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NICE and adult ADHD: an independent view

This talk was given as a “workshop” session at The Ninth International ADDISS Conference, London, on 1st April 2009. The conference was attended by a range of people with ADHD, parents, and professionals.

My views about the NICE guidance had previously been largely unexplored, but I previously had several discussions about the perception of ADHD by the public and the media, especially with Andrea Bilbow of ADDISS and Professor Peter Hill of 17 Wimpole Street.

[Note added 8th December 2010: I have left the talk and notes unchanged. Over the last nineteen months my views have changed only a little, except for the issue of SSRI's and paroxetine (Seroxat). More evidence has emerged that the media and regulatory actions of the last decade may have led to an even greater reduction in diagnosis and treatment of depression, and therefore even greater adverse consequences.]

“In this talk I am going to look at some of the issues around the diagnosis and treatment of adult ADHD, especially in the light of the recent NICE guidance. Although I think that the guidelines overall are very welcome, my key point is that the guidelines for adults are too pro-medication in recommending stimulants for adults with moderate ADHD as the first intervention [1], and I will spend the first 20-25 minutes looking at this, followed by a brief break for discussion, with another 10-15 minutes looking at related issues, and finishing with a final discussion.

Just to mention that my links to pharmaceutical companies have never been significant, and I give more detail of that on my website, which I will be altering because I have had a couple of comments that it comes across as a bit “holier than thou” [2].

Right from the start I emphasise that this is just my own opinion, and I cannot be absolutely sure that the NICE committee will not turn out to have made an inspired judgement, in the light of future research which clearly demonstrates the enduring superiority of medication. The situation is somewhat complicated by the fact that one

of my reasons for disagreement, is that the committee having made this recommendation, such research may never take place.

Right away, this makes the comparison of ADHD with depression relevant, because there is still no United Kingdom licence for the starting of any ADHD medication in adults, and it was the premature and widespread off-licence use of SSRI antidepressants in children and teenagers which has been the focus of much of the adverse public, media, regulatory, and parliamentary scrutiny of prescription medications over the last few years [3]. One prominent US child and adolescent psychiatrist, Benedetto Vitiello, said in 2006: “Once hailed by some as a panacea and, at times, casually prescribed as if devoid of any risk, and later demonized by others as toxic agents of questionable utility, SSRIs are neither...reports from drug prescription data show a decline of up to 20% in the pediatric use of antidepressants...it may mean that more youths with depression or anxiety disorders are left untreated.”[4]. On Monday, Professor Eric Taylor noted that current UK services for adolescent depression are even worse than those for adults, and the climate now is hardly one favourable to innovative research in this area.

Moving on to the adult context: depression, as the commonest mental health disorder, seems to point the way to how ADHD services might develop. In saying this I accept that there is a good case for saying ADHD is a developmental disorder, as distinct from a mental health disorder, but in terms of services in the current context, it might be more useful to leave this issue to one side. In any case, depression has a substantial developmental aspect, not least because ADHD is probably one of its commonest causes.

So what do the NICE adult depression guidelines, published five years ago in 2004, say? From our point of view, looking at the way in to specialist services, the key phrase is: “Moderate or severe depression can be treated in both primary and secondary care” [5]. Let me edit that slightly: “...severe depression can be treated in ...primary care”. Now of course, severe depression *may* need to be treated and managed by specialist services, but the key factor in obtaining entry to those specialist services is the presence of risk factors. What level of risk factors? Well, that is left undefined.

So, since 2004, GP's have been managing moderate and severe depression essentially on their own, with very limited ability to refer to psychotherapy. Following the recent plans and funding for the Improving Access to Psychological Therapies (IAPT) programme [6], however, they should soon be able to refer patients with all levels of depression and anxiety for Cognitive-Behavioural Therapy. As for specialist adult mental health services, which will remain separate from the IAPT centres, the focus will remain on risk issues and so-called "severe and enduring mental health problems" [7], especially schizophrenia.

