

**Shared Care Protocol for
Prescription of Medication in
Attention Deficit Hyperactivity
Disorder (ADHD)**

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1. PURPOSE AND BACKGROUND

The purpose of this document is to outline the basis for developing a shared care agreement between the ADHD Service for Children and Young People and General Practice about the prescription of medication for Attention Deficit Hyperactivity Disorder (ADHD) in children and young people.

ADHD is a relatively common childhood behavioural disorder, prevalence estimates depend to a great extent on diagnostic measures used, diagnostic criteria and a number of other factors but conservative estimates would put the prevalence rates of ADHD at 1-5% of school-aged children with a male: female ratio of 3:1.

The core features of children with ADHD are excessive motor activity, inattention and impulsiveness. These impairments are present in structured environments such as classrooms and in unstructured environments. Children with ADHD experience significant social, academic and psychological impairment at every stage of their development. Compared with their normally developing peers children with ADHD experience more negative peer relationships, higher rates of academic failure, earlier school leaving, and increased incidence of other psychiatric disorders such as anxiety, depression or substance misuse.

ADHD and its associated impairments can persist. It is estimated that up to two thirds of children affected by ADHD continue to have problems into adulthood.

ADHD is one of the most widely researched areas in Child and Adolescent Psychiatry but in spite of this there continues to be considerable variation in its management.

ADHD is a complex clinical condition to diagnose and manage. It often involves professionals from a variety of backgrounds, including general practitioners, health visitors, teachers, psychologists, psychiatrists, nurses, paediatricians and social workers.

Following initial diagnosis there is formulation of a treatment package, which must be individualised depending on the specific needs of the child or young person and their family.

Interventions can broadly be divided into non-pharmacological and pharmacological. Non-pharmacological interventions are not included within this draft protocol as this proposal applies solely to pharmacological interventions for the treatment of ADHD.

Pharmacological interventions are indicated in children and young people who have severe, pervasive and impairing symptoms of ADHD, or where other interventions have been unsuccessful and children's symptoms remain impairing.

Why Do We Need a Shared Care Protocol?

Research into treatment for ADHD particularly the MTA study (1), which compared various treatment strategies, has suggested the initiation of medication requires careful monitoring to achieve the optimum outcome and minimize adverse events.

Guidelines published by Scottish Intercollegiate Guideline Network (SIGN) (2) in June 2001 for ADHD in children were a major step in attempting to bring evidence-based guidelines into clinical practice.

This shared care protocol is based on the recommendations in the SIGN guidelines regarding shared care prescription and monitoring of medication.

2. CURRENT PRACTICE

General Practitioners prescribe medication on the recommendation of a Specialist in ADHD (currently this is a Child and Adolescent Psychiatrist)

Problems encountered with current practice

- Delay in initiation of treatment because of the time taken for communication to reach GPs, prescriptions to be written, and collection of prescription by patient or family
- Lack of control over medication once dispensed for full 4 week titration period
- Difficult to monitor treatment response if patients miss appointments
- Patients require additional trips to GPs to pick up prescriptions.
- Difficulty in making rapid medication changes in response to adverse events or alterations in clinical picture
- Medicine waste

3. PROTOCOL

This protocol is based on the SIGN shared care protocol (3) and clearly sets out the steps involved and responsibilities of the specialists and GPs

Aspects of care for which the ADHD Service would be responsible:

1. Assessment and Diagnosis of Children and Young people with ADHD
2. Initiation of psychostimulants or other medication for ADHD.
3. Prescription of medication for the initial titration period of approximately 1 month and for a further 2 months following dose stabilisation.
4. Clear communication to GPs regarding the transfer of prescribing once the patient is stabilised including review arrangements.
5. Patient monitoring during titration and stabilisation, including response to treatment, height, weight and blood pressure, then 6 monthly for those on long term therapy.
6. Prescriptions in cases where there is a change in medication type but NOT if this is purely a change in the preparation used. This would be for a similar time period as the initiation of medication, i.e. 3 months before transfer of prescribing to the General Practitioners.
7. Advising of GPs when medication should be discontinued and provision of necessary supervision during this phase.

Aspects of care for which the General Practitioners would be responsible:

1. Prescribing medication once the patient is stabilised.
2. Liaising with the Child and Adolescent Psychiatrist regarding any complications in treatment.

Conditions not proposed to be covered by this Protocol

1. Medication recommended for any other psychiatric disorder.
2. Patients transferring into the area already established on medication for ADHD.

Age Range covered by Protocol

This protocol would cover children from ages 6-16 or up to 18 if they were still at school.

