An auditable protocol for treating attention deficit/hyperactivity disorder

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Abstract
We present an auditable protocol for attention deficit/hyperactivity disorder (ADHD) or hyperkinetic disorder. The protocol is derived from standard recommendations and evidence, and is intended for outpatient medical clinic practice in secondary care. Suggested side effect rating scales are included.

(Keywords: attention deficit; hyperactivity disorder; protocol)

This management protocol can be applied within general or specialist clinics in child and adolescent psychiatry or paediatrics. It covers the basic management of suspected cases of attention deficit/hyperactivity disorder (ADHD), hyperkinetic disorder, or other clinical presentations characterised by apparent inattentiveness, impulsiveness, or overactivity. Cases entering the protocol may be selected according to the contents of a referral letter, by specific referral to a focused ADHD clinic within the general clinic, or as a result of screening by, for instance, the Strengths and Difficulties Questionnaire.

The terminology of conditions characterised by overactivity, impulsivity, impatience, and poorly managed attention is inconsistent. The emphasis in this protocol is on the American term ADHD since this is the most common pattern of disabilities found and is increasingly the most familiar diagnostic concept. It is a syndrome which can be caused by several different pathologies, among which a genetic susceptibility seems to be the most common. There is controversy as to how best to conceptualise the basic psychological deficit, but an evolving consensus that poor cognitive executive function is a fundamental issue.

Adoption of the American concept has meant adoption of the DSM-IV diagnostic criteria which identify a common condition affecting about 4% of primary school age children. This is four or five times as prevalent as the ICD-10 condition of hyperkinetic disorder, which has essentially the same symptom profile but requires more stringent criteria. Not surprisingly, services are having to adapt diagnostic and treatment practice rapidly because of the large number of children presenting. Although there is reasonable agreement among opinion leaders as to what constitutes good practice, there is ample anecdotal evidence that standards vary between practitioners. Recent advances in knowledge have not always been included into current practice. There have been excellent reviews of the evidence which should underpin clinical management, and recommendations concerning assessment and treatment, but the findings of the recent MTA trial, published since most of these were drafted, has led to some recommendations needing to be adjusted. Additionally, recent anecdotal evidence suggests that pressure on doctors in the UK to assess new cases within tight time limits might be a factor leading to superficial practice, so that crisp management guidelines, capable of audit and based on evidence would be valuable.

We have tried to bring together the elements of good practice and construct a protocol that is, as far as possible, evidence based and practical. We published a preliminary draft of the structure of a trial of medication within a collection of critical reading accounts of published papers on stimulants. Since then we have modified some aspects of the draft and expanded it to include assessment and psychological management.

This attempt at a protocol builds on apparent consensus among clinical scientists internationally that the following issues have to be taken into account.

- A large proportion of disruptive and disorganised children presenting to health services will fulfil diagnostic criteria for ADHD
- Among such children there will be extensive co-morbidity
- There will also be a high rate of educational failure
- Treatment effects have been shown for psychological interventions, dietary manipulation, and medication
- There are a number of treatment interventions for which there is little or no evidence for effect, or evidence for a lack of effect when compared with placebo.

The recent large MTA treatment trial in North America has not yet been completely reported and the interpretation of results is proving somewhat problematic. Nevertheless, from this and other recent work, the following important principles have emerged.
Inform and advise

Information for parents and child on nature of condition
Information about sources of information, local support group, etc.
Advice on parental handling
- realistic expectations, expressed in well communicated rules
- minimal confrontations
- positive parental attending to child plus praise for settled activities
- time out after (firstly) instruction and (secondly) warning for excitable and aggressive behaviour
- (can add) response cost programme
Inform GP, school doctor, and (with parents’ permission) school and educational psychologist of diagnosis. Liaise as appropriate

Insufficient improvement

1. Clue in history that dietary factors significant
2. Paediatric dietician available to monitor
3. Child and family can undertake diet regime

Elimination diet under using few foods (“oligoantigenic”) approach under supervision of paediatric dietician for at least three weeks
Add in separate foods sequentially to construct full diet

Insufficient improvement or excessive side effects

Consult specialist centre

Medication

1. Methylphenidate titration
2. Dexamphetamine titration
3. Imipramine titration

Insufficient improvement

Figure 1 Basic algorithm for treatment.

