Medical) at the University of the Witwatersrand, and designated clearance number M160406 (Appendix F). Permission to conduct research and access relevant patient records was granted by the Medical Advisory Committee, CHBAH (Appendix G).

2.2. Study design

This was a prospective, single-centre cross-sectional study of outpatients receiving treatment for non-specific LBP at a tertiary level hospital in Johannesburg, SA.

2.2.1. Study setting

Founded in 1941, CHBAH is based in Soweto, SA, and is one of the world's largest hospitals[92]. It is a tertiary institute that serves a population of approximately three million, within and without the local community south of Johannesburg. CHBAH welcomes over two thousand outpatients daily[93], and over half a million patients annually[94]. Approximately 17% of these patients are referred to the orthopaedic outpatient clinics[95, 96].The Spine Unit - one of six sub-specialist services provided by the Department of Orthopaedic Surgery at the hospital - runs a general outpatient clinic once a week, attending to approximately one hundred patients[97].

These patients are referred to the spine OPD from primary care facilities, neighbouring secondary facilities and other OPD departments within CHBAH. Usually they are commenced on treatment and referred for reassessment. No ODI is administered at these referring institutions, nor is it standard procedure to document a baseline or follow-up ODI at first contact with spine clinic doctors.

2.2.2. Study population and sampling

The study enrolled two hundred and eighty two (282) existing outpatients known to the spine clinic between the 1st of July 2016 and the 9th of September 2016.

The participants were selected using simple randomization. Patients were approached at varied points in the queue at the spine OPD while awaiting their consultation with the orthopaedic clinician, and had the study explained to them.

After counselling, if individuals accepted enrolment, they were subsequently consented and the same documented (Appendices A and B).

2.2.3. Selection criteria

Inclusion criteria

- At least 18 years of age
- Existing CHBAH spine unit patient attending the spine clinic served by the Department of Orthopaedic Surgery, CHBAH between 1st of July 2016 to 9th of September 2016
- LBP symptoms lasting more than 12 weeks

Exclusion criteria

- Prisoners or other institutionalised individuals
- Significant or poorly controlled medical conditions requiring immediate intervention
- Pregnant patients
- Patients with known, treatable spine conditions
- Incomplete data collection sheets

2.3. Recruitment

The target population was patients with existing LBP being attended to at the CHBAH spine OPD.

Patients were approached individually at the OPD clinic at their follow-up appointment and were recruited by Dr. Anne Maina, the Principal Investigator (PI), with the aid of a research assistant and/or staff nurse to translate where the patients' grasp of English was poor or for patients who preferred to converse in their native tongue.

A source document tracking the names of the clinical and research staff that obtained informed consent and specific details of the same was filled for each enrolled patient (Appendix C).

A hard copy of the patient consent (signed by the patient, PI and witness) permitting administration of the ODI as well as access to their records was safely filed by the PI for data capture (Appendices A and B).

Data were prospectively collected from each patient themselves. The ODI, a validated questionnaire was filled out by each enrolled patient with responses based on symptoms experienced at the time of presentation and within the preceding seven days (Appendix D).

2.4. Informed consent

Patients were counselled on the purpose of the study and their right to refuse or rescind consent, then, or at any time during the study. Hard copies describing the study and contact information pertaining to queries about the study and ethics approvals (for the PI and ethics committee) were given in person to the patients to take home for their reference (Appendix A). Once consent was obtained, this was documented in writing by both the patient (signed consent, including a witness to the same) and PI (Appendix C).

2.5. Data Collection and Capturing

2.5.1. Oswestry Low Back Pain Disability Questionnaire

Relevant identifiers and epidemiological data (patient's name, hospital number, age and sex) were captured at the top of the ODI questionnaire (Appendix D).

Patients presented themselves to the Records Department on the morning of their Spine OPD consultation with their appointment card as proof of their scheduled follow-up. Clerks gave the respective files to patients in person and directed them to queue in the orthopaedic OPD area for their appointment.

Patients were approached for enrolment from the Spine OPD area and, upon consenting to enrolment in the study, received a pen and version 2.1a[5] of the ODI questionnaire in English, which they filled out while waiting in queue.

Patients illiterate in English were assisted in completion of the ODI which was administered verbally to them and documented by the PI. The distance walked in the ODI was converted to metric units of length. One mile, half a mile and 100 yards were converted to: two kilometres, one kilometre and 500 meters respectively.

Patients were encouraged to ask questions to clarify any aspect of the ODI they were unsure of. There was no time limit placed on patients for completion of responses to the ten items in the ODI and they returned the questionnaire to the PI once complete. The PI reviewed the completion of the questionnaire and clarified any potential areas of confusion with the patient in person – for example, where more than one answer was selected for each section.

2.5.2. Pharmacological Data Collection

The PI reviewed medical records and analysed the medication prescribed following the patients' most recent visit to Spine OPD documenting the findings in the drug survey (Appendix E) as described below. The medication to take home (T.T.O.) was prescribed at the end of the consultation notes alongside which the pharmacist had documented the availability and quantity of drugs dispensed monthly through symbols and numbers (total number of pills was written adjacent to the specific medication).

The appropriate number of pills required (as per the clinician's prescription) was calculated. Where prescribed quantities matched that dispensed, "in stock" was documented in the drug survey adjacent the specific drug. Where the medication was not available (a stock out), and the symbol for it being out of stock "O/S" had been annotated and this was duly recorded. Any discrepancy in the quantity prescribed and that dispensed was documented as a "shortage".

As patients may have presented their file to the pharmacy several times since their previous clinical consultation and their presentation at the time of enrolment into the study (any number between one and six repeat T.T.O.'s), annotations from any single follow-up at the pharmacy was selected at random and documented.

The drug survey form classified drugs into several groups. Under these groups, commonly available medication available within SA was classified and listed. The drugs were listed under a variety of trade and generic names to avoid confusion and aid ease of data capturing for later analysis. These names were compiled from the SA's Monthly Index of Medical Specialities Desk Reference (MIMS).

These drug classes were listed as follows:

- Paracetamol
- NSAIDS
- Opioids
- Opioid-like drugs
- Combinations
- Muscle relaxants
- Topical analgesics
- Antiepileptics
- Antidepressants
- Antipsychotics

2.5.3. Data sorting

Patient information was subsequently captured using Research Electronic Data Capture (REDCap™) online software for analysis.

