

A Review of Psychotropic drug prescription for
patients with Intellectual disability at
Alexandra Hospital (a specialist Intellectual
Disability psychiatric hospital) outpatient clinic



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ABSTRACT

A Review of psychotropic drug prescription for patients with Intellectual disability at Alexandra Hospital (a specialist Intellectual Disability psychiatric hospital) outpatient clinic.

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Background: People with intellectual disability are more likely than the general population to be prescribed psychotropic agents. The most common indications include treatment of a psychiatric disorder and management of behaviours that challenge.

Aim: The study aimed to assess the prescribing patterns of psychotropic medication to outpatients with intellectual disability at a psychiatric hospital.

Setting: Alexandra hospital outpatient clinic, Cape Town.

Methods: This was a retrospective folder and prescription chart review. Folders of all new patients (103) seen between January 2018 and August 2019 were examined at two points, the initial appointment and again at six months. The information was examined against the World Psychiatric Association (WPA) and the National Institute for Health and Care Excellence (NICE) guidelines for prescribing in people with intellectual disability.

Results: psychotropic medication was prescribed to 88% of patients. Antipsychotics accounted for more than 56% of the medication prescribed and was used mainly to manage behaviours that challenge. Clinicians at Alexandra hospital followed

prescribing guidelines to some extent; however, more still needs to be done to ensure best practice and care.

Conclusion: This review revealed a few shortcomings in meeting prescribing guidelines by clinicians at Alexandra hospital. Measures to address these shortcomings could be the inclusion of medication review schedules and standardised forms for clerking and monitoring of side effects in patient files, the use of behavioural strategies as the primary management of behaviours that challenge, and the performance of regular clinical practice audits.

Key Words: Intellectual disability; learning disability, psychotropic medication; challenging behaviour, prescribing patterns

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Figure 1: Psychiatric diagnoses of patients**Error! Bookmark not defined.**

Figure 2: Medication prescribed at initial and 6-months assessment **Error! Bookmark not defined.**

Figure 3: Medication Changes**Error! Bookmark not defined.**

LIST OF ABBREVIATIONS

Attention Deficit and hyperactivity Disorder (ADHD)

Autism Spectrum Disorders (ASD)

Behaviours that Challenge (BTC)

General Practitioner (GP)

Intellectual disability (ID)

National Institute for Health and Care Excellence (NICE)

World Psychiatric Association (WPA)

CHAPTER 1

1.1 INTRODUCTION AND LITERATURE REVIEW

Introduction

Intellectual disability (ID), with onset before 18 years, is characterised by significant limitations in cognitive functioning and adaptive skills in the social, practical, and conceptual domains (1). To make the diagnosis, as stated in the fifth edition of the diagnostic and statistical manual of mental disorders (DSM-5), page 33, certain criteria should be met in those two major areas namely,

- Both individualised standardised intelligence testing and clinical assessment confirm the deficits in intellectual functioning. The deficits may manifest as difficulty with reasoning, planning, solving problems, judgement, abstract thinking, learning from experience and academically.
- Due to deficits in adaptive functioning, individuals do not meet the expected developmental and sociocultural standards of social responsibility and personal independence. These deficits are associated with limited functioning in tasks of daily life such as communication, personal independence, and social involvement and are noted as an issue across multiple settings, such as home, school, work, and the community (1,2).

While approximately 1% of the world's population is estimated to have intellectual disability (1,3), statistics among the South African population regarding the prevalence of ID are limited. Adnams (2010) noted a paucity of available data to estimate the prevalence of intellectual disability in the South African population. She reported on the findings of 3 regional household surveys, which estimated the prevalence of severe intellectual disability to be 1.1% in 1999, 0.5% in 2002, and 0.27% in 2007 (examining severe intellectual or learning disabilities) (4). Kleintjes et al. (2006). reported expert consensus prevalence estimates in the Western Cape Province of South Africa for adults with ID of 2.5% (IQ below 70), 0.4% (IQ below 50), and 0.1% (IQ below 30) (5). Similar rates were reported for children and

adolescents (5). The overall South African prevalence rate of ID may be higher than in other low- and middle-income countries due to the exceptionally high rates of several preventable conditions that may cause the onset of ID in the early period of life. These conditions include nutritional deficiencies, infectious diseases such as HIV/AIDS and tuberculous meningitis, foetal alcohol spectrum disorder (FASD) as well as violence and injury (4).

People living with ID are a unique population when compared to the general population. They are more likely to develop mental illness, occurring up to 2.5 times higher than the general population (6,7). The lifetime prevalence of comorbid mental illness for people with ID ranges from 15% to 50% (8). They may display various behaviours that challenge, which are often difficult to contain. Comorbid medical conditions may further complicate this. These and other factors greatly influence prescribing patterns of psychotropic agents. As with the general population, the patient with ID is entitled to high-quality health care. This care can be administered through pharmacological and non-pharmacological means. Pharmacological management of mental health issues with psychotropic agents includes various classes such as antipsychotics, antidepressants, and more. These drugs, in addition to strategies that include but are not limited to access to psychological and other allied services, appropriate residential, school, and occupational placement, and adequate support for the patient and caregivers, form part of a comprehensive management plan for the patient (9,10).

Alexandra Hospital is a specialist psychiatric hospital situated in Cape Town, South Africa. It provides healthcare to children, adolescents and adults with intellectual disability and associated complex mental health needs such as comorbid psychiatric and/or behavioural problems which are not manageable within the local community mental health services (11,12). The current study aims to assess the extent to which the prescribing patterns of psychotropic medication at Alexandra hospital meet international standards.

A rapid narrative review of the literature was conducted during the conceptualisation of the study to provide an overview of current research in the area of enquiry, prescribing patterns of psychotropic medication in patients with intellectual disability, as well as to identify suitable prescribing guidelines which could be used to inform

the assessment of current practice at the research site. The reviewed literature would also provide a framework of data to be extracted during the research endeavour.

Method

The Pubmed and Cochrane databases were searched directly, using the Medical Subject Heading (MeSH) terms 'intellectual disability', 'learning disability', and 'psychotropic medication' to access published peer-reviewed journal articles relevant to the study. Adding terms 'South Africa' or 'Africa' yielded no results. Inclusion criteria for the review were peer-reviewed journal publications, qualitative, quantitative, and mixed-method studies published in any language without restriction by date or country. An Internet-based translation application was used to translate foreign language articles. The title and abstracts of the sourced papers, 127 from Pubmed and 2 from Cochrane were scanned, and 42 publications found relevant by abstract were saved in an online folder with the full text of these then read by the researcher to assess if relevant to the review focus. Included full-text papers (n= 28) were then read to extract relevant data. Munn et al 2018. report that when literature is being reviewed to provide an overview of the available evidence, as in the case of a scoping review, quality assessment of included papers is not necessary (13). The 28 papers included in this study were reviewed to gain insight into the current trends in the field and thus were not subject to rigorous assessment of quality(13).

Findings

Each article was read and, using open coding, analysed for content related to prescribing practices and relevant principles. Once the documents were analysed, the content extracted from the articles was collated into meaningful themes. This process yielded five (5) main themes summarised below: indications for use, polypharmacy, adverse reactions, practitioner competence, and international guidelines.

Indications for psychotropic medication use

The reviewed literature indicates that psychotropic medication is often prescribed to people living with intellectual disability to treat a comorbid psychiatric disorder or manage behaviours that challenge, such as destruction of property, aggression, self-injurious behaviour, hyperactivity, stereotypies, and severe temper tantrums (9,14).

Reliable diagnosing of mental disorder in people living with ID, however, is complex due to a variety of factors, including the severity of ID; atypical presentation (for example, mood disorders that present with challenging behaviour and aggression rather than with sad mood); deficits in communication and health literacy; or difficulties in accessing services. These complicating factors may thus lead to over- or under-treating with psychotropic agents (3,8,15,16).