- Medication is best titrated against adverse and desirable effects rather than given on a predetermined milligram per kilogram basis
- Desired effects should include improved educational achievement and social relations within the peer group as well as behavioural control
- Psychological treatment adds little to optimised medication dosage, but can be of value for selected targets
- Psychological treatment reduces the dose of medication required.

The classroom is the setting in which inattention and inappropriate activity are most likely to be detected. Teachers are expert on the range of behaviour expected from children of the age they teach. Long term follow up studies of children with ADHD show that educational underachievement is extremely common. This all leads to a conclusion that involvement of teachers in rating severity and improvement is critical in assessing response to treatment.

In assessment, we recognise that some procedures such as psychometric assessment, are limited in their availability in some areas, but we have included them because of their importance in detecting coexistent problems. There are relatively straightforward measures of aspects of intelligence which can be carried out by non-psychologists (for example, Matrices, British Picture Vocabulary Scale) and we do not want to take an idealistic position and suggest that a full psychometric assessment, carried out by a chartered psychologist, is always essential.

The treatment algorithm in fig 1 establishes that basic psychological handling is always implemented in home and school before a trial of diet or medication. This is a departure from evidence based practice in the narrow sense, in that this has not been shown to be essential; but we consider there is enough of a consensus that it is good practice. We recognise that medication may improve the quality of parent–child interactions and thus conceivably make it occasionally sensible to use both medication and psychological management in parallel. Yet we also are cautious of medication being used as a “quick fix” and being focused only on behavioural control. With this in mind it seems to us appropriate to place basic psychological interventions ahead of a trial of medication or diet.

Antisocial behaviour commonly supervenes in children with ADHD. It is not known how to prevent this but epidemiological study indicates that it is most likely to arise in families where parenting is disrupted or distorted. There may be various reasons for this but the contribution of disruptive behaviour by an affected child needs to be taken into account. Because of the frequency of antisocial behaviour we have included advice on behavioural management as an intervention in all cases, preceding a decision as to whether to include a trial of medication. It is also possible that in some children adverse or suboptimal parenting can cause ADHD to persist rather than subside with time and development.

Although medication is the most powerful treatment in terms of effect size, not all cases will need it, not all families will accept it, and not all children will be suitable for it. Psychological intervention may prove sufficient. If it is not, there is evidence for the effectiveness of an individually constructed elimination diet. This is based on the principle of cutting out all foods apart from a very small number, testing for the effect of this, and if a positive effect is found, adding further foods singly and gradually, observing for adverse reactions. Foods so identified will then be removed from the child’s eventual diet. This is the “few foods” approach to constructing an elimination diet. We do not think there is adequate evidence for other diets such as the Feingold or gluten free diets, or those which include supplementation of certain fats, megavitamins, or herbs. There is no firm scientific evidence for the effectiveness on core ADHD symptoms of homeopathy, psychoanalytic psychotherapy, naturopathy, or cranial osteopathy, though we are aware of individuals, parents, and professionals, who express enthusiasm for one or the other. Accordingly we have actively excluded such interventions from our approach.

The position of family therapy and cognitive therapy is less clear. Effects of each can be shown on selected aspects of ADHD in individual children, but the effects are partial or unpredictable. We consider them to be supplementary interventions rather than core
components, the indications for which are not yet established. Accordingly we have not included them either.

We have omitted consideration of classroom management techniques because these are best implemented by educational rather than health service professionals. They have been shown to be effective and need to be deployed as a component of treatment. This makes the point that our suggestion is specifically about the contribution of the Health Service within a desirable multimodal, multiagency approach.\textsuperscript{11}

We assume that, where psychological intervention is insufficient in alleviating symptoms and promoting academic and social progress, a trial of medication will be indicated. There are preconditions to be met for this to be carried out. Although none are absolute, if any are not present we consider it wise to obtain a second opinion from a knowledgeable colleague before proceeding.