The data sets obtained from 279 enrolled patients included:

- Patient age
- Patient gender
- Responses to ODI items
- Availability of prescribed drugs

For each drug prescribed, availability was documented using the designations 1 (in stock), 2 (shortage) and 3 (stock out), 'substituted' (where the pharmacist had provided a similar class of drug to that prescribed due to drug shortage) and where drug status was not recorded, this was listed as 'not documented'.

ODI responses were also captured in REDCap™ with responses to all items of the questionnaire (sex life item was optional) recorded. Each answer was allocated a number (0 to 5) with increasing value allocated to responses indicating progressively worse disability.

2.6. Sample size

A sample size calculation was conducted to establish the numbers needed to recruit. A confidence interval of 95% was used with an estimated ODI value of 43%[5] in a

comparable population and a margin of error of 0.05[98]. The sample size calculation formula ($n = Z^2P(1-P)/e^2$) where 'n' is sample size, P is estimated prevalence, 'e' is the margin of error and 'Z^2' is the confidence interval was used. A minimum sample size of 192 was found to be representative of the population studied. The study managed to recruit 282 patients in total, three of whom were excluded due to several incomplete data sets.

2.7. Data analysis

Central tendencies of mean, standard deviation, median and interquartile range were used to summarise the data. Spearman's rank correlation and Mann Whitney U tests were both used in this study to test the non-parametric data collected. The one way ANOVA test was also applied to determine significant statistical differences in the non-normal data collected. All statistical tests were analysed by using IBM SPSS Statistics ® 24.0.

3. CHAPTER THREE – RESULTS

A total of 282 participants were recruited for the study. Only 279 participants were included in the data analysis. Three patients were excluded due to grossly incomplete responses.

3.1. Demographics and descriptive analysis of participants

3.1.1. Age

The mean age of the included participants was 57.1 ± 12.6 years. The youngest and oldest participants were aged 20 and 92 years old respectively.

3.1.2. Gender

The majority (79.6%) of participants were female as shown in Figure 3.1 below.

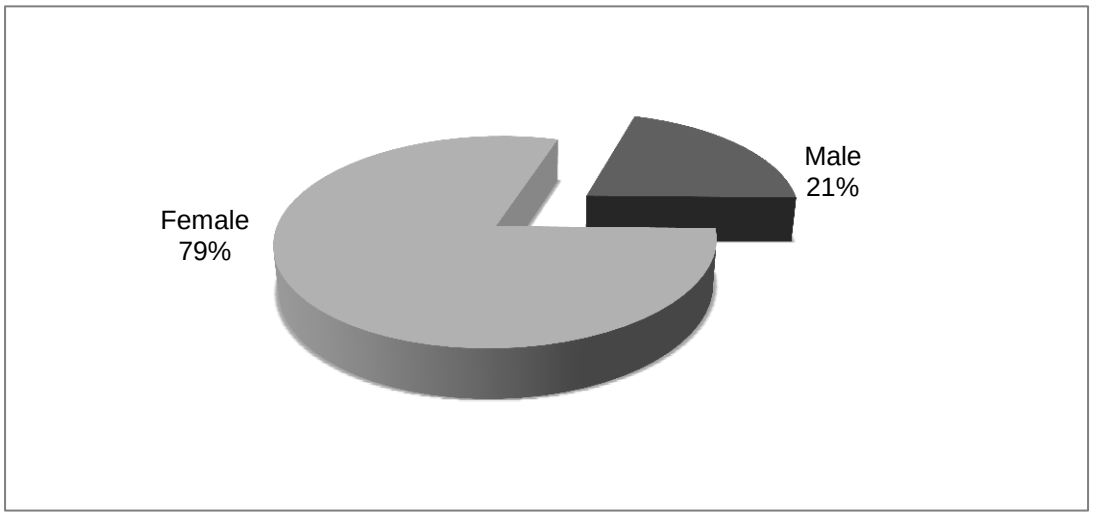

Figure 3.1: Participant gender distribution (N = 277)

3.2. ODI score outcomes

Of the 279 participants included in the study, only 42 participants completed the item related to their sex lives.

The median (interquartile range) ODI score of the participants was 48.9% (27) with a 25 - 75% interquartile range of 37.8 - 64.4%.

The minimum and the maximum percentage ODI score were 11% and 96% respectively. More than a quarter of the participants reported moderate disability

(28%), severe disability (35.1%) and crippling disability (28%) as shown in Figure 3.2 below.

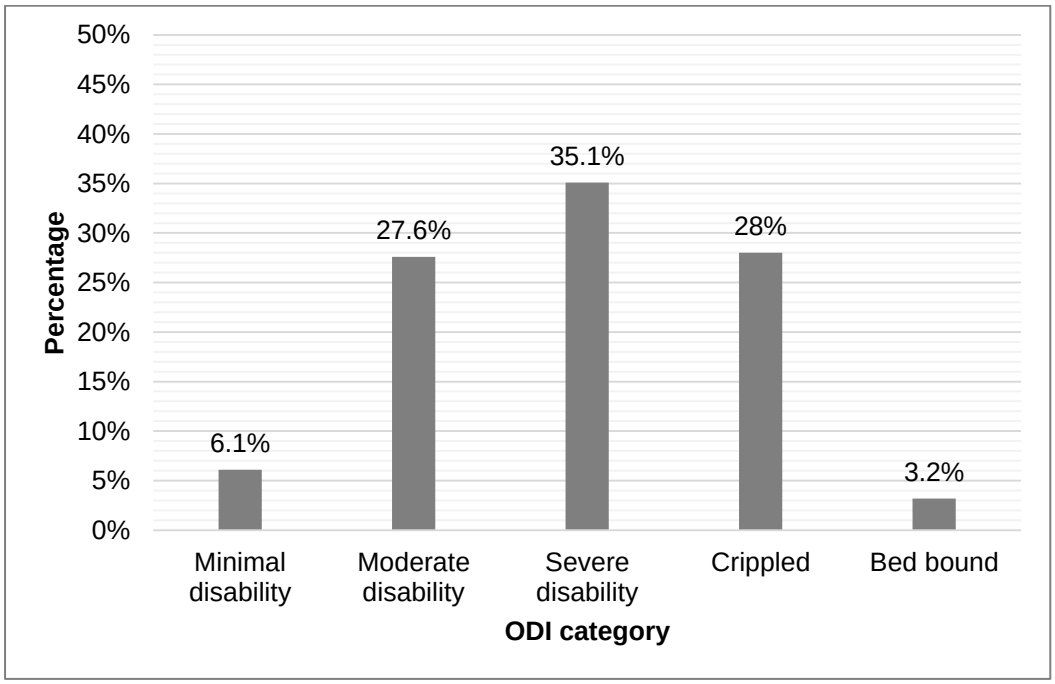

Figure 3.2: Participant ODI category (N = 279)

3.2.1. Gender and ODI scores

Table 3.1 below shows the ODI score with respect to the gender of the participants.

