

***Vertebral axial
decompression
therapy for
chronic low back pain***

June 2001

MSAC application 1012

Assessment report

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The Medical Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Aged Care on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which medical services should attract funding under Medicare.

This report was prepared by the Medical Services Advisory Committee with the assistance of Dr Sarah Norris and Ms Jacqueline Burrige from M-TAG Pty Ltd. The report was endorsed by the Commonwealth Minister for Health and Aged Care on 19 June 2001.

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MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Executive summary

The procedure

The vertebral axial decompression (VAX-D) system is a specialised table and computer designed to apply distractive tension along the axis of the spine. The VAX-D system allegedly decompresses herniated or degenerated intervertebral discs, and is claimed to alleviate pain and neurological deficits associated with nerve root compression.

Medical Services Advisory Committee—role and approach

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Aged Care on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. A team from M-TAG Pty Ltd was engaged to conduct a systematic review of literature on the Vertebral Axial Decompression Table. A supporting committee with expertise in this area then evaluated the evidence and provided advice to MSAC.

Assessment of the vertebral axial decompression table

The evidence pertaining to the vertebral axial decompression (VAX-D) table has been assessed in three separate patient groups with chronic (>3 months duration) low back pain that is refractory to conservative treatment: (1) patients with radiculopathy or radicular pain caused by a herniated intervertebral disc, (2) patients with radiculopathy or radicular pain caused by a degenerated intervertebral disc, and (3) patients with non-specific low back pain.

Each of the patient groups listed above has a different comparator, reflecting the differential treatment of patients with these distinct diagnoses. For patient group (1) the most appropriate comparator is discectomy or microdiscectomy. For patient group (2) the most appropriate comparator is laminectomy, with or without fusion, or laminotomy. And finally, for patient group (3) the most appropriate comparator is ongoing conservative treatment.

One randomised, controlled clinical trial of VAX-D therapy has been conducted, and the patients recruited to this trial correspond to patient group (1) above. The remaining evidence relating to VAX-D therapy is from quasi-experimental non-randomised studies and case-series, and was obtained from mixed patient populations. There is insufficient follow-up of patients from any of the groups listed above.

Clinical need

In Australia, low back pain is one of the most common causes of chronic disability, and one of the most common reasons for health-care resource utilisation. Chronic low back pain has a marked impact on a patient's quality of life and ability to engage in leisure activities and paid work. Moreover, early retirement due to chronic disability represents a large burden on society through work days lost and social welfare payments made. Thus, effectively treating chronic low back pain benefits both the individual patient and society as a whole.

As described in more detail below, there are many non-surgical, 'conservative' treatment options for individuals with chronic low back pain. However, for a significant proportion of patients low back pain can be refractory to conservative treatment. Depending on diagnosis, these refractory patients may be indicated for surgical decompression of the intervertebral discs. Although the outcomes associated with surgery are good, there are the attendant risks of surgery in general (eg, problems associated with anaesthesia, infection, scarring) and spinal surgery in particular (eg, neurological damage, paralysis, loss of visceral organ function). Therefore, if there is evidence of a non-invasive treatment for refractory chronic low back pain that is at least as effective as surgery, the new treatment could provide significant benefits to patients in terms of risks avoided.

Safety

Detailed evidence on the safety and complication rates of the VAX-D table is lacking.

Effectiveness

For patients with radiculopathy or radicular pain associated with a herniated intervertebral disc, there is some evidence to suggest that surgical discectomy is more effective than VAX-D therapy at relieving pain in the short to medium term. No comparisons can be made between these two therapies in this patient group over the long term (ie, 10 years).

For other patient groups (ie, patients with radiculopathy or radicular pain associated with degenerated intervertebral discs, and patients with non-specific low back pain) there is insufficient evidence to make any conclusions regarding the relative effectiveness of VAX-D therapy.

Cost-effectiveness

No evidence-based conclusions can be drawn regarding the cost-effectiveness of VAX-D therapy in any patient group. However, it is likely that discectomy is more cost-effective than VAX-D therapy for the treatment of patients with radiculopathy or radicular pain associated with herniated intervertebral discs.

Other considerations

There are concerns regarding the qualifications of the person who would deliver VAX-D therapy. The applicant states that VAX-D therapy is to be delivered by a 'certified'

VAX-D technician and implies that this technician may or may not be medically qualified. To be eligible for Medicare Benefits Schedule (MBS) funding, all treatments are either provided by a qualified medical practitioner or are provided under the supervision of a qualified medical practitioner. There is no intention in this report to consider the provision of VAX-D treatments under any other conditions.

There are also serious concerns of access and equity. As there is only one supplier of the VAX-D system in Australia, the company may be in a position to influence which doctors deliver the treatment and which patients receive treatment.

Recommendation

Since there is currently insufficient evidence pertaining to the effectiveness of vertebral axial decompression (VAX-D) therapy, MSAC recommended that public funding should not be supported at this time for this procedure.

The Minister for Health and Aged Care accepted this recommendation on 19 June 2001.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of the vertebral axial decompression (VAX-D) table, which is a therapeutic device for chronic low back pain. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while also taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are at Appendix A. MSAC is a multidisciplinary expert body, comprising members drawn from disciplines such as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer affairs and health administration.

This report summarises the assessment of current evidence for the VAX-D therapeutic table in the treatment of chronic low back pain.

Background

Vertebral axial decompression table

How it works

Therapy with the vertebral axial decompression (VAX-D) system is a non-invasive procedure designed to provide relief for low back pain caused by herniated or degenerated intervertebral discs. The VAX-D system consists of a specialised table with body and leg harnesses and safety hand grips, and a computerised control system. The patient lies face-down on the table, fastened in the harnesses and holding the hand grips. Tension is gradually applied along the spinal axis, which is claimed to generate negative pressure between the intervertebral discs, which in turn is said to decompress the discs.



Figure 1 A patient undergoing therapy on the VAX-D table (picture reproduced from Gose et al, 1998).

Each session on the VAX-D table is of 30–45 minutes duration. During a session, tension is applied in 1-minute cycles, with a period of relaxation between each cycle. While on the VAX-D table, the patient can release the tension at any time by releasing the hand grips. A complete course of treatment with the VAX-D system consists of 24 sessions: five sessions per week for four weeks followed by one session per week for four weeks. The procedure is to be carried out by a certified VAX-D technician under medical supervision. The VAX-D technician may or may not be medically qualified.

Intended purpose

It is claimed that the VAX-D table provides relief in a variety of conditions, including lumbar disc herniations, degenerated lumbar discs and posterior facet syndrome. The VAX-D table is not designed to treat low back pain due to soft tissue injury, muscle

strain or progressive inflammatory conditions. Treatment with VAX-D is contraindicated for patients with the following conditions: infection, neoplasm, osteoporosis, bilateral pars defect or Grade 2 spondylolisthesis if unstable, fractures, the presence of surgical hardware in the spine and cauda equina syndrome. In addition, the supporting committee considers the use of the VAX-D table to be inappropriate during the latter stages of pregnancy due to the increased laxity of the ligamentous structures and the requirement for the prone position on the table.

