Letters

Rethinking childhood depression

Does childhood depression exist?

EDITOR—For the debate about rethinking childhood depression to degenerate into a semantic argument about its existence would be unfortunate.[1] Reification of biomedical diagnosis acts as a justification for so called evidence based treatments, which currently in the case of childhood depression are antidepressant drugs, cognitive behaviour therapy, and interpersonal therapy. The question is whether this process of reification is necessary for clinical practice, and I agree with Timimi that it is not.[1]

The onus is on Spender and Wilkinson to define exactly what they mean when they use the term childhood depression, which they do not do in their commentaries.[1]

In the same issue Wade and Halligan ask whether biomedical models of illness make for good healthcare systems.[2] The potential danger of the biomedical model is reductionism. By contrast, psychosocial diagnosis does not necessarily require a single word label, and that single word label may not add much to the understanding and meaning of emotional problems. Such an approach is consistent with patient centred medicine and means that the patient is not merely seen as a passive recipient of treatment for which he or she has no responsibility.[3] A psychosocial perspective in clinical practice therefore has advantages.

I suspect that the issue in this debate boils down to the readiness to use antidepressant drugs in children. Both Spender and Wilkinson quote the treatment for adolescents with depression study (TADS) in favour of the use of fluoxetine,[4] but they do not mention criticisms of it.[5] Fluoxetine was not in fact statistically better than placebo in this study and only became so when added to cognitive behaviour therapy in an unblinded arm. Strictly speaking, Spender and Wilkinson have therefore not provided support for their position. I prefer Timimi's critical approach, which takes a sceptical stance on the evidence, more in keeping with the spirit of scientific inquiry.

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1 Timimi S. Rethinking childhood depression [with commentaries by Q Spender, P Wilkinson]. *BMJ* 2004;329:1394-7. (11 December.)
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Consider what it means to be a child these days

EDITOR—What we, as clinical practitioners (or, as in my own case, former practitioner, now service coordinator), may need to learn is that the supposedly patently obvious is often obscured by our particular conditioned professional mindsets. The mindsets are influenced by the sociopolitics of healthcare delivery, and by, I suspect, an overly major focus on the individual (at the expense of the social and collective).

With regard to rethinking childhood depression,[1] children these days are getting much less regular physical exercise than they used to 20 or so years ago and fewer opportunities exist for exercise. The prescribing of antidepressant drugs has gone through the roof in the past decade. Children now don't have the opportunities for essential play, to be a part of a social support network, or to be part of a cogent extended or otherwise "family" (read, again, "social support network"). They also do not have a reasonably viable outlet, for any and all those of the above, conflicts and frustrations.

Something has to be very wrong, don't you think?

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1 Timimi S. Rethinking childhood depression [with commentaries by Q Spender, P Wilkinson]. *BMJ* 2004;329:1394-7. (11 December.)

Treatment options may be limited by resources

EDITOR—Working in a large urban practice in a new town, I have witnessed a rise in the prevalence of distressed and, according to one's definition, depressed children in the past 15 years.[1] I have also been a school medical officer. Over the same period I have seen attention and resources diverted from psychiatric and children's services to chronic disease in elderly people. I have therefore often faced the dilemma of either offering antidepressant drugs or effectively nothing. I welcome the debate in response to this article and sympathise with Timimi's contention, but society has given me the responsibility to "treat" unhappy children without the means.

Politically, I believe that the agenda for the NHS is driven by ageing voters. It is far easier for me to access comprehensive support for someone with Alzheimer's disease than it is for me to help a family with young children. Grandparents, support your grandchildren.

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1 Timimi S. Rethinking childhood depression [with commentaries by Q Spender, P Wilkinson]. *BMJ* 2004; 329:1394-7. (11 December.)

