

ADD-vantage



c/o Multi Resource Centre, Villa Rossetta, 14, Triq Misrah il-Barriera, Msida
Tel: 233749, website: <http://www.vol.net.mt/adhd>

Attention Deficit/Hyperactivity Disorder Newsletter

*Issue 9
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Dear Members,

You may have noticed that it has been some time since we issued a Newsletter. Unfortunately this is due to lack of manpower. We have now employed a part-time Permanent Secretary and hope to have solved this problem. This is a special edition to circular the NICE Guidelines on the use of Ritalin since this was published last October and we thought you might all be interested in reading it. We have eliminated a few paragraphs since it is aimed at the UK public and they would not have been pertinent to Malta. However, you can access their web site if you wish to view it all. Hereunder is some information about what NICE means and their job.

What does NICE do/ What is NICE?

The National Institute for Clinical Excellence (NICE) is a part of the NHS.

Part of its work is technology appraisals. It produces guidance for both the NHS and patients on medicines, medical equipment and clinical procedures based on evidence of clinical and cost effectiveness. Each appraisal takes around 12 months to complete and involves the manufacturers of the technology, patient groups and professional organisations.

NICE promotes clinical and cost effectiveness through its technology appraisals, clinical guidelines and audit tools. NICE supports the work of those who make the complex treatment decisions - doctors, nurses, and other health professionals. The needs of the patient are central to NICE's work, and the Institute has forged strong links with patient groups and representatives.

NICE appraises new and existing health technologies, as selected by the Department of Health and the National Assembly for Wales and advises the NHS on how these technologies can best be used. It is also responsible for the production of national clinical guidelines, promoting best practice throughout the NHS. To support and assess the implementation of such guidelines, NICE will produce audit tools for use in the clinical setting.

NICE ISSUES GUIDANCE ON METHYLPHENIDATE (RITALIN/EQUASYM) FOR ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADHD)

The National Institute for Clinical Excellence has today issued its guidance to the NHS in England and Wales on the use of methylphenidate for attention deficit/hyperactivity disorder (ADHD). In summary the guidance recommends that:

- Methylphenidate should be used as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/Hyperactivity Disorder (ADHD).
- Diagnosis of ADHD should be made by a child/adolescent psychiatrist or a paediatrician with expertise in ADHD and should involve children, parents & carers and the child's school
- A comprehensive treatment programme should involve advice and support to parents and teachers, and could, but does not need to, include

specific psychological treatment (such as behavioural therapy).

- Children on methylphenidate should receive regular monitoring. When improvement has occurred and the child's condition is stable, treatment can be discontinued at intervals, under careful specialist supervision, in order to assess both the child's progress and the need for continuation of therapy.

Andrew Dillon, the Institute's Chief Executive, said, " The Institute's guidance is based on a very careful consideration of the evidence presented to the appraisal committee. I hope that it will be welcomed both by the families of children with ADHD and by health professionals."

Guidance on the Use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in childhood

This document has been circulated to many interested bodies in the UK.

This Guidance is written in the following context

This guidance represents the view of the Institute's Appraisal Committee, the membership of which is set out in Appendix A, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgment about the use of methylphenidate for Attention Deficit/Hyperactivity Disorder (ADHD) . This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Guidance This section (Section 1) constitutes the Institute's Guidance on the use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in Childhood. The remainder of the document is structured in the following way:

2. Clinical Need
3. The Technology
4. Evidence
5. Implications for the NHS
6. Related Guidance

7. Further Research
8. Implementation
9. Clinical Audit Advice
10. Review of Guidance

Appendix A: Appraisal Committee

Appendix B: Sources of evidence

Appendix C: Information for patients

The full document and a summary of evidence will be available from the website at www.nice.org.uk or by contacting 0541 555 455 and quoting reference number 22593.

1. Guidance

1.1 Methylphenidate is recommended for use as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/ Hyperactivity Disorder (ADHD). 'Severe ADHD' is broadly similar to a diagnosis of Hyperkinetic Disorder (HKD), although in some cases treatment may be appropriate for children and adolescents who do not fit the diagnostic criteria for HKD but are experiencing severe problems due to inattention or hyperactivity/impulsiveness.

1.2 Methylphenidate is not currently licensed for children under the age of six or for children with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; or thyrotoxicosis. Caution is required in the prescribing of methylphenidate for children and young people with epilepsy, psychotic disorders, or a history of drug or alcohol dependence.

1.3 Diagnosis should be based on a timely, comprehensive assessment conducted by a child/adolescent psychiatrist or a paediatrician with expertise in ADHD. It should also involve children, parents and carers and the child's school, and take into account cultural factors in the child's environment. Multidisciplinary assessment, which may include educational or clinical psychologists and social workers, is advisable for children who present with indications of significant comorbidity.

1.4 Treatment with methylphenidate should only be initiated by child and adolescent psychiatrists or paediatricians with expertise in ADHD, but continued prescribing and monitoring may be performed by general practitioners, under shared care arrangements with specialists.