The applicant has requested that VAX-D therapy be made available for patients with chronic discogenic low back pain which has been unresponsive to conventional therapy for a minimum of six to eight weeks. The applicant has requested that patients with radiculopathies also be eligible for VAX-D treatment.

It is claimed that the main advantage of therapy with the VAX-D table is that it is non-invasive, and may avoid the need for surgery.

Clinical need/burden of disease

In Australia, low back pain is one of the most common causes of chronic disability, and one of the most common reasons for healthcare resource utilisation. According to the Australian Bureau of Statistics (ABS 1996), in the 1995 calendar year 635,700 individuals experienced 'back problems' as a recent illness, and 895,200 individuals experienced 'back problems' as a long-term condition. Data from the Morbidity and Treatment Survey 1995 show that 'back complaint' was the fifth most common reason (after check-up, cough, prescription and throat symptoms) for consulting a general practitioner. For the period 1995–96 'medical back problems age < 75' was the Australian National Diagnosis Related Group (AN-DRG) with the twelfth highest number of separations across all hospitals (AIHW 1997).

However, it is likely that the above figures underestimate the true impact of back pain in Australia, as many individuals seek treatment from health professionals outside the jurisdiction of the Health Insurance Commission, and because a large proportion of back pain treatment is administered under workers compensation.

Chronic low back pain has a marked impact on a patient's quality of life and their ability to engage in leisure activities and paid work. Moreover, early retirement due to chronic disability represents a large burden on society through work days lost and social welfare payments made. Thus, effectively treating chronic low back pain benefits both the individual patient and society as a whole.

As described in more detail below, there are many non-surgical, 'conservative' treatment options for individuals with chronic low back pain. However, for a significant proportion of patients low back pain can be refractory to conservative treatment. Depending on diagnosis, these refractory patients may be indicated for surgical decompression of the intervertebral discs. For example, patients with radiculopathy experience an objective loss of sensory and/or motor function as a result of conduction block in axons of a spinal nerve or its roots. In these patients, surgical decompression can restore neurological deficit and alleviate pain associated with the nerve root compression.

Although the outcomes associated with surgery are good, there are the attendant risks of surgery in general (eg, problems associated with anaesthesia, infection, scarring) and

spinal surgery in particular (eg, neurological damage, paralysis, loss of visceral organ function). Therefore, if there is evidence of a non-invasive treatment for refractory chronic low back pain that is at least as effective as surgery, the new treatment could provide significant benefits to patients in terms of risks avoided.

Existing procedures

Currently a wide range of procedures are used to treat chronic (ie, >3 months duration) low back pain, including various classes of pharmaceuticals, exercise therapy, physiotherapy (with or without traction) and also including specific exercise and mobilisation/manipulation, acupuncture, massage and surgery. An individual patient can receive one or more of these treatment modalities depending on their diagnosis, prior treatment and the history of their condition. Typically, conservative (ie, non-surgical) treatment is administered initially, before any decision is made regarding the need for surgery.

If surgery is required, then the most appropriate type of surgery is determined by the patient's diagnosis. For example, for patients with a radiculopathy or radicular pain caused by a *herniated* intervertebral disc and for whom conservative therapy has failed, the most appropriate form of surgery would be discectomy or microdiscectomy. By comparison, for patients with a radiculopathy or radicular pain caused by a *degenerated* intervertebral disc and for whom conservative therapy has failed, the most appropriate form of surgery would be laminectomy, with or without fusion, or laminotomy.

It should be noted that no form of surgical intervention is indicated for patients with low back pain without radiculopathy or radicular pain (ie, non-specific low back pain). These patients should continue to be managed conservatively.

The primary rationale of any form of surgery for patients who present with radiculopathies or radicular pain is to relieve nerve root irritation or compression. Typically, this involves removing herniated disc material or resecting osteophytes that impinge on the nerve root. Depending on the access required to the pathological material, different operations can be performed. The simplest is called laminotomy, in which only the ligament between the laminae of adjacent vertebrae is removed to gain access to the material. When performed under a microscope to remove herniated disc material, this operation is called microdiscectomy. If greater access is required, not only the ligament is removed but the edges of one or other of the laminae may be partly resected. This is called a partial laminectomy. For still greater access, one or more laminae may be resected, in which case the operation is called a laminectomy. Although these various names apply, they refer to the mode of access involved. They do not refer to the active, therapeutic component of the operation, which is the resection of the offending material, whatever it might be. Less common variants of these operations include the resection of tumours or cysts that might irritate the nerve root.

Fusion involves joining adjacent vertebrae together with a bone graft, sometimes supplemented by metallic rod and screws. When undertaken for the treatment of radiculopathy, fusion does not treat the radiculopathy; that is achieved by removing offending material. The fusion is added to prevent instability of the spine that might result when too much of a lamina has to be removed.

Choice of comparator

As defined in the MSAC Guidelines, the appropriate comparator for a new procedure is the 'service most likely to be replaced or supplemented by the introduction of the new service'. If more than one potential comparator exists, then the most frequently used should be chosen.

Given the differences in treatment according to diagnosis, as described above, the supporting committee has advised MSAC that it is most appropriate to evaluate the evidence for VAX-D therapy in the following three patient groups, with a different comparator for each group:

Table 1 Appropriate comparators for VAX-D therapy according to patient type

| Patient group | Patient description | Most common treatment |
|---------------|--|--|
| 1 | Radiculopathy or radicular pain caused by <u>herniated</u> intervertebral disc, unresponsive to conservative therapy | Discectomy or microdiscectomy |
| 2 | Radiculopathy or radicular pain caused by <u>degenerated</u> intervertebral disc, unresponsive to conservative therapy | Laminectomy, with or without fusion, or laminotomy |
| 3 | Chronic non-specific low back pain, unresponsive to conservative therapy | Ongoing conservative treatment |

The therapeutic options for managing patients with chronic non-specific low back pain are diverse and a major challenge for researchers in this field is to provide evidence of which conservative treatment is most beneficial to these patients. Based on the expert advice provided by the supporting committee, in this review the most common conservative treatment for non-specific low back pain is defined as oral analgesics or non-steroidal anti-inflammatory drugs (NSAIDs), with or without physiotherapy.

Marketing status of the device

The VAX-D system was listed with the Therapeutic Goods Administration in Australia in 1998 (AUST L63968).

Current reimbursement arrangement

Currently there is no specific Medicare Benefits Schedule item number for VAX-D treatment or any similar therapies (eg, traction). VAX-D therapy is not reimbursed in other jurisdictions. Although a VAX-D treatment visit has been allocated a Medicaid number under the Alaska Medical Payment System, such a visit is not covered by Medicare in the USA.

Approach to assessment

MSAC reviewed the literature available on VAX-D therapy and convened a supporting committee to evaluate the evidence of the procedure and provide expert advice.

Review of literature

The applicant has requested that VAX-D therapy be subsidised for the treatment of chronic low back pain that is resistant to conservative treatment. Accordingly, our review of the medical literature has been limited to evidence of second-line treatment administered to patients with low back pain of at least three months duration (the definition of 'chronic' given by the International Association for the Study of Pain (IASP) (1994)).