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Summary of responses

Timimi argues that unhappiness among children seems to be rising, but labelling it as depression and prescribing antidepressants is ineffective and possibly harmful: it is time to focus on the underlying reasons. Many respondents agree, but whether the term depression is apt, whether what is under discussion is a disease or a normal reaction to life's events, and whether the normal range of human emotion is being made into a disease are debated.[1] The role of the family and what family life teaches children, the impact of the mass media and consumerism, the importance of nutrition, the diversion of resources in a cash strapped health service, politics, and toxic environments are some of the factors singled out as influencing children's health and wellbeing.

Several respondents explicitly reject drugs as a treatment modality—something which is taken up in the responses to the commentary by Wilkinson[2]—citing a press release from the European Medicines Agency that declares fluoxetine unsuitable for children.

Although there is no real dispute about whether childhood depression exists, whatever name you choose to give it, the condition might not be taken seriously if it is not given a serious enough label. Most respondents seem to see the causes for unhappiness in children in the way society operates, in traditional family structures falling apart, in the environment being hostile at many levels, and possibly in the intertwined interests of political rulers and the pharmaceutical industry.

All but one respondent agree that childhood depression is a discrete disease entity, different from adult depression, requiring its own treatment modalities. As Christine Singh, women's health fellow in Canada, puts it: improving the social determinants of health might be the only hope of "curing" illness such as depression, and money should be shifted towards humanity.

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Competing interests: None declared.

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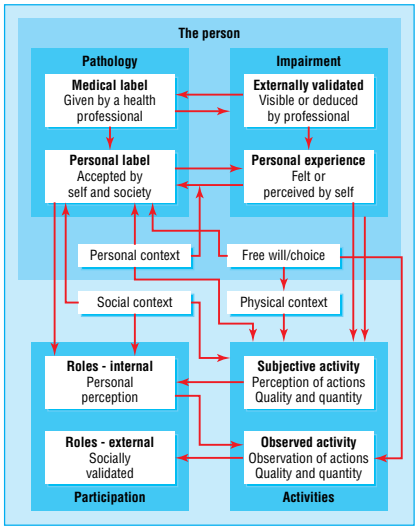
Biomedical models and healthcare systems



Proposed model of illness (*BMJ* 2004;329:1398-401)

New model will be useful if it alters allocation of resources

Editor—Wade and Halligan's new model will be useful if it encourages alternative ways of managing so called functional illnesses.[1] Take the example of low back pain as a condition where context is all important.

Patients with typical mechanical low back pain aggravated by prolonged standing will have a serious problem if, say, they work as a hairdresser but not if they have an office job. Thus their occupation rather than the disease will probably determine whether they seek medical attention. The new model implies that changing the context (suggesting the patient change jobs) is an equally valid way of managing the problem as looking for a "cure" for the low back pain. However, the model will be of real benefit only if policy makers transfer resources from diagnostic and treatment modalities to rehabilitative, educative, and occupational programmes, making the option of retraining realistic and achievable.

The new model also highlights the tension between the responsibility of individuals and that of society in managing "dysfunction." As a society we seem to be moving much more to the viewpoint that society's duty is to adapt to the dysfunction of individuals—see current disability regulations—rather than the individual's responsibility is to find ways of coping with a disability. Inevitably this view affects the range of "dysfunction" that healthcare systems are expected to deal with, and, as Wade and Halligan suggest, this needs to be openly debated.

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1 Wade DT, Halligan PW. Do biomedical models make for good healthcare systems? *BMJ* 2004;329:1398-401. (11 December.)

Developmental perspective may elucidate argument

Editor—Wade and Halligan asked whether biomedical models of illness make for good healthcare systems.[1] Alternative understanding of signs and symptoms can make for better healthcare systems. Signs relate to disease, symptoms to illness experience. Adapting Tinbergen's ethological quest for understanding behaviour to understanding illness behaviour points to four questions:

- Why is the behaviour shown now?
- How did the person grow to respond this way?
- What is the survival value of the behaviour?
- How has the behaviour evolved phylogenetically?

The biomedical model has concentrated on the first. How a person learns to present symptoms so that they achieve greatest survival value answers the second and third questions.

