Draft “Guidelines on Attention Deficit Hyperactivity Disorder (ADHD) Project Scope and Literature Review”

Feedback Template

In your submission please note the relevant page number/s that contain the issues on which you are providing comment. Please also provide complete references for any research articles you deem relevant that may not have been considered in the development of the guidelines. All comments will be considered by the RACP.

**Closing Date for Comments:** 23 November 2007, 5pm AEST

**Name:** Gillian Calvert  **Organisation:** NSW Commission for Children and Young People

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Sub-Chapter</th>
<th>Page number</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td>14</td>
<td>Recommended addition of a subchapter on Perspectives of children and young people to the existing list of sub-chapters under ADHD in Society. Evidence references: Harwood, 2000; Prosser, 2006; Travell &amp; Visser, 2006; Graham, 2007; Exley, 2008.</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>pp.15-17</td>
<td>The current list of assessment questions should consider the value of language assessments and other possible factors of influence including lead toxicity, epilepsy, autistic spectrum disorders, hearing/vision screening, adeno-tonsillar problems, or indeed, the effects of poverty, inter-generational disadvantage, quality of child care and diet. Research has consistently found that children in disadvantaged areas have poorer quality diets and poorer quality child-care. Research in social geography finds that the concentration of disadvantage leads to homogenous grouping in child-care, preschools, primary and secondary schooling, which compounds behaviour problems and difficulties in learning. Many parents of disadvantaged children do not have the skills to support their children's learning nor the means to access specialised tuition or remediation. Indeed, inadequate education is a cornerstone feature of Australia’s most disadvantaged communities (Vinson, 2007). This is a complex social problem and cannot be attributed to medical labels such as ADHD nor effectively resolved with medication. Such</td>
</tr>
</tbody>
</table>
intractable issues need to be addressed via a revised set of research questions and the expansion of the remaining 20.

The concept of ADHD has been criticised by some in the medical field (ie. Diller, 1998; Baughman & Hovey, 2006; and DeGrandpre, 1999) as well as social scientists (Conrad, 1975; Conrad & Potter, 2000) and researchers in education (Slee, 1995). There is also tension in the conceptualisation by different stakeholders (ie., see Barkley: ADHD primarily a problem of disinhibition; Tannock: ADHD primarily a problem of inattention).

There is ample literature from the fields of speech pathology and social work which introduce important qualifications in assessment and conceptualisation that should be taken into consideration in the research questions (Augustine & Damico, 1995; Damico & Augustine, 1995; Levine, 1997).

Consideration should be given to the inclusion of a question under the section ADHD in society on the impact of social/public policy, in terms of cost and access to services, on the lives of children and young people.

In response to the questions on ADHD in the Justice system it is recommended that the authors refer to Molina et al. 2007.

It is noted that stimulant medications are ‘thought to influence ADHD’ in certain ways and that “the precise mode of action that stimulants have on ADHD symptoms is not fully understood”. Given this, it is a concern that medication features first and foremost in the review and in the draft Table of Contents. This resonates with the enduring practice that medication is used as a “first-line approach” (Atkinson & Shute, 1999) in Australia, and not a last resort.

The primary focus of the review literature is “change in severity of symptoms” and secondary outcomes are reduced to whether there has been a “change in school/work achievement, quality of life and social function”.

The priority of focus on symptom severity is questionable as quality of life, health and well-being are the primary factors of concern with respect to children and young people.

It should be noted that the proportions of literature reviewed (eg. 10 adult studies, 4 children/adolescents, 2 preschoolers) is not representative of the population distribution currently receiving medication for ADHD. Caution should be exercised to avoid the results for the adult groups being extrapolated to represent children and young people.

The literature review (including the introductions or summaries) should clearly state that the medications reviewed are not approved for use in children under the age of 6 years nor have they been adequately tested for this group.

The review focused on behavioural interventions, academic instruction, material or environment, and more specifically,
organisational strategies, tutoring, and computer-based instruction. However as the search was restricted to psychology databases (excluding ERIC and other comprehensive educational databases) advancement and innovation in Australian pedagogy may have been omitted (see QSRLS, 1998/2000; and NSWDET, 2007). There is also significant relevant literature in special and inclusive education relating to inclusive practices and supports for children with learning and behaviour difficulties that could be included in the review (see Australasian Journal of Special Education, International Journal of Development, Disability and Education, International Journal of Inclusive Education).

It is recommended that the Reference Group extend the literature search to canvass the literature from research in education, especially with respect to advances in explicit teaching, small group instruction, use of visual cues, one-to-one ST:LA support, and the effect of education and social policy upon children’s access to services and quality of educational outcomes.