Evidence of VAX-D therapy

The medical literature was searched to identify relevant studies and reviews. Searches were conducted using the Medline (1966 – December Week 1 2000), EMBASE (1980 – Week 39 2000) and HealthSTAR (1975 to October 2000) online databases via Ovid. In addition, searches were performed on The Cochrane Library database (including The Cochrane Database of Systematic Reviews and Database of Abstracts of Reviews of Effectiveness) and the Clinical Evidence Site of the *British Medical Journal*.

Searches were also performed on several external databases, including those of the International Society of Technological Assessment in Health Care (ISTAHC) from 1985 and The International Network of Agencies for Health Technology Assessment (INAHTA), established in 1993. Information was also searched for on the National Library of Medicine site.

The search terms used included 'VAX-D', 'vertebral axial decompression' and 'low back pain'.

The applicant submitted seven pieces of evidence to support their application, including three published articles and unpublished results from a clinical trial in Australia. The search identified the three published articles submitted by the applicant. No additional articles or systematic reviews of VAX-D were identified. All available evidence on VAX-D was assessed and classified according to the MSAC preferred hierarchy of evidence set out below:

Table 2 Designation of levels of evidence

| | |
|-------|--|
| I | Evidence obtained from a systematic review of all relevant randomised controlled trials |
| II | Evidence obtained from at least one properly designed randomised controlled trial |
| III-1 | Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method) |
| III-2 | Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with a control group |
| III-3 | Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group |
| IV | Evidence obtained from case-series, either post-test or pre-test and post-test |

Source: NHMRC, National Health and Medical Research Council, A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: NHMRC, 1999.

Evidence of comparator therapies

The medical literature was also searched to identify relevant evidence of therapies considered to be appropriate comparators for VAX-D therapy. These searches were conducted in the same databases and over the same time periods described above.

For these searches the search terms used included but were not limited to the following: 'randomized controlled trial', 'controlled clinical trial', 'random allocation', 'double-blind method', 'single-blind method', 'clinical trial', 'placebo(s)', 'random\$', 'human', 'radiculopathy', 'sciatica', 'discectomy', 'diskectomy', 'low back pain' and 'traction'.

These searches were limited to published randomised controlled trials, systematic reviews and meta-analyses meeting the requirements for levels of evidence I and II according to the NHMRC designation of levels of evidence (see table above).

Expert advice

A supporting committee with expertise in neurological surgery, orthopaedic surgery, physiotherapy and general practice was established to evaluate the literature and provide advice to MSAC from a clinical perspective. A consumer representative was also included on the committee. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is provided at Appendix B.

Results of assessment

Only one prospective, controlled clinical trial of VAX-D therapy has been conducted. However this study suffers from several significant design problems and was conducted in a relatively small number of patients. The patients recruited to this trial were diagnosed with low back pain with associated leg pain and evidence of intervertebral disc herniation or protrusion. Thus the patients in the trial correspond to Patient Group 1 (see Table 1). This trial was assessed as level III-1 evidence.

The remaining evidence relating to VAX-D therapy is from quasi-experimental non-randomised studies, and case-series, and corresponds to level IV evidence or was unevaluable. The majority of this evidence was obtained from mixed patient populations (ie, patients with or without radiculopathy or radicular pain, associated with herniated or degenerated discs or posterior facet syndrome). No clear evidence is available for VAX-D therapy for patients with non-specific low back pain (ie, low back pain without radiculopathy or radicular pain, corresponding to Patient Group 3 in Table 1).

The applicant claims that VAX-D therapy reduces the need for surgical decompression of the spine, but no evidence is available for any patient group regarding the incidence of surgery after a course of VAX-D therapy.

Is it safe?

Detailed evidence on the safety and complication rates of the device is lacking.

The applicant claims that specific parameters of the VAX-D system make the device inherently safe. These safety features include: the use of air pressure as the energy source; the ramp characteristics employed in applying the distraction tensions; the release rate of the distraction and relaxation cycles; the cycle periodicity; the upper limits on the distraction tensions; the positioning of the patient and the means of fixing the upper body and the ability of the patient to release the handgrips if the distraction tensions cause pain or discomfort.

Information regarding the range and incidence of adverse effects that occur during VAX-D therapy is limited. Complications that have been reported with VAX-D include:

- the development of a sharp burning, radiating pain during therapy
- stress to the shoulder girdle and rotator cuff muscles, and
- overstretching of the soft tissues of the back.

None of the available studies describing VAX-D therapy report the incidence of these or any other adverse effects, or the patient drop-out rate associated with adverse effects. Anecdotal evidence from the applicant states that 10 per cent of patients are not able to tolerate the positioning of the table or the distractive pressures and discontinue therapy.

In addition, information on patient drop-out rates with VAX-D therapy is limited. In the single clinical trial of VAX-D therapy, 91 per cent (40/44) of patients completed the eight-week trial and were included in the 'evaluable patient' analysis. Two patients

withdrew during the course of the study, and a further two patients were subsequently excluded from analysis because they did not meet the study inclusion criteria. Drop-out rates could not be determined from the other studies of VAX-D because of the way the studies were performed or reported.

Is it effective?

Evidence of VAX-D therapy

There is only limited evidence of the effectiveness of VAX-D therapy in one patient group (patients with radiculopathy or radicular pain associated with herniated disc), and no good quality evidence of the effectiveness of VAX-D therapy in other patient groups. Overall, it appears that VAX-D therapy provides short-term symptomatic relief from nerve root compression. However, there is no evidence that VAX-D therapy provides longer term relief or cure of nerve root compression.

An unknown proportion of patients require more than the recommended 24 sessions and/or a second course of VAX-D therapy, and it is not known how many patients subsequently are referred for surgery. Furthermore, of the patients who have received VAX-D therapy, it is not known how many would have been prior candidates for surgery, and hence, how many 'successful' VAX-D treatments represent true cases of surgery avoided.

Three pieces of information submitted by the applicant were excluded from review on the following grounds:

- Ramos & Martin (1994): early phase clinical study in <10 patients
- Set of case reports: <10 patients
- Report on SF36-derived outcomes: unable to ascertain patient baseline characteristics or treatment received.

The four remaining pieces of evidence describing VAX-D therapy are summarised in the table below. As described earlier, there is only one randomised controlled trial of VAX-D therapy (Smart et al, unpublished results). This trial is described in more detail below.