It is also important to consider the age of patients to whom psychotropic medication is prescribed. Most recognized and approved psychotropic medications are trialled and licensed for use in adults. There is limited medication approved for use in children and adolescents, with psychostimulants for ADHD and some antidepressants for anxiety and depression licensed for use in young ones (17). As such, the informed use of unlicensed medications or licensed medication for unlicensed applications (known as “off-label” use) is often necessary in paediatric practice. In children with mild non-psychotic disorders, psychological or environmental interventions are usually recommended as the first line of management. Where medication is required, close monitoring for safety, efficacy, and adverse reactions, must be done (18). Reviewed studies primarily focused on adults. Where reference was made to children and adolescents, this is noted.

A consistent finding in the reviewed studies across various locations, such as the Netherlands, the UK, and Ireland, is that antipsychotics tend to be the most prescribed class of psychotropics. There is cause for some concern as the evidence showed that while only 3% of this population have a psychosis-related disorder, an estimated 30% - 50% of psychotropics prescribed are antipsychotics (8,15,19). The studies indicate that the reason for over-prescription of antipsychotic drugs to this population is often to manage behaviours that challenge, with those conducted in Sweden and the UK showing that this likelihood, possibly in combination with a

benzodiazepine derivative, is increased when there is comorbid autism spectrum disorder (ASD) or dementia (3,20).

ASD is a neurodevelopmental disorder that is characterised by difficulty with social interaction and communication, as well as restricted and repetitive behaviour. No pharmacological treatment has been licensed to manage these core symptoms of ASD. The complex mental and physical health problems associated with ASD and ID, along with communication difficulties, can lead to a display of maladaptive behavioural patterns that are often the target of psychotropic interventions (18,21).

The use of antipsychotics to manage BTC is classified as an off-label indication for use (10). When used in this manner, it is especially important that clinicians adopt the “start low and go slow” philosophy (10). A study from the UK notes the lack of evidence of efficacy of antipsychotics when used in this manner (3). This contrasts with a systematic review conducted in 2015, looking at 14 studies, which found antipsychotic medication use effective in reducing challenging behaviours at least in the short term in children with ID, with aripiprazole and risperidone providing the best effect. Evidence with respect long term effectiveness however was low, and caution was advised due to the number of side effects the child may experience (22). The European Medicines Agency approves on-label use of risperidone for management of persistent aggression in conduct disorder in children age 5 years and above, and adolescents with impaired intellectual functioning, however recommending that it be limited to short-term symptomatic treatment (up to 6 weeks) (23).

A study examining the quality of antipsychotic prescription in the ID population in the UK in 2016 found that just under two-thirds received antipsychotic agents (16). Within this sample population, only one-fifth had a diagnosis along the schizophrenia spectrum (18). People with a diagnosis of affective disorder or a disorder of psychological development such as autism spectrum disorder were more likely to receive an antipsychotic agent. Thus, while psychotic illnesses are recognized as an indication for antipsychotics, the manner of prescribing reflects that evidence-based guidelines have also identified a role for antipsychotic agents in the management of affective disorders and for improving behavioural disturbance in patients (24).

The use of psychotropics to manage behaviours that challenge raises concern because behavioural issues may arise due to not only psychiatric illness but also physical disorder or environmental factors (8,15). It is thus important to identify the function served by the BTC. Because people living with intellectual disability have less resilience and poorer coping strategies, e.g., due to deficits in social or communication skills, limited anger management abilities, coupled with delays in emotional and psycho-social development; when faced with adversity or any kind of suffering, e.g., pain, discomfort, chronic sleep problems, over-/under- stimulation, unmet needs, they may respond in a manner that is classified as behaviours that challenge. Multimorbidity is also associated with behaviours that challenge(16,21,25,26). Reliance solely on psychotropics could lead to neglect of these other important factors. Clinicians also need to be cautious in their assessments of patients and to avoid allowing the diagnosis of ID to overshadow complaints. Careful history taking and examination may allow one to decipher the possible cause of behaviours that challenge, after which appropriate treatment can be administered. The general recommendation is that other interventions be explored before antipsychotics are introduced (10,27). These interventions include but are not limited to pain management, appropriate treatment of medical conditions, and teaching behavioural strategies.

Behavioural strategies, taught either to the patient with ID and/or the caregivers, may help the patient with ID to communicate their needs in a manner suited to their level of intellectual functioning and/or regulate themselves in periods of high stress while also helping the caregiver offer appropriate care as demanded by various situations. Some examples of behavioural interventions that can be used include adjusting the environment, e.g., reducing noise; using structured and personalised activities to promote active engagement; using distraction or diversion techniques to defuse high-stress situations; and teaching relaxation techniques. Intervention strategies should be suitable and compatible with the resources and abilities of all involved in the care of the individual with ID. Strategies to be implemented should be documented and regularly reviewed to ensure that the unwanted behaviours decrease while the quality of life improves (28).

Polypharmacy

Polypharmacy is identified as the use of 3 or more psychotropic agents. It is associated with outcomes such as unfavourable drug reactions, drug-drug interactions, poorer quality of life, and untimely mortality. As such, it is a medication safety concern (29). The literature shows that this was more likely among women and those living in residential settings instead of living with family or independently (30), the latter finding consistent for elderly people living with intellectual disability in residential care (31). The severity of intellectual disability was not consistently found to be a predictive factor in the different studies (29–31). Monotherapy is ideal; however, it is recognized that when there is a severe illness or several comorbidities, the use of multiple agents might not be avoidable (18).

Psychotropic medication and adverse reactions

Psychotropic drugs have individual and systemic adverse implications. Using particularly the second-generation antipsychotics long-term may lead to hyperlipidaemia, weight gain, and glucose dysregulation. Other sequelae of long-term first- and second-generation antipsychotics use include emotional and cognitive blunting, osteoporosis, and extrapyramidal symptoms like akathisia, dyskinesia, and dystonia (2,3,15). Though there is little research directly comparing the side effect profile in people with and without intellectual disability, people with ID and/or ASD are more sensitive and thus considered to be at higher risk of developing these side effects (21,32). The risk is compounded by the fact that ID patients often have a compromised ability to self-report side effects (30). Adverse responses to medication may be atypical, e.g., they may present as behaviours that challenge due to pain or stiffness; thus, patients are at risk of having these responses overshadowed by their diagnosis, and therefore improperly managed with more medication (10,27).

Practitioner competence and confidence in prescribing.

People with ID's first contact with health services may be with a general practitioner (GP). A study looking at care offered to people living with intellectual disability by

primary care doctors in Australia noted that despite playing a central role in their healthcare management, many GPs lacked specific education and training in ID health and reported low confidence in their ability to provide optimum health care for this population (33). Factors associated with this low confidence were identified in studies conducted in Norway and Argentina to be linked to difficulties with communicating with the patients and their carers. Additionally, most medical and specialist psychiatric training is done with cognitively typically developed individuals in mind, which may influence the clinician's approach to managing individuals with ID (34,35). This training pattern is what is offered in South African medical schools too. Within the South African context, where most of the population does not have medical aid and relies on the public health sector, the first contact with health services would likely be through a public service primary care doctor/nurse such as in the community day hospitals or clinics. Patients whose presentations are not manageable at primary health care level, such as the complex presentations described above, are referred for in- or outpatient health care services at psychiatric hospitals.

The afore-mentioned Australian study found that GPs were more likely to recommend anticonvulsants and antipsychotics to people living with ID than they were to non-ID patients. The rate for antidepressant, anti-anxiety, and sedative or hypnotic medication recommendation remained the same amongst both patient groups (33). As there is an increased prevalence of epilepsy among people living with intellectual disability, the finding that anticonvulsants were more frequently prescribed within this group was not unexpected. The identical rate of prescription of anxiolytics and antidepressants between ID and non-ID patients, however, was surprising as some studies show elevated rates of depression and/or anxiety in the ID population (33). A study in the USA, however, found prescribing rates for antidepressants and antipsychotics in the ID population to be lower than the general population, suggesting psychiatric conditions may be undertreated in this population(14).