6.3 6.3.1 77 Include Pfiffner, 2007.

6.3 6.3.1 79 It should be noted that at the 14 month stage of the MTA study the Combined group showed superior results to MedMgt, Beh and CC groups.

6.3 6.3.3 91 Qualify the term "well" in the statement: "In other words, children with both ADHD and anxiety responded equally well to behavioural management, medication management and combined treatment".

6 6.4 100-119 The promising results for fatty acid supplementation, yoga/meditation and neurofeedback are noted. There is a lack of published research in the areas of behavioural optometry, chiropractic, homeopathy and cerebellar training.

General Comments

The Consultation Process
The Stage 1: stakeholder consultation on the draft guideline scope details a literature review pertaining to 26 of 46 research questions. These 26 questions relate specifically to ADHD management, including: medication management, management in an educational setting, psychosocial management and other forms of ADHD management.

From the description of process in the current draft consultation document, it appears that a second review of the literature for the remaining 20 questions will not be circulated for comment. This is a concern as Questions 1-9 (Assessment), and 36-46 (ADHD in Society, ADHD in the Workplace, ADHD and Driving, ADHD and Substance Abuse, ADHD in the Justice System, and Economic Considerations in ADHD) are all important topics of particular relevance to children and young people in NSW.

There is an absence of research questions relating to ethical considerations that are particularly relevant to the treatment of children and young people with ADHD these include: ethicality of administering medications to children against their consent, ethical conduct in sharing confidential information between parents, schools and health care professionals. Consideration should be given to the inclusion of questions on ethics.
Recommendations:

That the additional 20 questions are expanded to include the issues above. That a draft literature review for the remaining research questions be circulated for comment to key stakeholders as executed for the Stage 1 literature review (first 26 research questions). That the Reference Group include questions, in the remaining research questions, to address best practice in ethical considerations in the treatment of children and young people.

Stage 1 Literature review methodology

As mentioned in the detailed comments the restriction of the literature review search to psychology databases is an issue of concern. The restriction of the search to medical and psychological databases skews the results towards the medical conceptualisation, and medicalised interventions with detriment to alternative viewpoints, insights from social work and community group services, school-based practice and the nature and effect of educational and social policies. Thus what is taken to constitute evidence is restricted to randomized controlled trials and narrative based reviews from influential scholars in the field are excluded (see for example, Pelham et al., 1998 [143]).

The educational research database ERIC provides a much broader coverage of educational literature and was used by Hazell (2000), who also utilised the NHMRC standards for levels of evidence. Consideration could be given to augmenting electronic searching techniques with hand searching due to the low identification rate of electronic techniques.

Recommendation:

That a broader methodology is used for stage 2 literature review, with an emphasis on Australian research in the social sciences.

The diagnosis of ADHD and prescription of psycho-pharmaceuticals is concentrated by social disadvantage (Prosser & Reid, 1999; Issacs, 2006)

It has been suggested that medication is a more affordable option for lower-income families and that social support services are restricted by cost and availability (Gifford-Sawyer et al., 2004).

Significant increases in the medical diagnosis and treatment of ADHD has been noted in nearly all socio-demographic groups in the US, however the largest increases were among children from poor, near-poor and low-income families (Olfson et. al., 2003). The same study found a decline in the number of visits to health care providers but a significant increase in the number of stimulant prescriptions.

Reliance on medication is reflected in a recent Queensland survey that sought the voices of children and young people in care (CCYPCG, 2006). Queensland’s Commission for Children and Young People and Child Guardian found that 15.6% of young people (aged 9-18 years), 14.1% of children (aged 5-8 years) and 6% of young children (aged 0-4 years) were taking medication for ADHD. According to this survey, higher proportions of children in care relative to the general population are being treated for ADHD, some with up to three medications at a time.

It is concerning that greater proportions of children from vulnerable sections of society are receiving a diagnosis of and medication for ADHD, especially when the generally accepted prevalence rate for ADHD is considered to be about 3-6% of the population.

The Stage 1 literature review indicates that children from more-educated homes showed superior reduction of ADHD symptoms with combined treatment (Rieppi et al., 2002 as cited in RACP, 2007), whereas children of less-educated families showed no differential treatment responses. For oppositional-aggressive symptoms, children from lower SES homes benefited most from combined treatment, whereas children from higher SES homes generally showed no differential response. This suggests the symptoms in question arise from different sources and
that there is an aspect of parental modelling involved. There was no impact on outcomes for household income, nor for marital status. The evidence highlights the importance of issues of disadvantage being considered in the development of the revised guidelines for ADHD.