Table 3 Summary of evidence for VAX-D therapy

| Level | Author | Objective | Results/Conclusions |
|-------|----------------------------|--|--|
| III-1 | Smart et al (unpublished) | Prospective comparison VAX-D therapy with TENS for low back pain with associated leg pain caused by lumbar disc herniation | At the end of VAX-D therapy 68% (15/22) of patients were successfully treated, and six months after VAX-D therapy was completed the success rate was 27% (6/22). No patients were successfully treated with the TENS protocol |
| IV | Tilaro & Miskovitch (1999) | Retrospective before-and-after comparison of VAX-D therapy in patients with radiculopathy | At the end of VAX-D therapy 82% (14/17) of patients were successfully treated. No follow-up data were reported. |
| IV | Gose et al (1998) | Retrospective before-and-after comparison of VAX-D therapy in patients with herniated or degenerated disc or facet syndrome with or without leg pain | At the end of VAX-D therapy 72% (437/611) of herniated patients, 72% (106/147) of degenerative disc patients, and 68% (13/19) facet syndrome patients were successfully treated. No follow-up data were reported. |
| IV | Boudreau (unpublished) | Retrospective before-and-after comparison of VAX-D therapy in acute and chronic patients with herniated or degenerated disc with or without leg pain | Four years after a single course of VAX-D therapy the response rate was 56% (ie, 19/34 patients who received treatment had >50% improvement in VAS pain score). However, this 4-year rate cannot be attributed entirely to VAX-D as the rate is based on data from responders and non-responders to the initial therapy. |

The unpublished study by Smart et al was a randomised, controlled trial conducted in Australia. The study recruited 44 patients, aged 18–65, with low back pain of at least three months duration and a score of at least 2 on a 1–10 VAS pain scale. The patients were required to have associated leg pain and a diagnosis of disc protrusion/herniation confirmed by CT or MRI scanning. Patients were also self-rated according to a four-point disability scale.

The treatments that were compared in the trial were VAX-D therapy and transcutaneous electrical nerve stimulation (TENS). VAX-D therapy was administered five times per week for four weeks and then once a week for four weeks. TENS was administered in a clinic as 30-minute sessions given five times per week for four weeks and then once a week for four weeks. Successful treatment was defined as a $\geq 50\%$ improvement in the patient's pain score plus an improvement in their disability rating.

Although the trial was 'controlled', the treatment regimen employed for TENS therapy was sub-therapeutic. A trial of TENS therapy with selection of optimal electrical stimulation parameters would normally be undertaken for each patient. It is usual for TENS therapy to be an adjunctive tool administered by individual patients as required for their pain relief. Thus, TENS would be self-administered several times per day or continuously in the patient's own home. Moreover, TENS would not be administered as monotherapy, but would be part of a combined treatment program. Hence, the TENS regimen employed in the trial by Smart et al (ie, one session per day as monotherapy, administered by a technician in a clinic) differs markedly from an optimal TENS regimen. Furthermore, the expected outcome from TENS therapy is symptomatic relief, whereas the applicant is claiming that VAX-D therapy cures nerve root compression. Consequently, the TENS treatment administered in the trial by Smart et al is an inappropriate comparator for VAX-D therapy.

At the end of the eight-week treatment period, 15/22 (68%) patients in the VAX-D arm were successfully treated, compared to 0/22 (0%) patients in the TENS arm. This difference is statistically significant ($P < 0.01$). The absence of responders in the TENS treatment arm is not surprising, given that the TENS regimen was sub-therapeutic.

Six months after treatment was completed the success rate for VAX-D therapy had declined to 27% with only 6/22 of the randomised patients having a sustained response. The six-month success rate for the TENS treatment group was not reported but it is possible that a small proportion of these patients would have resolved as a consequence of the natural history of the disease. No level I to III-1 evidence is available for follow-up periods greater than six months.

The remaining studies of VAX-D therapy are retrospective reviews of data from selected patients. These studies are significantly confounded by bias and are unable to support evidence-based conclusions. The article by Tilaro and Miskovitch (1999) describes a retrospective analysis of data from 17 selected patients who met *post hoc* criteria. Although an objective measurement of neurological impairment was employed (ie, current perception threshold (CPT) neurometer testing), outcomes were reported at the completion of therapy only, and there was no parallel or historical control group. Only limited baseline patient characteristics were reported.

The article by Gose et al (1998) also describes a retrospective analysis of data from selected patients—in this case, patients who had received a minimum of 10 sessions of VAX-D therapy. Successful treatment was defined only as a reduction in pain to 0 or 1 on a 0–5 scale. Although mobility and activity scores were determined, they were reported for the entire patient population, which included patients with disc herniation, disc degeneration and/or posterior facet syndrome. Baseline disease and demographic characteristics were not reported, except that 4 per cent of patients had received previous lumbar disc surgery.

The unpublished article by Boudreau describes a retrospective follow-up of patients with acute or chronic pain who had received a course of VAX-D therapy four years earlier. Only limited baseline patient disease and demographic characteristics were reported, and it is not clear which of the patients were included in the four-year follow-up. Of the 34 patients who originally received VAX-D therapy, 23 participated in the follow-up survey. Of these 23 it is unclear which proportion responded to VAX-D therapy at the time of treatment and which proportion resolved due to the natural history of the disc disease. Furthermore, the 34 patients who received VAX-D therapy had various diagnoses, including herniated discs, degenerated discs or non-specific low back pain, each with or without sciatica or radiating pain. Finally, the between-patient consistency of treatment is called into question by the following statement by the author, ‘they [the patients] represented the first 34 patients treated by this physician on this device and thus were on the low end of the learning curve for this physician with this device’.

Evidence of comparator therapies

As described in Table 1, the most appropriate comparator for VAX-D therapy differs according to the patient group. However, for none of the patient groups listed above is TENS the most appropriate comparator. Therefore, to enable a more thorough evaluation of the *comparative* effectiveness of VAX-D therapy, a review has been undertaken of three alternative treatments (discectomy, laminectomy with or without

fusion, and conservative treatment) in three patient groups (radiculopathy or radicular pain associated with herniated disc, radiculopathy or radicular pain associated with degenerated disc, and non-specific low back pain; patient groups 1, 2 and 3, respectively, from Table 1).

As described earlier, these reviews were restricted to levels I and II evidence. Evidence relating to discectomy, included standard discectomy and microdiscectomy, but excluded percutaneous discectomy, laser discectomy and chemonucleolysis. Evidence relating to laminectomy included standard laminectomy with fusion, and laminectomy without fusion. For patient group 3, conservative treatment was defined as oral analgesics and/or NSAIDs with or without physiotherapy.

Summaries of the evidence identified in the medical literature are presented in Tables 4, 5 6 and 7 below.

Comparator 1—Discectomy in patient group 1

The search for evidence of clinical outcomes for discectomy identified two systematic reviews (level I evidence) and one randomised, controlled trial that compared discectomy to conservative treatment (level II evidence). These articles are summarised in Table 4 below.

The Cochrane review by Gibson et al (2000a) identified 27 trials of surgical treatment for lumbar disc prolapse. Despite the fact that many of these studies suffered from weaknesses in trial design, the authors concluded that there is evidence that discectomy is more effective than chemonucleolysis, and strong evidence that chemonucleolysis is more effective than placebo: ergo, discectomy is more effective than placebo. The meta-analysis showed that chymopapain was more effective than placebo with a random effects odds ratio of 0.40 (95% CL 0.21, 0.75) for treatment failure as rated by a surgeon or independent observer. The meta-analysis also showed that chymopapain was less effective than discectomy, with a fixed effects odds ratio of 0.52 (0.35, 0.78) and a random effects odds ratio of 0.37 (0.13, 1.05) for surgeon-rated treatment failures.

