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Examining the pharmacological and psychological treatment of child and adolescent ADHD in Australia: Protocol for a retrospective cohort study using linked national registry data

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ABSTRACT

Introduction Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder which affects 5% of children globally. In Australia, it is estimated that 4.1% of children and adolescents have ADHD. While research has examined the treatment and outcomes of children with ADHD attending public mental health services during their time in the public system in Australia, it is not known what treatment they received before and after these treatment episodes, which will provide a more complete understanding of these children’s treatment journey.

Methods and analysis We will link clinical data from cohorts of children and adolescents treated in the public child and youth mental health and/or child development services in Brisbane, Melbourne and Sydney to the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS) and National Death Index. MBS data will demonstrate the treatment journey with respect to clinicians seen, and treatment episodes from the public health service data sets will be examined to assess if the type and intensity of treatment are related to treatment outcomes. PBS data will reveal all psychotropic medications prescribed, allowing an examination of not just ADHD medications, but also other psychotropics which may indicate co-occurring conditions (eg, anxiety and mood disorders). Statistical analyses will include descriptive statistics to describe the rates of specific medications and clinician specialities seen. Linear and logistic regression will be used to model how treatment and sociodemographic variables relate to routinely collected outcome measures in the public health system while controlling for covarying factors.

Ethics and dissemination This study has been approved by the following institutional ethics committees: (1) Children’s Health Queensland Hospital and Health Service (HREC/21/QCHQ/76260), (2) The University of Queensland (2021/HEO20143) and (3) The Australian Institute of Health and Welfare (EO2021/4/1300). Findings will be disseminated through peer-reviewed journals, conferences, professional associations and to public mental health services that treat ADHD.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The ubiquity of federally subsidised medical care in Australia provides comprehensive information regarding medical care, medications, and to a lesser degree allied healthcare for mental health conditions.

⇒ By using a data linkage approach to the federal registries, we will be able to describe care across a child’s treatment journey, before, during and after their contact with state public healthcare systems.

⇒ Linked registry data are limited to attendance only for psychology, occupational therapy and social work; information regarding the reason for attendance and the intervention received is not available.

INTRODUCTION

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder characterised by inattentiveness, impulsivity, hyperactivity and executive function deficits, such as difficulties with motivation and planning. Additionally, problems with emotional and behavioural regulation are common.1 Globally, ADHD is estimated to affect 2%–7% of the population.2 In Australia, in 2018–2019, ADHD affected 4.1% of children and adolescents and had an estimated total cost of US$12.76 billion, including financial and productivity costs and well-being losses.3

Despite treatment for ADHD being demonstrated to improve a range of health, social and occupational domains,4 the disorder is still associated with a chronic course, with symptoms that continue through childhood into adolescence and often persist into adulthood.5 The chronic course and the difficult treatment of ADHD are a global rather than an exclusively Australian problem. In Italy,
for example, only around half of children with ADHD attending tertiary neuropsychiatry clinics improved on the Clinical Global Impression Scale after 1 year. While there are numerous known moderators of treatment outcome in ADHD (eg, co-occurring conditions, family income level and ADHD severity), it is necessary, first, to understand what treatment looks like in ‘real-world’ settings and whether treatment is consistent with the recommendations in clinical practice guidelines.

Psychostimulants (eg, methylphenidate and amphetamines) are the mainstay of pharmacological treatments for those with ADHD. The National Institute for Health and Care Excellence (NICE) developed guidelines for treatment of ADHD and recommended methylphenidate and lisdexamfetamine/dexamfetamine in the first instance, and atomoxetine or guanfacine for non-responders and patients with contraindications or severe adverse effects to stimulants. In a case audit of Australian paediatricians, the professional group in Australia most likely to be involved in the treatment of ADHD, Efрон et al. found that most children (75%) with ADHD were prescribed stimulant medications (most commonly methylphenidate), and in the case of new diagnoses a third were referred to psychologists for further care. The most recent published study of treatment of ADHD in Australian children found that Australian general practitioners (GPs) and paediatricians had a generally high adherence to clinical practice guidelines, with timely recognition of medication side effects noted as an area for improvement for GPs managing ADHD. Ellis et al.’s study did not examine the practice of psychiatrists and only examined pharmacological therapies. In Germany, adherence to the country’s clinical practice guideline with respect to prescribing pharmacotherapy for ADHD was very high (97.2%) in a study by Mücke et al. However, another German study of nearly 20000 initial paediatric ADHD medication claims found that, while the majority were commenced on stimulants, 13% of children were commenced on a second-line or combination of medications, rather than trialling a stimulant first. It is necessary, first, to understand what treatment looks like in ‘real-world’ settings and whether treatment is consistent with the recommendations in clinical practice guidelines.