1.5 Careful titration is required to determine the optimal dose level and timing. The drug should be discontinued if improvement of symptoms is not observed after appropriate dose adjustment.

1.6 A comprehensive treatment programme should involve advice and support to parents and teachers, and could, but does not need to, include specific psychological treatment (such as behavioural therapy). While this wider service is desirable, any shortfall in its provision should not be used as a reason for delaying the appropriate use of medication.

1.7 Children on methylphenidate therapy should receive regular monitoring. When improvement has occurred and the child's condition is stable, treatment can be discontinued at intervals, under careful specialist supervision, in order to assess both the child's progress and the need for continuation of therapy.

1.8 This guidance relates only to children and adolescents with ADHD.

2. Clinical Need and Practice

2.1 ADHD is defined by the 'core' signs of inattention, hyperactivity and impulsiveness. There are three subtypes of ADHD: 'combined type' with signs of inattention and hyperactivity/impulsivity; 'predominantly inattentive type' with inattention but not hyperactivity/impulsivity; and 'predominantly hyperactive-impulsive type' with hyperactivity/ impulsivity but not inattention. The diagnostic criteria further require that:

- the signs have persisted for at least six months to a degree that is maladaptive and inconsistent with the developmental level of the child;
- there must be clear evidence of clinically significant impairment in social or academic functioning;
- some impairment is present in two or more settings (usually at home and at school);
- some of the signs that caused impairment were present before the age of seven;
- and the signs do not occur exclusively during the course of a pervasive developmental disorder, schizophrenia or other psychotic disorder and are not better accounted for by other mental disorders (such as depression or anxiety).

2.2 The diagnosis of Hyperkinetic Disorder (HKD), sometimes used by UK clinicians, defines a subgroup of ADHD. HKD requires the presence of all three core signs - inattention, hyperactivity and impulsiveness. It also requires that all of the core symptoms were present before the age of 7 years, are pervasive (present in two or more settings) and cause impairment. HKD is broadly similar to severe combined-type ADHD.

2.3 ADHD often occurs along with other (co-morbid) disorders such as oppositional defiant and conduct disorders, learning disorders, anxiety, depression, tic disorders and Tourette's syndrome. Though the diagnostic criteria for ADHD exclude children with pervasive developmental disorders, such as Asperger Syndrome, some clinicians argue that these conditions can coexist.

2.4 Various genetic and environmental risk factors for ADHD have been identified. However, there is still controversy over the causes and diagnostic validity of ADHD.

2.5 The consequences of severe ADHD for children, their families and for society can be very serious. Children can develop poor self-esteem, emotional and social problems and their educational attainment is frequently severely impaired. The pressure on families can be extreme. The signs of ADHD may persist into adolescence and adulthood, and may be associated with continuing emotional and social problems, unemployment, criminality and substance misuse.

2.6 Estimates of the prevalence of the disorder vary widely within and between countries. It has been estimated that approximately 1% of school-aged children (about 69,000 6-16 year olds in England and 4,200 in Wales) meet the diagnostic criteria for HKD (i.e. severe combined-type ADHD). The estimated prevalence of all ADHD is considerably higher, around 5% of school-aged children (345,000 in England and 21,000 in Wales). Not all children who might meet the diagnostic criteria for ADHD are diagnosed.

2.7 Current treatments for ADHD include a range of social, psychological and behavioural interventions, which may be focussed on the child, parents or teachers. They may vary from the provision of information and advice through to formal psychotherapeutic interventions. Dietary interventions are seen as possibly useful in cases where a parent has observed that a particular food aggravates hyperactivity. The only medications that are currently licensed for the treatment of ADHD in the UK are the central nervous system stimulants methylphenidate and dexamphetamine. However, clinicians sometimes prescribe tricyclic and other antidepressants for this condition.

3. The Technology

3.1 Methylphenidate (Ritalin® produced by Novartis Pharmaceuticals and Equasym® by Celltech Medeva) is a central nervous system stimulant that is licensed for use in the treatment of children with ADHD. It is a Schedule 2 controlled drug. The licensed indication specifies that methylphenidate should only be used as part of a comprehensive treatment programme when remedial measures alone prove insufficient. A 'comprehensive treatment programme' is defined to include psychological, educational and social measures. The Summary of Product Characteristics (SPC) states that methylphenidate should only be prescribed for severe cases of ADHD following detailed history taking and evaluation. It is not currently licensed for use in children less than six years of age.

3.2 The manufacturers recommend that treatment should be initiated at 5 mg once or twice daily, and increased up to a maximum of 60 mg per day. If improvement of symptoms is not observed after

appropriate dose adjustment over one month, the drug should be discontinued. They suggest that methylphenidate should be discontinued periodically (under careful supervision) to assess the child's condition. Although no firm guidelines for withdrawal of treatment are given, they note that drug treatment should usually be discontinued during adolescence.