Table 4 Summary of evidence for discectomy in patient group 1

| Level | Author | Objective | Results/Conclusions |
|-------|----------------------|--|--|
| I | Gibson et al (2000a) | Meta-analysis of 27 trials that reported outcomes for surgery for lumbar disc prolapse. 11 trials describe discectomy (including Weber (1983), see below) and 16 trials describe chemonucleolysis. | After 6–24 months follow-up, discectomy is more effective than chemonucleolysis, and chemonucleolysis is more effective than placebo. 3 trials showed no difference in clinical outcomes between microdiscectomy and standard discectomy. |
| I | Hoffman et al (1993) | Meta-analysis of 81 studies including controlled trials and case-series. All studies reported outcomes for surgery for herniated lumbar discs. 56 trials had a standard discectomy arm, and 24 trials had a microdiscectomy arm. | One year after standard discectomy 65–85% of patients reported no sciatica compared with 36% of conservatively treated patients. Longer term outcomes were similar (based predominantly on Weber (1983) study, see below). Approximately 10% of discectomy patients underwent further back surgery. |
| II | Weber (1983) | Long-term (10 years) prospective comparison of discectomy and conservative treatment (6 weeks physiotherapy) in patients with L5/S1 root lesion with sciatica. | <p>1 year after the procedures 65% (39/60) of patients randomised to discectomy were rated as 'good', compared with 36% (24/66) of patients randomised to conservative treatment. This difference was statistically significant ($P < 0.05$).</p> <p>However, 10 years after the procedures there was no significant difference in the proportion of patients rated as 'good': 58% (35/60) of discectomy patients versus 56% (37/66) of conservative treatment patients.</p> <p>In addition, patients who crossed over from the conservative treatment arm to the discectomy arm due to progression of their condition, had a 10 year 'good' rate of 59% (10/17) that was no different to either the discectomy arm or the conservative treatment arm.</p> |

The review by Hoffman et al (1993) reached similar conclusions: despite design flaws in many of the 81 studies they included in their review, the authors concluded that there is sufficient evidence that standard discectomy provides superior short-term relief of sciatica to conservative treatment.

A number of conclusions can be drawn from the Weber study. In the short to medium term, discectomy is more effective than conservative treatment for relieving pain associated with nerve root compression. Furthermore, for those patients who respond to surgery, the effects are long-lasting. However, in the long term there is no difference between the two forms of treatment. The similar 10-year success rates are due to an increase in the proportion of conservative patients whose condition resolved, rather than to a decline in the proportion of discectomy patients whose condition resolved. In addition, the study demonstrated that the long-term outcomes for patients who were treated conservatively at first and were subsequently referred for discectomy, were no different to those for patients who were referred immediately to discectomy. Thus, postponing surgery did not alter the patients' long-term outcomes, but did deny them relief in the short to medium term.

Overall, the evidence confirms clinical experience that the primary benefit of discectomy is to provide more rapid relief of sciatica in those patients who have failed to resolve with

conservative management, even if it is unclear whether surgery alters the long-term natural history of the disc disease.

Comparator 2—Laminectomy in patient group 2

The search for evidence of clinical outcomes for laminectomy with or without fusion or laminotomy identified one systematic review (level I evidence) and one prospective randomised, controlled trial that compared surgery to conservative treatment (level II evidence). These articles are summarised in Table 5 below.

Table 5 Summary of evidence for laminectomy in Patient Group 2

| Level | Author | Objective | Results/Conclusions |
|-------|-------------------------|--|--|
| I | Gibson et al (2000b) | Systematic review of 16 trials which assessed the effects of surgical interventions for the treatment of lumbar spondylosis. Interventions assessed in the trials included laminectomy, laminotomy and fusion. | There is no adequate scientific evidence regarding the efficacy of any form of surgical decompression or fusion for degenerative spondylosis. |
| II | Möller & Hedlund (2000) | RCT to compare posterolateral fusion with an exercise program in patients with isthmic spondylolisthesis. | Differences in disability rating index (DRI) and VAS pain scores were statistically significant at 1 and 2 years follow-up for surgically versus conservatively treated patients. In the surgery group DRI decreased from 48 to 29 ($P<0.0001$), but was unchanged in the exercise group (44 at beginning and end, $P=0.53$). In the surgery group the pain index decreased from 63 to 37 ($P<0.0001$), compared with a decrease from 65 to 56 in the exercise group ($P=0.024$). |

The most recent Cochrane review by Gibson et al (2000b) on surgery for patients with degenerative lumbar spondylosis was based on randomised and quasi-randomised trials of all surgical treatments for lumbar spondylosis. Analysis of these trials was complicated by the variety of pathologies, including degenerative disc disease, spinal stenosis, isthmic spondylolisthesis and degenerative spondylolisthesis, and by the fact that not all of the patients recruited to the trials had a radiculopathy. The authors concluded that at present there is no adequate scientific evidence about the role or efficacy of any form of surgical decompression for degenerative lumbar spondylosis.

In the RCT by Möller & Hedlund (2000 and 1996) posterolateral fusion *in situ* with or without transpedicular Cotrel-Dubousset instrumentation was compared with an exercise program monitored by a physiotherapist. The outcomes measured in the trial were changes in pain score, disability rating, and subjective classification of the overall result of treatment two years after treatment was administered. It was found that improvements in both the disability rating and pain scores were significantly better in the surgically treated group than in the exercise group ($P<0.01$). Furthermore, 56 per cent of surgery patients were rated as 'much better' by an observer, compared with 9 per cent of exercise patients.

Thus, although there is only limited evidence available for laminectomy in patients with degenerative disc disease, the trial by Möller & Hedlund (2000) does provide good

evidence of the effectiveness of laminectomy with or without fusion in a clearly defined subset of the patients with disc disease. Conversely, no good quality evidence exists of the effectiveness of VAX-D therapy in any patient group with degenerative disc disease, which precludes any effectiveness comparison between VAX-D therapy and laminectomy in this patient group.

Comparator 3—Conservative treatment in patient group 3

The search for evidence of clinical outcomes for non-steroidal anti-inflammatory drugs identified two systematic reviews (level I evidence), and systematic reviews from the *British Medical Journal* Clinical Evidence database (level I). These articles are summarised in Table 6, and discussed below.

Table 6 Summary of evidence for conservative treatment in patient group 3—analgesics and/or NSAIDs

| Level | Author | Objective | Results/Conclusions |
|-------|--------------------------------|---|--|
| I | van Tulder et al (2000) | A meta-analysis of 51 trials assessing the effects of NSAIDs in the treatment of non-specific low back pain. | Sufficient evidence on chronic non-specific low back pain is lacking. There was a statistically significant difference in favour of NSAIDs compared to placebo in patients with acute low back pain. No particular NSAID is clearly more effective than others for short-term symptomatic relief. |
| I | van Tulder et al (1997) | To assess the effectiveness of the most common conservative types of treatment for people with chronic low back pain. Treatments assessed included analgesics/NSAIDs. | Moderate evidence that NSAIDs are effective for chronic LBP. |
| I | BMJ Clinical Evidence database | To assess the effects of oral drug treatment (analgesics or NSAIDs) on low back pain and sciatica. | One RCT concluded that patients treated with diflunisal rated the treatment as good or excellent when compared to paracetamol. Two RCTs found that NSAIDs were more effective than paracetamol for overall improvement and more effective than placebo for pain. |

The search for evidence of clinical outcomes for physiotherapy identified two systematic reviews (level I evidence) and three RCTs that compared physiotherapy/manipulation therapy to conservative treatment (level II evidence). These articles are summarised in Table 7, and discussed below.