Our general approach is to indicate what should be done for adequate management. We have prepared lists which include boxes against items so that these can be ticked when the task is completed. This means that the protocol can assist self monitoring as well as potentially being subject to audit in a quality assurance programme.

**Assessment**

The key issues in this section, in addition to establishing the primary diagnosis of ADHD, are as follows.

- The establishment of a comprehensive baseline which should go beyond the core symptoms of ADHD and include the problems that led to referral and impairments of functioning which follow or are associated with ADHD
- Establishing comorbidity.

A combination of history taking, individual examination, and correspondence will be required. Information should be obtained directly, for example, from school, rather than second hand.

- Request parental permission to contact school.

**Use the following sources of information**

- Parental interview
- Parental rating scale (e.g. Conners (short CRS or CRS-R), Brown, SDQ, or SNAP-IV)
- Child interview
- Teacher rating scale (e.g. Conners (short CRS or CRS-R), Brown, SDQ, or SNAP-IV)
- Teacher report (descriptive).

**Obtain baselines**

- Document presenting complaints or problems
- List core ADHD symptoms as described in DSM-IV or ICD-10-Research edn (see table 1 for summary)
- Document level of academic achievement
- Evaluate and record social relationships with peers, parents, and teachers

- Evaluate and record parental attitudes to child.

**Ensure adequate coverage**

- Current symptomatic review (other than core ADHD symptoms)
- Developmental history
- Family history
- Medical history (illnesses, injuries)
- Medication history (responses, adverse reactions).

**Physical examination**

- Plot height and weight on growth chart
- Inspect face, ears, skin, measure head circumference (consider, in particular: foetal alcohol syndrome, fragile X, neurocutaneous dysplasias)
- Check hearing clinically
- Assess motor coordination
- Cardiovascular examination including blood pressure.

**Psychometric assessment**

- Verbal abilities
- Non-verbal abilities
- Reading achievement.

**Check co-morbidity**

- Antisocial behaviour problem/disorder
- Emotional disorder
- Tic disorder
- Pervasive developmental (autistic spectrum) disorder
- Specific scholastic skills problem (“dyslexia”, “dyscalculia” are umbrella terms. Check reading, spelling, number work in relation to estimated intelligence and teaching)
- Developmental language impairment
- Motor planning problem/disorder (includes quality of handwriting)
- Self esteem problem.

**Treatment**

See treatment algorithm (fig 1).

**Table 1. Items for the diagnosis of ADHD (derived from DSM-IV).**

<table>
<thead>
<tr>
<th>Inattention</th>
</tr>
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<tbody>
<tr>
<td>Careless with detail</td>
</tr>
<tr>
<td>Fails to sustain attention</td>
</tr>
<tr>
<td>Appears not to listen</td>
</tr>
<tr>
<td>Does not finish instructed tasks</td>
</tr>
<tr>
<td>Poor self organisation</td>
</tr>
<tr>
<td>Avoids tasks requiring sustained mental effort</td>
</tr>
<tr>
<td>Loses things</td>
</tr>
<tr>
<td>Easily distracted</td>
</tr>
<tr>
<td>Seems forgetful</td>
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<table>
<thead>
<tr>
<th>Hyperactivity-impulsivity</th>
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<tbody>
<tr>
<td>Fidgets</td>
</tr>
<tr>
<td>Leaves seat when should be seated</td>
</tr>
<tr>
<td>Runs/climbs excessively and inappropriately</td>
</tr>
<tr>
<td>Noisy in play</td>
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<tr>
<td>Persistent motor overactivity unmodified by social context</td>
</tr>
<tr>
<td>Blurs out answers before question completed</td>
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<tr>
<td>Fails to wait turn or queue</td>
</tr>
<tr>
<td>Intercepts others’ conversation or games</td>
</tr>
<tr>
<td>Talks excessively for social context</td>
</tr>
</tbody>
</table>

Criterion for subtypes is 6/9 on either list or, for combined type, 6/9 on each of both lists (see text), together with preschool onset, pervasive, and impaired functioning.
Parents have been instructed in:

- Basic handling practices
  - How to structure their child’s day
  - Advantages of household rules e.g. in reducing confrontations.