Table 3.1: ODI scores according to gender

Gender	Median ODI	Interquartile range	p value
Female	53.3	26.5	0,001
Male	40.0	26.3	

As shown in Table 3.1, females reported a significantly higher ODI than males, $p < 0.05$.

3.2.2. Age and ODI category

Table 3.2 below shows the mean age of the participants classified according to the disability status.

Table 3.2: Age (in years) of participants according to ODI category

ODI-9: Social life (N = 279)	Mean Age	Standard deviation	p
Minimal disability	52.8	12.2	
Moderate disability	55.3	12.7	
Severe disability	59.2	12.7	0.19
Crippled	56.2	11.8	
Bed bound	56.4	16.5	

Table 3.2 above shows that participants with minimal disability were younger (52.8 ± 12.2) years than participants that reported moderate – severe disability. There was no significant difference in the disability status of the participants with respect to their age ($p > 0.05$).

3.3. ODI item classification and responses

The ODI items were classified into 'Activity limitation', 'Participation restriction' and 'Impairment' according to the ICF disability classification [6, 7].

3.3.1. Activity limitation

Table 3.3 outlines the activity limitation related items in the Oswestry Disability Index, which are personal care, lifting, sleeping, travelling and walking.

Table 3.3: Activity limitation

ODI-2: Personal care (washing, dressing etc.) (N = 279)	n	%
I can look after myself normally without causing extra pain	67	24
I can look after myself normally but it is very painful	107	38.4
It is painful to look after myself and I am slow and careful	38	13.5
I need some help but manage most of my personal care	44	15.8
I need help every day in most aspects of self-care	22	7.9
I do not get dressed, I wash with difficulty and stay in bed	1	0.4
ODI-3: Lifting (N = 279)	**n**	**%**
I can lift heavy weights without extra pain	5	1.8
I can lift heavy weights but it gives extra pain	17	6.1
Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed e.g. on a table	7	2.5
Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned	52	18.6
I can lift only very light weights	162	58.1
I cannot lift or carry anything at all	36	12.9
ODI-4: Walking (N = 277)	**n**	**%**
Pain does not prevent me walking any distance	37	13.3
Pain prevents me from walking more than 2 kilometers	50	18.1
Pain prevents me from walking more than 1 kilometer	31	11.2
Pain prevents me from walking more than 500 meters	81	29.2
I can only walk using a stick or crutches	73	26.4
I am in bed most of the time and have to crawl to the toilet	5	1.8
ODI-5: Sitting (N = 279)	**n**	**%**
I can sit in any chair as long as I like	36	24
I can only sit in my favourite chair as long as I like	38	38.4
Pain prevents me sitting more than 1 hour	108	13.6
Pain prevents me from sitting more than half an hour	76	15.7
Pain prevents me from sitting more than 10 minutes	20	7.9
Pain prevents me from sitting at all	1	0.4

Table 3.3b: Activity limitation (continued)

ODI-6: Standing (N = 279)	n	%
I can stand as long as I want without extra pain	12	4.3
I can stand as long as I want but it gives me extra pain	38	13.6
Pain prevents me from standing more than 1 hour	68	24.4
Pain prevents me from standing more than half an hour	79	28.3
Pain prevents me from standing more than 10 minutes	78	28
Pain prevents me from standing at all	4	1.4
ODI-7: Sleeping (N = 279)	**n**	**%**
My sleep is never disturbed by pain	47	16.8
My sleep is occasionally disturbed by pain	82	29.4
Because of pain I have less than 6 hours sleep	40	14.4
Because of pain I have less than 4 hours sleep	67	24
Because of pain I have less than 2 hours sleep	39	14
Pain prevents me from sleeping at all	4	1.4
ODI-8: Sex life (N = 42)	**n**	**%**
My sex life is normal and causes no extra pain	7	17.1
My sex life is normal but causes some extra pain	8	19.5
My sex life is nearly normal but is very painful	3	7.3
My sex life is severely restricted by pain	6	14.6
My sex life is nearly absent because of pain	10	24.4
Pain prevents any sex life at all	7	17.1
ODI-10: Traveling (N = 279)	**n**	**%**
I can travel anywhere without pain	22	7.9
I can travel anywhere but it gives me extra pain	100	35.8
Pain is bad but I manage journeys over two hours	48	17.2
Pain restricts me to journeys of less than one hour	24	8.7
Pain restricts me to short necessary journeys under 30 minutes	23	8.2
Pain prevents me from traveling except to receive treatment	62	22.2

Table 3.3 shows the results of the activity limitation related components of the ODI. Pain was reported to limit physical activities, predominantly walking (55.6%) and standing (56.3%). Sitting for more than 30 minutes exacerbated pain in 27.2% of the participants and 62.4% of the participants could groom themselves with little or no pain.

3.3.2. Participation restriction

Table 3.4 outlines the limitation in social activities due to pain.

Table 3.4: Participation restriction

ODI-9: Social life (N = 279)	n	%
My social life is normal and gives me no extra pain	43	15.5
My social life is normal but increases the degree of pain	96	34.5
Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc	17	6.1
Pain has restricted my social life and I do not go out as often	49	17.6
Pain has restricted my social life to my home	34	12.2
I have no social life because of pain	39	14

As shown in Table 3.4, 43.8% of the participants reported limited or no social life because of pain. Only, 15.5% reported normal pain free social life.

3.3.3. Impairment (Pain intensity)

Table 3.5 outlines the severity of pain in the participants studied.

Table 3.5: Impairment

ODI-1: Pain (N = 279)	n	%
I have no pain at the moment	14	5.3
The pain is very mild at the moment	48	17.4
The pain is moderate at the moment	65	23.3
The pain is fairly severe at the moment	75	26.2
The pain is very severe at the moment	67	24.2
The pain is the worst imaginable at the moment	10	3.6

As shown in Table 3.5, 50.4% of the participants reported severe pain at the time of presentation. Pain intensity from the ODI was isolated and analysed.

3.3.4. Pain intensity classified according to the ODI category

Table 3.6 outlines the pain intensity of the participants according to their disability category.