**Recommendation:**
That the research questions are reassessed to appropriately reflect important concerns regarding the concentration of ADHD diagnosis in vulnerable sections of the Australian community.

The use of psycho-pharmaceuticals (both stimulant and non-stimulant varieties) in young children

The research literature noted in Stage 1 of the draft consultation review reports higher incidence of adverse events and side-effects for young children treated with stimulant and non-stimulant medications. In addition the draft guidelines must emphasise that evidence indicates beginning medication later (ages 7 to 10) appears to have less detrimental effect on growth and severity of side-effects. Studies have shown at least 50% of preschool aged children diagnosed with ADHD at age four no longer met DSM criteria by age six (Hazell, 2000). In addition, the majority of psycho-pharmaceuticals routinely used in ADHD management have not been approved by regulatory authorities for use in children under the age of 6, and have not been adequately tested in this age group.

**Recommendation:**
That the draft guidelines caution against formal diagnosis and prescription of medication for ADHD in children under 7 years of age.

The majority of medication studies extracted for analysis in the Stage 1 consultation draft literature review were short in duration, rated as poor quality and a high proportion were industry funded

The studies extracted for review (Section 6.1 Medication Management) are, in the main, short-term studies of 12 weeks or less. Of the literature reported (RACP, 2007, pp. 35-38), only Wigal et al., (2005) examined academic performance and cognitive functioning; the rest focused on behaviour ratings.

Elsewhere, the research literature reports that medication effectiveness over the long term is equivocal at best and no more effective than other interventions (Jensen et al., 2007). It is important to note that medication had no effect on academic or social skills at any point in the MTA study and this is reflected in other studies listed (RACP, 2007). It should also be noted that the recent MTA study findings support those of respected leaders in the field and continue to cast doubt over the claims made on behalf of medication for the treatment of ADHD (Swanson et al., 1993). Appropriate reference should be made to the recommendations of this team of researchers as to what can realistically be expected from medication use (see Swanson et al., 1993, p. 159) as these recommendations are still relevant. Parents should be fully informed of what medication can and cannot do.

In addition, as noted in the consultation review, the long-term impact and safety of both stimulant (RACP, p. 29) and non-stimulant medications (RACP, p. 30) is still unclear – although available evidence indicates some consistency of side-effects for reduced appetite, growth retardation and increased anxiety. Adverse events (both cardiovascular and psychiatric) are rare, nonetheless severity of side-effects (i.e. tachycardia, anxiety, mood lability, appetite suppression, teeth-grinding, insomnia, headache, stomach cramps and more) vary on an individual basis and some children experience these intensely. The reporting of adverse events and side-effects to the TGA has not been comprehensive in Australia. Parent reports to health care professionals of side-effects, particularly those severe enough to result in discontinuation of medication, must be stringently reported to the TGA by health care professionals.
Recommendations:
That the draft guidelines include a statement on best practice for mandatory routine reporting of adverse events and side-effects of psycho-pharmaceutical treatment of children and young people under the age of 16 by health care professionals to the Therapeutic Goods Authority (TGA).

That the equivocal effectiveness noted in the research literature and lack of knowledge as to the long-term effects of ADHD medications be highlighted in the draft guidelines.

Lack of clarity around the use of the term “outcomes” in relation to the judgement of the effectiveness of medication

Many of the studies listed rate medication as effective in reducing hyperactivity and/or ADHD symptoms (indeed symptom reduction appears synonymous with “outcomes”). However, there is no fundamental examination of the nature of desired outcomes by the review team; that is, the desired end goal of medication treatment is not made explicit. As a result, medication could be rated as “successful” but the question remains: at what, and what for? This highlights one of the fundamental issues complicating ADHD research; that is, is it primarily a problem of behaviour or learning, and at what point does difference become impairment?

For example, the literature reviewed in the draft consultation document indicates that medication is successful at reducing behavioural symptoms of ADHD (NB: hyperactivity appears to be the most common measure) but little flow-on effect upon compliance and attention tasks, quality of parent-child interaction, academic and social functioning, or well-being has been recorded (RACP, 2007). This has been noted elsewhere (Swanson et al., 1993; Purdie, Hattie & Carroll, 2002), although the latter systematic review was not included in the draft consultation literature review. Moreover, results for quality of life were equivocal, side-effects remained un-reported in a high number of studies and non-responders were excluded which biased results in favour of the active drug.

Currently the enduring assumption is that behaviour problems lead to learning problems but some in the field argue that the reverse is more often the case (Tannock, 1998). Therefore the focus on whether medication affects/reduces externalising behaviour symptoms may well be critically misplaced.