3.3 The SPC states that methylphenidate should not be used for children with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; and thyrotoxicosis. Caution is advised in the use of methylphenidate for patients with epilepsy or psychotic disorders, and emotionally unstable patients, such as those with a history of drug or alcohol dependence. Moderately reduced weight gain and slight growth retardation have been reported; and so careful monitoring is recommended. The SPC also recommends that blood pressure should be monitored, particularly for patients with hypertension, and that patients on long-term therapy should have periodic blood and platelet counts.

3.4 Nervousness and sleeplessness are common side effects (310% of patients) at the beginning of treatment, but can usually be controlled by dose adjustment. Other relatively minor side effects have been reported. Adjustment of the dosage and timing of administration may reduce side effects.

4. Evidence

4.1 The ultimate measure of the effectiveness of methylphenidate is the overall long-term impact on the health and well being of children and their families. In practice, this is difficult to measure, and no such data were identified in the review of evidence that accompanied this appraisal. Six main types of outcome measures have been reported in research studies:

Overall incidence/severity of problem behaviours

Incidence/severity of individual core symptoms (hyperactivity, inattention and impulsiveness)

School/academic performance

Depression/anxiety-related outcomes

Conduct/oppositional-disorder-related outcomes

Adverse effects

Many instruments have been used to measure outcomes across these dimensions. These include direct observation, psychometric testing and behavioural rating scales. The most commonly reported measure is the Conners Teacher Rating Scale Hyperactivity Index (CTRS-HI).

4.2 A large number of randomised controlled trials (RCTs) of methylphenidate has been conducted. However, this evidence is predominantly from the US and does not necessarily generalise to a UK context.

4.3 There is evidence from placebo-controlled RCTs that methylphenidate is effective at reducing hyperactivity, inattention and impulsiveness in the short-term while children continue to take medication.

4.3.1 Ten out of thirteen RCTs that reported results on the CTRS-HI found significant improvements following short-term (twelve weeks or less) administration of methylphenidate. These trials included 638 children of school age (from 5 to 18 years).

4.4 There is insufficient evidence to judge the relative effectiveness of methylphenidate, dexamphetamine and antidepressants.

4.4.1 Four RCTs (n=224) compared methylphenidate with dexamphetamine. These were of relatively poor methodological reporting quality, were inadequately powered and had inconsistent results.

4.4.2 Two RCTs (n=105) compared methylphenidate with imipramine. These trials were both of relatively poor methodological reporting quality. Neither found a significant difference in core behaviours. No studies evaluating the relative effectiveness of the other tricyclic antidepressants that are currently licensed for use in children in the UK were identified.

4.5 Direct randomised comparisons suggest that medication is more effective than behavioural intervention. However, this evidence is of mixed quality.

4.5.1 Three RCTs (n=192) comparing methylphenidate with behavioural interventions were identified. These studies were of relatively poor methodological reporting quality. Two of the studies reported some significantly better outcomes with methylphenidate than with behavioural interventions.

4.5.2 A large, well-conducted RCT, the Multimodal Treatment Study for Children with ADHD (the MTA trial), compared the effects of medication management (most subjects receiving methylphenidate) with a comprehensive and intensive multimodal behavioural treatment programme including a child-focused summer treatment programme, individual and group family behavioural therapy and a school-based treatment programme. The results of this US trial showed that medication management (n=144) was superior to behavioural treatment alone (n=144) for three (of five) measures of ADHD core symptoms. No significant differences were observed for other outcomes. The MTA researchers have warned that there were some features of the study design that could have favoured medication over behavioural treatment.

4.6 There is RCT evidence, some of relatively good quality, which suggests that the addition of medication to behavioural treatment programmes is beneficial. Improvements in short and medium term outcomes were observed across a number of dimensions.

4.6.1 Four out of six RCTs (n=254) reporting the CTRS hyperactivity index showed significantly better outcomes with combined methylphenidate and behavioural treatment than with behavioural treatment alone. The other two trials showed no significant difference, although these trials were small. Evidence of better core behaviour with combined treatment was available from a further four RCTs. There was also evidence of better conduct and school performance with combined treatment, but no evidence of a reduction in anxiety or depression.

4.6.2 In the MTA trial combined medication and behavioural treatment (n=145) was superior to intensive behavioural management alone (n=144) on measures of core symptoms, oppositional behaviour, anxiety and depression and academic achievement. No significant differences were observed for social skills or parent-child relations.

4.7 Evidence from placebo-controlled clinical trials (n=1257) shows that common side effects of methylphenidate are relatively mild and short-lived, and that more severe side effects are very rare. However, these data are based on treatment and follow-up of less than one year. None of the studies included assessment of longer-term side effects or the risk of addiction or abuse with methylphenidate.

4.8 The cost of methylphenidate is about £200 per child per annum if the average daily dose is 30 mg. It has been estimated that the total annual cost of methylphenidate therapy, including additional costs of assessment and follow-up, would be £500 to £1,000 per child.

