National Institute for Health and Clinical Excellence

(265/2) – Prosthetic intervertebral disc replacement in the cervical spine

Consultation Comments table

IPAC date: Thursday 11th February 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	I have been implanting Â cervical disc replacement for over three years. I am collecting all data prospectively so we can have long-term outcome, I am yet to have to revise any. I recommend national data base like the VP shunt register for better and unified ways of collection of data	Thank you for your comment. The NICE IP programme welcomes collection of further long term data, particularly regarding the potential of artificial discs to maintain neck mobility and to reduce occurrence of adjacent segment disease or the need for additional treatment.
2	Consultee 2 DePuy Spine/Johnson & Johnson	**1**	DePuy Spine/Johnson & Johnson are in agreement with the recommendations as outlined in the reviewed guidance document	Thank you for your comment.
3	Consultee 3 Specialist Society	**1**	Agree One would not normally replace more than 2 or maximum 3 discs (rarely) at one operation.	Thank you for your comment. The consultee agrees with the guidance.
4	Consultee 4 Bupa	**1**	Essentially, Bupa agrees in relation to procedures to replace a single disc, or two adjacent discs. Is this what you are talking about, or are you talking about any number of discs being replaced at once? We do not feel that the evidence is in place to support three of more being replaced at once, or for combined replace one/ fuse another procedures.	Thank you for your comment. The description in the guidance states that 'More than one disc can be replaced during the same procedure'. The majority of the evidence considered by the Committee relates to treatment at either one or two levels. It is difficult to be definitive about an absolute upper limit as it is expected that cases would be considered on individual clinical need.

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5	Consultee 1 NHS Professional	**2.1**	I have no hesitaion to implant Â it for either radiculopathy or myelopathy so long as adequate decompression was achieved. I avoid using it in patients with high signal in the cord who may need further MRI postoperatively. As the metal artifact can obscure the view no matter what the manufacture would say about MRI compatibility.	Thank you for your comment.
6	Consultee 2 DePuy Spine/Johnson & Johnson	**2.1, 2.2, 2.3 and 2.4**	DePuy Spine/Johnson & Johnson have nothing further to add to this section at this time	Thank you for your comment.
7	Consultee 3 Specialist Society	**2.1 and 2.3**	Agree	Thank you for your comment.
8	Consultee 4 Bupa	**2.2, 2.3 and 2.4**	No comments other than those about number of discs replaced at once, as above (comment 4).	Thank you for your comment.
9	Consultee 3 Specialist Society	**2.2**	Some surgeons recommend this operation to the adjacent level at the time of performing a discectomy and fusion to prevent another operation being required when the scan reveals early degeneration at the adjacent level. The rationale behind this is yet to be confirmed with evidence. It is strictly inaccurate to describe the prosthesis as being mobile. The prosthesis allows mobility of the disc joint.	Thank you for your comment. The Committee agreed to remove the word ‘mobile’ from section 2.2.1 of the draft guidance.
10	Consultee 1 NHS Professional	**2.4**	Prestige LP is very safe in my experience, so long adequate training was done	Thank you for your comment. The Committee considered potential training requirements for this procedure and have stipulated that it should only be undertaken in specialist centres. The guidance is intended to be generic for all prosthesis types, and evidence on this device and others was included in the overview for this procedure.

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11	Consultee 5 NHS Professional	**2.4**	MRI compatibility is very important. If a patient presents post operatively with recurrent symptoms and needs further investigation, many of the artificial discs give off so much artefact (particularly cobalt) that it is impossible to see any pathology at that level. Therefore, the only investigation which would help would be an invasive CT myelogram. The patient should be warned that imaging studies postoperatively maybe affected by insertion of an artificial disc.	Thank you for your comment. The consequences of the treatment should be explained by the clinician to the patient during the consent process.
12	Consultee 3 Specialist Society	**2.4**	When spinal cord damage occurs in the cervical region the neurological is invariably a quadreplegia and not paraplegia as mentioned above. The procedure is more complex than a simple discectomy and fusion and varies depending on the type of prosthesis chosen.	Thank you for your comment. The Committee added quadriplegia to section 2.4.4, as this was highlighted by Specialist Advisers as a potential adverse event.