Symptoms are shaped depending on their communicative and survival value. Symptoms, as constituents of a language of illness, depend on an ability to take into account how others see them. Similarly medical practice becomes "mindful" medicine when it is aware of how the patient has developed a theory about how their symptoms are likely to be responded to.

As I have argued elsewhere,[2] children learn facts about disease and to allocate disease labels to their subjective illness experiences through parental attribution of sickness. Parents introduce them to an illness and disease vocabulary remembered in "semantic memory." Illness behaviour, evolving in parental care for children, becomes anchored in "implicit procedural memory," and so unavailable for recollection. The experience of symptoms of illness is remembered in patients' "episodic memory." Coherent integration of all memories can be surprisingly challenging.

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1 Wade DT, Halligan PW. Do biomedical models make for good healthcare systems? *BMJ* 2004;329:1398-401. (11 December.)
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Tangible pathology has great validity

Editor—Like Wade and Halligan,[1] I think that current medical thinking about illness has serious limitations, which leads to problems for doctors and patients and helps administrators with diagnosis and certification.[2,3] The traditional medical model is based on a direct link between lesion and symptom. Medical teaching rightly emphasises the processes linking symptoms with lesions.

Four groups of patients are discernible on the basis of such ideas.

The first comprises those whose symptoms are due to disease. This is home territory for doctors and reasonably well dealt with by current medical knowledge.

The second includes patients who have disease but no symptoms. This is the territory covered by screening, and, although of debatable worth, medicine has developed strategies for making progress in this area such as the Wilson-Junger screening criteria.

The third group consists of people who have no symptoms and no disease. These people are healthy as far as medicine is concerned and will not often attend the doctor.

The fourth group consists of patients who have symptoms but no disease. This group causes most of the problems in medical practice. In some of these people we as doctors can classify the symptoms into syndromes such as schizophrenia, depression, irritable bowel syndrome, and so we feel as if we are "diagnosing" an "illness." With some symptoms we struggle even to do this. We can feel that we are trying to "knit fog" as we attempt to build a coherent picture out of multiple inexplicable symptoms.

We forget that we are trying to catch the symptoms within a disease matrix, which may not be a valid concept when there is no lesion present. There is a solidity, and

validity, to the concept of any disease with a recognisable lesion that is lacking when no lesion has been shown.

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Selective serotonin reuptake inhibitors

Evidence base for older antidepressants is shaky too

Editor—In contrast to Geddes and Cipriani's assertion of a lack of clinical uncertainty about the efficacy of antidepressants,[1] a careful look at the evidence shows that this may not be true, even of the tricylic antidepressants. Although many trials show tricylic antidepressants to be superior to placebo, many find no difference, including some of the largest and best conducted older trials.[2 3] In addition several factors are likely to have inflated the apparent superiority of antidepressants over placebo.[4]

These include unblinding because of side effects of active drugs compared with inert placebos; and inclusion of items on rating scales, such as sleep and agitation, which are likely to respond to non specific sedative effects of drugs. Since differences often amount to only a few points on rating scales, antidepressants may seem superior to placebo due to these effects alone. The remaining factors are selective reporting of positive outcomes, excluding early withdrawals from analysis, and publication bias.

The fact that many agents not classified as antidepressants—including benzodiazepines, barbiturates, buspirone—and various antipsychotics are superior to placebo or equivalent to antidepressants in some trials shows that "antidepressant effects" may indeed be attributable to non-specific pharmacological or psychological factors.[4]

The lack of substantial differences between antidepressants and placebo cannot be explained away by assuming that effects are diluted by inclusion of patients with mild conditions. Research on who responds best to antidepressants is inconsistent and inconclusive. The belief that patients with more severe depression respond better is based on limited data, and other evidence shows the reverse.[5]

Neither new nor older antidepressants have been shown to have specific "antidepressant" effects. Neither is consistently distinguishable from placebo, and the superiority sometimes observed may be attributable to non-specific effects or other methodological artefacts.

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Competing interests: None declared.