Recommendation:
That the Reference Group consider in more depth the question of medical treatment aim. It should be made very clear to parents and the wider target audience of stage 2 consultations that the aim of any intervention should be the long-term health and well-being of the child. To this point, the research evidence does not support the role of medication as a primary resource.

Treatment of non-stimulant medications in the RACP review

Atomoxetine is newly developed and approved for use in Australia but already carries a Therapeutic Goods Administration (TGA) black-box warning for suicide ideation in children. This is not noted in the introduction to Section 6.1.2 Non-stimulant medication, although later it is noted that “the incidence of suicidal ideation was significantly greater in ATX-treated paediatric patients compared with placebo” (p. 66).

The RACP acknowledges that “the mechanism by which Atomoxetine impacts upon ADHD symptoms is unknown” (RACP, 2007, p. 30) and that “the long-term safety and efficacy of ATX has not been established” (p. 33). Atomoxetine became available on the Pharmaceutical Benefits Scheme in 2007 under the brand name Strattera but is not approved for use in children under the age of 6 years.

Recommendations:
That the Reference Group include a statement to the effect that the long-term effects of Atomoxetine are unknown, is available only on authority prescription from a paediatrician or psychiatrist, and has not been approved by the relevant regulatory authorities for use in children.
That these and other issues mentioned in this submission in relation to medication be emphasised in the revised draft guidelines to allow parents to make a genuinely informed choice.

**Side effects of ADHD medications**

With respect to side-effects of the medications canvassed in this review, is it concerning that only some adverse events (ie. cardiovascular and psychiatric) are considered serious, particularly as the research literature points to clinically low-grade side-effects as distressing to individual children and young people.

There is a need for social research in Australia into the nature of side effects from ADHD medications from the perspective of children, young people and their parents. The views of those affected must be included and reasons for parental decision to medicate (or not) must be better understood. As the side-effects of medication reported in the consultation document are not insignificant, due care must be taken in the final guidelines to emphasise that not all children respond well to medication, and approximately 30% do not respond at all (Swanson et al., 1993).

The decision to medicate is a choice that parents and children must make for themselves, without pressure and undue influence from teachers or health care providers. In several states in the US, legislation forbids teachers from recommending medication (Graham, 2007). It should be made very explicit in the final Australian guidelines that a diagnosis of Attention Deficit Hyperactivity Disorder should only be made by trained medical doctors and confirmed by expert clinical psychologists, paediatricians and/or child psychiatrists.

Parents and school personnel should be made very aware that recommendations relating to medication by teachers, principals and/or school nurses/counsellors are highly unethical, inappropriate and may be reported to the relevant Department of Education.

**Recommendation:**

It should be emphasised that methylphenidate, dexamphetamine sulfate and atomoxetine can only be prescribed by paediatricians and child psychiatrists.

**Non-stimulant medication**

The Reference Group has not sought to examine the research evidence around other non-stimulant medications prescribed to children for ADHD. As noted in the Stage 1 literature review (p. 34), these include tricyclic anti-depressants, clonidine, and guanafacine. There are a number of other medications prescribed for ADHD including: selective serotonin reuptake inhibitors (eg. SSRIs, such as Zoloft and Prozac), anti-psychotic medications (such as Risperidone), and mood-stabilisers (including lithium). Whilst the latter may not be routinely prescribed, only methylphenidate, dexamphetamine sulfate and atomoxetine are currently monitored and that the non-stimulant medications listed above can be prescribed by general practitioners. This may be leading to the over-laying of anti-depressants and other non-stimulants on top of stimulant medications, potentially leading to pharmaceutical toxicity and multiple-incidence side-effects.

**Recommendations:**

It is recommended that:

- children under the age of 6 should not be prescribed psycho-pharmaceuticals for ADHD,
- prescriptions for all psycho-pharmaceutical medications to children and young people under the age of 16 be monitored via Medicare authority prescription in the same way that stimulants (and atomoxetine) are now; and
- a central monitoring database trigger automatic review should more than one of these medications be prescribed for simultaneous use in a child or young person under the age
Consideration should be given to expanding the current research questions to include literature regarding the effects of combining ADHD medications with medications for anxiety, epilepsy, diabetes, asthma, etc. as appropriate. The final guidelines should clearly state known or suspected contra-indications.