It may well be that there are significant numbers of people, already in the specialist adult mental health services with "severe and enduring" diagnoses, who can benefit from an additional diagnosis of ADHD, and even some with more severe ADHD who have been misdiagnosed. But it seems to me that it will be very difficult for the large numbers of people with moderate ADHD [8] to be absorbed without additional resources, as seems to be recommended in the NICE ADHD guidelines, because most of them will not present the required level of risk [9]. I suggest that at least some of the parents and service users in the audience will have encountered this hurdle.

Now, ADHD *is* a new diagnosis, unlike depression, which GP's have got used to dealing with over decades. The implication of the ADHD guidelines is that a new group of nurse specialists will take over much of the clinical care [10], but it is not at all clear how this will be structured in terms of case load, and I suggest that there is significant potential for diagnostic error, missing of co-morbidity, undertreatment and overtreatment [11]. It may be relatively straightforward to run such a clinic in the clinically abundant environment of the Maudsley hospital; quite another in areas where resources are much tighter [12].

Therefore, my first reason for suggesting that severe ADHD be the only explicit group for medication at this stage is the purely practical one that the initial focus can then be on those already within the mental health system, especially those with diagnoses of personality disorder; but in fact as the guidelines explore very well, the range of possible co-morbidities and misdiagnoses is wide. In any case, there are probably many people also with severe ADHD who are struggling in the community with a lot

of support from their family, involved with substance misuse services, or in prison, who can be picked up by specialist services if there is any spare capacity.

What is the evidence for preferring medication anyway in adults [13]? In formal terms, that is in terms of randomised controlled trials (RCT's), very weak, with only two trials comparing methylphenidate to placebo, and neither containing a cost-benefit analysis. There are no trials comparing methylphenidate to any other intervention [14]. There was one RCT for psychotherapy.

Would members of the committee argue that they had no choice but to recommend medication so strongly, because the trials were there? If you look at other recent clinical guidelines, there is in fact a wide variation in the nature of recommendations made, even in cases where there are large numbers of trials. Borderline Personality Disorder (BPD) is a good example, and seems especially relevant because BPD may often be a continuation of childhood ADHD. The BPD guidelines committee were able to recommend structured psychotherapy, even up to twice a week, despite a lack of evidence that any of several different forms of therapy was cost-effective to the level of £30,000 per Qaly. [15]

A reminder about what I am saying about treatment in moderate adult ADHD: not that we should never use medication right away, but the initial treatment should be left to clinical judgement and patient choice. I think it makes sense, if there are co-morbidities such as depression or problem behaviours, and a non-medication-based treatment is available, such as those coming along with IAPT, or the varied interventions which can be available in many settings such as psychotherapy for borderline personality disorder, contingency management strategies in addictions, or the CBT approaches to offending used by the rapidly-expanded numbers of forensic psychologists in prisons, to at least consider trying one of those first. It may well be that the depression [16] has been coming and going over many years, masking what could have been a considerable improvement in the “underlying” ADHD: just because we now recognise that ADHD features persist into adulthood, should not mean that we ignore the general tendency for improvement in many people [17].

My final point about medication in moderate ADHD returns again to the question of risk and public perception. The MTA trial has so far shown no evidence that stimulant treatment leads to risky thoughts or behaviour, rather the reverse, although the initial suggestion that drug misuse was less has not been maintained in the follow-up, with the behavioural intervention now showing some superiority over medication [18]. Therefore we may have already left behind the kind of scenario which arose over paroxetine. However, what will clearly require many more years of follow-up is the question of the development of bipolar disorders and schizophrenia. Methylphenidate can exacerbate symptoms of both of these, so there is clearly a theoretical risk. What may be in favour of ADHD treatment in general is that all kinds of stresses have been shown more systematically in recent years to contribute significantly to causation in schizophrenia [19], so that by improving functioning ADHD medication could well be protective rather than psychosis-promoting.

So to summarise this first part of the session: a definite recommendation for medication should have been restricted to severe ADHD in adults because of the limited, although encouraging, evidence, and a much more positive, if vague, recommendation for non-medication-based approaches could have been made. There is a danger of a “boom and bust”, probably not of unwanted effects in the short-term, but possibly in the longer term.

