How should ADHD be treated?

STEVE BALDWIN *thinks that drugs should never be used in the treatment of attention deficit hyperactivity disorder (ADHD).* **PAUL COOPER** *argues for a multimodal response in which drugs can sometimes play a role.*

STEVE BALDWIN

Is ADHD a biochemical imbalance? No. In November 1998 the federal government of the United States of America reported there was no evidence to support the proposition that ADHD was a biological brain dysfunction (NIH, 1998). In the absence of a biological basis for hyperactivity disorders, there is no clinical rationale for drugging children and teenagers with amphetamines. When children are given amphetamines, this is for purposes of social control. Misrepresenting social control as a clinical intervention is health fascism (Baldwin & Anderson, 2000).

Should ADHD be treated with psychostimulants, including methylphenidate (MPH)? No. The diagnosis of ADHD is based on observations about the behaviour of children and teenagers, not on scientific biochemical markers such as blood analysis, genetic screening or metabolic tests. There are no reliable scientific criteria for an ADHD diagnosis. Judgements are made by parents, teachers and medical personnel using unreliable and invalid checklists. In the UK many children have been given a blind diagnosis (i.e. via the internet or telephone) by paediatricians, psychiatrists and educational psychologists who have not even completed a clinical interview (Baldwin & Anderson, 2000). When these so-called 'experts' are presented with the evidence of hyperactivity disorders, they are unable to recognise it reliably (Anderson & Baldwin, 2000). Economic self-interests (e.g. parents charged exorbitant fees for supposed advice and interventions) have prevailed over clinical science.

There is no scientific evidence for drugging minors with MPH, as no adequate dataset (i.e. from randomised controlled trials or double-blind studies) has ever been published in international refereed journals. The most recent report (MTA Cooperative Group, 1999a, 1999b) that claims support for drugging children has many flaws (e.g. 'testing' the efficacy of behavioural therapies by medical staff unqualified to complete such work) (Breggin, 2000). Many of the researchers in the MTA study were funded by the drug industry. All the evidence from 45 years of research with MPH has confirmed its toxicity, its potential for outright addiction and the high probability of irreversible side-effects when prescribed to infants, juveniles and teenagers.

Is MPH addictive? Yes. Methylphenidate is a core member of the family of amphetamines. In every organised economy worldwide, health departments and government agencies have regulated and then prohibited the use of amphetamines because of their extreme abuse potential, addictive properties and the stupefyingly obvious risks to psychological and physical health. Amphetamines are so addictive, toxic and dangerous that even adults cannot take them legally without prescription anywhere in the world. Clinically, the effects of MPH are almost indistinguishable from other amphetamine substances such as methamphetamine and dextroamphetamine.

In the USA the manufacturers of MPH now face a class action alleging fraud and conspiracy in a lawsuit aimed to win damages for prescribing drugs to minors as young as two. On their website (www.ritalinfraud.com) the law firm Waters and Kraus accuse pharmaceutical companies Ciba and Novartis of 'improper conduct', saying the manufacturers of MPH have '…conspired, and colluded to create, develop and promote the diagnosis of [ADHD] in a highly successful effort to increase the market for its product Ritalin…by [a]ctively promoting and supporting the concept that a significant percentage of children suffer from a "disease" which required narcotic treatment/therapy' (Waters & Kraus, 2000). This effort included the funding of US$0.75m to one so-called 'parent support group' between 1991 and 1994. Such funds were directed to 'promote and support (as supposed neutral party) the ever-increasing implementation of ADD/ADHD diagnoses as well as directly increasing [MPH] sales'. The defendants are alleged to have made 'efforts to increase…the supply of MPH available in the United States, and to reduce or eliminate laws and restrictions concerning the use of [MPH]' (Waters & Kraus, 2000).

In the UK psychiatrists, paediatricians and psychologists have colluded with the pharmaceutical industry to maintain the fiction that ADHD is a biochemical brain

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dysfunction best treated with amphetamines. Rather, hyperactivity disorders are reversible, socially constructed conditions, optimally treated with psychosocial interventions and never with amphetamines (Baldwin & Anderson, 2000).

PAUL COOPER

Allow me to comment on specific points, and extend the discussion to encompass what I see as other (sometimes more pertinent) critical points for debate.

ADHD and neurology Evidence concerning brain abnormalities and the cognitive and behavioural characteristics associated with the ADHD diagnosis has frequently appeared in peer-reviewed journals (see Tannock, 1998). These studies do not claim to have established definitive causal relationships between specific brain abnormalities and ADHD. In fact, abnormalities in different areas of the brain (including the striatal region and the frontal lobes) have been implicated in different studies. Given the complexity of the human brain, and the relatively primitive state of cognitive neuroscience as an empirical discipline, this is not surprising.