The Cochrane review by van Tulder et al (2000) identified a total of 51 RCTs of NSAID therapy in patients with acute or chronic low back pain. Of these 51 trials, only four studies reported on patients with chronic low back pain (≥ 3 months). Each of the four trials included different comparisons and so subgroup analysis for chronic low back pain was not performed in the review. Despite the fact that the authors could not provide evidence on the efficacy and effectiveness of NSAIDs in chronic low back pain, one high-quality trial reported better outcomes for those patients on NSAIDs than for those on paracetamol.

Table 7 Summary of evidence for conservative treatment in patient group 3—physiotherapy

| Level | Author | Objective | Results/Conclusions |
|-------|-------------------------|---|---|
| I | van Tulder et al (1997) | Systematic review of RCTs assessing the effectiveness of the most common conservative treatments (including manipulation therapy) for acute (68 trials), chronic (81 trials), or acute and chronic (1 trial) low back pain. | For chronic low back pain there is strong evidence of the effectiveness of manipulation therapy over placebo treatment. In addition, there is moderate evidence that manipulation is more effective for chronic LBP than usual care by the GP, bed rest, analgesics and massage. |
| I | Koes et al (1991) | Systematic review of RCTs to assess the efficacy of physiotherapy exercise on low back pain. 6 trials evaluated physiotherapy exercises for chronic low back pain. | 2 high quality trials and 1 low-quality trial reported positive conclusions regarding physiotherapy exercise when compared to the control treatment. 3 low-quality trials reported negative outcomes. |
| II | Torstensen et al (1998) | To determine the efficacy of medical exercise therapy (MET), conventional physiotherapy (CP) and self-directed exercise (SE) in patients with chronic LBP. | MET and CP are equally effective and superior to SE in terms of lowering pain intensity (VAS) after treatment. Compared with pre-treatment, pain after treatment and at 1 year post-treatment showed a highly significant difference in favour of MET and CP versus SE. |
| II | Bronfort et al (1996) | RCT to determine the relative efficacy of three different treatment regimens for chronic low back pain. a) Spinal manipulative therapy (SMT) + trunk strengthening exercises (TSE) b) NSAIDs + TSE c) SMT + trunk stretching exercises | No clear clinically important or statistically significant differences were observed between the groups. A tendency was noted towards group differences in pain between SMT/TSE and NSAID/TSE groups favouring NSAID/TSE at week 3 and SMT/TSE at 11 weeks with the level of significance approaching $p < 0.05$. A significant increase in trunk flexion/extension strength and endurance was observed after 11 weeks in both the SMT/TSE and NSAID/TSE group but not the SMT/stretching group. |
| II | Mannion et al (1999) | RCT to examine the relative efficacy of three active therapies for chronic low back pain a) physiotherapy, b) aerobics and c) training with devices. | The three treatments were equally effective in reducing pain intensity. No significant difference was observed between groups. Greatest improvements were observed during lateral bending and axial rotation of the lumbar spine in the aerobics and devices groups, which was significantly greater than the improvements observed after physiotherapy ($P = 0.04$). |

Abbreviations: SMT, spinal manipulation therapy; NSAID, non-steroidal anti-inflammatory drugs; TSE, trunk strengthening exercises

The systematic review by van Tulder et al (1997) evaluated the effectiveness of common conservative treatments for patients with acute or chronic non-specific low back pain. Of six included studies evaluating NSAIDs, three reported a positive result, indicating that NSAID therapy was more effective than the reference treatment with respect to pain intensity, overall improvement and functional status. One study reported a negative result and two studies reached no conclusions. Despite the fact that the trials were of varied quality, the authors concluded that there was moderate evidence that NSAIDs are effective for chronic low back pain and there is strong evidence that various types of NSAIDs (piroxicam, indomethacin, ibuprofen, diclofenac, ketoprofen, naproxen and diflunisal) are equally effective.

Furthermore the *British Medical Journal* Clinical Evidence database reports that NSAIDs are more effective than paracetamol and more effective than placebo for pain. Moreover,

NSAIDs plus vitamin B are more effective than NSAIDs alone, based on data from RCTs.

The primary focus of physiotherapy is the restoration of function to the patient. Physiotherapists combine manual therapies, movement training and physical and electrophysical agents to achieve desired functional outcomes for their patients. Management of low back pain by physiotherapists focuses on assessment, specific therapeutic exercises, manipulation and mobilisation and advice on posture, movement and manual handling.

The systematic review by van Tulder et al (1997) identified two high-quality and seven low-quality trials of manipulation on patients with chronic (>12 weeks) non-specific low back pain. The two high-quality trials reported a positive result of manipulation therapy compared with placebo, a further four low-quality trials also reported positive effects of manipulation therapy compared with a reference treatment. The author concluded that there is strong evidence that manipulation is more effective than placebo and moderate evidence that manipulation is more effective for chronic low back pain than usual care by the general practitioner, bed rest, analgesics and massage. A second review by Koes et al (1991) reported positive effects of physiotherapy exercises for chronic low back pain from two high-quality trials (methodological score >50/100) and one low-quality trial (methodological score <50/100).

The RCT by Torstensen et al (1998) observed statistically significant responses in favour of medical exercise therapy (MET) and conventional physiotherapy (CP) over self-directed exercise (SE) in terms of lowering pain levels. In the MET group pain levels decreased from 53.1 at baseline to 40.5 at one-year follow-up, and in the CP group pain levels decreased from 50.9 at baseline to 42.9 at one-year follow-up. By comparison, there was no change in pain levels in the SE group (55.0 at baseline versus 50.0 at one-year follow-up). The treatment differences between MET and SE, and between CP and SE were statistically significant ($P=0.00006$ and 0.0002 , respectively).

The RCT by Bronfort et al (1996) compared the following three therapeutic regimens: (1) spinal manipulative therapy combined with trunk strengthening exercises, (2) spinal manipulative therapy combined with trunk stretching exercises, and (3) NSAIDs combined with trunk strengthening exercises. The authors concluded that the regimens were associated with similar and clinically important improvements that were superior to the natural history of long-standing chronic low back pain. The authors also concluded that for the management of chronic low back pain spinal manipulation therapy or NSAID therapy seemed to be beneficial and worthwhile.

Finally, the RCT by Mannion et al (1999) reported equally effective pain responses with the following three treatments: (1) modern active physiotherapy, (2) muscle reconditioning on training devices, and (3) low-impact aerobics. In addition, Mannion et al (1999) observed an improvement in lateral bending and axial flexion in the aerobics and devices groups which was statistically significant over the minimal improvements with physiotherapy.