Recent research by our group has examined the differences in outcomes of children treated at Brisbane Child and Youth Mental Health Service community clinics. It was found that, compared with those with emotional disorders, children with neurodevelopmental disorders (ADHD and/or autism) had poorer outcomes in relation to behavioural, attention and social problems on the Health of the Nation Outcome Scales for Children and Adolescents, the Strengths and Difficulties Questionnaire (SDQ), and the Children’s Global Assessment Scale. Despite having poorer response in behavioural, attention and social difficulties, in Payne et al.’s study, children with ADHD and/or autism improved on comorbid emotional symptoms to the same extent as those with emotional disorders.

This good response to treatment of comorbid emotional conditions is in line with the findings of Gould and colleagues, who found the presence of comorbid ADHD did not affect treatment outcomes of CBT for anxiety disorders. The poorer response to treatment for attention symptoms found by our group is in line with previous studies. A notable discrepancy is that these findings of suboptimal improvements in attention symptoms in clinical settings are in contrast to the good outcomes reported in medication treatment trials. Those trials demonstrate improvements in core ADHD symptoms and improvements in health-related quality of life when medication is taken.

There is a gap between clinical trial and real-world outcomes, and the concept of ‘voltage drop’ is well known, whereby over time day-to-day practice and organisational demands may result in reduced fidelity to recommended treatment or research study protocols. Specific to Australia, community-based public mental health services (in contrast to private services) focus on the more complex cases, typically with comorbidities. Children under the care of these services may experience a treatment ceiling; having already received evidence-based treatment from a primary care provider, there may be fewer gains to be made in the public system. This was confirmed by Payne et al., who showed that the severity of symptoms in children attending CYMHS in Queensland, Australia, played a role in explaining poorer routine outcome measure improvement. Few studies have explored the treatment provided to children with ADHD.

Regardless of whether the treatment is pharmacological or non-pharmacological, it is important that the child receives a sufficient number of appointments to meet the criteria for a minimally adequate treatment (MAT). For children experiencing mental health problems, MAT is defined as more than four appointments where medication is used as an intervention and more than eight appointments for a non-pharmacological intervention. Of concern, Sawyer et al. found that only one-tenth of Australian children with a mental disorder, including children with ADHD, received MAT, half received some care insufficient to meet MAT, and another third received no healthcare for their mental health difficulties at all.
 Provision of care in Australia for children with ADHD occurs in the outpatient health system (both public and privately funded). GPs can refer children to other private practitioners, including psychiatrists, paediatricians and psychologists.26 GPs or other specialists can also make referrals to publicly funded specialist services such as child and youth mental health services (CYMHS) or child development services (CDS). Public CYMHS accept children who have severe and complex mental health problems for treatment, meaning they do not only see children with ADHD. A diagnosis of only ADHD with no comorbidities is uncommon in CYMHS, with 86.2% of CYMHS children with ADHD also having at least one additional diagnosis.19 CDS focus on the assessment and diagnosis of children with neurodevelopmental disorders, as opposed to other mental disorders, and children are mostly seen by developmental paediatricians. Given the severity and acuteness required to be seen in the public health system in Australia, young people who have lesser symptom severity or who are not accepted into a public clinic will therefore be seen by private practitioners in the community, with the fees of medical practitioners and some allied health practitioners partially subsidised by a government Medicare rebate. Despite these government rebates, Australian parents seeking paediatric, psychiatric or psychological consultation for their child’s ADHD often face high out-of-pocket costs. Depending on the clinician specialty, these out-of-pocket costs can be up to US$110 per appointment on average.27

In this study, we aim to provide a more complete description of the treatment provided to children with ADHD who have had at least one treatment episode in the Australian public system, either CYMHS or CDS. To this end, we will examine their Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) data. Around 85% of all Australian prescriptions are PBS-subsidised,28 and the medications routinely used to treat ADHD (stimulants and second-line medications such as atomoxetine and guanfacine) are PBS-eligible. This means that PBS data provide a reliable source for ADHD medications prescribed. PBS data will show psychotropic prescriptions a child received, when the drug was prescribed and the specialty of the prescriber. MBS data relate to Australia’s publicly subsidised health insurance scheme and will reveal how often a child attended for medical care, the specialty of those practitioners as well as some allied health attendance data (mostly psychologists). We will also extract data from the National Death Index (NDI) (date of death and underlying/other causes of death), which may help explain some cases where the child has been shown to prematurely cease treatment (both medications and healthcare provider appointments) before reaching the threshold for a MAT. Furthermore, the NDI will contribute to understanding if the mortality rate in paediatric ADHD is similar to that of the general paediatric population.