Definitive conclusions about the relationship between brain physiology, higher cognitive functions and human psychopathology are few and far between. Inherited neurological differences, such as those associated with ADHD, put their possessors at greater risk than members of the general population of developing certain disorders. Whether the disorder develops and the nature of its development depend upon the complex interaction that takes place within and between the molecular level, the cellular level and the organism in the external environment.

This interaction makes it entirely disingenuous to frame a discussion around the simplistic dichotomy of whether 'ADHD is a biological brain dysfunction' — this is inaccurate and misleading. ADHD is best understood as a biopsychosocial problem, and the 'bio' is in there because the research evidence indicates that it is an important factor. The research evidence does not tell us the precise nature of the association between neurology, cognition and behaviour in ADHD, but it does point to some powerful hypotheses. In this way ADHD is no different from many other clinical disorders. If psychologists were to demand definitive evidence of causal relationships between variables as a minimum standard for accepting the validity of psychological theories, then they would be left with a very shallow pool of knowledge (if any at all).

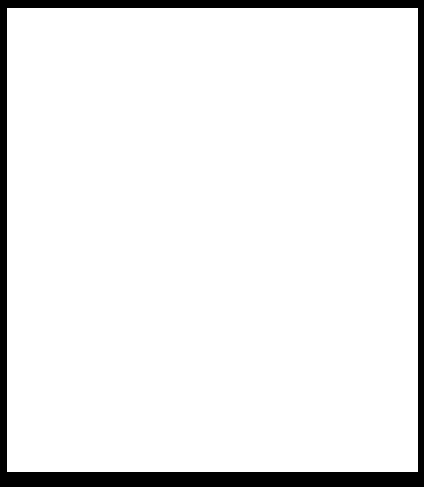
A crucial issue here is the practical value of psychological and other theory. The theoretical underpinnings of the ADHD diagnostic category provide professionals in various fields with valuable insights that inform their practice. Biochemical theories have also given rise to non-pharmacological treatments that are employed by some physicians (Kinder, 1999). At a more fundamental level, an informed understanding of ADHD challenges the deeply embedded, pernicious belief that deviant behaviour in young people is always either primarily volitional in nature or the product of neglectful or deviant parenting.

Furthermore, the misrepresentation of ADHD as a solely biological phenomenon misses the point that a biopsychosocial phenomenon, such as ADHD, requires a multimodal treatment response requiring multidisciplinary collaboration (British Psychological Society, 2000). Medication is largely regarded by informed and competent clinicians as a sometimes necessary but never sufficient intervention for ADHD. Non-pharmacological interventions include parent and family interventions, behavioural, classroom, pedagogical and social interventions, social skills training, group and individual psychotherapy (Teeter, 1998).

The use of medication The use of medication in the treatment of ADHD, particularly in children, has to be an issue of concern to any thoughtful, socially responsible person; not least because of the scope for misuse of the drug for control purposes. The ethical use of medication is always for the benefit of the client. In the case of methylphenidate the appropriate dosage will have the effect of enabling the individual to focus on tasks, thus facilitating the learning of academic, social and self-regulatory skills that are delivered through other elements of the multimodal approach. There is evidence to suggest that its effectiveness in contributing to improved social, behavioural and academic performance is enhanced by the use of additional non-pharmacological interventions, and in some cases the dosage level is reduced or the drug rendered unnecessary by such non-pharmacological interventions (Hinshaw *et al*., 1998).

With regard to the alleged absence of a research base published in 'international refereed journals' concerning the use of medication, Greenhill (1998) provides a comprehensive review of effectiveness identifying 20 randomised clinical trials. He concludes that there is 'proven efficacy of these compounds [i.e. psychostimulants] during short-term controlled studies, as shown by global ratings of ADHD symptoms by teachers and parents' (p.55).

It may certainly be the case that some clinicians opt far too readily for medication when deciding on treatment for ADHD. The review conducted by Hinshaw *et al*. (1998) of non-pharmacological approaches would suggest that there are viable alternatives to medication and that these should be widely disseminated and be given more attention by researchers from a range of disciplines. However, the claims that stimulant medication is the only intervention used with ADHD, and that this intervention has no 'scientific' credibility, are frankly wrong.



