

## Complementary medicine: implications for informed consent in general practice

THERE is now compelling evidence to suggest that more and more people use complementary medicine.<sup>1</sup> The 1-year prevalence figures in the UK are around 25%,<sup>2</sup> and this figure can be considerably higher in patient populations.<sup>3</sup> In 1995, 39% of British general practices provided some access to complementary medicine; this figure had risen to 49% in 2001.<sup>4</sup> Considering this level of popularity, complementary medicine will certainly impact significantly on conventional general practice. In this article I will discuss potentially important implications for informed consent.<sup>5</sup> It is not aimed at providing definitive solutions, but at alerting doctors to issues that, so far, have largely remained unnoticed.

General practitioners (GPs) have the obligation of informing patients about material risks of their medical treatments, and this may include the risks associated with complementary medicine. Most patients and many healthcare professionals view complementary medicine as virtually risk free, a notion that is seriously misguided.<sup>6</sup> It may be less risky than most conventional therapies but it is not totally devoid of adverse effects. Examples include toxic herbal remedies, interactions between herbal and synthetic medications, hepatitis C after acupuncture, or stroke after chiropractic manipulation of the neck.<sup>6</sup>

*'The trends in the courts, hospital guidelines and the advice from professional ethicists all point towards more comprehensive disclosure of risks involved in treatment.'*<sup>7</sup>

An instructive case recently described a patient who died after an intracerebral haematoma caused by the combined effects of non-steroidal anti-inflammatory drugs (NSAIDs) and ginkgo biloba.<sup>8</sup> Ginkgo is a popular and usually very safe remedy, but it has potent anti-platelet effects which can cause bleeding when combined with NSAIDs.<sup>6</sup> If this patient had taken the NSAID on prescription from his GP, would the GP be liable? One could argue that the possibility of interactions between ginkgo (which has the legal status in Britain of a food supplement) and other anti-platelet drugs is well known and publicised.<sup>6</sup> GPs are responsible for warning patients of risks incurred by the combination of prescribed drugs and food, and for giving appropriate, evidence-based advice. The omission of not warning about ginkgo self-medication when prescribing a NSAID could thus be seen as a serious omission, perhaps not in legal but in ethical terms. As present monitoring of herbal remedies is far from effective, the question, how likely are these adverse effects, is not answerable. To err on the safe side, one should assume they are sufficiently frequent to be clinically relevant.

The above case highlights that GPs should include questions about complementary medicine use in their routine medical history taking, be knowledgeable about the risks of complementary medicine, and they should advise their patients according to the current best evidence. These are

perhaps not legal, but ethical obligations. Traditionally, the legal standard of care has been determined by the Bolam test, that is, a practice is legal as long as it is supported by a reasonable body of GPs. This situation seems to be changing. A recent judgement by the House of Lords stated that the standard must be justified on a logical basis and should include consideration of the risks and benefits of competing therapeutic options.<sup>9</sup>

Many GPs believe that all forms of complementary medicine lack evidence of benefit. This is clearly not the case. If Cochrane reviews are anything to go by, several herbal remedies are of proven efficacy. For instance, St John's wort is an effective symptomatic treatment for mild to moderate depression,<sup>10</sup> so is horse chestnut seed extract for primary venous insufficiency,<sup>11</sup> and so is ginkgo for dementia.<sup>12</sup> Such evidence may not yet constitute a legal duty, but, again I would argue that it amounts to an ethical obligation for GPs to consider such therapies.

Consider the hypothetical case of a patient with dementia treated with conventional drugs. Owing to serious adverse effects, his compliance is poor; in turn, clinical deterioration is rapid and death occurs within 2 years of diagnosis. Subsequently, his children learn about the fact that ginkgo has been shown to significantly delay the clinical decline without major adverse effects. They eventually decide to sue the GP, maintaining that he or she caused an unnecessary loss of quality of life and hastened the death of their father. They also point out that their father had repeatedly asked the GP for a 'natural cure'. Is the GP liable?