4. BENEFITS OF SHARED CARE

For the Patient and their Parents/Carers

- Reduction in the time taken to commence medication
- Greater convenience as prescriptions will be given at clinic appointments rather than additional visits required to General Practitioner
- Improve clarity regarding source of prescriptions

For the ADHD Service

- Ability to closely monitor the initiation of medication, in terms of clinical efficacy and minimisation of side effects
- Ability to make rapid adjustments to medication if required
- Improvement in safety as initiation and initial stability on psychostimulants (Class B substances under The Misuse of Drugs Act 1971) would be dependant on patients attending the ADHD Service for review
- Possible improved attendance at clinic during titration and stabilisation so reduction in wasted clinical time due to non-attendance
- Greater compliance with SIGN clinical guidance

For General Practice

- Reduction in time spent providing prescriptions for titration period and initial stabilisation
- Greater clarity about medication as GPs would only take over prescription of medication once stable dose established or if preparation changed
- Possible improved satisfaction regarding safety issues as patients would not receive medication during titration and stabilisation without being reviewed by the ADHD Service

Risks if Shared Care Protocol not implemented

- Continued cost of wasted medication when patients non-compliant
- Safety issues regarding uncertainties about what medication a patient is taking if they do not attend appointments
- Continued non compliance of the service with current evidence based guidelines

5. IMPLICATIONS OF IMPLEMENTING SHARED CASE PROTOCOL

For General Practice

- Reduction in time spent providing prescriptions over initial 3 month period when psychostimulant treatment initiated
- Reduction in General Practice prescribing costs

For the CAMHS Service

- Increased demand on medical time to provide prescriptions particularly for psychostimulants as they are controlled substances and hence require to be written in a standard format by hand
- There will be a delay in implementing the protocol Tayside wide because of variations in availability of medical and nursing staff
- Ability to sustain the protocol as current figures would suggest 5-10 new patients a month commencing medication

6. MONITORING AND REVIEW

Once approved by the Directorate the protocol will be taken to the Primary Care Executive Group to clarify funding sources, thereafter it is planned to role out the policy through the LHCCs once prescribing facilities are available at the Centre for Child Health in Dundee.

The Developmental Psychiatry Team in consultation with Pharmacy and LHCCs following implementation will review the policy on an annual basis.

APPENDIX 1

Cost Implications for ADHD Shared Care Protocol

- Assume there are 15 new referrals per month of which 60% of the patients receive medication

i.e. 9 patients per month requiring medication

= 108 patients per year

Treatment with Methylphenidate

1 month treatment	£19.50
108 patients would receive 1 month treatment	£2,106
$\frac{6}{10}$ i.e. 44 patients would receive a further 2 months	£1,716
$\frac{2}{10}$ i.e. 22 patients would change to Extended Release Preparations of Methylphenidate for 2 months	£1,617

Treatment with Dexamphetamine

$\frac{4}{10}$ Of patients would be titrated to Dexamphetamine	£5,070
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Total Medicines Costs	£10,500
Dispensing Costs	£2,500

Grand Total Cost Per annum	£13,000
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The dispensing costs given are on the based on consultants prescribing of medication and dispensing by Community Pharmacy.

APPENDIX 2

References

1. A 14-month randomised clinical trial of treatment strategies for attention-deficit hyperactivity disorder. The MTA cooperative Group. Multimodal Treatment Study of Children with ADHD. Archives of General Psychiatry 1999; 56 1073-86.
2. Attention Deficit and Hyperkinetic Disorders in Children and Young People. Scottish Intercollegiate Guidelines Network, June 2001.
3. Attention Deficit and Hyperkinetic Disorders in Children and Young People, Guideline 52 – Supporting Material, Scottish Intercollegiate Guidelines Network

APPENDIX 3

Additional notes re shared care protocol

1. The ADTC process for shared care has been followed in developing this protocol.
2. The SMC status of the medication prescribed will be taken into account at all stages of patient treatment.
3. The Shared Care protocol has been developed in conjunction with Pharmacy at Ninewells Hospital, General Practice within Tayside, and the Developmental Psychiatry Team at the Centre for Child Health. It has been distributed within these departments for consultation and has been submitted to Tayside, Perth and Kinross and Angus LHCCs for consultation. Consultation has also taken place with the Directorate Management Team.

Pharmacy, General Practice and the Developmental Psychiatry Team at The Centre for Child Health, March 2005 have jointly prepared this protocol

TAYSIDE PROTOCOL FOR PRESCRIBING ATOMOXETINE (STRATTERA®)

Licensed indications:

Strattera is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older and in adolescents as part of a comprehensive treatment programme.

Scottish Medicines Consortium advice:

Atomoxetine (Strattera®) is accepted for restricted use within NHS Scotland for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older or in adolescents. It is restricted to use in patients who do not respond to stimulants or in whom stimulants are contraindicated or not tolerated. It is restricted to use by physicians with appropriate knowledge and expertise in treating ADHD. This advice concerns use in children and adolescents only and does not cover use in adults. Atomoxetine (Strattera®) is not a Controlled Drug under the Misuse of Drugs Regulations 2001.