CHRIS CHAPERON

Ritalin and Equasym (two brands based on the generic drug methylphenidate) are likely to be made far more widely available after winning approval from the National Institute of Clinical Excellence (NICE), it was reported in November. The guidance bans prescription to children under the age of six and recommends use only as part of a comprehensive treatment programme; but NICE does conclude that the drug is effective. Andrew Dillon, Chief Executive of NICE, said the guidance was based 'on a very careful consideration of the evidence'. But Janice Hill from the support group Overload said that NICE 'do not address any of the safety concerns about Ritalin'.

Of course, the decision to prescribe medication and other interventions should always be based on data from the outcome of a thorough multimodal assessment procedure. A current example of good practice in the UK includes the assessment model described by Detweiler *et al*. (1999). This is carried out by a multidisciplinary team and involves clinical interviews, the use of standardised, norm-referenced behaviour-rating scales, a medical examination, a computerised test of vigilance and a cognitive ability test. The use of neuroimaging technology in assessment is uncommon. In time such technology might form a valuable component of assessment, but it would be a mistake to believe that ADHD could ever be diagnosed on the basis of a brain scan alone.

The defining feature of a disorder such as ADHD is the harmful effect of the presenting symptoms on the individual's functioning at the personal and social level. This means that the observational, personal and historical data are always going to be of central importance in assessing ADHD.

It must be stated that the assessment techniques available for detecting ADHD are far from perfect. Given the complexity of the condition, this is hardly surprising. However, the claims that ADHD is sometimes diagnosed without adherence to an appropriate assessment procedure ('via the internet or by telephone') are alarming. Such practice is thoroughly indefensible.

MPH and addiction The claim that MPH is an addictive substance that is abused must be treated with extreme caution. It is true to say that, as an amphetamine, it is one of a group of substances favoured by drug abusers. As such, MPH should be, and often is, treated as a substance that has potential to be abused. Robin and Barkley (1998) reviewed a number of US studies carried out between 1980 and 1994. These studies indicate that between 0.4 per cent and 0.8 per cent of adolescents self-reported using MPH for non-medical purposes, with no significant increase in these figures over time. This would indicate that the overwhelming majority of youngsters being prescribed MPH (approximately 3 per cent of US school students) are not abusing it. As for its addictive qualities, Stahl (2000) reports that patients show little or no evidence of tolerance, the need for escalating doses, or withdrawal symptoms.

Finally ADHD is a controversial topic that can give rise to passionate support on the one side and vehement rejection on the other. Neither of these positions is viable. We cannot jump to the erroneous conclusion that ADHD is caused by biological factors alone, or that the diagnosis is synonymous with the use of medication, or that the fact that some clinicians employ dubious assessment methods means that all diagnoses of the condition are bogus.

On the other hand, the extreme evangelists for the condition make dogmatic claims about the science underpinning the condition. Their ideological position allows them to accept the very lowest standards of 'proof' when they marshal evidence to support their case. While they do this, the ideologically opposed demand unrealistically high standards of proof that they would not require for topics that they found more congenial.

In this case, we find the drug companies vilified for their self-interest fuelled by the profit motive, while the US federal government becomes the arbiter of absolute truth. I don't have difficulty accepting the possibility that commercial enterprises may sometimes actively mislead the public in order to make profits, or that governments don't always tell the truth. But I also believe that if we are going to make allegations of these kinds we have to substantiate them with hard evidence.

More to the point, what are non-specialists meant to make of this fruitless game of assertion and denial? I am thinking of children with the diagnosis, their parents and the front-line professionals, such as teachers and social workers, who work with them. They deserve and need an honest account of ADHD that separates evidence from ideology and belief. Without such an account how are they to make informed decisions and choices about the position they must take to make sense out of a subject as complex as ADHD?

What constitutes 'scientific evidence'? It is frankly unsurprising that 'short-term controlled studies' of methylphenidate show modifications in a child's behaviour. Amphetamines are powerful drugs that act directly on the still-developing central nervous system of the youngster. It is precisely these blunting effects of MPH (i.e. narrowing of focus, constriction of spontaneity) that are favoured by some parents and teachers. In real life, however, psychostimulants are not used for the 'short term'.

A recent audit survey has reported that children aged 13 and 14 have been prescribed psychostimulants continuously for seven or eight years (Baldwin, in press). Other children in the study were first prescribed MPH at the age of three, four or five, despite manufacturer guidelines not to prescribe the drug to children younger than six. Such flagrant disregard of clinical guidelines is indefensible and unethical.