One could argue that GPs have an ethical obligation to advise patients about the optimal treatment. Optimal therapies are those with the most encouraging risk-benefit balance, and the least cost. It seems to me that, in the above case, ginkgo might fulfil these pre-conditions.<sup>12</sup> The fact that, contrary to the Bolam test, the House of Lords wants GPs to consider the risks and benefits of competing treatments, might have a powerful influence on cases like the one above.<sup>9</sup>

In future, adequate informed consent might also include information about alternative options, in this case, ginkgo:

*'health professionals should try to ensure that the patient is able to make a balanced judgement on whether to give or withhold consent.'*<sup>13</sup>

A balanced judgment, it seems to me, requires information on a range of evidence-based treatment options, and the 'prudent patient' would usually require information about the 'risks and benefits of alternatives and of non-treatment'.<sup>14</sup> This view seems to be supported by the General Medical Council, which wants doctors to find out about patients' individual needs and priorities when providing information about treatment options.<sup>15</sup> The hypothetical case above implies that GPs

should consider complementary therapies that are evidence-based, at least if patients specifically ask about such options

In conclusion, complementary medicine is likely to become relevant to the informed consent obligation of GPs. Informed consent is a 'process of weighing up the range of management options with a patient in the light of evidence from a broad range of quantitative and qualitative research approaches, while utilising the clinical skills and judgement of the practitioner and giving due consideration to the patient's bio-psycho-social factors'.<sup>16</sup> As the popularity of complementary medicine grows, and as informed consent becomes more and more comprehensive,<sup>7</sup> its relevance for general practice will increase. At present, however, GPs' ethical obligations still exceed the legal ones.

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# Post-traumatic stress disorder: a challenge for primary care — misunderstood and incognito

WHEN we primary care physicians think of post-traumatic stress disorder (PTSD) what is it that comes to mind? For most of us it is perhaps the haunting and troubling memories that can affect refugees after coming to their new haven of safety, or possibly the nagging, unyielding recollections of a person's first-hand encounter with a large scale catastrophe. PTSD, while the subject of much discussion and research on the other side of the Atlantic ocean, remains rather anonymous and ignored here in Europe.

According to the *International statistical classification of diseases and health related problems* (10th revision) (ICD-10) definition,<sup>1</sup> PTSD arises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive stress in almost anyone. The diagnosis is relatively new and was only included in the ICD during the 1990s. On the other hand, PTSD was first included in the *Diagnostic and statistical manual of psychiatric disorders* (3rd edition) (DSM-III) category of psychiatric diagnoses in 1980,<sup>2</sup> listed as an anxiety disorder. The DSM is used in the United States (US) and

some countries within Europe for classifying and defining different psychiatric disorders. From the beginning, the PTSD diagnosis was used primarily for holocaust victims, soldiers, and even ordinary people who had experienced horrendous catastrophes, man-made or natural disasters, or extreme crimes of violence, such as rape. Over the years, perhaps no other psychiatric diagnostic category has undergone as many alterations and permutations,<sup>3</sup> and PTSD has been the subject of much scrutiny and debate, with the majority of it being done within the US. According to the present definition stated in DSM-IV-TR (text revision),<sup>4</sup> PTSD must firstly include: (criterion 1) a history of exposure to a traumatic event or series of events; as well as (criteria 2-4) symptoms from each of three symptom clusters: intrusive recollections, avoidant and/or numbing symptoms, and hyperarousal symptoms. A fifth criterion is included, which concerns the duration of symptoms (at least one month), and a sixth demands significant levels of distress or impairment in social, occupational or other areas of functioning.