In the second part I will say something about my final reason for adopting a more cautious approach with medication: public and media perceptions about so-called medicalisation of normal behaviour, and [about] the influence of the pharmaceutical industry. And I will give some additional reasons why NICE and clinicians more generally might want to adopt a more pragmatic approach about such views.

[20]

Part II

As the NICE guidelines point out, methylphenidate has been available since 1955. It is currently available in generic form, which means that the price of the branded product, Ritalin, is kept low. Although the situation is complicated by the patent on

Concerta, which has been very profitable, this difference from the conditions under which many newly-licensed medications are actively promoted during their short patent life, as happened with paroxetine, has not (as far as I can tell) emerged at all in the public and media debate of the last ten years. This is just one way in which a more nuanced understanding of the “vested interests” argument could emerge. One suggestion that we could discuss is that the nature of journalism and the media is such, with intense attention rapidly engaging and then moving on, that many individuals with ADHD traits [21] or even ADHD are likely to be working in this area.

My own view is that in order for this more nuanced understanding to happen, the perceptions around the influence of the pharmaceutical industry on research more widely have to be addressed and not ignored. In psychiatry, the publications of Professor David Healy alleging suppression of data on adverse reactions, ghost-writing, and excessive marketing, have been largely upheld by the 2005 parliamentary health committee report, and in February 2009 in a report from the Royal College of Physicians [22]. For ADHD, it would seem possible to point to the MTA study, much larger and very different to the ordinary company-funded treatment trial aimed at getting a licence, as exempt from these kinds of problems. What I have already said about avoiding “boom and bust” is in line with David Healy’s own views, because he is by no means anti-medication. Although he has been sceptical about ADHD, he regards stimulants as effective antidepressants: rather better, in fact, than SSRI’s [23].

On Monday Professor Taylor was telling us about the focus group of teenagers on medication [24], who were handling the issues around diagnosis and treatment very well. This is certainly a good example of how the ADHD guidelines committee openly and transparently explored the “anti-medicalisation” side of the argument. I even suggest that by stating that ADHD only exists where impairment is severe or moderate [25], there is a concession to the anti-medicalisation point of view, a concession that I myself do not feel completely at ease with, because as an independent clinician I would like the freedom to be able to diagnose and treat mild ADHD, and even ADHD traits, even though those milder conditions are excluded from the NHS [26]. It seems a pity, then, that the evidence from the consensus conference is said to be in the end irrelevant because: “the research literature reflects

the dominant medical scientific paradigm and hence the nature of the evidence base.” [27].

In my view this “anti-medicalisation” argument is just as important to address as that about pharmaceutical companies. In fact the two are related in that David Healy has repeatedly claimed that diagnosis is an extension of pharmaceutical marketing. What should be of concern to the ADHD context is that this claim has become much more acceptable within mainstream adult psychiatry, especially in respect of depression [28], which as I said before is now managed by GP’s. What this is of course is a new variation on the “labelling” concept, which has been around for a long time.

So to summarise this briefer second half, I have looked at some of the issues around public perceptions of pharmaceutical industry influence, and the “anti-medicalisation” argument. I hope I have managed to suggest how a “zero tolerance” approach [29] to such views held by members of the public or the media may be counterproductive, and a proper engagement will be more helpful in getting greater acceptance for the diagnosis and treatment of ADHD.

Notes

Page number references to “NICE ADHD guidelines” are to the printed guidelines, dated 9th March 2009 by the NICE website, at:

<http://www.nice.org.uk/guidance/index.jsp?action=download&o=42060>

(1) “For adults with ADHD, drug treatment should be the first-line treatment unless the person would prefer a psychological approach.”: Nice ADHD guidelines, page 323.

(2) I have never been important enough to be seen as an “opinion leader”: although at one point I did wonder if I was being sounded out about such a role, at a very local level, it may well just have been that particular pharmaceutical representative being friendly (i.e. doing his/her job).

(3) (See pages 3-22 of: Royal College of Physicians. *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*. Report of a Working Party. London: RCP, 2009. Available at the time of writing at: <http://www.library.nhs.uk/HealthManagement/ViewResource.aspx?resID=308791&tabID=290> , or at the RCP website.

