

## REVIEW OF NICE GUIDELINES

**Dr J C D Wells**

The guidelines state that they cover non-specific low back pain between 6 weeks and 12 months. They exclude malignancy, infection, fracture, ankylosing spondylitis and other inflammatory disorders. They also specifically mention that they do not cover radicular pain from nerve root compression or cauda equina syndrome. Given that they ban the use of MR scans and X-rays, they fail to explain how these conditions can be diagnosed. Indeed, one of their great failings is that they do not address, in any way, the diagnosis of low back pain, prior to labelling it "non-specific". They do, however, point out that several structures, the joints, discs and connective tissue may contribute to symptoms, and presumably they also accept that psychological issues are important, although they do not mention this in the introduction.

They suggest one-third of the UK adult population suffer from low back pain (LBP) every year, that is, 20 million people, although they do not refer to this many people in their costings (only 350,000). I am uncertain as to what happens to the other 19,650,000 people. Presumably they hope they will all get better with no treatment, although they suggest that 4 million of these patients (20 per cent) will attend their GP with back pain.

The guidelines go on to discuss information and education, which is hardly new. Recommendations about physical activity and exercise have been given by Physiotherapists and Pain Specialists - and indeed by most GPs - since the CSAG Report was published in 1994, 15 years ago.

Specific treatment includes physical activity and exercise in a structured group programme, which is fine, manual therapy including spinal manipulation, of 9 sessions over 12 weeks, and acupuncture, 10 sessions over 12 weeks, which are classified as an invasive procedure.

At least 3 of the committee members were committed manual and spinal therapists, including Professor Underwood, the author of a randomized trial on manipulation, the BEAM trial. This concluded that manipulation followed by exercise achieved a moderate benefit at 3 months and a small benefit at 12 months, as indeed did spinal manipulation. The committee also includes Vogel, an Osteopath, and Dixon, Chairman of the General Chiropractic Council (who runs 6 private chiropractic clinics, the website for which claims that this is suitable for the symptoms of stress and for enhancing well-being; it also charges £50 for one session (see pricing later)). For more

information on this, look at <http://www.dscience.net/?he=1542>.

Reviews of acupuncture and manual therapy, including manipulation, have shown that there is evidence that they produce initial pain relief, but very scant evidence that there is any long-term relief\* (references here). I was involved in setting up the first acupuncture treatments available in the NHS at The Walton Centre in 1982, and have written papers about its efficacy. I think it is a useful analgesic, but its effect is mild. The Chinese think we are quite strange in advocating a treatment every week; if you were in China, you would have 3 treatments a day. They recognise that acupuncture has a short-term benefit and needs to be repeated regularly. They would think 9 or 10 treatments over 12 weeks to be as strange as us giving someone an anti-hypertensive once every week for 10 weeks and then expecting the blood pressure to drop. However, certainly it is a reasonable form of analgesia, although there is absolutely no evidence to suggest that it reduces distress or disability, and indeed all of the trials reviewed by the NICE committee indicated this.

All of the independent evidence on manual therapy indicates the same thing. There is some initial benefit. There is very little benefit at 1 year. Thus the 3 main treatments offered would produce some mild to moderate analgesia, and indeed this is no bad thing. It is unclear, however, where all of the therapists will be found who are available to produce at least 7 times the present amount of treatment via these therapies (see NICE costings).

The guidelines point out that another of these options should be used if the chosen treatment does not result in satisfactory improvement, and also that combined physical and psychological treatment programmes (ie, Pain Management Programmes, PMPs) should be considered for ALL of those who have received one less intensive treatment and have high degrees of disability or significant psychological distress. In the pricing section, they estimate that this will require an increase of facilities so that 3,500 patients can be treated instead of 1,000 at present (again see comments on pricing). This is not many treatments for the 20 million sufferers, of whom we can estimate that at least 2 million will have significant long-term disability and psychological distress (in fact, if someone has back pain for a whole year it would be a little bit odd if they did not have significant psychological distress).

The ignorance of the committee continues in their suggestion of referral for surgery. This is only for "people who have completed an optimal package of care", including a Pain Management

Programme (PMP). This is the absolute antithesis of selection for PMPs. They are only offered when there is no further treatment contemplated. The purpose of this is to stop patients not engaging in the Programme. For instance, if someone attends a Programme, knowing that if it fails they will then have a spinal fusion which will fix them, they may not concentrate on the aims of the Programme, self-help, coping skills and exercise. The Programme is offered on the assumption that there is no further effective treatment.