4.9 UK estimates suggest that the additional cost of methylphenidate therapy compared to no treatment would be in the region of £10,000 to £15,000 per quality adjusted life year (QALY) gained. These estimates are based on the assumption that quality-of-life would be improved by about 6-7 percentage points over one year of treatment. Changes to this and other assumptions suggest that the incremental cost-effectiveness ratio could be as low as £5,000 or as high as £28,000 per QALY gained. There is no reliable estimate of the incremental cost per QALY gained of adding methylphenidate to behavioural therapy, although this would be expected to be somewhat higher than the above estimates.

5. Implications for the NHS

5.1 It has been estimated that approximately 1% of school-aged children (about 69,000 of 6-16 year olds in England and 4,200 in Wales) meet the diagnostic criteria for HKD (i.e. severe combined-type ADHD), of these approximately 48,000 are not currently receiving methylphenidate (45,000 in England and 3,000 in Wales). If all of these children were to have a trial of methylphenidate, the cost of the drug alone, for both responders and non-responders (approximately 30%) would be an estimated £7 m (£6.6 m in England and £0.4 m in Wales) in the first year. This is an upper limit to the additional annual cost of methylphenidate if the above guidance is followed.

5.2 Health, social and education services will also incur costs for assessment and follow-up of these children. These costs have been estimated at about £23 m for initial specialist assessment (£21.8 m in England and £1.5 m in Wales) and £14 m for follow-up care over one year (£13.4 m in England and £0.9 m in Wales). However, some of these costs relate to services that are already in place, and one hundred percent uptake of medication is unlikely. It is also possible that better treatment for children with ADHD could avoid some health, education and social costs in the longer term.

5.3 Access to child and adolescent mental health services is variable, with long waiting times in some areas. Children with severe ADHD need prompt assessment and treatment. The NHS will wish to consider how it makes provision for adequate specialist services to meet this need. The uptake and effectiveness of methylphenidate should be increased by the availability of improved inter-disciplinary and inter-agency working. Health authorities and trusts should work together with local authority social services and education services and the voluntary sector to ensure appropriate provision.

6. Further Research

6.1 Further research is required to determine the best treatment strategy for children with ADHD: a) medication as the first-line, followed by behavioural treatment only if necessary; b) behavioural treatment, followed by medication if necessary; or c) combined medication and behavioural treatment initiated at the same time.

6.2 Research is needed to clarify the role of medication for children with comorbidities and less severe forms of ADHD, and for children below the age of six.

6.3 Long-term follow-up is also recommended to monitor the incidence of adverse effects, the true potential for misuse of the drug, to assess the long-term benefits and health gain into adulthood, and assess how far prescribing should continue into late adolescence and adulthood.

6.4 Further research would also be useful to establish the current patterns of treatment and prescribing for ADHD

7. Implementation

7.1 As they reach the appropriate stage in their treatment patients should be offered the therapies set out in section 1 of this guidance.

7.2 Child/adolescent psychiatrists and paediatrician with expertise in ADHD should review their practice in line with the guidance set out in Section 1 of this guidance.

7.3 Trusts managing services specialising in ADHD should ensure that methylphenidate is used as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/Hyperactivity Disorder (ADHD). They should ensure that appropriate links are established with those organisations supporting multidisciplinary assessment, which may include educational or clinical psychologists and social workers; and that appropriate management programmes are in place.

7.4 Treatment with methylphenidate should only be initiated by child and adolescent psychiatrists or paediatricians with expertise in ADHD, but continued prescribing and monitoring may be performed by general practitioners, under shared care arrangements with specialists. Trusts and Primary Care organisations should ensure that appropriate shared care arrangements are in place.

7.5 The patient Information, attached to this guidance as Appendix C, can be drafted into local information leaflets and could also be used to help inform patients and their families.

8. Clinical Audit Advice

8.1 To enable clinicians to audit their own compliance with this guidance it is recommended that treatment plans are recorded for each patient.

8.2 This information should be incorporated into local clinical audit data recording systems, and consideration given (if not already in place) to the establishment of appropriate categories in routine electronic record keeping systems used in hospitals and the multi-disciplinary groups working in this area.

8.3 Relevant clinical guidelines and protocols linking the multi-disciplinary groups working in this area should be reviewed in light of this guidance

8.4 Prospective clinical audit programmes should record the proportion of treatments adhering to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific post-graduate activities

9. Review of Guidance

9.1 This guidance will be reviewed in August 2003

Andrew Dillon
Chief Executive
October 2000

Dr Karl Claxton
Lecturer in Economics
University of York

APPENDIX A

Appraisal Committee Members
This is a statutory committee, and the Standing Members are appointed for three years. The committee is supplemented by technology specific experts as identified in Appendix B.