In summary, although evidence relating to therapies for chronic non-specific low back pain is somewhat limited (and there is a need for RCTs conducted in homogeneous populations of chronic low back pain patients), there is sufficient evidence to conclude that for patient group 3 NSAIDs provide greater relief from pain when compared to the natural course of the injury/disease. There is also sufficient evidence to conclude that

physical manipulation is effective in relieving chronic non-specific low back pain. In contrast, there is no evidence regarding the effectiveness of VAX-D therapy in these patients. Consequently, no conclusions can be made regarding the relative effectiveness of VAX-D therapy for patients with non-specific low back pain.

Comparative effectiveness of VAX-D therapy and discectomy in patients with radiculopathy or radicular pain associated with disc herniation

Although a direct comparison of VAX-D therapy and discectomy cannot be made (because of the absence of a head-to-head trial), there is sufficient evidence for an indirect comparison of the two treatments. Response rates for the two treatments and for conservative treatment options are presented in Table 8 below, bearing in mind that the conservative treatment arm of the Smart et al trial (ie, TENS therapy) was sub-therapeutic.

Table 8 Comparative effectiveness of VAX-D therapy and discectomy

| Treatment Source of evidence | Response rate | | | | |
|---------------------------------|------------------------|-------------|-------------|-------------|-------------|
| | At end of treatment | At 6 months | At 1 year | At 4 years | At 10 years |
| VAX-D | | | | | |
| Smart et al | 68% (15/22) | 27% (6/22) | nr | nr | nr |
| Conservative | | | | | |
| Smart et al (TENS) | 0% (0/22) | nr | nr | nr | nr |
| Weber (1983) (Physiotherapy) | nr | nr | 36% (24/66) | 52% (34/66) | 56% (37/66) |
| Discectomy | | | | | |
| Weber (1983) | nr | nr | 65% (39/60) | 67% (40/60) | 58% (35/60) |

The six-month time point from the data of Smart et al can be compared with the one-year time point from the data of Weber (1983). When this is done then the following observations can be made:

- At 6 months/1 year VAX-D therapy offers nominally poorer outcomes than a six-week course of physiotherapy: 27 per cent versus 36 per cent respectively. The difference between these two treatment options is not statistically significant, with an absolute risk difference of -9.1 per cent (95% CL -31.0% and 12.8%).
- At 6 months/1 year the response rate with discectomy is more than twice the response rate with VAX-D therapy: 65 per cent versus 27 per cent respectively (see Table 9). These response rates yield a relative risk of 2.38 (95% CL 1.18 and 4.83), and an odds ratio (OR) of 4.95 (95% CL 1.69 and 14.6) for discectomy versus VAX-D therapy. Both the relative risk and the OR are significantly in favour of discectomy.

It is worth noting that the assumption made above is favourable to VAX-D therapy, as there is no evidence that the six-month VAX-D response rate will be maintained at one year. It is also true that, as an indirect comparison has been made, the results presented

here are indicative only and more definite conclusions could be drawn only from a head-to-head trial.

What are the economic considerations?

Economic evaluation of new health care technologies is particularly important where the new technology offers health benefits at additional cost. It is clear that there is always a limit to the additional cost which would be paid for a given health gain. Economic evaluation is generally concerned with assisting determinations of whether such incremental costs and health gains represent value for money.

When undertaking an economic evaluation of a new device or procedure both the costs and benefits associated with that device or procedure are assessed. The usual process for an economic evaluation is first to consider the additional benefits accrued with the new device/procedure relative to the comparator (ie, the incremental effectiveness), and to then proceed with determining cost differences between the new procedure and the comparator (ie, incremental costs). When both of these quantities are known, then a cost-effectiveness ratio can be determined. In cases where a new technology offers inferior or equal health benefits at a higher cost it is clearly not cost-effective.

Indirect comparison of VAX-D therapy with discectomy

Based on the evidence from the trials by Smart et al and Weber (1983), the indicative incremental effectiveness of VAX-D therapy over discectomy can be determined (see Table 9). The incremental effectiveness for VAX-D therapy is –38 per cent; that is, VAX-D therapy is possibly less effective than discectomy.

As VAX-D therapy offers no gains in health outcomes relative to discectomy, it is inappropriate to proceed with a cost-effectiveness analysis. Furthermore, as VAX-D does not appear to offer similar health outcomes to discectomy but at lower cost, it is inappropriate to proceed with a cost-minimisation analysis. Accordingly, the cost differences between VAX-D therapy and discectomy have not been determined for this report.

Table 9 Incremental effectiveness of VAX-D therapy over discectomy

| | VAX-D therapy | Discectomy | Incremental effectiveness (VAX-D minus Discectomy) |
|------------------------------|---------------|------------|--|
| 6 month/1 year response rate | 27% | 65% | –37.7% |
| 95% CI | | | 59.9% to –15.5% |

Published economic evaluations

The literature review undertaken for this assessment identified one published economic evaluation of discectomy for the treatment of herniated discs (Malter et al, 1996). This article describes a cost–utility analysis (CUA) based on clinical evidence from the trial by Weber (1983; this trial was discussed above).

The CUA by Malter and colleagues is well conducted and meets the criteria for critically assessing an economic evaluation as described by Drummond et al (1987). In particular:

- The study posed a well-defined question, and a description of the competing alternative treatments was given.
- The effectiveness of the alternative treatments was established through a randomised, controlled trial, and utilities were derived from a similar patient group to that in the trial, using a time-trade off method.
- Key costs for each alternative treatment were identified, and costs and consequences were measured in appropriate physical units.
- Costs were valued credibly, using insurance data from 2,175 herniated disc patients: of these patients 372 underwent surgery and 1,803 were classified as having received medical management. Charges to the insurers were used as proxies for costs.
- Costs and outcomes were adjusted for differential timing, and both were reported as undiscounted and at a 5 per cent discounted rate.
- Costs derived from a 1989 database were adjusted to 1993 dollars using the medical component of the Consumer Price Index.
- An incremental analysis of costs and consequences of the alternative treatments was performed.
- Reasonable sensitivity analyses were performed around the estimates of effectiveness and costs.
- The authors present a comprehensive discussion of their findings in the context of other treatments for low back pain, and also in the context of cost-effectiveness ratios for unrelated treatments.

Malter et al (1996) concluded that, for carefully selected patients with herniated discs, surgical discectomy is a cost-effective treatment when compared to ongoing medical treatment. The authors found that surgery led to an improvement in quality adjusted life years (QALYS) of 0.43 during the decade following treatment (equivalent to extending a healthy life by five months).

Although this CUA was undertaken in the USA, where there may be differences in costs and service utilisation rates relative to Australia, it is likely that discectomy would remain cost-effective in the Australian setting when compared to ongoing conservative treatment.

Given that VAX-D therapy is no better (and may be worse) than standard conservative treatment (see discussion above), it is likely that discectomy is more cost-effective than VAX-D therapy for patients with herniated discs who are indicated for surgery.

Financial implications for DHAC

Financial implications were considered by the Committee. However, the costings are in-confidence and are not included in this report.

Other considerations

The supporting committee has concerns regarding the delivery of VAX-D therapy. These concerns cover two issues: (1) the person who delivers the treatment, and (2) how the treatment is accessed.