Another study, set in England, also noted that the majority of people living with ID are seen in primary care settings and sought to assess how well guidelines were being followed. It took note of three significant challenges in meeting audit standards

in this setting. Firstly, the difficulty in changing a longstanding prescription that may or may not have been appropriately prescribed. Secondly, as specialist teams typically saw more complex patients, ID patients seen in primary care were found to be on repeat prescriptions, at times recommended by specialists without proper review. Lastly, to adequately address these difficulties, primary care facilities would need access to scarce resources such as psychologists, social workers, and other secondary care services (36).

International guidelines on prescribing principles

The literature reviewed references several guidelines against which clinical practice can be measured. One such guideline is the World Psychiatric Association (WPA) international guideline which recommends that if there is no treatable general medical or psychiatric disorder, behavioural strategies should be employed as the first line of treatment to manage behavioural challenges (3,8,15,37). Principles recommended by the WPA guidelines for consideration before medication is prescribed include:

- Assessing the decision-making capacity of the patient. Appropriate legal and ethical frameworks should be followed if the patient is found lacking in capacity. A major principle in treatment is to start low and titrate slowly to effect.
- Safe management and dispensation of medication (e.g., blister packs) must be ensured. A responsible person should assist in this regard.
- As individuals with ID tend to require complex care networks (e.g., family, carers, school staff members), all relevant members should be informed of medication, particularly when there are changes.
- Where possible, a standardised instrument should be used to monitor response and side effects to treatment received. This is especially important with patients who have limited communication abilities. The example of the Dyskinesia Identification System Condensed User Scale (DISCUS) is noted in this guideline (6,24)

The most commonly referenced guideline was the National Institute for Health and Care Excellence (NICE) guidelines from the United Kingdom (UK). These guidelines are accessible for use by a range of clinicians, including non-specialists or those who service primary health care. It recommends that individuals with learning disabilities- the term used for intellectual disability in the UK- should only be given antipsychotic medication when other interventions have not been helpful or the risk to the person and/ or others is very severe, perhaps due to extreme violence, aggression towards self, others and/or property or self-injury/self-neglect (6,16,36,38). When prescribed for difficult behaviour, and preferably by a specialist, the target behaviour should be regularly monitored as well as the effectiveness of treatment. A single antipsychotic using the lowest effective dose is the standard. If there is no response at six weeks, the medication should be stopped (38). The guidelines, however, do not indicate what is considered a good enough response to justify continued use of the antipsychotic. Guidelines also do not give practical advice on how best to reduce and stop antipsychotic use, particularly in patients who have been prescribed these medications for extended periods of time (21).

In some of the articles, locally developed guidelines, such as studies located in the Netherlands, Australia, Canada, and Argentina, were used to assess clinician prescribing behaviours. These guidelines, however, reflect much of the same care and consideration that is to be taken when prescribing within the population of individuals with intellectual disability as highlighted in NICE or WPA guidelines. This rapid review yielded no documented local studies on similar local prescribing guidelines for use in the South African context.

Discussion

Our literature review shows that the prescribing pattern of psychotropics amongst the ID population is an important field of interest. Issues noted in the articles considered include polypharmacy, adverse reactions to medication, and practitioner competence and confidence in prescribing psychotropic medication. Antipsychotics as a class have repeatedly been shown to be the most common agent prescribed to this

population, often in the absence of a primary psychotic disorder. As we have noted, this is not without potential for consequence in the form of adverse effects.

As the ID population is vulnerable, and individuals may not always be able to adequately advocate for themselves, the regular review of clinical practice allows for identifying any problems and reducing over- and unnecessary prescriptions. Clinical practice in the literature has been reviewed against international or, when available, local prescribing guidelines to ensure that patients are receiving the best care. It is thus important that South African clinicians tending to individuals with ID regularly review the available literature to ensure that they too are offering the best care to patients. In the absence of local prescribing guidelines in South Africa, guidelines such as those developed by the World Psychiatric Association (WPA) or the National Institute for Health and Care Excellence (NICE) in the United Kingdom (28,39) could serve as a guide for practicing clinicians in the interim and inform the development of local guidelines.

Conclusion

The search of the selected databases for information pertaining to the use of psychotropics, prescribing patterns, and agents used in the ID population within the South African population yielded no documented local studies, reaffirming the need for the current study to contribute valuable information of this nature our context. Alexandra Hospital renders an essential service to a vulnerable population, which often includes optimising medication. It is appropriate to review the prescribing practices in the facility to add to the body of knowledge concerning prescription practices for people with ID experiencing mental health conditions in South Africa. It will be insightful to compare findings in our local setting to the international setting.

AIM AND OBJECTIVES

The aim of this study is to assess the prescribing patterns of psychotropic medication to outpatients with ID at Alexandra Psychiatric Hospital.

OBJECTIVES

1. To provide an audit of psychotropic prescribing practice at Alexandra Psychiatric Hospital
2. To identify which factors were associated with psychotropic medication prescriptions
3. To assess whether psychotropic prescriptions meet current prescribing standards for patients with ID

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2.1 ABSTRACT

A Review of psychotropic drug prescription for patients with Intellectual disability at Alexandra Hospital (a specialist Intellectual Disability psychiatric hospital) outpatient clinic.

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Background: People with intellectual disability are more likely than the general population to be prescribed psychotropic agents. The most common indications include treatment of a psychiatric disorder, and management of behaviours that challenge.

Aim: The study aimed to assess the prescribing patterns of psychotropic medication to outpatients with intellectual disability at a psychiatric hospital.

Setting: Alexandra hospital outpatient clinic, Cape Town.

Methods: This was a retrospective folder and prescription chart review. Folders of all new patients (103) seen between January 2018 and August 2019 were examined at two points, the initial appointment and again at 6 months. The information was examined against the World Psychiatric Association (WPA) and the National Institute for Health and Care Excellence (NICE) guidelines for prescribing in people with intellectual disability.

Results: 88% of patients were prescribed psychotropic medication. Antipsychotics accounted for more than 56% of the medication prescribed and was used mainly for

management of behaviours that challenge. Clinicians at Alexandra hospital followed prescribing guidelines to some extent, however, more still needs to be done to ensure best practice and care.

Conclusion: This review revealed a few shortcomings in meeting prescribing guidelines by clinicians at Alexandra hospital. Measures to address these shortcomings could be the inclusion of medication review schedules and standardised forms for clerking and monitoring of side effects in patient files, the use of behavioural strategies as the primary management of behaviours that challenge, and the performance of regular clinical practice audits.

Key Words: Intellectual disability; learning disability, psychotropic medication; challenging behaviour, prescribing patterns

2.2 INTRODUCTION

Intellectual disability (ID), with onset before 18 years, is characterised by significant limitations in cognitive functioning and adaptive skills in the social, practical, and conceptual domains. The worldwide prevalence for ID is estimated at 1% (1,2). Statistics within the South African population are limited. Adnams (2010) reported on the findings of three (3) regional household surveys, which estimated the prevalence of severe intellectual disability to be 1.1% in 1999, 0.5% in 2002, and 0.27% in 2007 (examining severe intellectual or learning disabilities) (3). Kleintjes et al. (2006) reported expert consensus prevalence estimates in the Western Cape Province of South Africa for adults with ID of 2.5% (IQ below 70), 0.4% (IQ below 50), and 0.1% (IQ below 30) (4). However, the overall prevalence rate of ID in South Africa may be higher than in other low- and middle-income countries due to the exceptionally high rates of several preventable conditions that may cause the onset of ID in the early period of life. These conditions include nutritional deficiencies, infectious diseases such as HIV/AIDS and tuberculous meningitis, high rates of foetal alcohol spectrum disorder, and cognitive impairment due to violence and injury (3).

People living with ID are 2.5 times more likely than the general population to develop a mental illness. In addition, people living with ID may display behaviours that challenge (BTC) and are at higher risk of having medical comorbidities. As such, they form a unique and vulnerable population (5–7). Most medical personnel, including psychiatric specialists, express low confidence in their ability to provide optimum care to people living with ID (8). This low confidence could be due to difficulties with communicating with patients and their carers (8). Additionally, most medical and specialist psychiatric training is done with typically developing individuals in mind, affecting the clinician's expertise in managing individuals with ID (9,10).