Professor Duncan Colin-Jones
Professor of Gastroenterology
University of Southampton

Professor R. L. Akehurst
Dean, School of Health Related Research
Sheffield University

Professor Sarah Cowley
Professor of Community Practice Development
Kings College, London

Professor David Barnett (Chairman)
Professor of Clinical Pharmacology
University of Leicester

Dr Nicky Cullum
Reader in Health Studies
University of York

Professor Sir Colin Berry
Professor of Morbid Anatomy
St Bartholomew's and Royal London School of Medicine

Mr Chris Evennett
Chief Executive
Mid-Hampshire Primary Care Group

Dr Sheila Bird
MRC Biostatistics Unit,
Cambridge

Ms Jean Gaffin
Formerly Executive Director
National Council for Hospice and Specialist Palliative Care Service

Professor Martin Buxton
Director of Health Economics Research Group
Brunel University

Mrs Sue Gallagher
Chief Executive
Merton, Sutton and Wandsworth Health Authority

Professor Yvonne Carter
Professor of General Practice and Primary Care
St Bartholomew's and Royal London School of Medicine

Dr Trevor Gibbs
International Medical Operations Director
Glaxo-Wellcome R&D Ltd

Mr John Goulston
Director of Finance
The Royal Free Hampstead NHS Trust

Professor Philip Home
Professor of Diabetes Medicine
University of Newcastle

Dr Terry John
General Practitioner
The Firs, London

Dr Diane Ketley
Clinical Governance Programme Leader
Leicester Royal Infirmary

Dr Mayur Lakhani
General Practitioner,

Highgate Surgery, Leicester and
Lecturer, University of Leicester

Mr M Mughal
Consultant Surgeon
Chorley and South Ribble NHS Trust

Mr James Partridge
Chief Executive
Changing Faces

Professor Philip Routledge
Professor of Clinical Pharmacology
University of Wales

Professor Andrew Stevens
Professor of Public Health
University of Birmingham

APPENDIX B

The following documentation and opinion, on the use of methylphenidate for hyperactivity in childhood, was made available to the Appraisal Committee:

a. Assessment Report:

Lord J, Paisley S. The clinical effectiveness and cost-effectiveness of methylphenidate for hyperactivity in childhood. London: National Institute for Clinical Excellence, July 2000.

b. Manufacturer/sponsor submissions:

1. Celltech Medeva
2. Novartis Pharmaceuticals UK

c. Professional/specialist group, patient/carer group and trade association submissions:

1. ADD Information Services
2. AD/HD Family Support Group UK
3. Young Minds
4. Association of Child Psychotherapists
5. The British Psychological Society
6. Royal College of General Practitioners
7. Royal College of Paediatrics and Child Health
8. Royal College of Psychiatrists

d. The following experts were invited to make submissions to the committee:

1. Professor Eric Taylor, Professor of Child and Adolescent Psychiatry, Institute of Psychiatry
2. Dr Daphne Keen, Consultant in Child Health, St. George's Hospital

Appendix C

Guidance on the use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in childhood

Patient Information

The patient information in this appendix has been designed to support the production of your own information leaflets; you can download it from our website where it is available in English. A printed version of this

text is available in English. If you would like copies of the printed leaflet please contact 0541 555 455, and quote the reference number 22594 for the English version.

What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical & surgical procedures and where they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients.

NICE was asked to look at the available evidence on methylphenidate (Ritalin, Equasym) and provide guidance that would help the NHS in England and Wales decide where it should be used in for Attention Deficit/Hyperactivity Disorder (ADHD) in childhood.

What is Attention Deficit/Hyperactivity Disorder (ADHD)?

ADHD does not have clear physical signs that can be seen in an x-ray or a laboratory test. ADHD can only be identified by looking for certain characteristic types of behaviour. The main types are inattention, hyperactivity and impulsiveness.

Inattention. People who are inattentive have a hard time keeping their mind on any one thing and may get bored with a task after only a few minutes. They may give effortless, automatic attention to activities and things they enjoy. But focusing deliberate, conscious attention to organizing and completing a task or learning something new is difficult.

Hyperactivity. People who are hyperactive always seem to be in motion. They can't sit still. They may dash around or talk incessantly. Hyperactive children can squirm in their seat or roam around the room. Or they might wiggle their feet, touch everything, or noisily tap their pencil.

Impulsivity. People who are overly impulsive seem unable to curb their immediate reactions or think before they act. As a result, they may blurt out inappropriate comments or they may run into the street without looking.

Some people may show signs of all three types of behaviour (combined-type ADHD), others may only show inattention or hyperactivity/impulsivity. Not everyone who is overly hyperactive, inattentive, or impulsive has an attention disorder. Specialists must also consider that the following are present to diagnose ADHD:

- the signs have persisted for at least six months to a degree that is impairing the child's development;
- there must be clear evidence of clinically significant impairment in social or academic functioning;
- some impairment is present in two or more settings (usually at home and at school);
- some of the signs that caused impairment were present before the age of seven;
- the signs do not occur exclusively during the course of a pervasive developmental disorder, schizophrenia or other psychotic disorder and are not better accounted for by other mental disorders, such as depression or anxiety.

The diagnosis of Hyperkinetic Disorder (HKD), sometimes used by UK clinicians, defines a subgroup of ADHD. HKD is broadly similar to severe combined-type ADHD and requires the presence of all three core signs - inattention, hyperactivity and impulsiveness - and that all of the core symptoms were present before the age of 7 years, that they are present in two or more settings and that they cause impairment. The consequences of severe ADHD for children, their families and for society can be very serious. Children can develop poor self-esteem, emotional and social problems and their educational achievement is frequently severely impaired. The pressure on families can be extreme.