1 Geddes JR, Cipriani A. Selective serotonin re-uptake inhibitors remain useful drugs which need careful monitoring. *BMJ* 2004;329:809-10. (9 October.)
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Placebo washouts inflate antidepressant effects in general practice

Editor—Geddes and Cipriani fear that regulatory bodies overrate the importance of placebo controlled trials.[1] We disagree. The placebo controlled randomised trial is still the best test of efficacy available, although several improvements in conventional methodology are necessary to prevent selection biases.[2] However, selection bias owing to a placebo washout period has not yet been tackled.

Although no doctor uses a placebo washout in real life practice, most antidepressant trials use such a period before randomisation. To demonstrate their effect: say, 200 patients are available, and 20 placebo responders are excluded before randomisation. The remaining 180 patients are then randomised to treatment with antidepressant or placebo. However, as it is not known whether all placebo responders in the antidepressant arm would have recovered if they had been given antidepressants, the direction of this differential selection may favour antidepressants.

Other necessary methodological improvements are: more use of "active" placebos to allow better blinding as they contain substances that mimic the specific side effects of antidepressants[3]; better concealment of allocation;[4] independent outcome assessment[4]; independent funding[4]; inclusion of relevant groups such as general practice patients and elderly people; and the use of the preferred more conservative intention to treat analyses.[5]

Most known biases inflate the effects of antidepressants. Intention to treat analyses would, for example, decrease the risk difference between antidepressant drugs and placebo from 28% to 19%.[2] A large, independently funded, good quality general practice trial of antidepressants versus placebo is much needed now, without placebo washouts.

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THREAD trial may show way forward

Editor—Geddes and Cipriani comment that available randomised evidence does not provide reliable estimates of the costs and benefits of treatment with selective serotonin reuptake inhibitors (SSRIs) in patients with varying degrees of severity and laments the decline in non-commercial funding.[1] Recent guidelines from the National Institute for National Excellence (NICE) also lack evidence.[2] The NHS health technology assessment programme is funding a trial to tackle this very question. Led by the University of Southampton, in partnership with the University of Liverpool and Institute of Psychiatry, the THREAD (threshold for antidepressants) trial is comparing the effectiveness of SSRIs combined with supportive care with supportive care alone in primary care.

Since Paykel said that severity of depression around the threshold of DSM major depressive episode was the level at which antidepressant drugs were more effective than placebo,[3] two recent studies have shown that SSRI antidepressants may be effective in patients with depressive symptoms of lesser severity.[4 5] Confusion results from the inexact use of terminology: what is described in NICE guidance as "mild" depression is actually subsyndromal depression by ICD-10 criteria. THREAD is using a continuous measure of symptom severity, the Hamilton depression rating scale, as its chief predictor variable, and recruiting patients with a score of ≥ 12, likely to lie in at least the "moderate" range.

One finding of the trial already apparent, however, is that patients' and doctors' preferences make randomisation a difficult proposition in this context. As previously observed in trials of counselling and drug treatment in this population, truly randomised evidence may be obtainable only in a group of participants who are unusual in other respects, and we need to learn more about the strengths and weaknesses of randomised and preference designs for investigating the value of treatments in such contexts.

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Competing interests: RP and TK have received hospitality, and fees for speaking and consultancy from Lilly, GlaxoSmithKline, and Lundbeck, and research funds from the Department of Health.

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The Mexico Summit on Health Research 2004

Mexico agenda was informed by wide consultation

Editor—Three issues raised by Abbasi in his editorial on the recently concluded Ministerial Summit on Health Research in Mexico deserve comment.[1]

Firstly, Abbasi laments the lack of translatable actions but did not mention additional action items. These were related to a call to donors for more substantive support for health systems research, a call to governments to allocate a certain percentage of national health expenditures to research, and a call to work more closely with countries to use evidence better in health decision making.