Diagnosing mental illness within this population is a challenge due to factors such as the severity of intellectual disability; atypical presentation (for example, mood disorders that present with challenging behaviour or aggression and not the expected sad or elevated mood); deficits in communication and health literacy; or difficulties in accessing services (6,11,12). BTC, such as temper tantrums, self-injury, aggression, and stereotypies, may be due to numerous factors such as

nonverbal patient attempts to communicate pain, deficits in emotional regulation, poor social skills, and multimorbidity (11–15).

These complicating factors may lead to over- or under-treating with psychotropic agents (2,11–13). Psychotropic medication is often prescribed to people living with ID to treat a mental illness or manage BTC without adequately investigating or addressing possible causes (11–13,16–20).

This is done despite limited to moderate evidence for the efficacy of psychotropics in treating psychopathology in this population and evidence that psychotropic drugs have individual and systemic adverse implications. Side effects due to long-term use of first- and second-generation antipsychotics include glucose dysregulation, weight gain, emotional and cognitive blunting, hyperlipidaemia, osteoporosis, and extrapyramidal symptoms like dystonia, dyskinesia, and akathisia (2,11,21). People with ID are considered at higher risk of developing these side effects, though there is little research that directly compares the side effect profile in people with and without ID (22). The risk is compounded because patients with ID often have a compromised ability to self-report side effects (23). Adverse responses to medication may even be atypical; for example, pain and stiffness caused by the medication may present as BTC. Diagnostic overshadowing could then lead to these responses being improperly managed with more medication (14,24).

Despite only 3% of this population experiencing a psychosis-related disorder, antipsychotics are estimated to account for 30% - 50% of all psychotropics prescribed for this population (13). A study done within the UK found that antipsychotic drugs are overprescribed to this population, often prescribed for BTC management (especially in those with autism spectrum disorders) despite lack of evidence of efficacy (2). In a study conducted in Sweden, it was found that benzodiazepine derivatives and antipsychotics are also more likely prescribed to people living with intellectual disability and comorbid dementia and /or autism spectrum disorder (25).

In 2010, a Dutch study assessing the prevalence of and rationale for antipsychotic drug use in a population of adults with ID noted that antipsychotic medication was prescribed to almost a third of the population. Behavioural problems were the most common reason for use (58%), whereas psychosis accounted for only 25% (11,13).

A systematic review conducted in 2015, looking at 14 studies, found antipsychotic medication use effective in reducing challenging behaviours in the short term in children with ID, with aripiprazole and Risperidone providing the best effect. However, evidence regarding long-term effectiveness was low, and caution was advised due to the number of side effects the child may experience (26).

People living with intellectual disability living in a residential setting as opposed to living with family has been found to be a predictor of psychotropic polypharmacy - identified as the use of 3 or more psychotropic agents. This is more likely if the person is elderly (23,27,28). The severity of ID or the presence of autism spectrum disorders was not a consistent predicting factor across various studies (23,27,28). One of the studies conducted in Ireland noted that those with psychotropic polypharmacy had a history of manic depression or a psychotic disorder (27).

With these factors in mind, it becomes clear that a comprehensive assessment should precede the inclusion of psychotropic agents as part of the management plan of patients with ID (16,24).

Prescribing guidelines, whether international such as from the World Psychiatry Association (WPA) or the more commonly referenced National Institute for Health and Care Excellence (NICE) guidelines or locally available such as in The Netherlands or Australia, aid clinicians in best practice in respect prescribing psychotropics to the ID population (2,7,12,20,23,29–33).

In our brief review of the literature, no studies published within the South African context were identified that assessed psychotropic prescribing patterns among the ID population nor identified local prescribing guidelines.

As such, we sought to contribute to work aimed at addressing this gap in knowledge by assessing the current prescribing patterns of psychotropic medication to outpatients with ID at a local specialist intellectual disability psychiatric hospital. Our objectives were to provide an audit of psychotropic prescribing practice at Alexandra Hospital, identify factors associated with psychotropic medication prescriptions, and assess whether psychotropic prescriptions meet current prescribing standards for patients with ID.

2.3 MATERIALS AND METHOD

Study setting

Alexandra Hospital is a specialist psychiatric hospital situated in Maitland, Cape Town, in the Western Cape Province. It provides in- and outpatient services, offering outpatient treatment and rehabilitation for children, adolescents, and adults (including those above age 60) who have ID and associated complex mental health needs (5,34).

Newly referred patients to the outpatient department are screened at a weekly multidisciplinary team meeting. They may already have a diagnosis or history strongly suggestive of ID, which may or may not be accompanied by an additional psychiatric diagnosis. These patients, who form the focus of this study, may already be on medication.

Prescribing and optimising medication at Alexandra Hospital outpatient department is the task of the psychiatry consultant, rotating general psychiatry registrar, and a medical officer. Patients' conditions are diagnosed according to DSM-5 criteria, including those whose files were included in the audit.

Ethics approval

Ethics approval was obtained from the Human Research Ethics Committee (HREC) of the Faculty of Health Sciences at the University of Cape Town; (809/2019). As the study was a retrospective folder review, with no names or physical patient involvement, consent was not required. The folders involved in the study were assigned a study number to avoid any possibility of confidentiality being breached. Clearance to start the study at the hospital was also obtained from the Western Cape Department of Health and Alexandra hospital Chief Executive Officer.

Research design

The study was a cross-sectional retrospective folder and prescription chart review. Folders selected for inclusion in the study were of all patients who attended the OPD

clinic for the first time from January 2018 to August 2019. The timeframe was determined by considering the calculated sample size against the rate and volume of patients seen at the OPD clinic per week. The folders were examined at two points - at the initial presentation to Alexandra hospital and again at a follow-up visit six months later. This allowed for reviewing the prescribing practices at two different points in their time at Alexandra hospital and assessing for any changes/progression in applying guidelines over time. There were no exclusion criteria. Folders of patients who had been discharged or had defaulted follow-up by the 6-month mark were examined at the initial assessment. Demographic information was collected based on the initial visit, while the remainder of the information collected reflected both visits.

Sampling and materials

Our minimal recommended sample size was 72 files, as determined in consultation with a statistician. The total amount of files included in that study was 103 at the initial visit and 87 at follow-up.

The research team developed a data extraction form based on a review of the literature and, in particular, the requirements of the World Psychiatric Association (WPA) and the National Institute for Health and Care Excellence (NICE) guidelines for practitioners prescribing in this population. These guidelines were chosen as South Africa does not have local guidelines, and our brief review of the literature found that these were most frequently used in other studies as a reference.

The data elements of the extraction form are summarised in **Error! Reference source not found.** and **Error! Reference source not found.**

Table 1: Data extraction form: patient, diagnosis, and psychotropic prescription

1. Demographics	Age, sex, living arrangements (family home or residential facility)
2. Severity of ID	Mild, moderate, severe, profound, not documented
3. Patient diagnosis	Psychiatric: Behaviours that challenge, mood disorders (depressive and bipolar disorders), anxiety disorders,

	psychotic disorders, autism spectrum disorders (ASD), attention deficit hyperactivity disorder (ADHD), and other Medical: epilepsy, dementia, and other
4. Psychotropic drug prescription	Grouped as antipsychotic agents, antidepressants, mood stabilisers, ADHD agents, anxiolytic or sedative agents, no medication, and other
5. Type of antipsychotic prescribed	Haloperidol, olanzapine, risperidone, other

Table 2: Data extraction form - in relation to WPA & NICE guidelines

1. The rationale for antipsychotic noted
2. Medication review schedule present in the file
3. Presence of a standardised instrument for monitoring side effects in the file
4. Whether behavioural strategies were recommended
5. Whether support (e.g., referral to social work or other support groups/health services) was provided
6. Whether the lowest effective dose of the chosen psychotropic agent was prescribed.