It has been estimated that approximately 1% of school-aged children (about 69,000 of 6-16 year olds in England and 4,200 in Wales) meet the diagnostic criteria for severe combined-type ADHD.

Current treatments for ADHD include a range of social, psychological and behavioural interventions, which may be focussed on the child, parents or teachers. They may vary from the provision of information and advice through to formal psychotherapeutic interventions. Dietary interventions are seen as possibly useful in cases where a parent has observed that a particular food aggravates hyperactivity. The only medications that are currently licensed for the treatment of ADHD in the UK are methylphenidate and dexamphetamine. However, clinicians sometimes prescribe antidepressants for this condition.

What is Methylphenidate?

Methylphenidate (sold in the UK as Ritalin and Equasym) is licensed for use in the treatment of children with ADHD and it is a controlled drug. The license for these products specifies that methylphenidate should only be used as part of a comprehensive treatment programme when remedial measures alone prove insufficient. A 'comprehensive treatment programme' includes psychological, educational and social measures. It also states that methylphenidate should only be prescribed for severe cases of ADHD following detailed history taking and evaluation and that it is not currently licensed for use in children less than six years of age.

What has NICE recommended about the use of Methylphenidate?

The NICE guidance relates only to children and adolescents with ADHD. NICE has advised the NHS that:

1. Methylphenidate is recommended for use as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/ Hyperactivity Disorder (ADHD). Severe ADHD is broadly similar to a diagnosis of Hyperkinetic Disorder - HKD. Although in some cases treatment may be appropriate for children and adolescents who do not fit the diagnostic criteria for HKD but are experiencing severe problems due to inattention or hyperactivity/impulsiveness.

2. Methylphenidate is not currently licensed for children under the age of six or for children with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; or thyrotoxicosis. Caution is required in the prescribing of methylphenidate for children and young people with epilepsy, psychotic disorders, or a history of drug or alcohol dependence.

3. Diagnosis should be made on a timely, comprehensive assessment conducted by a child/adolescent psychiatrist or a paediatrician with expertise in ADHD. It should also involve the child, his/her parents and carers and the child's school, and take into account cultural factors in his/her environment. Multidisciplinary assessment, which may include educational or

clinical psychologists and social workers, is advisable for children who show signs of other significant disease or conditions.

4. Treatment with methylphenidate should only be started by a child and adolescent psychiatrist, or a paediatrician with expertise in ADHD. Prescribing of the drug and monitoring of the patient may be performed by a GP, but only under shared care arrangements with the specialists.

5. Care is required when starting the drug to find the dose level and timing that provides the best results for the patient. The drug should be discontinued if an improvement of symptoms is not seen after appropriate dose adjustment.

6. A comprehensive treatment programme should involve advice and support to parents and teachers, and could, but does not need to, include specific psychological treatment (such as behavioural therapy). While this wider service is desirable, any shortfall in provision should not be used as a reason for delaying the appropriate use of the medicine.

7. Children on methylphenidate therapy should receive regular monitoring. When improvement has occurred and the child's condition is stable, treatment can be discontinued, under careful specialist supervision, in order to assess both the child's progress and the need for carrying on with the medicine.

What should I do?

If you, or a child you care for, has ADHD, then you should discuss this advice with your specialist at your next appointment. If you have access to the internet and would like to find out more about ADHD visit the NHS Direct website www.nhsdirect.nhs.uk

Will NICE review its guidance?

Yes. The guidance will be reviewed in August 2003

Further Information:

Further information on NICE, and the full guidance issued to the NHS is available on the NICE web site (www.nice.org.uk). It can also be requested from 0541 555 455, quoting reference 22593.

Use of Methylphenidate (Ritalin, Equasym) for ADHD in childhood - Questions and Answers

Guidance on the use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in childhood

Question and Answer Document

1. What is methylphenidate?
2. What is Attention Deficit/Hyperactivity Disorder (ADHD)?
3. What does NICE recommend about the methylphenidate in ADHD?
4. Can I find out more about ADHD?
5. Impact for Patients
6. Impact for the NHS
7. Impact for Professionals
8. NICE & the Appraisal Process

1. What is methylphenidate?

Methylphenidate (sold in the UK as Ritalin and Equasym) is licensed for use in the treatment of children with ADHD and it is a controlled drug. The license for these products specifies that methylphenidate should only be used as part of a comprehensive treatment programme when remedial measures alone prove insufficient. A 'comprehensive treatment programme' includes psychological, educational and social measures. It also states that methylphenidate should only be prescribed for severe cases of ADHD following detailed history taking and evaluation and that it is not currently licensed for use in children less than six years of age.

2. What is Attention Deficit/Hyperactivity Disorder (ADHD)?

ADHD does not have clear physical signs that can be seen in an x-ray or a laboratory test. ADHD can only be identified by looking for certain characteristic types of behaviour. The main types are inattention, hyperactivity and impulsiveness.