Minimum scientific standards should always apply when determining what would constitute an adequate dataset published in international refereed journals. Many of the 20 studies cited by Greenhill (1998) were completed by non-independent researchers funded by pharmaceutical companies, then reported in journals sponsored by drug companies. Results from these studies can scarcely be considered as valid, robust, independent scientific research and should be discounted when considering the supposed 'evidence' to support MPH prescription to minors. Laurence Greenhill has received research funds (or other financial assistance) from at least six different drug companies, including Richwood, Bristol-Myers, Solvay, Wyeth-Ayerst, Glaxo-Wellcome and Eli Lilly (Breggin, 2000). Studies that reflect such obvious vested

The full range of psychosocial and educational interventions should be made available

interests can hardly be considered to be scientifically independent.

It is irrefutable that drug companies fund researchers to complete trials that showcase their products favourably. The so-called 'drug approval process' merely requires that the minimum positive findings are obtained and reported. In the process, scores of trials with negative outcomes may have been discarded and never reported in science journals (Ruesch, 1992). There are obvious linkages between pharmaceutical companies and health policy makers both in the UK (via the Department of Health) and the USA (via the National Institutes of Health).

In the USA congressional contributions from drug companies in the first six months of 1999 included Bristol-Myers (US$1.6m), Glaxo-Wellcome (US$1.54m) and Eli-Lilly (US$2.13m). Total drug company contributions to congress between January and June 1999 exceeded US$28.9m. According to one medical observer:

> *…the ties between clinical researchers and industry include not only grant support, but also a host of other financial arrangements. Researchers serve as consultants to companies whose products they are studying, join advisory boards and speakers' bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company-sponsored symposium, and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity in the companies…* (Angell, 2000, p.517)

In 1998 the reported income for the first- (Novartis), second- (Merck & Co) and third-ranked (Glaxo-Wellcome) pharmaceutical companies was US$10.6 bn, US$10.6 bn and US$10.5 bn respectively (BW Health Wire, 1999). Clinical psychologists in the USA will likely be granted limited prescribing rights in 2001. In the UK this debate about prescribing has not yet been concluded.

The National Institutes of Health Consensus Conference (NIH, 1998) rejected the suggestion that MPH was of proven benefit in social or educational domains. The proposition that MPH will assist school performance remains unproven after more than 40 years of psychostimulant prescription. Rather, MPH is used for the social control of children and teenagers. In the UK the National Institute of Clinical Excellence (NICE) has confirmed that MPH should not be used with children younger than six. However, the NICE guidelines have not given definitive prescription advice to clinicians about children older than six.

What is the nature of ADHD? ADHD, like other developmental disorders, can be framed as a 'biopsychosocial problem'. Obviously, all disorders have some biological component. The real clinical challenge for psychologists, however, is to provide effective psychosocial and educational intervention alternatives that work for children and their families. Although a multimodal treatment response is desirable, most children are prescribed psychostimulants as a front-line, first-choice treatment by paediatricians and psychiatrists (Baldwin, in press). Many children prescribed psychostimulants in the UK are simultaneously prescribed sedatives, although this is specifically contra-indicated owing to the risk of a drug interaction. The complex nature of ADHD means that the full range of psychosocial and educational interventions should be made available for children and teenagers.

What are the toxic properties of methylphenidate? The proposition that MPH is 'safe, effective and not addictive' requires much closer scientific scrutiny. Results from low-level, quasi-scientific, pharmaceutical industry-funded drug trials are discordant with the actual experience of clinicians working with children diagnosed with ADHD. Adverse drug reactions (ADRs) from MPH have been reported to include (but are not limited to) confusion, depression, zombie-like constriction of affect, tachycardia, pituitary dysfunction, blurred vision, dizziness, and evening crash (Breggin, 1999).

Outcomes from an audit survey of children referred to a university clinic confirmed these ADRs, as well as a long list of other symptoms, including agitation, dyskenesias, tics, Tourette's, nervous habits, stereotypies, depression, amphetamine look, stomach-ache, dry mouth, diarrhoea, weight loss, growth suppression, chest pains, psychosis with hallucinations, insomnia, anorexia, vomiting, disturbed sexual function, headache, and hypersensitivity (Baldwin, in press). Every parent in this study of 80 families with children diagnosed with ADHD reported they had not been told about the addictive properties of MPH. Moreover, none of them had been offered treatment other than psychostimulants. Some children had been prescribed quantities of MPH that grossly exceeded the recommended dosage levels. Many children had been given MPH for seven or eight years, against the manufacturer's recommendation for short-term use.

What is the value of 'evidence-based practice'? There is no dispute that the debate about ADHD, psychostimulants and alternative psychosocial and educational treatments should be based on facts, not ideology. The only real debate seems to be about which information is considered acceptable in the scientific community as 'evidence'. Evidently there is agreement about the need for 'evidence-based practice', although disagreement about what constitutes 'evidence'.