Medicines Advisory Group advice:

- Atomoxetine is recommended locally for the treatment of ADHD in the following groups of children/adolescents:
 - those who have not responded to stimulant medication
 - those who have been unable to tolerate stimulant medication (eg due to decreased appetite, growth problems, sleep disturbance, depressed mood or mood lability or exacerbation of comorbid tics)
 - those in whom stimulant medication is contraindicated (such as those with co-morbid chronic motor tics or Tourette's syndrome)

Treatment should be under the direction of a specialist in childhood behavioural disorders.

The first three months of treatment should be prescribed by the Child & Adolescent Mental Health Service (CAMHS).

Prescriber details:

Prescription for the first three months of treatment should be from CAMHS thereafter by the patient's general practitioner in accordance with the local ADHD shared care protocol.

Criteria for patient selection:

Treatment should be considered in the groups of patients described above:

(The SPC states that in adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. However, start of treatment in adults is not appropriate.)

Administration details:

Atomoxetine can be administered as a single daily dose in the morning, with or without food. Patients who do not achieve a satisfactory clinical response or have significant adverse effects when taking atomoxetine as a single daily dose might benefit from taking it twice daily as evenly divided dose in the morning and late afternoon or evening.

Refer to SPC for dose titration details according to body weight.

No distinct withdrawal symptoms have been described. In patients where there are significant adverse effects, atomoxetine may be stopped abruptly; otherwise atomoxetine may be discontinued by tapering off over a suitable period of time.

Patients and families should be advised that clinical improvement in symptoms will take up to 2-6 weeks to become apparent and may take longer.

Contra-indications:

Atomoxetine should not be used in combination with monoamine oxidase inhibitors (MAOIs).

Atomoxetine should not be used within a minimum of 2 weeks after discontinuing therapy with a MAOI.

Treatment with a MAOI should not be initiated within 2 weeks after discontinuing atomoxetine.

Patients with narrow angle glaucoma, as trials have indicated use of atomoxetine was associated with an increased incidence of mydriasis.

Interactions:

Atomoxetine should not be used with MAOIs (see above).

Atomoxetine should be administered with caution to patients being treated with high dose nebulised or systemically administered salbutamol or other beta₂ agonists.

Use atomoxetine with caution with pressor agents.

Drugs that affect noradrenaline including antidepressants such as imipramine, venlafaxine and mirtazapine, or the decongestants pseudoephedrine or phenylephrine, should be used cautiously when co-administered with atomoxetine because of the potential for additive or synergistic pharmacological effects.

CYP2D6 inhibitors (eg fluoxetine, paroxetine) slower titration of atomoxetine may be necessary if co-administered.

Atomoxetine does not cause clinically significant inhibition or induction of cytochrome P450 enzymes.

Side-effects/cautions:

Common >10% patients: abdominal pain, nausea, decreased appetite, dry mouth

Less common 1-10% patients: anorexia, weight decrease, dyspepsia, constipation, dizziness, somnolence, cold/flu symptoms, early morning wakening, irritability, mood swings, mydriasis, dermatitis, rash, pruritis.

Other effects: several reports of hepatic disorders have been noted in patients treated with atomoxetine.

Many of these cases have been found to have other risk factors. The risk is estimated at below 1 in 50,000 patients treated. Patients and their parents/carers should be made aware of these risks and of potential signs and symptoms of hepatic disorder.

In paediatric trials patients taking atomoxetine experienced an increase in heart rate of about 6 beats/minute and mean increase in systolic and diastolic blood pressure of about 2 mmHg compared with placebo, none of these effects have been found to be clinically significant.

Atomoxetine should be used with caution in patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.

In patients with pre-existing renal or hepatic disease, initial and target dose should be reduced.

Monitoring - response to treatment:

Clinical response should be monitored by physicians with appropriate knowledge and expertise in treating ADHD. In Tayside this remit falls to CAMHS. Contact details as follows:

Dundee: Centre for Child Health, 19 Dudhope Terrace, tel: 01382 204004

Perth: Child & Family Psychiatry, Pitcullen House, Murray Royal Hospital, tel: 01738 621151

Monitoring response to treatment should include the use of standardised rating scales completed by clinician, parents/carers and teachers.

Periodic assessment of the need for ongoing treatment during long-term treatment will also be made by the CAMHS professionals.

Monitoring – treatment safety:

Growth rates (height and weight) together with blood pressure and pulse should be routinely monitored throughout treatment, at least twice yearly following treatment stabilisation, by CAMHS professionals unless alternative arrangements have been agreed with an individual's general practitioner.

There is no requirement for a pre-treatment ECG or baseline blood testing to be performed. There is no requirement for such measures to be routinely performed during treatment with atomoxetine unless indicated by clinical presentation.

Written by: Dr Sarah Seth

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