Table 3.6: Pain intensity according to ODI category

Pain intensity	Minimal disability N = 17		Moderate disability N = 77		Severe disability N = 98		Crippled N = 78		Bedbound N = 9	
ODI response	N	%	N	%	N	%	N	%	N	%
No pain	3	17.6	6	7.8	4	4.1	1	1.3	-	-
Mild Pain	8	47.1	25	32.5	10	10.2	5	6.4	-	-
Moderate Pain	5	29.4	24	31.2	27	27.6	9	11.5	-	-
Fairly severe	1	5.9	17	22.1	35	35.7	20	25.6	2	22.2
Very severe	-	-	5	6.5	21	21.4	36	46.2	5	55.6
Worst imaginable	-	-	-	-	1	1	7	9	2	22.2

As outlined in Table 3.6 above:

- in participants with minimal disability (as determined by their ODI score), pain intensity was mainly mild (47.1%)
- in participants with moderate disability, pain was mostly mild-moderate (63.7%)
- in participants with severe disability, pain was moderate-fairly severe (63%)
- in participants with crippling disability, pain was mostly fairly severe – very severe (71.8%)

Spearman correlation coefficient showed significant moderate positive correlation between ODI score and pain intensity ($r_s = 0.61$, $p < 0.001$).

There was no significant correlation between age of the participants and the ODI score ($r_s = 0.03$, $p = 0.62$).

3.4. Association between pain, demographics and ODI items

There was no significant correlation between age of the participants and the ODI score ($r_s = 0.03$, $p = 0.62$). Further correlation analysis between the ODI items and pain is outlined in Table 3.7 below.

Table 3.7: Correlation analysis between ODI items and pain

Variable	Spearman rho	p value
Age	-0.05	0.45
Personal care	0.45	<0.001
Lifting	0.14	0.02
Walking	0.29	<0.001
Sitting	0.34	<0.001
Standing	0.32	<0.001
Sleeping	0.37	<0.001
Social life	0.33	<0.001
Travelling	0.35	<0.001
Sex life	0.18	0.27

As shown in Table 3.7 above, pain showed a weak, positive significant correlation with all the participation restriction and activity limitation ($p < 0.05$) except for the sex life category ($p > 0.05$).

3.5. Drug prescriptions

Table 9 outlines the summary of the prescribed drug into broad categories – antidepressants, antiepileptics, antipsychotics, combinations, muscle relaxants, opioid-like drugs, paracetamol, topical drugs and NSAIDs.

3.5.1. Generic and trade names of drugs prescribed

Clinicians had prescribed drugs using both generic and trade names, but the drugs were analysed under the generic name of their active ingredient.

- Paracetamol is the active ingredient in Painamol™ and Panado™.
- Celebrex™ contained the active ingredient celecoxib - a COX-2 selective NSAID.
- Diclofenac sodium is the active ingredient in Volatren™.
- Ibuprofen is the active ingredient in Nurofen™ and Brufen™.
- Indomethacin is the active ingredient in Arthrexin™, Arthrotec™ and Indocid™.
- Mefenamic acid is the active ingredient in Fenamin™.
- Piroxicam is the active ingredient in Feldene™ and Pixicam™.
- Tramadol hydrochloride (tramadol) is the active ingredient in Tramal™.
- Ibuprofen + paracetamol = Panado Plus™.
- Paracetamol + codeine = Painamol Plus™/ Spectrapain Forte™ / Stillpane™ / Paracods™
- Diclofenac diethylamine (diclofenac) is the active ingredient in Voltaren Emulgel™, Panamor Gel™.
- Methyl salicylate is the active ingredient in “rub rub”.
- Carbamazepine is the active ingredient in Tegretol™.
- Sodium valproate is the active ingredient in Epilim™.
- Clonazepam is the active ingredient in Rivotril™.
- Amitriptyline hydrochloride is the active ingredient in Trepiline™.
- Aripiprazole is the active ingredient in Abilify™.

3.6. Prescription Frequency by Drug Category

Table 3.8 outlines the summary of the prescribed drugs.

Table 3.8: Summary of drug categories prescribed to participants

Drug category	N
Paracetamol	101
NSAIDS	200
Opioid-like	239
Combination drugs	98
Muscle relaxants	10
Topical	63
Antiepileptics	13
Antipsychotics	1
Antidepressants	139

As outlined in Table 3.8, opioid-like drugs (n = 239), non-steroidal anti-inflammatory drugs (n = 200) and antidepressants (n = 139) were the most commonly prescribed drugs.

3.7. Drug Availability

Table 3.9 (following page) outlines the availability of drugs for the participants.

Table 3.9: Drug availability

NSAIDS	In stock	Shortage	Out of stock	Substituted	Not documented	Total	%
Diclofenac	71	41	10	4	5	131	65.5
Naproxen	9	9	5	2	2	27	13.5
Indomethacin	3	11	-	-	-	14	7
Piroxicam	7	3	2	-	2	14	7
Ibuprofen	1	8	-	-	2	11	5.5
Celebrex	-	1	-	1	-	2	1
Fenamin	1	-	-	-	-	1	0.5
Paracetamol	5	78	6	-	12	101	-
Combination drugs							
Paracetamol + codeine	5	74	6	-	9	94	95.6
Paracetamol + ibuprofen	-	4	-	-	-	4	4.1
Opioid-like Drugs							
Tramadol	15	197	7	-	20	239	-

Table 3.9 above outlines the availability of the prescribed NSAIDs for the participants. Diclofenac was the most prescribed NSAID contributing to 65.2% of all the NSAIDs prescribed, and it was in stock 54.2% of the time.

Paracetamol was prescribed a total of 101 times and there was a 77.2% shortage of the dose dispensed to the patients.

Of the 98 combination drugs prescribed, 95.6% were paracetamol + codeine, and it experienced a shortage in 78.7% of the prescriptions fulfilled.

3.8. Drug prescription and ODI status

Table 3.10 outlines the frequency of the prescribed analgesic and the disability status of the participants.

Table 3.10: Drug category prescribed to participants and disability category

Rx category, N	Minimal disability	Moderate disability	Severe disability	Crippled	Bedbound
Paracetamol	2	30	40	26	3
NSAIDS	11	57	65	60	7
Opioid-like	13	61	85	71	8
Combination drugs	11	26	33	23	3
Muscle relaxants	1	5	3	1	-
Topical	6	13	25	16	3
Antiepileptics	1	3	7	2	13
Antipsychotics	-	-	1	-	-
Antidepressants	3	37	51	42	6

As shown in Table 3.10, in the participants with minimal – moderate disability, opioid-like drugs (n = 74) and NSAIDs (n = 68) were mainly prescribed. Patients with severe and crippling disability were mainly prescribed opioid-like analgesics (n = 156), NSAIDS (n = 125) and anti-depressants (n = 93).