Inattention. People who are inattentive have a hard time keeping their mind on any one thing and may get bored with a task after only a few minutes. They may give effortless, automatic attention to activities and things they enjoy. But focusing deliberate, conscious attention to organizing and completing a task or learning something new is difficult.

Hyperactivity. People who are hyperactive always seem to be in motion. They can't sit still. They may dash around or talk incessantly. Hyperactive children can squirm in their seat or roam around the room. Or they might wiggle

their feet, touch everything, or noisily tap their pencil.

Impulsivity. People who are overly impulsive seem unable to curb their immediate reactions or think before they act. As a result, they may blurt out inappropriate comments or they may run into the street without looking.

Some people may show signs of all three types of behaviour (combined-type ADHD), others may only show inattention or hyperactivity/impulsivity. Not everyone who is overly hyperactive, inattentive, or impulsive has an attention disorder. Specialists must also consider that the following are present to diagnose ADHD:

- the signs have persisted for at least six months to a degree that is impairing the child's development;
- there must be clear evidence of clinically significant impairment in social or academic functioning;
- some impairment is present in two or more settings (usually at home and at school);
- some of the signs that caused impairment were present before the age of seven;
- the signs do not occur exclusively during the course of a pervasive developmental disorder, schizophrenia or other psychotic disorder and are not better accounted for by other mental disorders, such as depression or anxiety.

The diagnosis of Hyperkinetic Disorder (HKD), sometimes used by UK clinicians, defines a subgroup of ADHD. HKD is broadly similar to severe combined-type ADHD and requires the presence of all three core signs - inattention,

hyperactivity and impulsiveness - and that all of the core symptoms were present before the age of 7 years, that they are present in two or more settings and that they cause impairment. The consequences of severe ADHD for children, their families and for society can be very serious. Children can develop poor self-esteem, emotional and social problems and their educational achievement is frequently severely impaired. The pressure on families can be extreme.

It has been estimated that approximately 1% of school-aged children (about 69,000 6-16 year olds in England and 4,200 in Wales) meet the diagnostic criteria for severe combined-type ADHD.

Current treatments for ADHD include a range of social, psychological and behavioural interventions, which may be focussed on the child, parents or teachers. They may vary from the provision of information and advice through to formal psychotherapeutic interventions. Dietary interventions are seen as possibly useful in cases where a parent has observed that a particular food aggravates hyperactivity. The only medications that are currently licensed for the treatment of ADHD in the UK are methylphenidate and dexamphetamine. However, clinicians sometimes prescribe tricyclic and other antidepressants for this condition.

3. What does NICE recommend about the methylphenidate in ADHD?

The NICE guidance relates only to children and adolescents with ADHD. NICE has advised the NHS that:

A. Methylphenidate is recommended for use as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/ Hyperactivity Disorder (ADHD). (Severe ADHD is broadly similar to a diagnosis of Hyperkinetic Disorder - HKD). Although in some cases treatment may be appropriate for children and adolescents who do not fit the diagnostic criteria for HKD but are experiencing severe problems due to inattention or hyperactivity/impulsiveness.

B. Methylphenidate is not currently licensed for children under the age of six or for children with marked anxiety, agitation or tension; symptoms or family history of tics or Tourette's syndrome; hyperthyroidism; severe angina or cardiac arrhythmia; glaucoma; or thyrotoxicosis. Caution is required in the

prescribing of methylphenidate for children and young people with epilepsy, psychotic disorders, or a history of drug or alcohol dependence.

C. Diagnosis should be made on a timely, comprehensive assessment conducted by a child/adolescent psychiatrist or a paediatrician with expertise in ADHD. It should also involve the child, his/her parents and carers and the child's school, and take into account cultural factors in his/her environment. Multidisciplinary assessment, which may include educational or clinical psychologists and social workers, is advisable for children who show signs of other significant disease or conditions.

D. Treatment with methylphenidate should only be started by a child and adolescent psychiatrist, or a paediatrician with expertise in ADHD. Prescribing of the drug and monitoring of the patient may be performed by your GP, but only under shared care arrangements with the specialists.

E. Care is required when starting the drug to find the dose level and timing that provides the best results for the patient. The drug should be discontinued if an improvement of symptoms is not seen after appropriate dose adjustment.

F. A comprehensive treatment programme should involve advice and support to parents and teachers, and could, but does not need to, include specific psychological treatment (such as behavioural therapy). While this wider service is desirable, any shortfall in provision should not be used as a reason for delaying the appropriate use of the medicine.

G. Children on methylphenidate therapy should receive regular monitoring. When improvement has occurred and the child's condition is stable, treatment can be discontinued, under careful specialist supervision, in order to assess both the child's progress and the need for carrying on with the medicine.

4. Can I find out more about ADHD?

You can find out more about ADHD from the NHS Direct web site, their address is www.nhsdirect.nhs.uk

5. What does this guidance mean for Patients?

This guidance will mean that no matter where they live in England or Wales, both patients, their families/carers and health professionals, have access to the same information on what the NHS considers to be best practice in the

use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in children.