Since the adoption of the DSM-IV,<sup>5</sup> the definition of PTSD has been broadened by including the traumatic stressor

criteria as follows:

*'The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death, or serious injury to the physical integrity to self or others ...'*

This implies that a person who merely learns about someone else being threatened with harm or danger (or interprets a situation so) now qualifies as having been exposed to trauma that meets the requirements for a PTSD diagnosis (assuming fulfilment of the other symptomatic criteria). This new factor allows for the inclusion of many new patients, such as those people who learn about the unexpected death of a close friend or relative,<sup>6-8</sup> parents of children diagnosed with serious illnesses,<sup>9</sup> or those who watch television in the safety of their homes and witness news coverage of atrocities and/or catastrophes (something that we are bombarded with practically every evening). Another important result of the acceptance of the DSM-IV definition is the changing of the stressor criterion from being one major life-threatening event, to the additional possibility of experiencing a series of smaller individually non-life-threatening occurrences, as seen with bullying in school or in work situations, or repeated incidents of verbal or physical abuse (actual or threatened), as in troubled marital or domestic relationships.

How common is the problem? Prevalence results for PTSD found in studies over the last 10 years have shown varying results. The US National Comorbidity Survey in 1995 estimated a 7.8% lifetime prevalence (5% for males and 10.4% for females) in the US population aged 15-55 years.<sup>10</sup> The Australian National Survey of Mental Health and Well-being,<sup>11</sup> which looked at a 12-month prevalence instead, revealed only a 1.3% prevalence, while the previous mentioned US study showed a 3.9% 12-month prevalence. Very little research exists regarding PTSD within the primary care setting outside of the US. A literature search revealed a limited number of such investigations over the last 10 years,<sup>12-20</sup> the majority having been studies examining the situation in the US, with one study from each of the following countries: Australia, Germany, Israel, and Sweden.<sup>21</sup> Iceland,<sup>22</sup> and, as already mentioned, Australia, have included PTSD in national prevalence studies, but no epidemiological research results could be found regarding the situation in the United Kingdom.

Another issue of utmost importance, which makes PTSD an often invisible problem, is the extremely high comorbidity it shares with a number of other problems that patients often seek medical help for in the first place. PTSD sufferers are commonly frequent users of health care, seeking help for a myriad of somatic symptoms. The most common of these include fatigue, sleep disturbances, myalgia and joint pain, loss of memory and/or concentration, and headache. The process of somatisation may very well be one potential expression for trauma to manifest itself, in a similar way that physical and biological symptoms often appear in conjunction with depression and other anxiety disorders.<sup>3</sup> Epidemiological studies have, furthermore, consistently corroborated a high comorbidity of PTSD together with other mental conditions.<sup>10,11,18,23-25</sup> Lifetime comorbidity rates have been found to be as high as 62-92%, revealing considerable association with anxiety,

affective, and substance abuse disorders.<sup>10,26</sup>

An extensive investigation carried out at the end of the 1990s within a large health maintenance organisation in the US found that 38.6% of patients referred for mental health services met DSM-IV criteria for PTSD.<sup>13</sup> Very many of these patients had been referred for other problems, as the comorbidity of PTSD is exceptionally high with other psychiatric disorders associated with anxiety symptoms, as well as depression. The consequence of these facts means that a large number of undiagnosed cases of PTSD most probably exist in the general population, with those people not receiving proper treatment for their problems. Considerable research data has shown that the combined mental health burden of PTSD by itself and along with other comorbid psychiatric disorders has a direct negative relationship with physical health that, in turn, is associated with more frequent use of primary health care services.<sup>11-12</sup> For this reason, (if the fact of finding the underlying cause for our patient's symptoms is not enough), it is in our own interest to be aware of PTSD. Listening to our patients and explaining about the nature of the problem is the first step in helping them towards recovery. Is this not a fundamental part of our job?

Owing to the complexity and diversity of the symptoms associated with PTSD, along with its high levels of comorbidity with other somatic and psychiatric problems, diagnosis of this disorder is not easy. When identified, patients with PTSD can often be helped by suitable medication and/or psychotherapy (cognitive therapy has shown the best results). However, in order to achieve this we first have to make the diagnosis.

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