4. CHAPTER FOUR – DISCUSSION

4.1. Disability Status and pain intensity of patients with cLBP

This study examined the disability status of patients treated at the spine OPD for cLBP. It also assessed whether patients received the prescribed medication to manage their cLBP and, furthermore, analysed clinicians' prescribing habits.

A median disability score of 48.9% was reported among the participants in this study, whereas, an average ODI score of 43.3% was reported in one meta-analysis among chronic back pain patients receiving treatment[99] . This study showed slightly higher than the average disability scores, relative to other cLBP studies, where post-therapeutic disability was analysed[5, 100, 101].

In line with preceding studies, chronic back pain showed a significant effect in limiting several activities of daily living in participants[102-104]. The pain intensity item of the ODI questionnaire was used as a comparative item as well as an outcome measure in this study in documenting the severity of pain in the patients enrolled in this study. Pain intensity ratings leant towards the higher end of the scale, with 73% of patients reporting pain intensity as being 'moderate' to 'very severe'. The resultant outcome of chronic back pain was found in limited function and reduced activities of daily living due to pain, ultimately causing patient disability[102-104]. The ODI scores in this study classified 56% of enrolled patients as suffering from 'moderate' to 'crippling' disability. The increase in pain in our study was directly proportional to an increase in disability[105]. The investigators reasoned that, adequate pain management would reduce discomfort and pain, hence eventually reducing disability with improved quality of life[106].

One of the most affected activities of daily living reported in this study was mobility. Approximately fifty six percent (55.6%) of patients required the use of a walking aid and/or could not walk a distance of 500m without discomfort or pain. In contrast, 70.6% of patients were capable of standing for more than half an hour without pain. With a slow cadence of gait in cLBP, these altered biomechanics of the lower back and increased spinal loading elicited pain when walking rather than an upright posture alone would have done[49, 50]. In a not too dissimilar fashion, increased spinal

loading on lifting objects worsened back pain as evidenced by a significant proportion of patients who reported an ability to carry only light objects (58.1%).

Sitting was modestly impaired. While well over half (62.4%) of patients reported being able to sit as long as they wished, most of these patients (38.4%) reported a preferred type of seat. With respect to travel, most patients (53%) were able to take journeys of over two hours with their lumbar spine kept in relative lumbar flexion while presumably seated.

The nominal effect of pain was further evidenced by data on sleeping habits. A large sum of patients (46.2%) reported being able to sleep well unaffected by, or with minimally disrupted sleep, in spite of pain. Similarly, social life was another item disproportionately affected - 50% of patients maintained a normal social life despite aforementioned ‘severe disability’ or ‘crippling’ pain.

Personal care remained largely unaltered for a majority of patients, with 62.4% reporting normal grooming habits without, or despite, pain. This was presumptively because their posture (standing upright or sitting down) while getting dressed, did not exacerbate

It was found that pain had no correlation with the sex life category ($p>0.05$). It should be noted that only 42 (15%) of the participants responded to this question. The relatively small number of patients who elected to complete this item made us question the statistical value of our findings. Several studies cite local (South African) and global cultural taboos surrounding discussions about sex, to explain their similarly low response rate to this particular ODI item[107-110]. Some researchers even questioned the inclusion of this item in the ODI, citing the concern that its inclusion may be discouraging patients from participating in the questionnaire entirely[110]. These social norms were, presumably, the cause of the meagre response rate to this question in this study.

Although this study did not objectively document the ambulatory status of participants, researchers anecdotally reported that a majority of patients recruited for this study were mobile and most had walked several hundred meters through the hospital building to access the Spine clinic. In contrast, a large percentage of participants’ results suggested that patients suffered ‘crippling’ symptoms, and that

their pain had caused them to be ‘bed ridden’. The raised median functional disability scores in our study population, conflicted findings that indicated a majority of participants coped well in most (five out of eight) ‘activities’ and did well in the ‘participation’ item.

Several possible reasons for this apparent discrepancy were entertained. Firstly, the self-reported nature of the study lent itself to inaccuracies. This notion was consistent with other studies based on self-reported data[111, 112].

Medical literature has identified catastrophising of pain as a coping mechanism in patients. Albeit, a maladaptive technique found in patients suffering from chronic pain, this problematic technique has been well recognised as a potential reason behind higher pain, and hence disability, scores[111].

The majority (79.6%) of participants were female in this study. A statistically significant difference was found between the ODI scores of females in comparison to the males. Females had a median ODI score of 53.3% and males 40.0%. This gender disparity was consistent with several studies and large scale trials on LBP, in which females reported higher pain intensity, disability and interference with activity of pain, than men[113, 114]. Given the significant number of female participants, their higher scores would have raised the median ODI in this study.

Chronic pain is more disabling for women than men for the same condition[115, 116]. Pain also has a raised prevalence in women attributed to gender differences in coping strategies, and higher rates of catastrophising in women[115, 116]. Various responses to drug therapies differ between males and females. Although it is unclear why, women have been shown to respond better to morphine analgesia than with other types of analgesia[116]. Additionally, hormonal changes have been associated with an increased incidence of back pain in peri- and post-menopausal women[117]. These hormonal changes are associated with an increased risk of co-morbidities such as osteopaenia and osteoporosis, which, by definition, increase the risk of vertebral fractures[117].

Women, in general, demonstrate better health-seeking behaviour than men and

have historically been reliable in attending to their health care concerns [118]. This is evidenced by the fact that, even when corrected for female-specific conditions, women visit health care providers more often, and even have longer consultation times than men[119]. This is, perhaps, why this study enrolled a significant number of women.

Although race was not documented, the local population in Soweto served by CHBAH is predominantly Black (98.4%)[120]. American literature on the association between race and a perception of pain suggests that historically, socially disadvantaged populations – Blacks, Hispanics and Asians - reported higher pain intensity, disability and interference of pain with activity compared to other racial groups[121-123]. Our patients' demographic background – particularly in the light of their upbringing in a racially segregated society – may have influenced their perception of pain[123].

Another potential reason for higher pain scores was the likelihood of secondary gain[124-127]. Patients enrolled may have embellished their responses in order to influence the clinician's documentation of symptoms on their disability grant application. Soweto, as an economically impoverished precinct of Johannesburg, has a significantly indigent population. In SA, women have higher unemployment rates[128]. Disability in this population has an untold a knock-on effect on the local economy through lost productivity and a raised demand on healthcare systems and social services[126].