I set up the first PMP in the UK, at The Walton Centre, in 1983. The Programme is still running and we know that it helps significantly about half of the people who attend. Unfortunately this means that it doesn't help the other half - but mainly this is because these people have such major psychological burdens, or secondary issues, that they are beyond redemption. It doesn't mean that they are suitable candidates for spinal surgery! Indeed, and of course, if there is a problem which requires spinal surgery, this should be diagnosed early at about 6-12 weeks, and this treatment should be given, rather than waste precious resources in pushing them through a Pain Management Programme which is very expensive (again, the costings of the Programmes have been greatly underestimated) and unlikely to work against a background of spinal instability.

The guidelines go on to include some useful information, for instance, pointing out that interventional physiotherapy such as laser, interferential and ultrasound do not show any benefits. In particular they also deny lumbar supports and traction, but this is not new information, it has all been addressed in the CSAG report many years earlier. However, under section 1.5.4, the guidelines blandly indicate that transcutaneous electrical nerve stimulation (TENS) should not be used.

There is as good evidence for TENS as for acupuncture. That is, it is rather weak evidence. However, TENS has 2 benefits - first of all, it is less expensive than acupuncture and secondly it is patient-administered and encourages self-reliance. Furthermore, the active mechanism by which we understand TENS works, a-beta fibre stimulation and spinal inhibition of pain, is also the same mechanism by which spinal cord stimulation is thought to be effective. Spinal cord stimulation has been recommended by NICE for failed back surgery syndrome and complex regional pain syndromes, and TENS was originally developed as a means of assessing patients for these conditions.

When we get on to the pharmacological therapies, the committee flounders. They point out that no opioids, COX2 inhibitors, tricyclic antidepressants and indeed only some non-steroidal anti-inflammatory drugs (NSAIDs) have a UK authorisation for treating low back pain. Then they recommend them anyway. They start with Paracetamol, which we know helps about 37 per cent of

patients. They go on to recommend NSAIDs and COX2 drugs, which is reasonable although not really evidence-based, and they adapt the recommendations for osteoarthritis, although there is absolutely no evidence that osteoarthritis is a cause of the low back pain they are discussing.

They recommend weak opioids even though again they accept that there is absolutely no evidence to suggest that they work. In fact the relevant section states that "*no data were available to support use of mild ( I assume weak) opioids therefore the recommendation was made by consensus of the GDG*" So that's all right then, if there is no evidence, put in what you like.

They go on from this to recommend strong opioids, for which there is some evidence, although they do suggest referral for specialist assessment for those who require prolonged use of strong opioids, whilst at the same time pointing out that they should not be used for too long, as there is little evidence for long-term use. They don't explain how they should be stopped, and what happens then

They state that SSRIs should not be used. Given that there is no evidence for them, not a lot of evidence for tricyclics and no evidence for weak opioids, why should they pick on SSRIs in this way. Some might certainly consider them safer than Amitriptyline, albeit more expensive.

Whilst accepting that patients should have an opinion on spinal fusion, for which there is weak evidence, they feel that they should not have IDET or intradiscal radiofrequency thermocoagulation, which seems reasonable, or radiofrequency facet joint denervation, which does not seem reasonable. They only looked at 3 papers on this technique. Two out of the 3 revealed improvement in pain. Under section 4.5, they discussed invasive procedures. They said they were usually undertaken "after the condition has lasted a long time (more than 12 months)". This is of course only because Pain Clinics are so poorly resourced that patients cannot be seen before 12 months. Obviously, if a patient has a specific problem with their facet joints, which is causing pain, and simple treatments are offered and fail, the procedure could be carried out before 12 months, and before spinal fusion.

The guidelines go on to accept that there is evidence that pain arising from the facet joints can be a cause of low back pain, although they say that the role of specific therapeutic interventions remains unclear. After issuing the draft report, the committee was sent several RCTs showing the effectiveness of these treatments, but chose not to review them. They did ask that there should be development of specific criteria for patient selection, and a comparison with non-invasive therapies, and this does seem appropriate in the longer term, although who knows who will fund this!