Secondly, he was critical of the Mexico agenda, which he states was "drafted largely by representatives of the rich." It should be pointed out that the development of the agenda was informed by wide ranging consultations and meetings in all WHO regions which involved researchers, policy makers, and non-governmental organisations. Ultimately, the agenda will be discussed at the governing bodies of the WHO where all member states will have a chance to comment and take ownership.

Thirdly, to state that "everything under the sun" was tied to the millennium development goals is not correct. The agenda clearly acknowledges the importance of other communicable diseases, non-communicable diseases, sexual and reproductive health, injuries, violence, and mental ill health. Together with its member states the WHO is committed to translating the agenda into measurable actions.

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Competing interests: None declared.

1 Abbasi K. The Mexico Summit on Health Research 2004. *BMJ* 2004;329:1249-50. (27 November.)

Medical community in developing countries has duty to promote healthcare research

Editor—Abbasi's editorial on the Mexico Summit on Health Research 2004 aptly emphasises the significance of formulating and implementing national health research agendas.[1] Although this is essential for rich and poor governments alike, it is even more imperative for developing countries to devise appropriate research strategies to reduce child mortality, prevent infectious diseases, and combat AIDS. The medical communities in these countries should take an active part and adopt reforms within the medical system to face the above challenges.

Unlike in developed countries, research is neither integrated into the medical curriculum nor considered to be part of routine medical practice. Medical students seldom have the opportunity to undertake research; the training solely emphasises providing health care to individual patients but fails to appreciate the significance of research in enhancing the wellbeing of society. There is no structured career path to encourage clinicians to undertake medical research, clinician-scientists being crucial for translating basic science research into clinical practice—"from bench to bedside."[2]

Medical research is rarely given a high priority in the government's healthcare planning. Because of governments' reluctance to support research, it is mainly undertaken by pharmaceutical companies and selected private institutions; in such instances, financial gains may take precedence to the health of the nation. The research undertaken in a few government institutions may be hampered by political interference and stifling bureaucracy. Capital investment in new facilities and high technology equipment appeals to politicians, even when they are the least cost effective and seldom benefit public health.

Governments should strive to apportion a substantial amount of their national budget towards medical research, mainly public health; this is crucial for the health and wellbeing of present and future citizens. The medical community, through its representative organisations, in conjunction with the government, should create appropriate regulatory bodies and develop national guidelines to encourage medical research in an ethical and transparent manner. The medical community has a duty to guide the government to develop and implement meaningful research strategies and national health policies.

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1 Abbasi K. The Mexico Summit on Health Research 2004. *BMJ* 2004;329:1249-50. (27 November.)
2 Kreeger K. From bench to bedside. *Nature* 2003;424:1090-1.

Trial protocols: time for more than tinkering

Editor—The *BMJ*'s recent requirement that authors include a trial protocol when submitting research papers for publication seems reasonable to expose deviations from the original protocol.[1] However, Abbasi and Jones's comment that "identifying deviation from the protocol is another important step in ensuring that the findings of a study are reported with honesty and transparency" rings hollow.

What are the other "important steps"? Is there, for instance, any evidence that such steps taken in the past have made a genuine difference to the reliability of data from clinical trials? Despite the many attempts to address the poor quality of reporting of trials, studies suggest that there has been little improvement in the standard.[2 3]

In any case, compelling researchers to include their protocols will have no effect on their honesty. If people are dishonest and intent on committing research misconduct, then they will do so—preventing them from deviating from the protocol will simply encourage them to seek other ways to achieve their aims. And, it is not difficult to discover many instances of investigators being willing to manipulate data in other ways.[4 5]

The point is surely this: current clinical research relies on a methodology that is readily open to abuse. The mechanics of large scale randomised trials are highly complex, the data opaque, and the results marginal—all features that prevent a clear view of any research misconduct. Moreover, the absence of any method to confirm or refute the results means that such behaviour is likely to go undetected.

Dishonest researchers exist and randomised clinical trials allow them to flourish. Tinkering with new rules—such as that proposed in the editorial—will do little to improve the reliability of the results of clinical trials. What is needed is a complete reappraisal of large scale randomised trials.

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