Women earn less and experience worse states of poverty than men and male-headed households do[128]. Furthermore, nationwide, a significant proportion of grant recipients are Black women (63.4% of whom live below the poverty line) [128]. Without trivialising the disability brought on by cLBP, the physical limitation associated with pain would exacerbate female patients' difficulty in finding or keeping employment, so, while their symptoms with activities of daily living may be tolerable, manual labour may exacerbate their cLBP, thus necessitating an increasing dependency on social grants. The disadvantaged socioeconomic status of our patient population could result in malnutrition.

The impeding effect of raising children on women's careers, also distributes the working population of women towards their middle age. Approximately 30% of employed women in SA are at least 45 years old[128]. The impact of LBP in a socioeconomically active population would have a negative knock-on effect on SA's economy due to absence from work, inability to return to work and increased dependency on social grants. While information on financial and employment status was neither sought after by investigators in this study, nor had investigators any influence on treating clinicians' opinions with respect to disability grant applications, it is possible, however, that patients may have overstated the severity of their pain.

Lastly, the raised ODI median found in this study may also have been as a result of drug shortages. While patients with acute LBP present with relatively high ODI scores that improve with time, our population appears to have failed to follow a similar improving pattern, possibly due to lack of access to therapeutic drugs as a consequence of health care system failures. It is probable that the incongruous results are as a result of both erratic drug availability and selective use of analgesics by patients. It is entirely conceivable that the shortages would force patients to ration their use of analgesics, preferring to use them on certain occasions rather than to maintain pain control. These occasions may be saving analgesia for use exclusively before bed, prior to travel or attending social events.

The population studied comprised predominantly of a middle aged population with a mean age of 57.1 ± 12.6 years. The youngest and oldest participants were aged 20 and 92 years old respectively. While the data showed that participants with minimal disability were younger (52.8 ± 12.2 years) than those who reported 'moderate' to 'severe' disability, there was no significant difference in the disability status of the participants with respect to their age ($p > 0.05$) and no significant correlation between age of the participants and the ODI score ($r_s = 0.03$, $p = 0.62$).

While LBP generally shows a higher prevalence in older adults, our study was unable to replicate this. This may potentially have been because the sampling method used in this study was purposive in nature[113, 129]. By default, investigators may have been more likely to interact with a certain age of patients owing to patient level of literacy, willingness and ability to engage in turn with investigators, lending

bias to the age group enrolled. As a significant proportion of patients were of a similar age, no statistically significant correlation between age and disability to function was found.

4.2. Prescribed Medication

Clinicians followed local and international guidelines in their prescribing habits. While paracetamol was prescribed to patients, it was always recommended for use in concert with other drugs (NSAIDS, tramadol, trepiline etc.).

Opioid-like drugs (n = 239), NSAIDS (n = 200), antidepressants (n = 139) and paracetamol (n = 100) were the top four most prescribed drugs. Patients with 'severe' and 'crippling' disability were mainly prescribed opioid-like analgesics (n = 156), NSAIDS (n = 125) and anti-depressants (n = 93) and paracetamol (n = 66).

Diclofenac sodium was the most prescribed NSAID in this study - contributing to 65.2% of all the NSAIDs prescribed. Clinicians prescribed diclofenac nearly five times more often than any other NSAID, but it was in stock and available as prescribed only 54.2% of the time. In fact, nearly every NSAID prescribed experienced shortages, except Fenamin™ (mefenamic acid), which was prescribed (and readily available) once.

Patients with 'severe' and 'crippling' disability were most likely to be prescribed anti-depressants (n = 93), while those with crippling pain received the bulk of antiepileptics prescribed (n = 13).

Paracetamol was prescribed a total of 101 times during this study, but there was a shortage of the drug for 77.2% of patients. In order to benefit from the use of this drug, patients would be required to take up to the maximum daily recommended dose of 4 000mg[70].

Of the 98 combination drugs prescribed in this study, 95.6% were paracetamol and codeine, which experienced a shortage in 78.7% of the prescriptions fulfilled.

Muscle relaxants were among the least prescribed drug (n = 10). Opioids were not prescribed for any patient in the study.

Topical medication was prescribed for 63 patients, likely for patient self-massage or for a family member to use in a simplified version of physical therapy at home. Their biochemical action has not been proven to improve symptoms in cLBP.

With the exception of the use of rubefacients in 23% of patients, the study found that clinicians prescribing habits followed evidence based guidelines.

4.3. Conclusion

To the best knowledge of the investigators, this is the largest study to date, analysing cLBP symptoms in an out patient population in South Africa. It is also the largest, formally documented survey of drug shortages at a single centre in South Africa.

Relative to other studies using ODI scores to analyse patient outcomes, an above-average disability score median of 48.9% was found.

The investigators believed that the significant disability described was aggravated by an inadequate supply of pain medication. Notwithstanding the adverse influence of disability on the South African economy, the current health care system appears to be failing to meet the needs of a significant population suffering with chronic LBP.

Clinicians prescribing habits followed evidence based guidelines - with the exception of the use of rubefacients in approximately 23% of patients. Tramadol was the most prescribed drug overall and was followed by NSAIDS in combination with other drugs. Despite the preferential use of tramadol, it was only available as prescribed 7% of the time. Paracetamol was available only 23% of the time and prescribed, and non-steroidal anti-inflammatories freely accessible only 46% of the time.

4.4. Limitations and recommendations

The limitations encountered during this study were that a self-administered assessment was used rather than the clinician’s subjective analysis of pain. A single ODI also has limited value in assessing patient response to treatment, however ODI questionnaires should be filled out at primary care clinics prior to therapy and referral to secondary or tertiary medical institutions to aid in analysing response to therapy and disability status.

Drug supply issues should be redressed at every level of healthcare in SA. It is clear that the current steps taken to resolve chronic drug shortages and stock-outs have failed.

Future studies on back pain management in our setting should be expanded to include the contribution of allied and alternative health care options in the management of cLBP.