First, the applicant states that VAX-D therapy is to be delivered by a 'certified' VAX-D technician. The applicant states that this technician may or may not be medically qualified. To be eligible for MBS funding, all treatments are either provided by a qualified medical practitioner or are provided under the supervision of a qualified medical practitioner. There is no intention in this report to consider the provision of VAX-D treatments under any other conditions. Moreover, similar treatments such as traction are not listed as items on the MBS.

Second, the VAX-D system is supplied in Australia by a single company. This raises concerns about the company's ability to exert monopolistic power, and thereby restrict access to the procedure, although VAX-D Australasia asserts that it does not wish to restrict access to its therapy. Items currently listed on the MBS can be provided by any suitably qualified medical practitioner, regardless of which company or companies supply the required devices. As the VAX-D proposal stands, the supplier of VAX-D tables in Australia may be able to influence which doctors deliver the treatment and which patients receive treatment. This raises serious concerns about access and equity. In particular, VAX-D Australasia Pty Ltd expects that a significant number of patients treated with VAX-D therapy will not be covered by MBS but by workers compensation. Given that there will be a finite number of VAX-D tables in Australia, treatment of compensable patients may limit access to treatment by non-compensable, (ie, MBS) patients.

Conclusions

Safety

Detailed evidence on the safety and complication rates of the device is lacking.

Effectiveness

For patients with radiculopathy or radicular pain associated with a herniated intervertebral disc, there is some evidence to suggest that surgical discectomy is more effective than VAX-D therapy at relieving pain in the short to medium term. No comparisons can be made between these two therapies in this patient group over the long term (ie, 10 years).

For other patient groups (ie, patients with radiculopathy or radicular pain associated with degenerated intervertebral discs, and patients with non-specific low back pain) there is insufficient evidence to make any conclusions regarding the relative effectiveness of VAX-D therapy.

Cost-effectiveness

No evidence-based conclusions can be drawn regarding the cost-effectiveness of VAX-D therapy in any patient group. However, it is likely that discectomy is more cost-effective than VAX-D therapy for the treatment of patients with radiculopathy or radicular pain associated with herniated intervertebral discs.

Other considerations

There are concerns regarding the qualifications of the person who would deliver VAX-D therapy. The applicant states that VAX-D therapy is to be delivered by a 'certified' VAX-D technician and implies that this technician may or may not be medically qualified. To be eligible for MBS funding, all treatments are either provided by a qualified medical practitioner or are provided under the supervision of a qualified medical practitioner. There is no intention in this report to consider the provision of VAX-D treatments under any other conditions.

There are also serious concerns of access and equity. As there is a sole supplier of the VAX-D system in Australia, the company may be in a position to influence which doctors deliver the treatment and which patients receive treatment.

Recommendation

As there is currently insufficient evidence pertaining to the effectiveness of vertebral axial decompression (VAX-D) therapy, MSAC recommended that public funding should not be supported at this time for this procedure.

The Minister for Health and Aged Care accepted this recommendation on 19 June 2001.

Appendix A MSAC terms of reference and membership

MSAC's terms of reference are to:

- advise the Commonwealth Minister for Health and Aged Care on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Commonwealth Minister for Health and Aged Care on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Commonwealth Minister for Health and Aged Care on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

| Member | Expertise |
|----------------------------------|--|
| Professor David Weedon (Chair) | pathology |
| Ms Hilda Bastian | consumer health issues |
| Dr Ross Blair | vascular surgery (New Zealand) |
| Mr Stephen Blamey | general surgery |
| Dr Paul Hemming | general practice |
| Dr Terri Jackson | health economics |
| Professor Brendon Kearney | health administration and planning |
| Mr Alan Keith | Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Aged Care |
| Associate Professor Richard King | internal medicine |
| Dr Michael Kitchener | nuclear medicine |
| Professor Peter Phelan | paediatrics |

| | |
|-------------------------|--|
| Dr David Robinson | plastic surgery |
| Professor John Simes | clinical epidemiology and clinical trials |
| Professor Bryant Stokes | neurological surgery, representing the Australian Health Ministers' Advisory Council |

Appendix B Supporting Committee

Supporting committee for MSAC application 1012: Vertebral axial decompression for chronic low back pain

| | |
|--|---|
| Professor Bryant Stokes (Chair) MBBS, FRACS, FRCS Neurosurgeon Chief Medical Officer Health Department of Western Australia | member of MSAC |
| Dr Ross Blair MbChB, RACS Director of Vascular Surgery Waikato Hospital, New Zealand | member of MSAC |
| Professor Nikolai Bogduk BSc(Med), MBBS, PhD, DipAnat, MD, FAFRM, DSc, FFPMANZCA Director Newcastle Bone and Joint Institute Royal Newcastle Hospital | co-opted member |
| Professor Paul Glasziou MBBS, DipCompSc, PhD Head, Department of Social and Preventive Medicine University of Queensland | co-opted member |
| Ms Tricia Greenway Senior Manager, Policy and Planning Arthritis Victoria | nominee of the Consumers' Health Forum |
| Mr Michael Johnson MBBS, FRACS Consultant Orthopaedic and Spinal Surgeon Richmond, VIC | nominee of the Royal Australian College of Surgeons |
| Professor Joan McMeeken DipPhysio, BSc, MSc Head, School of Physiotherapy The University of Melbourne | co-opted member |
| Dr Michael Yelland MBBS, FRACGP, GDipMuscMed General Practitioner Inala Community Health Centre, QLD | nominee of the Royal Australian College of General Practitioners |

Abbreviations

| | |
|---------|--|
| ABS | Australian Bureau of Statistics |
| AIHW | Australian Institute of Health and Welfare |
| AN-DRG | Australian National Diagnosis Related Group |
| BMJ | <i>British Medical Journal</i> |
| CI | Confidence intervals |
| CL | Confidence limits |
| CP | Conventional physiotherapy |
| CPT | Current perception threshold |
| CT | Computed tomography |
| CUA | Cost–utility analysis |
| DHAC | Department of Health and Aged Care |
| DRI | Disability rating index |
| GP | General practitioner |
| IASP | International Association for the Study of Pain |
| INAHTA | International Network of Agencies for Health Technology Assessment |
| ISTAHC | International Society of Technological Assessment in Health Care |
| L5/S1 | Lumbar vertebra 5/Sacral vertebra 1 |
| LBP | Low back pain |
| MBS | Medicare Benefits Schedule |
| MET | Medical exercise therapy |
| MRI | Magnetic resonance imaging |
| MSAC | Medicare Services Advisory Committee |
| NHMRC | National Health and Medical Research Council |
| nr | Not reported |
| NSAID/s | Non-steroidal anti-inflammatory drug/s |
| OR | Odds ratio |
| QALY/s | Quality adjusted life year/s |
| RCT/s | Randomised controlled trial/s |
| SE | Self-directed exercise |
| SMT | Spinal manipulation therapy |
| TENS | Transcutaneous electrical nerve stimulation |
| TSE | Trunk strengthening exercise |
| VAS | Visual analogue scale |
| VAX-D | Vertebral axial decompression |

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