Parents have been advised about:

- Basic handling framework
  - Appropriate expectations
  - How to structure their child’s day
  - Advantages of household rules e.g. in reducing confrontations.

Parents have accepted medication as a contribution to management.

Establish basic conditions for a trial of medication

- Full diagnostic assessment confirms hyperkinetic disorder or ADHD
- Child is age 6 or over (although dexamphetamine is licensed for younger children, the effects of stimulants on preschool children are unpredictable)
- Parents accept medication as a contribution to management
- School will cooperate in administration of medication and monitoring its effect (essential that school can store and give child drug safely. Beneficial effects more likely to be seen in classroom than at home. Unsafe to allow child to take own drug to school. Use of long acting forms (where and when available) may avoid need for school to administer but monitoring by teachers still needed)
- No previous sensitivity to methylphenidate
- Child has normal heart and blood pressure on physical examination (not an absolute requirement but wise to obtain opinion from paediatric cardiologist if not normal)
- Child is seizure free or has treated epilepsy with infrequent seizures (current thinking is that risk of destabilising epilepsy with methylphenidate has been overstated unless seizure control unstable. Convention is to use dexamphetamine as alternative stimulant when child has seizures but hard evidence for this is lacking)
- Child does not have Tourette’s syndrome (not an absolute contraindication but consider using clonidine first. Simple tics not a contraindication though may be temporary worsening of these for a few weeks)
- Child does not have pervasive developmental disorder (unpredictable effects mean best carried out by, or in consultation with, specialist centre)
- Household does not contain substance misusers (misuse by patient very unlikely indeed but siblings or parents may misuse for weight loss or possibly intranasally for stimulation. Can theoretically be sold for (small) profit to the unsophisticated).

If these are not met:

- Obtain assistance of paediatric dietician and implement elimination diet, using few foods (“oligoantigenic”) approach
- Monitor using frequent measures as for medication.
- If no improvement, reappraise whether medication feasible.

Obtain baselines

- Weigh and measure height, plotting on growth chart
- Parent and teachers’ rating scales (e.g. Conners (short CRS or CRS-R), Brown, or SNAP-IV)
- Parent and teachers’ side effects questionnaires (side effects questionnaires below).

START TITRATION OF METHYLPHENIDATE

It is usually best to aim for maximum coverage during the day: 5 mg in the morning, 5 mg at midday, 5 mg in mid-afternoon.

With a young primary school age child (aged 6–8) who has one class teacher, consider trying a single morning dose trial so that mornings can be compared with afternoons, especially if school cooperation with administration of medication is uncertain. If so, start with 5 mg in the morning. Whether to include weekends and holidays is discretionary.

Monitor with regular questionnaires from parents and school (precise timing will depend on school terms; aim for fortnightly). A checklist is given below. The following need to be established:

1. Symptomatic and behavioural gain
2. Performance improvement (academic, peer group)
3. Adverse effects.

After two to four weeks (depending on availability of teacher questionnaires), review personally and enquire about beneficial and adverse effects. If there is room for improvement, increase the dose to 10 mg in the morning, 10 mg at midday, and 5 mg in mid-afternoon. If a single dose regime is being used, increase dose to 10 mg in the morning (a 5 mg scored tablet preparation (Equasym) is now available in the UK and allows fine tuning since a 2.5 mg dose increment becomes reliable;
quartering 10 mg tablets is not reliable). Continue to monitor at home and school with questionnaires. After approximately a further four weeks (that is, six to eight weeks from baseline), review personally and enquire about beneficial and adverse effects. If there is room for improvement, increase dose to 15 mg in the morning, 15 mg at midday, and 5–10 mg in mid-afternoon. A single dose regime should provide clear evidence of benefit or not by now. Try to move to three times daily. Continue to monitor at home and school with questionnaires. Ask specifically if child is dazed or perseverating (dose related side effect). Adjust afternoon dose according to difficulty settling or discontinuation (rebound) reaction. (If cardiovascular system is normal, can add clonidine 50–250 µg as evening dose, utilising drowsiness side effect. Increase dose with caution; ECG monitoring recommended. Advise against sudden discontinuation. Alternatively use night sedation: antihistamine (promethazine, trimeprazine, diphenhydramine) or (anecdotally) trazodone or melatonin at bedtime, dose according to age and weight.)