No distinction was made in the data collection sheet as to whether the medication prescribed at the initial assessment had already been initiated by the referral facility before presentation or newly by clinicians at Alexandra hospital.

The lowest effective dose was determined by comparing the medication dosage given to the recommended dosage range of prescribed medication.

Information was manually extracted from the files and inserted into the data extraction form by the first author. An initial trial run with ten folders not included in the study was done to ensure that the data collection form collected all necessary data. The data collection form was then refined based on the findings of the trial run. A random selection of files was chosen for the second round of review to ensure that the information collected was accurately captured.

Statistical analysis

The data analysis was conducted using Statistical Package for Social Sciences (SPSS), Version 25 (35). Descriptive statistics were generated for all variables and included means, standard deviation, and 95% confidence intervals for continuous numerical data and frequencies and proportions for categorical variables. A series of chi-square tests were performed to examine the demographic data (age, sex, living setting) and clinical factors (diagnosis and severity of ID) associated with the prescription of each class of various psychotropic agents. Statistical significance was set at $\alpha = 0.05$.

2.4 RESULTS

Demographic data

Of the 103 patients, 58.2% (n=60) of patients were below age 18, evenly split into 30 patients each when further subdivided into children (younger than 12) and adolescents (13-18). 39.8% (n=41) of patients were between age 19 and 59, and 1.9% (n=2) above age 60. 70% (n= 72) were male, and 87.4% (n = 90) lived in their family home compared to the remainder who lived in a residential home. Only 13 % (n=2) of those who lived in a residential home were below age 18. 64% (n=42) of the male population were below age 18 compared to 45% (n=14) of the female population.

Intellectual Disability

26.2% (n=27) of patients were recorded as having mild ID, 32% (n=33) as having moderate ID and 24.2% (n=25) as having severe ID. Only one patient was recorded

as having profound ID. The severity of ID was not documented in 16.5% (n=17) of patient files.

Diagnosis

Error! Reference source not found. illustrates patient's diagnosis, with 74.8% (n=77) of patients presenting with BTC, just over one-third (36.9%) having either autism (n=38) or ADHD (n=38), and less than 15% having a psychiatric diagnosis of either anxiety (n=16), mood (n=11, where 1 had bipolar disorder and 10 had a depressive disorder) or psychotic disorders (n=11) (14.6% v 10.7% v 10.7% respectively). Children and adolescents accounted for 95% (n=36) of the diagnosis of ADHD, 62% (n=48) of BTC, and 71% (n=27) of ASD, whilst adults accounted for 91% (n=10) of psychotic disorders, 44% (n=7) of anxiety disorders and 100% (n=10) of depressive disorders. 5.8% (n=6) had a psychiatric diagnosis of "other" (which included Borderline Personality Disorder, Tourette's syndrome, and Oppositional defiant disorder). The mean number of diagnoses per patient was 1.9 (SD = 0.8, range 1-4).

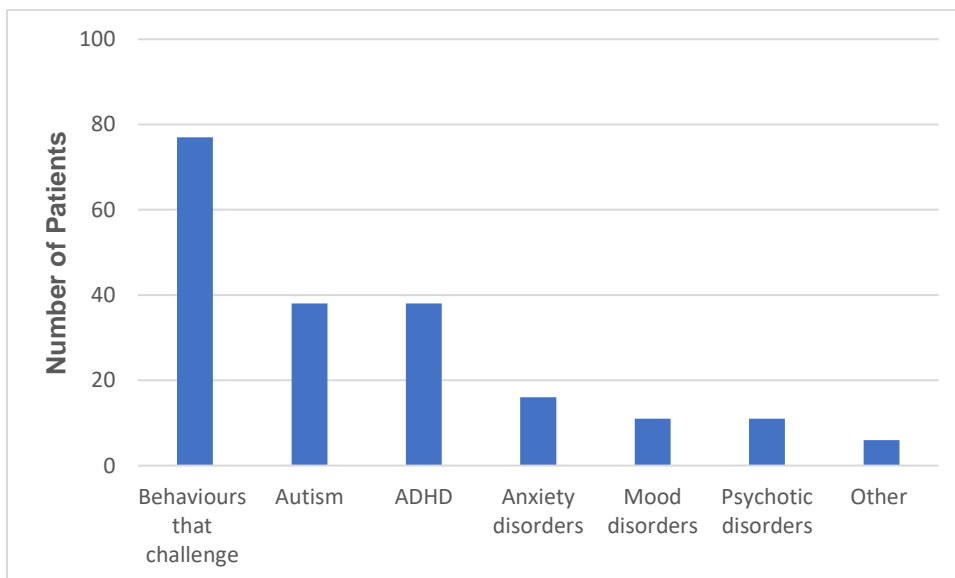


Figure 1: Psychiatric diagnoses of patients

35.9% (n=37) patients had only one diagnosis, 40.8% (n=42) had two, 20.4% (n=21) had three, and 2.9% (n=3) patients had four diagnoses. The most common singular diagnosis was BTC at 21.3% (n=22), followed by psychotic disorders at 3.9% (n=4). The most common comorbid diagnoses in patients with BTC (n= 45) were autism

and ADHD, either as a dual or triple diagnosis. Adults accounted for the majority of the single diagnosis at 49% (n=21). Children and adolescents were more likely to have comorbid diagnoses. 37% (n=11) of those below age 12 had two diagnoses, while 37% had more than three. 50% (n=15) of adolescents had a dual diagnosis. Forty-seven patients (46%) had a comorbid medical diagnosis: 10 had more than one medical condition. Only one patient had dementia diagnosed along with dyslipidaemia; 25 patients had epilepsy, 9 of which were diagnosed with another comorbid medical condition. The remainder of the 47 patients had another medical condition such as osteoporosis, hypothyroidism, or asthma.

Medication prescribed

The most common medication prescribed was antipsychotics (in 59.2% (n=61) of patients at initial assessment and 56.3% (n=58) at 6-months; see **Error! Reference source not found.**). The most common antipsychotic prescribed at both points was Risperidone, followed by Olanzapine. Antipsychotics were prescribed more to children and adolescents than to adult patients at the initial visit (56%, n=34) and the 6-month visit (62%, n=36). Anticonvulsant mood stabilisers were prescribed primarily to patients who had epilepsy. It was the main agent used to manage behaviours that challenge in only 33% of patients (n=8) at the initial visit and 24% (n=4) at the 6-month visit. The mean number of psychotropics was 1.61 (SD = 1.1) at the initial assessment and 1.65 (SD = 1.1) at 6-months. At initial assessment, 15 patients were on no medication, 36 on one medication, 33 on two types of medication, 14 on three medications, 3 on four medications, and 2 on five types of medication. Of the remaining 87 patients still attending at 6-months, 12 patients were on no medication, 24 on one type of medication, 24 on two types of medication, 23 on three medications, 3 on four medications, and 1 on five types of medication. Children and adolescents were more likely to be on two or fewer medications at both visits, while adults were more likely to receive three or more agents. The vast majority (>80%) of patients had no change in medication from initial assessment to 6-months (see **Error! Reference source not found.**).