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APPENDIX A: PATIENT INFORMATION/CONSENT SHEET

Dear Patient, I am Dr. Anne Maina, a registered medical doctor practicing as an orthopaedic registrar at Chris Hani Baragwanath Academic Hospital (CHBAH). You are invited to volunteer for a research study which I, Dr. Maina, am conducting as the Chief Investigator with the assistance of a spine specialist, Dr. Ukunda as well as the Head of Clinical Orthopaedic Service, Prof. Ramokgopa. This will be done with the help of Orthopaedic Registrars and Medical Officers working in the spine unit. This form is to help you decide if you would like to participate. Before you agree to take part in this study, you should fully understand what is involved. If you have any questions that are not answered in this document, do not hesitate to ask your treating doctor or me. You should not agree to take part unless you are completely happy with the process involved.
What is the purpose of this study? You have been diagnosed as suffering with low back pain and the investigator would like you to consider answering two questionnaires that involve determining how severe your low back pain has been in the three months as well as the medicine you have taken over the same time.
How long will it take for me to complete the questionnaire? It will take you ten minutes to complete the back pain questionnaire.
Has this study received ethical approval? This study Protocol has been submitted to the Faculty of Health Research Ethics Committee (Medical), University of Witwatersrand. Written approval to conduct this study has been granted by the Health Research Ethics Committee (HREC). The study has been structured in accordance with the Declaration of Helsinki (last update: October 2008), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from me should you wish to review it. To contact the HREC directly, please call Prof. Cleaton-Jones on 011 717 2301, email: peter.cleaton-jones1@wits.ac.za alternatively contact the administrative officers Ms. Z. Ndlovu / Mr. Rhulani Mkansi / Mr. Lebo Moeng on 011 717 2700 / 2656 / 1234 / 1252; email zanele.ndlovu@wits.ac.za, rhulanimkansi@wits.ac.za or lebo.moeng@wits.ac.za. Protocol reference number: M160406
What are my rights as a participant in this study? Your participation is entirely

voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to medical care at CHBAH. If it is discovered that you did not give an accurate indication of medication taken or did not follow the instructions provided on the questionnaires, you may be withdrawn from the study at any time.

Financial arrangements: There is no financial reimbursement for participating in this study. Neither you nor CHBAH are required to make any payment to participate in this study.

Source of additional information: These questionnaires are distributed by, and will be collected and assessed by me. The collection of information for this study will be conducted with the assistance of spine specialist Dr Ukunda and other orthopaedic doctors working in the spine unit. If at any time you have any questions or concerns about the study, please do not hesitate to contact me on 011 933 8914.

Confidentiality: All information obtained from these questionnaires is strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a patient in this study. Any information regarding your treatments and condition will be held in the strictest confidence.

Informed consent: I hereby confirm that I have been informed by the treating doctor, about the nature, conduct, benefits and risks of this study on management of my back pain. I have also received, read and understood the above information leaflet regarding this study. I am aware that the results of this study including my patient number, age and sex will be anonymously processed into a study report. I may at any stage, without prejudice, withdraw my consent and participation in the trial.

I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Patients full name: _____

Patients ID number: _____

Patients signature: _____ Date: _____

I, Dr. _____ herewith confirm that the above patient has been fully informed about the nature and conduct of this study.

Investigators name: _____

Investigators signature: _____Date: _____

Translators name: _____

Translators signature: _____

Witness name: _____

Witness signature: _____Date: _____

APPENDIX B: PATIENT CONSENT FORM FOR ANOTHER PERSON TO ACCESS THEIR MEDICAL RECORDS

Patient consent form for another person to access their medical records			
Patient Details			
Surname			
First Names			
Date of Birth		Sex	
Address			
Contact Number			
Details of persons to be given access to this patient's information			
Full Name	Dr. A. Maina, Dr. F. Ukunda, Prof. M. T. Ramokgopa and attending doctors at the Chris Hani Baragwanath Spine OPD		
Address	Chris Hani Baragwanath Academic Hospital, Soweto Contact: 011 933 8914		
I confirm that I give permission for Chris Hani Baragwanath Academic Hospital to communicate with the persons identified above in regards to my medical records.			
Signature			
Date			

APPENDIX C: INFORMED CONSENT SOURCE DOCUMENT

Informed consent source document	
Full Patient Name:	Patient ID number:
Patient No.:	Protocol No.: M160406
Date consent obtained:	Time consent obtained:
Name of person who explained study:	
Subject verbalised understanding of risks, benefits and other relevant issues.	
Initials:	Date:
All questions and concerns addressed and answered to the patient's satisfaction.	
Initials:	Date:
Patient stated they understood they would receive standard medical care regardless of participation in study	
Initials:	Date:
Patient verbalized understanding that they could withdraw consent at any time.	
Initials:	Date:
Patient given a copy of the signed and dated information and consent form	
Initials:	Date:
Patient signed a copy permitting access to their medical records.	
Initials:	Date:
No research study procedures done prior to consenting	
Initials:	Date:
Comments:	
Translator Name:	Translator Signature:
Witness 1 Name:	Witness 1 Signature:
Witness 2 Name:	Witness 2 Signature:
Signature of investigator:	Date:

APPENDIX D: OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE

Oswestry Low Back Pain Disability Questionnaire
Patient number: Age: Sex: Female/Male
Instructions: This questionnaire has been designed to give us information on how your low back pain is affecting you every day. Please check ONE statement in each section that best describes how your low back pain has affected you over the last seven (7) days.
Section 1 – Pain intensity ☐ I have no pain at the moment ☐ The pain is very mild at the moment ☐ The pain is moderate at the moment ☐ The pain is fairly severe at the moment ☐ The pain is very severe at the moment ☐ The pain is the worst imaginable at the moment
Section 2 – Personal care (washing, dressing etc.) ☐ I can look after myself normally without causing extra pain ☐ I can look after myself normally but it is very painful ☐ It is painful to look after myself and I am slow and careful ☐ I need some help but manage most of my personal care ☐ I need help every day in most aspects of self-care ☐ I do not get dressed, I wash with difficulty and stay in bed
Section 3 – Lifting ☐ I can lift heavy weights without extra pain ☐ I can lift heavy weights but it gives extra pain ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed e.g. on a table

- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 2 kilometers
- ☐ Pain prevents me from walking more than 1 kilometer
- ☐ Pain prevents me from walking more than 500 meters
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time and have to crawl to the toilet

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than 1 hour
- ☐ Pain prevents me from sitting more than half an hour
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing more than 1 hour
- ☐ Pain prevents me from standing more than 30 minutes
- ☐ Pain prevents me from standing more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain

- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Traveling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from traveling except to receive treatment

APPENDIX E: MEDICATION SURVEY

Medication Survey		
Patient number:	Age:	Sex: Female/Male
Instructions This questionnaire has been designed to give the investigators information on how much and what medication the patient takes for his/her back pain. 1. Circle the drug(s) in each section that the patient is taking for their pain (there may be more than one medicine in each section). 2. Draw a line connecting the drug to the dose of medication that is taken daily or regularly (i.e. more than 3 days in a week). 4. If there are drugs prescribed but not dispensed due to “stock outs” (indicated by the symbol “O/S”) indicate how long (weeks/months) the patient did not have access to this medicine over the last three (3) months 5. If you note any discrepancy between the volume prescribed and volume dispensed indicate this using the means described above.		
Medication Type and name (please circle applicable medication taken)	Dose (no. tabs/caps/supps)	No. of times taken/day
PARACETAMOL: Napamol, Painamol, Panado, Paracetamol, Prolief		
NSAIDS: Advil, Aleve, Arcoxia, Arthrexin, Arthrotec, Betacin, Betagesic, Betaprofen, Brexecam, Brufen, Catafast, Cataflam D, Celebrex,		