(4) Vitiello, Benedetto (2006) Selective Serotonin Reuptake Inhibitors (SSRIs) in Children and Adolescents. *Journal of Child and Adolescent Psychopharmacology*. Vol 16, pages 7-8

(5) NICE Adult Depression Guidelines, revised 2007, page 56

(6) IAPT Implementation Plan: National Guidelines for Regional Delivery.
February 2008:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083150 .

(7) “Severe and enduring”: NICE Adult Depression Guidelines, revised 2007, page 109 (it is surprising, I think, that this phrase occurs only in the context of a discussion about day hospitals). A Google search will turn up many examples of its “official” use: for a bleakly humorous one from a service user see

<http://www.scottishrecovery.net/content/mediaassets/doc/Severeandenduringrecurrentdepressionwithpsychoticepisodes-speaksforitselfdoesntit.pdf> .

(8) I assume that people with “moderate” ADHD outnumber “severe” considerably, if the underlying condition follows a statistical “bell-curve” or “normal distribution” (NICE guidelines page 124), and both have the same range of severity. But the guidelines are not explicit on this last point. See also note 25.

(9) The Royal College of Psychiatrists has recently expressed concern about this focus: “...a culture preoccupied with risk to others has emerged within the UK...This concern with risk, instead of stimulating better and safer practice, appears to have had a negative impact on mental health professionals, professional practice, service users and the public.” Royal College of Psychiatrists (1998) *Rethinking risk to others in mental health services*, Council Report CR150. Page 9.

(10) And as commented on by Professor Phil Asherson (who was on the NICE ADHD guidelines committee) at the Royal Society of Medicine conference on “Developmental disorders across the life span” of 13th January 2009.

(11) “Drug treatment for adults with ADHD should be started only under the guidance of a psychiatrist, nurse prescriber specialising in ADHD, or other clinical prescriber with training in the diagnosis and management of ADHD.”, NICE guidelines page 308. This might be taken to imply that specialist nurses have the skills to diagnose ADHD (and distinguish it from other conditions, which might include bipolar disorder or schizophrenia) with minimal, or even no, input from a psychiatrist.

(12) The NICE ADHD guidelines committee did not recommend that additional NHS funds be made available for adult ADHD. This was confirmed by Professor Phil Asherson [incorrect – I meant Eric Taylor...note added 3rd April 2010] in his talk at the ADDISS conference on April 1st.

(13) I accept that the clear benefit of medication in children, demonstrated in the original 1999 MTA report, is also of relevance for adults. Ideally, there would be a large MTA-style study of adults as well.

(14) NICE ADHD guidelines, page 301.

(15) Borderline Personality Disorder: treatment and management. NICE, January 2009. Pages 206-7.

(16) Or other problem.

(17) NICE ADHD guidelines, page 27.

(18) This was a poorly framed sentence which was not corrected in time for the talk. I meant to compare encouraging evidence from older teenagers, with the MTA study. The MTA children having behavioural intervention initially showed reduced substance misuse, but this was not sustained at follow-up. I do not think this makes a significant difference to my overall argument. See (1) Wilens et al (2008), referred to at pages 36-7 of the NICE ADHD guidelines, and (2) Molina et al (2007), NICE ADHD guidelines pages 253 and 335.

(19) Myin-Germeys, I ; van Os, J (2007) Stress-reactivity in psychosis: Evidence for an affective pathway to psychosis. *Clinical Psychology Review*: 27, 409.

(20) The initial discussion touched on the mild/moderate/severe issue, and the comparison with depression.

(21) As I suggested in the discussion, the NICE ADHD guideline committee's separation of "ADHD symptoms" from "impairment" is not logically consistent, because, in my view, the term "symptom" necessarily implies impairment. In any case, "ADHD" already contains two words which imply impairment: "deficit" and "disorder". My own practice at the moment is to talk about "ADHD features", but of course this could be seen as not wholly logical either.