6. What will be the impact on the NHS?

NICE's guidance means that for the first time there are clear standards set by the NHS, for the NHS, on the use of methylphenidate for children with Attention Deficit Hyperactivity Disorder. The guidance has been made available to all Consultant Child and Adolescent Psychologists, and all GPs in England and Wales.

It has been estimated that approximately 1% of school-aged children (about 69,000 6-16 year olds in England and 4,200 in Wales) meet the diagnostic criteria for HKD (i.e. severe combined-type ADHD), of these approximately 48,000 are not currently receiving methylphenidate (45,000 in England and 3,000 in Wales). If all of these children were to have a trial of methylphenidate, the cost of the drug alone, for both responders and non-responders (approximately 30%) would be an estimated £7 m (£6.6 m in England and £0.4 m in Wales) in the first year. This is an upper limit to the additional annual cost of methylphenidate if the above guidance is followed.

Health, social and education services will also incur costs for assessment and follow-up of these children. These costs have been estimated at about £23 m for initial specialist assessment (£21.8 m in England and £1.5 m in Wales) and £14 m for follow-up care over one year (£13.4 m in England and £0.9 m in Wales). However, some of these costs relate to services that are already in place, and one hundred percent uptake of medication is unlikely. It is also possible that better treatment for children with ADHD could avoid some health, education and social costs in the longer term.

Access to child and adolescent mental health services is variable, with long waiting times in some areas. Children with severe ADHD need prompt assessment and treatment. The NHS will wish to consider how it makes provision for adequate specialist services to meet this need. The uptake and effectiveness of methylphenidate should be increased by the availability of improved inter-disciplinary and inter-agency working. Health authorities and trusts should work together with local authority social services and education services and the

voluntary sector to ensure appropriate provision.

7. What will the impact be on professionals?

Will the NHS to review its current practice in this area?

Yes -This is a specialist area of medicine and we recommend that patients discuss the guidance with their consultant.

Child/adolescent psychiatrists and paediatrician with expertise in ADHD should review their practice in line with the guidance .

Trusts managing services specialising in ADHD should ensure that Methylphenidate is used as part of a comprehensive treatment programme for children with a diagnosis of severe Attention Deficit/ Hyperactivity Disorder (ADHD). They should ensure that appropriate links are established with those organisations supporting multidisciplinary assessment, which may include educational or clinical psychologists and social workers; and that appropriate management programmes are in place.

Treatment with methylphenidate should only be initiated by child and adolescent psychiatrists or paediatricians with expertise in ADHD, but continued prescribing and monitoring may be performed by general practitioners, under shared care arrangements with specialists. Trusts and Primary Care organisations should ensure that appropriate shared care arrangements are in place.

What if the guidance is not followed?

The guidance represents the view of the Institute's Appraisal Committee, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement about the circumstances in which it is appropriate to use methylphenidate for children with ADHD. This guidance does not, however, override the individual responsibility of health professionals to make the appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or their guardian/carer. It is good practice to make a note on the patients record and to which treatment option has been chosen and why.

Who makes sure the NHS is implementing the guidance at a local level?

The guidance itself recommends that audit strategies are implemented at a local level to monitor the uptake of the NICE guidance and that the guidance should form part of local

Clinical Governance arrangements. The Commission for Health Improvement will review the implementation of this guidance.

8. NICE and the Appraisal Process

How does the appraisal process work/ what is HTA?

NICE follows an transparent and well structured process for its technology appraisals, which gives appropriate groups (patients professionals and manufacturers) with the opportunity to submit evidence, to comment on draft conclusions and to appeal, if required, to a panel of those independent of the original judgement.

Its task is to assess the evidence of all the clinical and other health related benefits of an intervention. This will include impact on quality of life, relief of pain or disability as well as any impact on likely length of life; to estimate the associated costs and to reach a judgement as

to whether, on balance, the intervention can be recommended.

Does the Government influence your decision?

No. Our appraisal process is independent and transparent. The appraisal committee is made up of a large independent group of health professionals and patient representatives. At the same time the provisional guidance is made available to manufacturers, sponsors and patient representatives for consultation it is also provided to the Department of Health and the National Assembly for Wales at specific stages of the appraisal process for comment.

Our work programme is given to us by the Department of Health and the National Assembly for Wales, and therefore represents their priorities.

NOTICES

The next Group Meeting will be held on 20th April 2001 at Gian Francisk Abela 6th Form, at 6.30 p.m. and as usual there will be the child minder and two PSE teachers for the older children. We urge you to make use of this service since the Group is here to help you and your children. We will shortly be announcing new opening hours for the office, which will be manned by our new Permanent Secretary, Vivien Portelli. We are sending this Newsletter to all 2000 members as the final reminder to pay your subscriptions for 2001.

We hope to be able to schedule the Annual General Meeting for May and since Vivien Portelli will be resigning as Chairperson, Annabelle Cassar will be resigning as Hon. Treasurer and I will be resigning as Hon. Secretary, we look forward to receiving some nominations for these posts and having some new blood on the Committee.