Looking at the committee, there appear to be 2 GPs, (one a great advocate of manipulations) a Rheumatologist (Walsh) who has a special interest, and indeed is Chair of the Pain Management Programmes Special Interest Group (SIG) of The Pain Society, 2 Physiotherapists who have always advocated exercise programmes, ( one of whom is anti MR, and a friend of the Osteopath, speaking at the meeting on manipulation he chaired last year) a Chiropractor, an Osteopath (doing research with the GP), a spinal surgeon, a nurse, 2 patient representatives, a Health and Safety specialist and a Consultant Psychologist at Halton and St Helens; an Acupuncturist and an Occupational Therapist were co-opted on to attend meetings at which their expertise was required so that they could give evidence about their field.

Nobody was co-opted on to explain about drugs, TENS or interventional procedures. The abysmal ignorance of the committee is reflected in the poor overall advice. So if you have a committee with special interests in Exercise, Manipulation, PMP's, and Surgery, and you call an expert on Acupuncture, you get advice to use Exercise, Manipulation, Acupuncture, PMP's and Surgery. Amazing . But hardly unbiased. I wonder why and how this group were selected, bias toward manipulation perhaps? Perhaps we should be told.

## **Costings**

The costs report assumes 350,000 patients will require treatment per year. The guidelines assume that 20 million people will have back pain per year. What happens to the other 19,650,000?

Let us assume that of those 20 million people who get back pain, the majority get better quickly or have got only mild pain (90 per cent). That still leaves 2 million requiring treatment. So their figures may be out by a six-fold amount !

Even taking their figures, they only price in one treatment. Exercise programme treatments will increase by 35,000 to 70,000, acupuncture will increase by 17,500 to 122,500 and manual therapy by 17,500 to 122,500, of the 350,000 patients they envisage will require treatment (remember that 4 million will be seeing their GP with back pain, there is no advice on how the GP will reduce this amount of patients down to the lucky less than 10 per cent who will get treatment).

We also know that these 3 treatments, however helpful they are, do not cure. Some of the patients will improve in any case, and maybe a few more will with the analgesia provided by acupuncture and possibly by manipulation therapy. The guidelines state that more than one

treatment will be needed, even though this is not priced in. Using the low figures suggested, one could assume 350,000 patients at 6 weeks, 250,000 at 3 months, 150,000 at 6 months, 100,000 at 9 months and 70,000 at 12 months. Of those at 3 months, all will have had an initial treatment, so 150,000 further treatments need to be provided. At 6 months, a further 75,000 treatments will be needed.

So the likely increase in patients treated by exercise therapy will be from 35,000 to 120,000, from acupuncture will be 17,500 to 225,000 and from manipulation therapy will be from 17,500 to 215,000.

The costings report states that at present there are 1,000 places a year available on PMPs. They estimate that this will need to go up to 3,000 places a year (they have not said how that will happen!) This is 1 per cent of patients. And yet ALL of those patients with disability or significant psychological distress should go on them. That is more likely to be 35,000 (10 per cent of the total). Let's assume 35,000, if it were possible, and let's assume that half of those patients fail and are offered spinal surgery. Let's assume that the Surgeons only take one-fifth of those, that is 7,000. Let's assume that half of those fail, that is 3,500 spinal cord stimulators. I am not sure of the costs of spinal surgery, what is done now. Spinal cord stimulation costs £15,000 per patient. £50 million more to fund.

In the cost savings section, NICE assume that 95 per cent of all interventions will stop. This includes interventions for spondylosis and intravertebral disc prolapse, which were specifically excluded at the beginning of the guidelines (page 4) as specific causes of low back pain. So the savings of £33,000,000 on injections per year is false. Even if the interventions that we know and value are excluded, for instance, facet joint radiofrequency (saving 1.5 million ) and half of the rest (saving £16,000,000) it still doesn't pay for the other treatments.

Again the estimation is that £11,800,000 million will be saved in MR scans. However, the whole point of an MR scan is to diagnose a specific intravertebral disc displacement and therefore these will have to be done in order to implement the guidelines. So once again we have very false costings.

Also in the guidelines on costings, there is the statement that the NHS cost of treatment for low back pain is a thousand million (£1,000,000,000) per year. It is interesting to reflect that injection therapy only accounts for 3.5 per cent of this. Where does the rest of the money go?