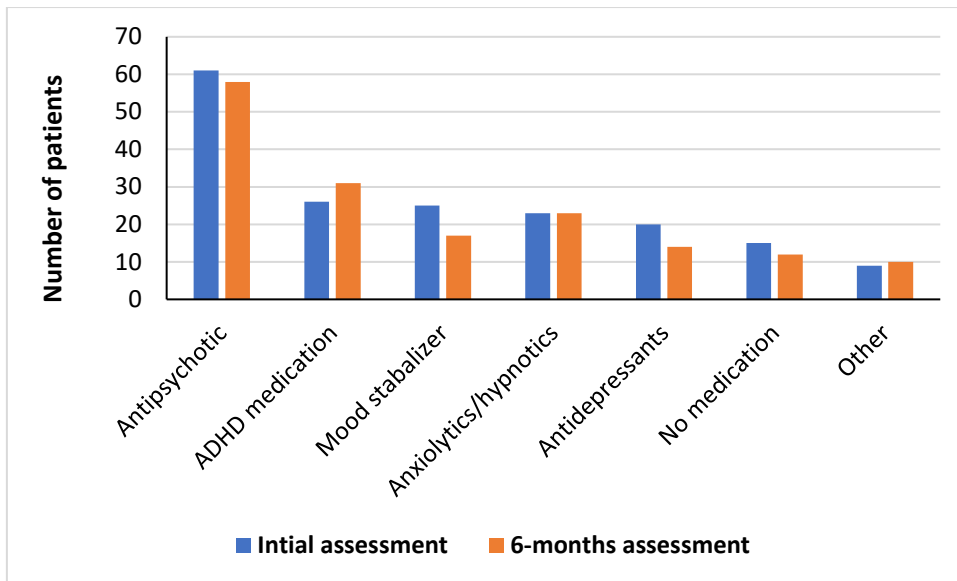


Figure 2: Medication prescribed at initial and 6-months assessment

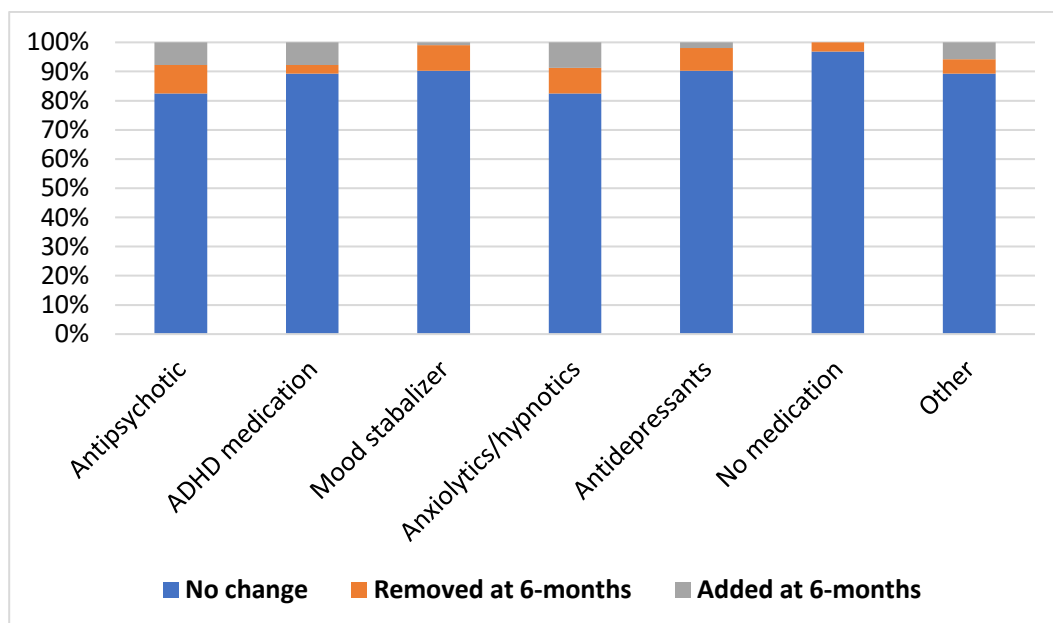


Figure 3: Medication Changes

The association between demographics/diagnoses and interventions

Demographics and medication prescribed

Age: Patients who were younger than 18 years of age (n=25 of the 60, 41.7%) were significantly more likely to be given ADHD medication at initial assessment

compared to those who were 19 years and older (n= 1 of 43, 2.3%) (Fisher's test, $p < .001$, Cramer's $V = 0.45$). Patients who were 19 years and older (n=14 of the 43, 32.6%) were significantly more likely to be given Anxiolytics/hypnotics at initial assessment compared to those who were younger than 18 years of age (n=9 of the 60, 15%) (chi-square = 4.45, $p = .035$, Cramer's $V = 0.21$). Patients who were older than 18 years of age (16 of the 43, 37.2% were significantly more likely to be given antidepressants at initial assessment compared to those who were younger than 18 years of age (4 of the 60, 6.7%) (Fisher's test, $p < .001$, Cramer's $V = 0.38$).

Patients who were younger than 18 years of age, 30 of the 60, 50%) were significantly more likely to be given ADHD medication at 6-months compared to those who were older than 18 years (n=1 of the 43; 2.3%) (Fisher's test, $p < .001$, Cramer's $V = 0.51$).

Gender: There was a trend towards significantly more females (11 of the 31 females, 35.5%) being given Anxiolytics/hypnotics at initial assessment compared to males (12 of the 72 males, 16.7%) (chi square = 3.41, $p = 0.065$, Cramer's $V = 0.18$).

Living arrangements: Patients living in residential facilities (7 of the 13, 53.8%) were significantly more likely to be given Anxiolytics/hypnotics at initial assessment compared to patients living at home (12 of the 72, 16.7%) (Fisher's test performed, $p = 0.007$, Cramer's $V = 0.28$

The severity of ID was not associated with the medication prescribed.

Diagnoses and medication prescribed

Medication prescribed was consistent with expected practice:

Patients diagnosed with ADHD (24 of the 38, 63.2%) were significantly more likely to be given ADHD medication at initial assessment compared to those not diagnosed with ADHD (2 of the 65, 3.1%) (chi square = 45.9, $p < .001$, Cramer's $V = 0.67$).

Patients diagnosed with ADHD (4 of the 38, 10.5%) were significantly less likely to be given Anxiolytics/hypnotics at initial assessment compared to those not

diagnosed with ADHD (19 of the 65, 29.2%) (chi square = 4.8, $p = .028$, Cramer's $V = 0.22$). Patients diagnosed with ADHD (2 of the 38, 5.3%) were significantly less likely to be given antidepressants at initial assessment compared to those not diagnosed with ADHD (18 of the 65, 27.7%) (chi square = 7.7, $p = .005$, Cramer's $V = 0.27$). Patients diagnosed with mood disorders (9 of the 11, 63.6%) were significantly more likely to be given antidepressants at initial assessment compared to those not diagnosed with mood disorders (11 of the 92, 12%) (chi square = 30.6, $p < .001$, Cramer's $V = 0.55$). Likewise, patients diagnosed with mood disorders (7 of the 11, 63.6%) were significantly more likely to be given antidepressants at 6-months compared to those not diagnosed with mood disorders (7 of the 92, 7.6%) (chi square = 26.3, $p < .001$, Cramer's $V = 0.51$).

In addition, patients diagnosed with anxiety (6 of the 15, 40%) were significantly more likely to be given antidepressants at 6-months compared to those not diagnosed with anxiety (8 of the 88, 9.1%) (chi-square = 10.4, $p = .001$, Cramer's $V = 0.32$).

Compliance with Prescribing Guidelines

A rationale was given for 68.9% ($n=42$) of cases where antipsychotic medication was prescribed. The most common rationale was BTC (57.1%, $n=24$), followed by sleep and other. The lowest effective dose of antipsychotic was in use in all cases. There were, however, no review schedules nor standardized instruments for monitoring side effects in any of the files.

Regarding managing BTC ($n=77$), the results show that beginning with behavioural interventions was not uniform. Of the 77 patients, only 46.8% ($n=36$) were managed with behavioural interventions only at the initial point of contact, with nine patients subsequently receiving medication by the 6th month. A combination of behavioural intervention and medication, and at times medication only, was used to manage the remainder of patients with BTC.

All patients, however, were informed of support structures available, such as referrals to organisations like Autism Western Cape or social services. Referrals

were also made to other members of the comprehensive treating team, such as psychology and occupational therapists in some cases.

2.5 DISCUSSION

This study set out to assess the psychotropic prescribing patterns and their conformity to existing international guidelines at Alexandra hospital, Cape Town.

Of the 103 patient files reviewed, approximately 88% (n=91) received at least one psychotropic agent. The severity of ID did not correlate with medication choice, in keeping with standard prescribing guidelines which do not reference the severity of ID in prescribing.