**Study aims**

This exploratory study will describe the treatment provided (via MBS and PBS) to a sample of children and adolescents (5–17 years) who were treated within the public mental health outpatient system or CDS between 2013 and 2020, and either received a diagnosis of ADHD in the public system or whose history of prescribed medication suggests a previously made ADHD diagnosis, and to specifically:

- Describe the prevalence of treatment of ADHD by medication type (including treatment received both before and after the treatment episode/s within the public outpatient system; ie, 2002 to the date the data are provided). Examining the entire medication history allows for an evaluation of the appropriateness of the medication prescribed over time both within and outside the public service. ‘ Appropriateness’ refers to the order in which different medications were trialled (eg, Were stimulants trialled before atomoxetine/guanfacine?), and if medication dose or agent was changed if significant symptoms remained on the outcome measures available.

- Describe the prevalence of treatment with medication for comorbid disorders, for example, antidepressants or antipsychotics (including any treatment received before and after the treatment within the public outpatient system or within the private system).

- Describe the prevalence of treatment with non-pharmacological therapies (such as psychotherapies) for those with ADHD, as far as can be assessed, including using MBS data to identify non-medication treatments received in the private system.

- Describe the prevalence of treatment with stimulants to children and adolescents who did not receive a diagnosis of ADHD within the public system (to capture those who received their ADHD diagnosis before or after the treatment within the public outpatient system or within the private system).

- Assess as far as possible the extent to which treatment for ADHD adheres to the current NICE guideline (NG87); that is, are the steps recommended by NICE in the medication treatment followed?

- Assess whether both medication and non-medication treatments of ADHD meet the criteria for MAT in terms of number of visits with treatment providers.

- Assess the extent to which sociodemographic variables as collected in the public system (eg, Indigenous status, ancestry, language, postcode) are associated with treatment type, comorbidities and MAT.

- Assess the extent to which MAT and adherence to the NICE guideline are associated with outcomes as measured during the treatment in the public system or in longitudinal follow-up.

**METHODS AND ANALYSIS**

**Study design**

This protocol describes an observational, retrospective cohort study. Retrospective data from children
and adolescents managed by the public health system, including demographics, diagnoses, scores on routine outcome measures and service use, will be linked via the Australian Institute of Health and Welfare (AIHW) with PBS, MBS and NDI data. The linked data set will be analysed per the study aims to provide an overview of treatment of ADHD provided to children and adolescents in Australia.

Study setting
This is a multisite study using data from Children’s Health Queensland Hospital and Health Service (CYMHS and CDS), Royal Children’s Hospital Melbourne (Department of Mental Health), Sydney Children’s Hospitals Network (SCHN), and the Clinic for Autism and Neurodevelopmental (CAN) Research and the Brain and Mind Centre, University of Sydney. The study will be administered by the Child Health Research Centre of The University of Queensland.

Study population and eligibility criteria
There will be no active participant recruitment as the research team will be accessing previously collected data and linking to the PBS, MBS and NDI data via the AIHW. Children and adolescents who meet the following criteria will be eligible for linkage:

► Were between the ages of 5 and 17, inclusive, at first treatment episode, who received an episode of care at CYMHS community clinics—Children’s Health Queensland Hospital and Health Service, or Department of Mental Health, Royal Children’s Hospital Melbourne—between 1 January 2013 and 31 December 2018. Or

► Were assessed/treated at CDS at either CHQ HHS or the SCHN, or at the Autism Clinic for translational Research, Brain and Mind Centre, University of Sydney, and are participating in the Improving Outcomes for Mental Health Study in Brisbane or the Child Development Registry Study in Sydney.

By including young people who had any recorded mental or neurodevelopmental disorder diagnoses (not only ADHD) in their medical records, we can identify if their medication history suggests that they received a diagnosis of ADHD within the private system or within the public system outside of the known treatment dates.

Exclusion criteria
Children seen at CYMHS were excluded if the treatment episode was <30 days. A treatment episode of this length suggests the child was referred to another practitioner or service after the initial screening assessment and that a proper diagnostic assessment was not performed.

For the CDS cohort, it is not uncommon for children to be referred to other services or practitioners after assessment and diagnosis. As such, the treatment episode length exclusion criterion used for CYMHS is not appropriate for this cohort. Children from the CDS cohort will be excluded if no diagnosis was reached because the assessment was not finished.