**Table: Additional Costings**

120,000 patients having structured exercise at £24 per head, plus	£ 2,880,000
207,500 extra acupuncture courses (8.6 sessions, at £25 per head)	£44,612,000
197,500 extra manipulation courses at £25 per head, 6.5 sessions (excluding an initial £45 consultation)	£32,093,000

The funding for Pain Management Programmes is underestimated. The Walton Centre charges £2,500 for initial assessment and then £6,500 for the Programme. Hope Hospital charge even more (I believe in excess of £10,000). Assume an average of £8,500 rather than £4,000.

The total requirement is likely to be 35,000 patients at a cost of £8,500, equals £297,000,000.

So the total cost of implementing the guidelines properly equals in excess of £424,000,000. The total savings would amount to £17,500,000 if all of the denied interventions were removed from the equation. That would ensure that 33,000 patients a year, at present adequately treated with injections, will now go on to suffer with pain and psychological distress, meaning they would need Pain Management Programmes.

One really upsetting thing about the guidelines is that they go on about patient choice, and then deny it. It seems millions will get no treatment, and some will be denied treatment that really might work. Perhaps patients should be asked if they would prefer 9 manipulation sessions, followed by 7 acupuncture sessions, OR one single injection from a pain specialist (similar costings), not both, and they could decide what they wanted, rather than the decision forced on them by a vested interest group, some of whom will derive financial benefit from the guidelines.

I am a Specialist in Pain Management, who has worked both as a GP and an Anaesthetist. At the time I started work at The Walton Centre, in 1979, we were just developing the use of acupuncture and we were the first NHS clinic to offer this regularly for patients with chronic pain.

At this time I worked with an Osteopath in the clinic, and fought for his sessions to continue. I also set up, in 1983, the first Pain Management Programme in the UK, which has been running continuously for the last 26 years. There are now 2 of these Programmes; one is a 100 hour programme, as described in the NICE report and one is a shorter course for selected patients. In order to attend either course, the patient is seen for assessment, which costs £ 2500. About 10 per cent of patients are turned down, about 30 per cent go on to the short-form course and 60 per cent go on to attend the longer course. The longer course costs £6500.

I am also an interventionist, having had proper training in techniques, and have the Fellowship of Interventional Pain Practice. I am an Honorary Member of the British Pain Society and I was also recently chosen to speak at the 1st International Course on Pain Medicine, sponsored by the International Association for the Study of Pain (IASP), on neck and low back pain. Also speaking on the programme were Professor Gerry Gebhardt, President of IASP, Dr Beverly Collett, Treasurer of IASP and Professor Troels Jensen, Immediate Past President of IASP (abstract of lecture below). I have a broad interest and 30 year experience with all treatments used for Low Back Pain. I was not asked to give evidence.

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## **International Course on Pain Medicine 2009 ~ Granada, Spain**

### **Back and Neck Pain**

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Back pain is very common. About 80% of people report back pain at some time in their life. In various studies, between 15% and 30% of people report some back pain or trouble on the day of interview and up to 40% report having had back pain in the last month. On the other hand, true nerve root pain or sciatica affects only 3% to 5% of people at some time in their life.

It is well established that the complaint is a symptom only, and there are multiple causes. The bio-psycho-social model is used to understand the various contributions from physical, psychological and social factors. Acute back pain usually settles rapidly, but those who are not better by 6 weeks need careful assessment. Appropriate treatment at this stage can reduce chronicity, but as yet there is no agreement on best practice. Attention should be paid to reducing pain and encouraging mobilisation. Selected patients benefit from Pain Clinic referral, for closer attention to psychological and physical treatments.

Chronic back and neck pain is difficult to assess and treat. Although in some patients, no specific cause for the pain can be found, this does not mean that no diagnosis should be attempted, and there is good evidence that carefully selected patients benefit from minimally invasive techniques such as facet joint injection and pulsed radiofrequency, and even some from carefully selected surgical management. Multidisciplinary assessment is essential, followed by appropriate treatment. This can include medication, stimulation techniques such as acupuncture and TENS and effectively applied psychological management. Sadly, the multidisciplinary model, first recommended by Bonica, continues to be ignored by specialist clinics, who apply only monotherapeutic techniques, such as psychological management, acupuncture or nerve blocks, in isolation. This type of treatment does our patients, and our society, a disservice and is not fit for purpose.

Whilst General Practitioners can manage the majority of back pain patients, they cannot manage all cases. Neither should they attempt to do so. The importance of fully-funded and fully functional Pain Management Clinics, for early assessment and appropriate long-term management, is paramount.