After approximately two further weeks (that is, eight to 10 weeks from baseline), consider: (1) whether an effect has been obtained in health and educational gain terms; (2) if so, and if child weighs more than 25 kg, consider increase to 20 mg morning, 20 mg midday, 5–10 mg mid-afternoon; (3) if not, stop methylphenidate and change to dexamphetamine; (4) whether side effects are tolerable (reduce dose if necessary). Enquire about desired and undesired effects at school and home. (Some weight loss is not unusual but reconsider if growth crosses a centile line. Abdominal pain or headache may persist beyond the first few weeks and be distressing, indicating a need to change medication.) Monitor home and school with questionnaires monthly until six months, then six monthly. Review personally, weighing and measuring height at least six monthly. Observe effects of unintentional withdrawal of medication, making an active attempt to assess whether to continue. If there has been no unintentional withdrawal, discontinue each 12 months to test continuing requirement (in some studies, a significant minority (up to 25%) no longer require medication at this point).

Checklist for administering rating scales
The following are administered at 2–4 weeks, 6–8 weeks, 8–10 weeks, and 3, 4, 5 and 6 months.
- Parents’ rating
- Teachers’ rating
- Parents’ side effects
- Teachers’ side effects.

If no benefit is obtained from methylphenidate, withdraw over a few days and substitute dexamphetamine.

TITRATION WITH DEXAMPHETAMINE
This follows the same principles of basic conditions, baseline, and monitoring.
- Baseline measurements
- Two to four weeks—dexamphetamine 2.5 mg morning, 2.5 mg midday, 2.5 mg mid-afternoon
- Two to four further weeks—if room for improvement, dexamphetamine 5 mg morning, 5 mg midday, 2.5 mg mid-afternoon (can omit if insomnia)
- Two to four further weeks—if room for improvement, dexamphetamine 7.5 mg morning, 7.5 mg midday, 2.5–5 mg mid-afternoon (can omit if insomnia).

An antihistamine, clonidine, or melatonin can be used as evening dose as per methylphenidate. Follow up is as for methylphenidate.

The checklist for administering rating scales is as for methylphenidate.

If no benefit is obtained from dexamphetamine, or if side effects unacceptable, withdraw over a few days and substitute imipramine.

TITRATION WITH IMIPRAMINE
- Baseline measurements
- Two weeks—50 mg daily dose (single or divided). Regular monitoring as before, with parent and teacher symptom questionnaires but not side effect questionnaires
- Two further weeks—75 mg daily dose (single or divided). (This seems to us to be a sensible upper limit. Some, but not all, studies suggest that there may be further improvement with higher doses. With this in mind it may be appropriate to increase up to a total dose of 150 mg per day. With doses over 50 mg daily the risk of cardiac dysrhythmia increases and it is wise to monitor with ECGs monthly.) Regular monitoring as before, with questionnaires. If appraisal is satisfactory, follow up is as for stimulants. The checklist for administering rating scales is as for methylphenidate.

If no benefit is obtained from imipramine and if there are excessive side effects, a specialist centre should be consulted.

NO RESPONSE TO ABOVE MEDICATION
If there is no response to any of the above medication, continue, reviewing personally no less frequently than six monthly with a growth chart and enquiry about tics. If there has been no incidental/inadvertent discontinuation, stop medication temporarily at 12 month intervals to test whether it is still required using teachers’ and parents’ rating scales. If there is no response to medication, review diagnosis. If diagnosis is confirmed, consult a tertiary care centre.


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