Coxflam, Disprin, Tora-Dol, Diclofenac, Dicloflam, Diclohexal, Dynak-50, Ecotrin, Fenamin, Flamecid, Flexocam, Fortfen, Iboflam, Ibucine, Ibuprofen, Indomethacin, Inza, K-fenak, Ketoflam, Loxiflam, Mefenamic acid, M-cam, Medoxicam, Meloxicam, Mobic, Nafasol, Napflam, Nurofen, Painil, Ponac, Ponstan, Ponstel, Panamor, Naproxen, Pixicam, Pyrocaps, Ranfen, Rayzon, Rheugesic, Synflex, Veltex, Vimovo, Voltaren, Xefo		
OPIOIDS: Adco Tenyl, Cyclimorph, DF-118, Durogesic, Jurnista, Morphine MST, Ompon, Oxycontin, Oxynorm, SRM Rhotard, Subutex, Temgesic		
OPIOID-LIKE: Dolotram, Domadol, Methadone, Nobligan, Tramahexal, Tramadol, Tramal, Tramaspen, Tramazac, Tramagesic		
COMBINATIONS: Abflex-4, Acurate, Adco-Dol, Adco-Napacod, Aco-Payne, Adco-Salterpyn, Antipyn Forte, Ban Pain, Besemax, Betapyn, Co-codamol, Codoxol, Compral, Dentopain, Doxyfene, Empacod, Excedrin, Gen Payne, Go-Pain, Ibucod, Ibumol, Ibupain, Lenadol, Lenapain, Lentogesic, Lotem, Meprogesic, Mepromol, Mybucod, Mybulen, Mypaid, Myprodol, Norflex		

Co, Painagon, Painamol Plus, Panado Plus, Propain, Pynmed, Pynstop, Spasmend, Spectrapain Forte, Stilpane, Stopayne, Suncodin, Synaleve, Synap Forte, Syndol, Tensolve, Tensopyn, Tenston, Tramacet		
MUSCLE RELAXANTS: Baclofen, Lioresal, Myprocam, Norflex, Robaxin		
TOPICAL: Sovenor, Counterpain, Diclohexal gel, Fastum, Panamor gel, Reparil gel, Rheugesisc, Transact, Voltaren Emulgel, “Rub Rub”		
ANTIEPILEPTICS: Carbamazepine, Convulex, Degranol, Epanutin, Epilim, Epilizine, Epiproate, Epitec, Epitoz, Epleptin, Keppra, Lamictin, Lamidus, Lamitor, Lamotrigine, Levetiracetam, Lyrica, Mysoline, Navalpro, Neurontin, Phenytoin, Redilev, Rivotril, Sabril, Tegretol, Topalex, Topamax, Topiramate, Toplep, Trileptal, Zarontin		
ANTIDPRESSANTS: Amitriptyline, Anafranil, Aropax, Camcolit, Cilate, Cilift, Ciloram, Cipralex, Cipramil, Citalohexal, Citalopram, Citraz, Cymbalta, Cymgen, Deparoc, Depnil, Depramil, Deprozan, Edronax, Efegen, Efexor, Emdalen, Equinorm, Escitalopram, Ethipramine,		

Faveran, Fluoxetine, Flutinol, Fluvoxamine, Illovex, Lantanon, Lexamil, Limbitrol, Lorien, Ludiomil, Luvox, Mirteron, Mirtazapine, Molipaxin, Mytra, Nuzak, Odiven, Parax, Paroxetine, Paxil, Parnate, Prohexal, Prozac, Ramure, Ranflocs, Remeron, Rezak, Scripto-metic, Serdep, Serlife, Sertra, Sertraline, Talomil, Thaden, Tofranil, Traxodone, Trepiline, Trizac, Tydamine, Valdoxane, Venlafaxine, Venlor, Wellbutrin, Xet, Zolid, Yelate, Zoloft, Zosert, Zydus, Zylin, Zytomil		
ANTIPSYCHOTICS: Abilify, Cloment, Clopixol, Clozapine, Dopaquel, Eglonyl, Espiride, Etomine, Fluanxol, Geodon, Haloperidol, Invega, Largactil, Leponex, Modecate, Oleanz, Olexar, Orap, Perizal, Psyquet, Quetiapine, Redilanz, Risinia, Rispacor, Risperidal, Risperidone, Risperlet, Risponz, Rutra, Schizorol, Scriptometic, Serenace, Serez, Seroquel, Solian, Stelazine, Sulpiride, Truvain, Xepilon, Zoxadon, Zyprexa		

APPENDIX F: CONFIRMATION OF STUDY APPROVAL (WITS HUMAN RESEARCH AND ETHICS COMMITTEE)

R14/49 Dr Anne Wanjiru Maina and Dr Ukunda

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160406

NAME: (Principal Investigator)	Dr Anne Wanjiru Maina and Dr Ukunda
DEPARTMENT:	School of Clinical Medicine Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Adequacy of Back Pain Management at the Orthopaedic Spine Clinic (OPD) Located at Chris Hani Baragwanath Academic Hospital (CHBAH)
DATE CONSIDERED:	06/05/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Mmampapatla Ramokgopa
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	22/06/2016

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 the conditions under which I am/we are authorised 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 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 review in April and will therefore be due in the month of April each year.

Principal Investigator Signature

Date 12 Mar 2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX G: PERMISSION TO CONDUCT RESEARCH (MEDICAL ADVISORY COMMITTEE, CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL)

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 27 May 2016

TITLE OF PROJECT: Patient perception of back pain management at the Orthopaedic Spine Clinic located at Chris Hani Baragwanath Academic Hospital

UNIVERSITY: Witwatersrand

Principal Investigator: AW Maina

Department: Orthopaedics

Supervisor (If relevant): F Ukanda

Permission Head Department (where research conducted): Yes

Date of start of proposed study: May 2016
Date of completion of data collection: Dec 2018

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: 27 May 2016

Received by: ..... Date: 7/6/16.

.....
Approved/Not Approved
Hospital Management
Date: 31/05/16.