Patients younger than 18 were more likely to receive ADHD medication, while older patients were more likely to receive anxiolytics/hypnotic agents or antidepressants, which is consistent with the typical distribution of psychiatric diagnosis; for example, ADHD is more commonly diagnosed in childhood than adulthood. Females were more likely to be given anxiolytics/hypnotic agents than males, as were those living in residential facilities compared to those living at home. This latter finding is consistent with other studies where residential facility living has been demonstrated to be linked to exposure to psychotropic agents and even polypharmacy (23,27,29). Patients with comorbid ASD were more likely to be on Risperidone.

It is noteworthy that although only 10.7% (n=11) of the reviewed population had a diagnosis of a psychotic disorder, antipsychotics accounted for the most common medication prescribed at both points. This aligns with various international studies that have noted a higher prescription rate of antipsychotics in the ID population compared to the actual diagnosis of psychotic disorders (2,29). Where prescribed, medication usage was generally in keeping with management protocols for disorders such as ADHD, anxiety, mood, and psychotic disorders; for example, patients received stimulants for managing ADHD or antidepressants to manage depressive mood or anxiety disorders(7,16,36). The second most common psychotropic agent noted was ADHD agents, while many studies typically find antidepressants the

second most common psychotropic agent. This may be explained by the fact that most patients (66%) included in this study are young individuals less than 18 years old, while most studies reviewed in preparation for this study looked at the adult population.

Where antipsychotic medication was used other than for treatment of psychotic disorders, Risperidone was the agent of choice, and it was used primarily for the management of BTC; this was particularly the case amongst the child and adolescent population of the sample, as well as those with ASD. This trend was also noted in the literature reviewed (7,20), although, encouragingly, it was most frequently offered along with behavioural strategies. WPA and NICE guidelines suggest employing behavioural strategies to manage BTC before adding pharmacological agents if indicated (2,6,11,13,37). Psychological and environmental management, for example, through behavioural therapies, providing the parent or carer training specifically tailored to individuals with ID, optimising the living environment, and accessing support services, should be utilised as needed (7,37,38).

The tendency for clinicians to resort to antipsychotic use as a management strategy for BTC could be remedied by improving clinician competence and confidence in dealing with individuals with ID, such as by providing more specific ID-related training (39). There is also a need to conduct clinical research into developing contextually appropriate and effective behavioural interventions in the South African context (40).

Relatively simple procedural amendments can be introduced to improve compliance with NICE guidelines on documentation (12,21,30–33). This includes, for example, developing a standardised protocol and reporting forms to document the guideline principles in each patient's folder to support clinicians working in pressured outpatient settings to follow through consistently on recommended prescribing principles.

The guidelines do not prescribe what might be considered a good enough response to justify continued use of the antipsychotic but recommend that the agent be stopped if there is no response at six (6) weeks and caution against prolonged use of psychotropic agents for the management of BTC. Medication optimisation, such as

through dosage reduction and possible withdrawal of antipsychotic medication, should be individualised, considering that social, environmental, and staff factors may affect the success of such attempts (15,18). This is particularly important as the outpatient population at Alexandra Hospital leans towards younger individuals who are at greater risk of side effects on these medications (26).

Most patients initiated on antipsychotic agents at the initial visit were still taking them at the 6-month review. It is unclear whether this was for the drug's efficacy or because of clinicians simply renewing scripts, again motivating the importance of reporting rationale for medication prescription.

2.6 STRENGTHS

This appears to be the first study of this kind within the South African setting, examining the prescribing practices amongst the ID population. The result of this study can lead to enhancing patient care at Alexandra hospital and encourage similar reviews at other facilities across South Africa.

2.7 LIMITATIONS

As this was a folder review, information obtained is subject to the diligence of the treating clinician, that is, writing the correct diagnosis or noting the reason for using a particular drug. It is not possible to know if the information we hoped to collect was discussed verbally with the patient and family and simply not documented.

Although DSM-5 criteria is used for diagnosing patients at Alexandra Hospital, we did not review how closely these were followed by treating clinicians when making the final diagnosis; therefore, room must be left for inaccurate diagnoses.

The generalisability of our findings may be limited as these data may be different from those in other OPD settings.

2.8 CONCLUSION

This study has provided a small window into prescribing practices at Alexandra hospital outpatient clinic measured against the WPA and NICE guidelines.

Regarding indications for prescribed medication, patients primarily receive appropriate medication for their diagnosis when looking at ADHD, anxiety, or mood disorders. BTC is the most common issue that patients with ID are presenting with at Alexandra hospital and is managed through a combination of behavioural strategies and psychotropic agents, although not consistently so for behavioural strategies. The majority of patients are managed on two or fewer agents, likely indicating that clinicians are on guard against polypharmacy and the associated risk.

The data collected shows that clinicians are meeting some of the guidelines for prescribing psychotropic agents. They do well in prescribing medication at the lowest effective dose and mobilising support structures to aid patient care. However, improvements can be made with regards to recommending and giving time for implementation of behavioural strategies, noting rationale for antipsychotic medication, setting up a review schedule, and observing for side effects as per guidelines. Doctors also need to be aware of prescribing antipsychotic medication for an excessively long period when there is no primary psychotic diagnosis. The use of standardised checklists would also make it easier to track problem behaviour and response to medication uniformly. Further research could lead to the development of local tools for this purpose.

It is hoped that these findings can motivate for the development of or incorporation of existing reviewing schedules and side-effect instruments for use by clinicians. Providing such documents visibly in the files would ensure that clinicians are always conscious of following best practice.

It would be interesting to conduct such a study on a larger scale, perhaps through similar facilities across South Africa, to accurately assess what is being done and determine whether adaptations to the guidelines discussed in this paper may be indicated for the local setting. Other aspects of the prescribing guidelines, such as assessing patient capacity to consent and involvement in their management could also be topics for future research endeavours.

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Data Availability Statement

The data supporting the findings in this study are available from the corresponding authors upon reasonable request.

Conflict of interest

The authors declare they have no conflict of interest.

Disclaimer

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article. The views expressed in this article are the authors' own and do not reflect the views of the University of Cape Town or Alexandra Hospital.

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APPENDICES

APPENDIX A: “Mental health problems in people with learning disabilities: prevention, assessment and management”

Adapted from NICE Guidelines of September 2016 (33)

Where learning disability (intellectual disability) is defined by 3 core criteria: lower intellectual ability (usually an IQ of less than 70), significant impairment of social or adaptive functioning, and onset in childhood (before 18 years)

Principles of pharmacological interventions

1. Before starting medication for a mental health problem in children, young people or adults with learning disabilities
 - Consider medication interactions, the potential impact of medication on other health conditions and the potential impact of other health conditions on the medication
 - Consult necessary specialists when necessary
 - Prescribe antipsychotics carefully, due to risk of lowered seizure threshold
 - Consider implications for treatment should nonadherence occur, or regular monitoring tests be needed
 - Establish a review schedule to reduce polypharmacy
 - Provide support to improve adherence
 - Agree on who will play what role with respect monitoring (e.g. who will carry out investigations/blood tests between primary and secondary care)

2. Monitor and review the benefits and possible harms or side effects
 - Use agreed outcome measures
 - Use timescale given for specific disorder if stated in relevant NICE guidelines.
 - Adjust to individual needs

3. On initial dose and subsequent increases
 - aim for the lowest, effective dose.
 - Consider side effects (and potential difficulties reporting them)
 - Avoid subtherapeutic dosing

4. Prescribers should record:
 - What information was provided about the medication
 - When medication will be reviewed
 - Plans for reducing or discontinuing medication, if appropriate
 - Details of the person taking the medication, including doses, frequency and purpose.

5. If on antipsychotics with no psychotic symptoms
 - Consider reducing or discontinuing long-term prescriptions of antipsychotic drugs
 - Review condition after reduction or discontinuation
 - Document reason for continuation annually, if not reduced or stopped

6. On switching medication
 - Change one drug at a time
 - Watch for any effects from discontinuation or interactions during cross titration

APPENDIX B: Challenging behaviour and learning disabilities: prevention and intervention for people with learning disabilities whose behaviour challenges.