Linkage procedure
Figure 1 outlines the process of data linkage from individual site data sets through to federal data integration, secure storage and provision of results to the research team. Site data sets with identifying information are transmitted to the AIHW, which uses the identifying information to integrate the site data sets with the federal MBS and PBS information. The AIHW removes the identifiers and replaces this with a linkage key connecting the site content files with the federal content files, before transmitting the deidentified linked data into the secure environment for the researchers to access. The removal of the original identifiers prevents the researchers from reidentifying children in the final linked data set which contains federal MBS and PBS data. It is a requirement of AIHW ethical approvals that analysis be performed in the secure environment, and only results, not the linked data sets, can be exported from that secure environment.

Outcomes
Primary outcome
The primary outcomes of this study are the description of the ADHD medications children were prescribed and whether the sequence of medications trialled followed the NICE guideline for ADHD (NG87). To describe medication treatment of ADHD, we will (1) examine the frequency and dosage of prescription for each drug across our cohorts (both before and after service episode in the public mental health system), and (2) establish if the sequence of medications trialled was consistent with recommendations 1.7.7 through 1.7.10 of NG87.

Secondary outcomes
The following secondary outcomes for ADHD and comorbid conditions will be assessed:

► Frequency of visits with treatment providers, including medical practitioners, and also private psychology/mental health occupational therapy and mental health social work (if billed through MBS), to assess the extent to which MAT has been met. The data are limited to the extent that we will not be able to examine the reasons for professional attendances or what treatment was provided except for medications through the PBS.

► Treatment of comorbid psychiatric conditions including medications (all other psychotropics in Anatomical Therapeutic Chemical Codes N03 Antiepileptics, N05 Psycholeptics and N06 Psychoanaeptics).

► Percentage of children who received an ADHD diagnosis (International Classification of Diseases [ICD-10] or Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition [DSM-5] depending on site), before or after being treated by the public system.

► How routinely collected outcomes (varying by site; see table 1) are affected by treatment prior to and during
contact with public health and whether Routine Outcome Measures (ROMs) in state public health services predict future Medicare or PBS medication use.

Data analysis

Table 2 reports the sociodemographic variables to be described from each of the sites and for inclusion as covariates in regression analyses.

Table 3 outlines the statistical analyses to be conducted and maps these onto the study aims described earlier in the paper.

Figure 1  Linkage flow and procedure for Australian Medicare and Pharmaceutical Benefits Scheme data. AIHW, Australian Institute of Health and Welfare; MBS, Medicare Benefits Schedule; NSW, New South Wales; PBS, Pharmaceutical Benefits Scheme; QLD, Queensland; VIC, Victoria.

<table>
<thead>
<tr>
<th>Study cohort</th>
<th>Available routine outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Queensland: Child and Youth Mental Health Service</td>
<td>CGAS, SDQ, HoNOSCA</td>
</tr>
<tr>
<td>Queensland: Child Development Service</td>
<td>CBCL, SRS</td>
</tr>
<tr>
<td>Melbourne: Royal Children’s Hospital Department of Mental Health</td>
<td>CGAS, SDQ, HoNOSCA</td>
</tr>
<tr>
<td>Sydney: Sydney Children’s Hospitals Network and Autism Clinic for Translational Research</td>
<td>CBCL, EQ-5D-Y, CHU9D, PedsQL</td>
</tr>
</tbody>
</table>

CBCL, Child Behavior Checklist; CGAS, Children’s Global Assessment Scale; CHU9D, Child Health Utility 9D; EQ-5D-Y Proxy, EuroQoL Five-Dimension Youth Proxy; HoNOSCA, Health of the Nation Outcome Scales for Children and Adolescents; PedsQL, Pediatric Quality of Life Inventory; SDQ, Strengths and Difficulties Questionnaire; SRS, Social Responsiveness Scale.
There was no patient and public involvement in the study design.

This study has been approved by the following human research ethics committees (HRECs): (1) Children's Health Queensland Hospital and Health Service HREC (HREC/21/QCHQ/76260), (2) The University of Queensland HREC (2021/HE002143) and (3) the AIHW...
HREC (EO2021/4/1300). It was impractical to seek consent for a large-scale data linkage study. Appropriate lawful waivers have been attained from state and federal health authorities.

The data set for this study will be stored within the Sax Institute’s Secure Unified Research Environment. In effect, each research project operates within an operating system virtual machine, isolated from other projects and parts of the network. The system is rated as a tier 3+ data centre, ensuring the highest levels of information security and integrity and physical server security. The linked data set will be securely archived for 10 years and then destroyed.

