Why NICE is wrong on OA

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Viscosupplementation, or use of hyaluronan injections, is a very useful, simple and costeffective treatment for osteoarthritis of the knee. NICE is wrong to 'not recommend' it.

Dr Ted Willis's article was a runner-up in our <u>clinical writing competition</u>.

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For many years, I have used intra-articular steroid injections to treat degenerative arthritis of the knee. Patients are usually very pleased with the effect after a few days, but they often come back after a month asking for another one – as the effect has worn off.

Three or four steroid injections per year is regarded as the maximum safe frequency, which is quite the workload. So when I heard about hyaluronan injections, a treatment that worked for several months, I was interested.

Hyaluronans are a type of large molecule called glycosamino-glycans produced by synovial joint-lining cells. They increase joint fluid viscosity, and help maintain tissue hydration and lubricate the joint. They are extracted from chicken rooster combs and have been used in eye

surgery since the 1960s. In recent years, chemical cross-linking of some of the molecules – such as Hylan GF-20 – has increased the molecular weight, which is claimed to prolong the intra-articular life and hence the effectiveness of the product.

I started doing the injections for patients without gross inflammation and have been very pleased with the results. The result is that I now refer fewer patients for knee replacements, which do serious harm to a small but significant proportion of patients. The injections are simple and only take five minutes once a week for three weeks, so the workload is not bad, and there are very few problems.

So I am amazed that few GPs use this treatment, and few patients are aware of it. Most orthopods are positive about viscosupplementation – but they aren't funded to do it by PCTs. But I thought this would change in 2006, when a Cochrane review came out strongly in favour.

'Overall, the analyses support the use of the hyaluronan class of products in the treatment of knee osteoarthritis,' the review said.

The authors found very good evidence

of effectiveness – P values for pain at rest, pain on walking, pain at night and functional scores compared with placebo injections

were typically less than 0.0001. The maximum effectiveness was between five and 13 weeks, and there was a significant improvement in function at the last review at nine months.

But there was little publicity – no big pharma company was involved and nothing much happened. The review also confirmed that the benefit of steroid injections was limited to about a month. And it included results of several trials directly comparing hyaluronan products with steroid injections, which overwhelmingly favoured the hyaluronan injections.

When NICE started working on its osteoarthritis guideline, I was confident change was finally coming. I knew that guideline CG59 had come out when my PCT – which had been paying me a small fee per injection – notified me that this would stop. It quoted the new NICE guidance: 'Intra-articular hyaluronan injections are not recommended for treatment of osteoarthritis.' I was surprised I was still offered money to give steroid injections, in view of the poor duration of effect.

Of course, nobody at the PCT had bothered to actually read the full NICE guidance – which is laughable. NICE admits that hyaluronan injections are clearly effective, but says it needs evidence of cost-effectiveness – even though there is no analysis of cost-effectiveness for steroid injections. It looks at economic evaluations on hyaluronan from four countries. The following are quotes from the document:

- **France** 'Synvisc would appear to be cost-effective... The reimbursement regime in France means that this study cannot be used to make evidence statements.'
- CanadaThe cost per quality-adjusted

life year was under \$10,000 – well within NICE's limit – but: 'The fact that the study was not blind may weaken any evidence statements made, and so again, given these problems, no evidence statements are made.' How does one do a blind cost-effectiveness study?

- Taiwan 'Being set in Taiwan makes the study of limited use.'
- US 'The study is not a formal cost-effectiveness or cost-utility analysis, as it does not include a measure of health gain attributable to the treatment.'

So NICE approves the less effective treatment for which there is no cost-effectiveness analysis. NICE does not recommend a more effective treatment for which there is an economic analysis showing cost-effectiveness because the studies are not British or not blind. In my view, it is the British who are blind.

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