It might be better, if a separation from "impairment" is really needed, to simply talk about the underlying "attentional pattern", or to use a term more familiar in ordinary language, "attention span". A journalist might readily acknowledge that his or her "short attention span" was very useful in the job; but this might apply to a whole range of other occupations, such as a general practitioner seeing a patient every ten minutes.

(22) The MHRA (Medicines and Healthcare products Regulatory Agency) report on Seroxat came in between these two reports. See: "GSK investigation concludes." MHRA press release, 6 Mar 2008. Available at www.mhra.gov.uk.

(23) David Healy (2002) *The Creation of Psychopharmacology*, page 62.

(24) NICE ADHD guidelines, Appendix 15, pages 474-498.

(25) "Moderate impairment is a requirement for the diagnosis of ADHD. Moderate ADHD in children and young people is taken to be present when the symptoms of hyperactivity/impulsivity and/or inattention, or all three, occur together, and are associated with at least moderate impairment...". NICE guidelines, page 126.

"Impair", "Impairing", or "Impairment" occur altogether 354 times in the full guidelines. As here, the discussion of impairment usually implies that its severity is in

accordance with the severity of the underlying ADHD. This supports my view that the committee, in effect, stated “mild ADHD does not exist”.

I think this is a much more worrying distortion of logic than the ADHD/impairment distinction (see 21, above), because it actually means that the committee have stated *most* ADHD does not exist (and this applies to all age groups).

This follows from the “normal distribution” of ADHD severity (see 8, above). If, for example, we take the frequency of moderate plus severe ADHD (said by the guidelines committee to be clinically significant for the NHS) to be 2.2%, then if the range of severity for severe, moderate and mild is the same, that would give a frequency for mild ADHD of 13.6% (see Wikipedia’s “probability distribution” http://en.wikipedia.org/wiki/Probability_distribution for how this follows from the properties of the curve: I have made the reasonable technical assumption that the boundaries of mild, moderate and severe are one, two, and three “standard deviations”, expressed using the Greek letter σ in the Wikipedia graph, from the mean average. My example of mild + moderate + severe giving a total prevalence of 15.8% is, I think, not unreasonable, however it is for illustration only: if the overall prevalence is lower, then I believe it follows that the ratio of mild to moderate + severe is even higher, but the mathematics of this is beyond me).

(26) Although in the talk I only referred to the suppression of mild ADHD as an issue for independent practice, on further reflection it seems to me that a diagnosis of mild ADHD could be very useful for many adult NHS patients right away, as a co-morbid factor in addition to the primary “severe and enduring” disorder which gains them entry into the system. Similar considerations might apply for children and adolescents.

(27) “While it is important to acknowledge the validity of the social scientific paradigm and its body of literature, in the context of the development of practical clinical guidelines, it is not possible to offer alternative processes for clinical assessment or treatment. It is accepted that the research literature reflects the dominant medical scientific paradigm and hence the nature of the evidence base.” NICE guidelines, page 119.

A neutral observer might wonder what the point of the “Consensus conference” was, if in the end the “medical scientific paradigm” was going to be preferred as “dominant”.

My own interpretation is that the ADHD guidelines committee in effect constructed a boundary in between mild and moderate ADHD, enabling an excessively medicalised (and pro-medication) stance for moderate and severe ADHD, and an excessively de-medicalised stance for mild ADHD and ADHD traits.

(28) This impression of an increasing, but selective, anti-medicalisation view within the psychiatric establishment, is based on “peer-reviewed” publications, but also on my own conversations with NHS and academic psychiatrists. See: Joanna Moncrieff (2006) Psychiatric drug promotion and the politics of neoliberalism. *The British Journal of Psychiatry*. 188: 301 – 302 (note that this is not a fringe publication but the primary peer-reviewed journal of the Royal College of Psychiatrists. The article is

available free at www.bjp.rcpsych.org). For David Healy's views on diagnostic distortion see: *The Antidepressant Era* (1997) and *Let them eat Prozac* (2006).

(29) I mean, a “zero tolerance” approach by those who support the diagnosis and treatment of ADHD, towards the sceptical view.