The results of this study will inform clinical practice in the management of ADHD nationally and internationally. We will disseminate our findings through peer-reviewed journals, conferences, professional associations and to public mental health services that treat ADHD.

At the time of the present publication, the site data sets from Brisbane, Melbourne and Sydney are being collated by the research team, in preparation for transmission to the federal registry custodians to perform data linkage. It is anticipated that analyses will be completed within 1 year following provision of the linked data set back to the research team.

**DISCUSSION**

Previous research has demonstrated that, compared with those with emotional disorders, children with ADHD in the public child and youth mental health system improve to a lesser extent on routine outcome measures and are more likely to remain in the clinical range at the end of treatment. The current study provides a broader evaluation of the public health system’s treatment of ADHD by studying both CDS and CYMHS. The types of children typically seen in CDS and CYMHS, respectively, tend to differ. Both focus on complex cases, but CYMHS often only see children with neurodevelopmental disorders when there is comorbidity, as these services are intended to treat severe mental and behavioural disturbance. CDS is dedicated to the assessment and treatment of neurodevelopmental disorders and so often see children earlier in life but who are still presenting with complex developmental issues. The high threshold for acceptance of a referral by CYMHS generally means that children within CYMHS have received input prior to this episode of care. Extending the data collection outside the CYMHS and CDS clinical episodes will provide a more comprehensive view of the treatment received by these both before and after this episode of care. In particular, capturing the treatment children received after their contact with public health services will allow us to estimate long-term engagement with treatment. Insight into the treatment received prior to entry into the public system (eg, Did the child see a paediatrician or psychiatrist? Were psychotropics prescribed, and if so were the script repeats filled? Did the child see a private psychologist?) will generate important information describing patient journey and understanding the outcomes of children, as their improvement in the public system may have a ceiling effect if there have already been substantive interventions trialled previously.

**Limitations and future research directions**

While linkage studies in Australia generally provide a comprehensive overview of the points of clinical service a child has received due to the ubiquity of Medicare, there are key limitations on the information provided by federal registries. With regard to the PBS, the issuing of a prescription does not guarantee the child took the medication. Medication compliance is a known issue in ADHD, with Perwien et al finding in a US setting that by the second month of treatment less than 20% of children were compliant in taking their medications. Similarly, Australian data analysed by Efron et al found that children prescribed medication for ADHD only took the medication for approximately 40% of the time period they were under treatment. Further limitations of this study relate to the MBS data; while the MBS data tell researchers the type of practitioner the child saw, the reason for an attendance with a physician or allied health practitioner is not necessarily known. For example, a child with ADHD seeing a paediatrician may be attending for another unrelated concern. Similarly, a child may attend a session with a psychologist under a mental healthcare plan (the mechanism allowing a patient to see an allied health practitioner specialising in mental health under the MBS), resulting in a billed MBS item; however, there is no way of knowing if ADHD symptoms or strategies were the focus of that session, or if another problem was the focus of treatment, and what the exact intervention was. A further issue with psychology is that until the COVID-19 pandemic mental health MBS benefits with allied health practitioners were limited to 10 sessions per year, meaning there is a possibility that some children continued seeing their psychologist privately after the initial sessions and that this information would not be recorded in the MBS data. Additionally, other than private psychology, mental health occupational therapist and mental health social work, other mental health services, such as those provided by state governments and public hospitals, are block-funded and therefore would not appear in the MBS output for a particular patient had they attended these services. These situations would lead to underestimating the level of professional input received (ie, the ‘dose’ of the non-pharmacological intervention).

While we will use Saloner et al’s definition of MAT based on previous literature—four sessions for medication, eight sessions for non-pharmacological treatment—there are limitations in the use of this categorisation. MAT is defined for paediatric psychiatric problems broadly, so it is unclear whether the true threshold for MAT for ADHD is in line with Saloner et al’s definition, or whether ADHD requires more or even fewer professional attendances to result in effective treatment. Additionally, Ride
et al.\textsuperscript{31} found, in a sample of 600 Australian children, that MAT did not improve clinical outcomes in routine practice, indicating that quality of treatment may be more important than quantity/frequency. Ride et al.'s study,\textsuperscript{31} however, examined outcomes on the SDQ and did not have diagnostic information available, which may limit its applicability to an ADHD cohort.

Furthermore, with the cohorts involved, we will not capture the data of children whose entire pathway from diagnosis of ADHD to treatment was conducted privately, and subsequently whether there are differences in treatment between children treated solely within the private system and those who were treated in the public system or both public and private, as included in our cohorts. Future research could investigate the treatment of children solely seen in the private system and whether the findings are comparable with the results of this study.

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