Diagnosis of young children with ADHD and the use of psycho-pharmaceuticals

Hazell (2000) reports that the potential for over-diagnosis of young children with ADHD has increased since the release of the DSM-IV subtypes: combined, predominantly inattentive and predominantly hyperactive-impulsive types. Subsequent field trials conducted in the US have 'shown a skewing in the age distribution of ADHD subtypes [and] nearly 80% of those labelled as hyperactive-impulsive are under the age of 7 years' (Hazell, 2000, p. 10).

Recent reports from the 36 month follow-up of the MTA study (Jensen et al., 2007) suggest that a natural maturation process may be responsible for an overall improvement in all four study cohorts after 3 years. The convergence of treatment groups after 36 months could well indicate that children (who were on average 10-11 years of age at the post 36 month stage) had improved for developmental reasons and, indeed, that ADHD may be more appropriately conceived as a developmental disorder than a disruptive behaviour disorder. Certainly the MTA study casts doubt on the “reach before you can teach” rationale for initial intervention using psycho-pharmaceuticals as a learning aide (Green & Chee, 1997) since neither the intensive medication-only group nor the intensive medication plus psychosocial intervention group improved over time, relative to the behaviour modification or community care groups. While the MTA results have been criticised by some public commentators in Australia “because it started as a randomised study but then changed half-way, making it difficult to interpret the results” (Parry as cited in O’Leary, 2007, p. 3), it is noted in Jensen (2007, p. 998) that:

*Even though medication use patterns changed significantly from 14 to 36 months, with more cases assigned to the Comb and MedMgt conditions stopping medication and more cases from the Beh starting medication, the initial differences in medication use (especially Beh) and the two MTA medicated groups (Comb and MedMgt) were not completely eliminated. That is, at 36 months, 71% of Comb and MedMgt participants were using medication at high levels compared to 62% and 45% of CC and Beh participants, respectively. Groups also continued to differ in average medication doses as well. Yet these medication use variables during the year from 24 to 36 months did not reveal any advantage on 36-month outcomes and instead showed a tendency toward disadvantage.*

There is a lack of effectiveness for the MTA study community care (CC) regime “despite 68% of CC participants receiving medication sometime during the study” (Jensen et al., 2007, p. 990). While the US and Australian community care situations are somewhat different, both countries report significant problems in the area of service access; lack of communication between parents, professionals and schools; and the tendency for medication to be a first-line approach as opposed to a last resort (Bussing et al., 1998; Gifford-Sawyer et al., 2004).

In 2005, a survey of Australian parents of children with ADHD indicated that the recommended 1997 NHMRC guidelines were not being adequately followed; especially in relation to school feedback, hearing and vision testing (Concannon & Yang, 2005). This finding correlates with the observation by UNSW Brain Sciences Professor Florence Levy (2003) that paediatricians are responsible for the bulk of prescriptions, perhaps because their shorter consultation times prevent them from examining other mediating factors. Moreover, Issacs (2006, p. 546) maintains that young paediatricians report lack of training and expertise in diagnosing and treating ADHD, reporting that: ‘although 75% of general paediatricians felt that their knowledge of ADHD was deficient, 75% of general paediatricians prescribed stimulants to children with behavioural problems at least once a week’.
In light of this independent review of the literature, emphasis could be given in the draft guidelines for specialists to routinely assess: lead toxicity levels, vision, hearing, epilepsy, speech/language ability, allergies and intolerances, social skills, presence of abuse/neglect and deprivation before making a formal diagnosis of ADHD and/or prescribing psycho-pharmaceuticals to children and young people.

In the first instance parents could be provided a comprehensive management plan consisting of: fatty acid supplementation, completion of specialised parenting programs (see Hoath & Sanders, 2002), as well as a series of appointments with specialist psychological practitioners to devise appropriate psychosocial supports and behavioural interventions for use in the home (the availability of which has improved since Medicare inclusion of psychological services).

This, together with the results of the comprehensive assessment regime above, should be provided to the child’s preschool or kindergarten and school support services organised to coincide with school enrolment. Should the child already be enrolled at school, extra care should be taken to work in concert with the school system and support services to enable compassionate and supportive care through appropriately adjusted curriculum, pedagogy and classroom environment (see Graham, 2007; Harwood, 2006; Prosser, 2006).

**Recommendations:**
The research evidence for long-term effectiveness of medication is equivocal and should be noted in the revised guidelines.

Children and young people should be screened for cardiovascular abnormalities before any prescription of medication.

**References:**


Damico, J. S. and Augustine, L. E. (1995) Social Considerations in the Labeling of Students as...


Exley, B. (2008) 'Staying in class so no one can get to him': a case for the institutional reproduction of ADHD categories and behaviours. International Journal of Inclusive Education, 12:1, pp. in press.