Adapted from NICE Guidelines of May 2015 (32)

1. Consider antipsychotic medication to manage behaviour that challenges only if:
 - psychological or other interventions alone do not produce change within an agreed time or
 - treatment for any coexisting mental or physical health problem has not led to a reduction in the behaviour or
 - the risk to the person or others is very severe (for example, because of violence, aggression or self-injury).

2. Choosing which antipsychotic medication to offer, take into account the person's preference (or that of their family member or carer, if appropriate), side effects, response to previous antipsychotic medication and interactions with other medication.

3. Antipsychotic medication should initially be prescribed and monitored by a specialist (an adult or child psychiatrist or a neurodevelopmental paediatrician) who should:
 - identify the target behaviour
 - decide on a measure to monitor effectiveness including frequency and severity of the behaviour and impact on functioning
 - start with a low dose and use the minimum effective dose needed
 - only prescribe a single drug
 - monitor side effects
 - review the effectiveness and any side effects of the medication after 3–4 weeks

- stop the medication if there is no indication of a response at 6 weeks, reassess the behaviour that challenges and consider further psychological or environmental interventions
- only prescribe as-needed medication for as short a time as possible and ensure that its use is recorded and reviewed
- review the medication if there are changes to the person's environment (for example, significant staff changes or moving to a new care setting) or their physical or mental health.

4. Document

- the rationale for medication
- how long the medication should be taken for
- a strategy for reviewing the prescription and stopping the medication.

5. With a positive response to antipsychotic medication:

- record the extent of the response, how the behaviour has changed and any side effects or adverse events
- conduct a full multidisciplinary review after 3 months and then at least every 6 months covering all prescribed medication (including effectiveness, side effects and plans for stopping)
- only continue to prescribe medication that has proven benefit.

6. When prescribing is transferred to primary or community care, or between services, the specialist should give clear guidance to the practitioner responsible for continued prescribing about:

- which behaviours to target
- monitoring of beneficial and side effects
- taking the lowest effective dose
- how long the medication should be taken for
- plans for stopping the medication.

APPENDIX C – UCT human research ethics committee approval and extension



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za

Website: www.health.uct.ac.za/fhs/research/humanethics/forms

02 April 2020

HREC REF: 809/2019

Prof S Kleintjes
Drs Bungalows-GSH
Email: sr.kleintjes@uct.ac.za
Copy to student researcher: Id.akpabio@yahoo.com

Dear Prof Kleintjes

PROJECT TITLE: A REVIEW OF PSYCHOTROPIC DRUG PRESCRIPTION FOR PATIENTS WITH INTELLECTUAL DISABILITY AT ALEXANDRA HOSPITAL (A SPECIALIST INTELLECTUAL DISABILITY PSYCHIATRIC HOSPITAL) OUTPATIENT CLINIC (MMed CANDIDATE Dr I Akpabio)

Thank you for your response addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020.

Approval is granted for one year until the 30 April 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Idorenyin Akpabio will also be involved in this study.


Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

HREC REF: 809/2019 sa

Yours sincerely

pp 

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE


Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.



FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30.4.22
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	8/4/2021

Note: Please note that incomplete submissions will not be reviewed. Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	2021/04/08		
HREC REF Number	809/2019	Current Ethics Approval was granted until	2021/04/30
Protocol title	A review of psychotropic drug prescription for patients with Intellectual Disability at Alexandra Hospital (a specialist Intellectual Disability psychiatric hospital) outpatient clinic		
Principal Investigator	Sharon Kleintjes		
Department / Office Internal Mail Address	Sr.kleintjes@uct.ac.za		
1.1 Does this protocol receive US Federal funding?			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

2. Protocol status (tick ✓)

<input type="checkbox"/>	Research-related activities are ongoing
<input checked="" type="checkbox"/>	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	
Not Applicable	
The research is a review of folders and prescription charts set at Alexandra hospital. There is no pre-existing database containing the information that was being extracted from the records.	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval	103
Total number of records or specimens collected, reviewed or stored since last progress report	



Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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4. Signature

Signature of PI		Date	2021/04/08
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APPENDIX D – Western Cape Department of Health approval letter

• FW: Research at Alexandra Hospital; Dr Akpabio 4

Psychiatry .../Inbox ☆



Health Research <health.research@westerncape.gov.za>

To: id.akpabio@yahoo.com

Cc: Lynette.vanderBerg@westerncape.gov., Joy Harding

Wed, 08 Jul at 14:18 ☆

Dear Dr Akpabio

Thank you for your query. Your research has been approved to gain access at Alexandra Hospital. Please contact the Chief Executive Officer, Mevrou Lynette van der Berg before starting with your project to make the necessary logistics arrangements. Please provide the Department with your final report within six weeks of completing your study.

All the best

Health Research| HIA Directorate

Western Cape Department of Health

8 Riebeeck Street, Norton Rose House, Cape Town, 8000

www.westerncape.gov.za/health

APPENDIX E : Alexandra Hospital CEO Approval letter

From: Lynette van der Berg <Lynette.vanderBerg@westerncape.gov.za>
Sent: 05 July 2020 01:19 PM
To: Health Research <Health.Research@westerncape.gov.za>
Cc: Gerrit Thomas <Gerrit.Thomas@westerncape.gov.za>; Joy Harding <Joy.Harding@westerncape.gov.za>
Subject: Research at Alexandra Hospital: Dr Akpabio

Dear Colleague

I have perused the request by Dr Akpabio and hereby give approval for access to Alexandra Hospital to undertake the said research. She is requested and required to engage the CPD team via Mr Thomas to assist her with the necessary access.

Regards

Lynette van der Berg
Chief Executive Officer
Alexandra Hospital
General & Specialised Emergency Services
Department of Health

APPENDIX F – Submission Guidelines for the South African Journal of Psychiatry
Instructions for authors SAJP

Word limit	3000-4000 words (excluding the structured abstract and references)
Structured abstract	250 words to include a Background, Aim, Setting, Methods, Results and Conclusion
References	60 or less
Tables/Figures	no more than 7 Tables/Figures
Ethical statement	should be included in the manuscript
Compulsory supplementary file	ethical clearance letter/certificate

Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Aim, Setting, Methods, Results and Conclusion.

- Background: Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.
- Aim: State the overall aim of the study.

- **Setting:** State the setting for the study.
- **Methods:** Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.
- **Results:** State the main findings.
- **Conclusion:** State your conclusion and any key implications or recommendations. Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

- **Social value:** The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.
- **Scientific value:** The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.
- **Conceptual framework:** In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.
- **Aim and objectives:** The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

- **Study design:** An outline of the type of study design.
- **Setting:** A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

- **Study population and sampling strategy:** Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.
- **Intervention (if appropriate):** If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.
- **Data collection:** Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.
- **Data analysis:** Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.
- **Ethical considerations:** Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the [SI convention](#) and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

- **Key findings:** Summarise the key findings without reiterating details of the results.
- **Discussion of key findings:** Explain how the key findings relate to previous research or to existing knowledge, practice or policy.
- **Strengths and limitations:** Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

- Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.
Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements: Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named. Refer to the acknowledgement structure guide on our *Formatting Requirements* page.

Also provide the following, each under their own heading:

- Competing interests: This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: *The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.* Read our [policy on competing interests](#).
- Author contributions: All authors must meet the criteria for authorship as outlined in the **authorship** policy and **author contribution** statement policies.
- Funding: Provide information on funding if relevant
- Data availability: All research articles are encouraged to have a data availability statement.
- Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

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A Review of Psychotropic drug prescription for patients with Intellectual disability at Alexandra Hospital (a specialist Intellectual Disability psychiatric hospital) outpatient clinic



Dr Idorenyin Ubon Akpabio
AKPIDO001

Submitted to the University of Cape Town
In partial fulfillment of the requirements for the degree
MMed Psychiatry
Faculty of Health Sciences
University of Cape Town
Supervisor: Prof Sharon Kleintjes
Co-supervisor: Dr Peter Smith

1

Sharon Kleintjes