I would stress that I agree with the values and ideas underlying Steve's position. We share a commitment to the view that children with social, emotional and behavioural difficulties should be helped. Like him, I deplore the indiscriminate use of psychostimulant medication in the treatment of children with ADHD and advocate evidence-based practice as a guiding principle to the 'treatment' of children with ADHD. Where we appear to part company, however, is, as he suggests, on the issue of evidence.

I agree entirely with the requirement for good-quality scientific evidence published in internationally respected journals. However, I question the accuracy of the claim that the studies reviewed by Greenhill are published mainly in journals 'sponsored by drug companies', with its implication that the review should be dismissed as unreliable. The journals drawn upon in this review are: *Archives of General Psychiatry*, *Journal of Child Psychology and Psychiatry*, *Journal of the American Academy of Child and Adolescent Psychiatry*, *Psychiatry Research*, *Journal of Learning Disabilities*, and *Psychopharmacology Bulletin*. I think readers would be surprised to see the majority of these journals described in the way Steve Baldwin describes them. If Steve is making this claim then he needs to provide evidence. Also, the strident conclusion that these studies are fatally

flawed by the assertion that their authors are funded by or otherwise associated with a drug company, is more the sort of inference that sensationalist journalists rather than academics make. Furthermore, the evidence for his own claim as to the treatment practices of clinicians and the experience of diagnosed individuals is supported primarily by reference to a single study of 80 families.

There is a contradictory element to Steve's account. On the one hand the evil empire of the pharmaceutical industry is ruthlessly and indiscriminately forcing drugs down children's throats. Yet by his own admission there is evidence that, if clinicians followed the drug companies guidelines, at least one group of children (i.e. those under six) would not actually be prescribed medication. Also, the side-effects he claims are, by and large, reported by the manufacturers, and can be controlled through the adjustment of dosage. If children continue to be prescribed medication after they have displayed seriously adverse reactions to it that have not responded to changes in dosage, then the prescribing physician is responsible for this situation.

This brings me to another important point of which Steve seems oblivious. The relationship between clinical practice and scientific research is not as straightforward as Steve portrays it. Until the scientific community comes up with cast-iron research evidence capable of offering definitive guidance to clinicians on every eventuality that they are likely to encounter, then clinical judgement will continue to be an important clinical tool. This means that 'front-line' professionals, whom academic and research psychologists work to support, are required to make practical judgements often in the absence of a definitive research-evidence base. Of course, the available research should inform clinical judgement. However, as the current dialogue suggests, sometimes there are conflicting ways of interpreting this research. It is not responsible to exaggerate or misrepresent either the flaws or the merits of this research.

Steve rejects and maligns the research and the researchers whose understanding of ADHD conflicts with his own. In so doing, he undermines his own case. In my view there is a promising (though as yet not definitive) body of neuroimaging and genetic research pointing to the role of biological factors in ADHD. As such, ADHD offers a paradigm for researching the relationship between biological, psychological, sociological and cultural factors.

The diagnosis is widely accepted by clinicians throughout the world. More importantly, perhaps, it is widely accepted by a large portion of the potential clients of these clinicians (including parents, adult sufferers and the children themselves). Many clinicians employ MPH in the treatment of ADHD, though best clinical practice is widely believed to require a multimodal and, therefore, multidisciplinary approach to treatment (British Psychological Society, 2000). There are examples of bad clinical practice, poor research and unethical behaviour in relation to ADHD (and everything else). We will not further the interests of individuals suffering directly or indirectly from ADHD by basing our understanding of ADHD solely on these negative cases.

There is clearly a great deal of progress still to be made in developing effective responses to ADHD. The complexity of the problem is such that it is unlikely that any single form of intervention will ever be appropriate for all cases of ADHD. What we now call ADHD will probably be called something else in the fullness of time, and the details of the diagnostic criteria and subtypes will change. In the meantime we need to acknowledge that 'multimodal' often equates with 'multidisciplinary'. Effective multidisciplinary working involves disparate workers bringing their distinctive expertise to a problem and interacting in a mutually supportive and co-operative manner. It would be foolish to rule out the possibility of medical expertise contributing something positive to such a multimodal approach (sometimes in the form of medication), just as it would be foolish to see ADHD as a solely medical problem.

This is the first of our 'Head to head' debates. If you have an idea for a topic that would interest our readers and can suggest two people (psychologists, other academics, practitioners or policy-makers) to take part, please e-mail your suggestions to the Editor on jonsut@bps.org.uk.

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