Appendix D Health Economics Extractions

What is the effectiveness and cost effectiveness of performing x-ray or MRI compared with no investigation to improve functional disability, pain or psychological distress?

Study Quality: No

Intervention: Random allocation to immediate referral for x-ray

Comparison: No referral for x-ray

Population: LBP > 4 weeks

Perspective: NHS, Societal (separately reported)

Study type: CMA, CEA (for completeness)

Methods: RCT

Health valuations: TTO (EQ-5D)

Cost components: NHS, time off work

Currency: £

Cost year: 1999-2000

Time horizon: 1 year

Discount rate: 2%

Results-cost: CMA: in RCT (n=153), the difference in NHS costs were significant at 3 months (£41.90) but not at 12 months as higher consultation rates in control group offset initial x-ray costs in the intervention group. However, in the observational arm of the trial (n=506) there were significantly higher costs in intervention group both at 3 and 12 months. CEA: mean difference of £42 in direct NHS costs at six weeks.

Results-effectiveness: CMA: not applicable (RCT did not show a statistically significant difference on the physical subscales of the SF-36, EuroQol, Hospital
Anxiety and Depression Scale or Roland and Morris Depression scale after 6 weeks and 1 year).

CEA: 8 percentage points in the mean SF-36 Mental Health scores for patients who were referred for x-ray compared to those who were not, after adjustment for age, sex and length of episode at six weeks.

Results-ICER:

C/e of early GP referral for x-ray for LBP at £5.25 per percentage point gain in SF-36 mental health dimension.

Result-Uncertainty:

CMA: univariate SA. Unit costs were varied -50%, +100%. Results of CEA sensitive only to cost of X-ray over either time period, which had to be £88 or more in order to make the statistical difference significant.

CEA: PSA using non-parametric bootstrapping/2000 replications presenting a CEAC. CE plane shows high uncertainty as, at 6 weeks, most points lie in NE quadrant but many in NW. At 12 months, bootstrap replication points are spread across all four quadrants. As for the CEAC, at 95% CI immediate referral for x-ray is cost effective provided a WTP of £93 or more per percentage point in SF-36 mental health scale at 6 weeks or £10 or more per percentage point improvement at 12 months.

Source Funding:

Public

Comments:

In the RCT, referral for X-ray led to a small improvement in patient psychological well-being over the next 12 months, but there were no differences in physical outcomes, further consultations or referrals to other health professionals. Patients referred for X-ray have higher costs in the short term than patients who are not, a difference that is almost entirely due to the cost of the X-ray itself. There were no significant differences in costs over a 1-year period.

In the RCT, a difference of 8 percentage points was found in the mean SF-36 mental health scores for the patients who were referred for X-ray and those who were not, after adjustment for age, sex and length of episode (see Table 10). Although not large, this difference was statistically significant and was used as the basis for the CEA.

In the observational arm, referral for X-ray was associated with length of episode at presentation, which is an indicator of poor prognosis. Patients referred for X-ray had poorer physical outcomes at 6 weeks and 1 year; however, after adjustments were made for length of episode at presentation, effect sizes were similar to those in the RCT. In the observational arm, patients referred for X-ray had higher costs, both in the short term and in the long term. The poorer prognosis of patients referred for X-ray probably explains these differences.
The one percentage point improvement in mental health scores at six weeks at a cost of £93 must still be offset by the potential cost of radiation and the potential benefit of a reduction in the probability of failing to detect serious disease as neither were included formally in the evaluation. It cannot be concluded if this intervention is a worthwhile use of NHS resources.

<table>
<thead>
<tr>
<th>No</th>
<th>Study Quality:</th>
<th>Cost-effectiveness of lumbar spine radiography in primary care patients with low back pain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Author:</td>
<td>Miller P; Kendrick D; Bentley E; Fielding K</td>
</tr>
<tr>
<td></td>
<td>Intervention:</td>
<td>X-ray</td>
</tr>
<tr>
<td></td>
<td>Comparison:</td>
<td>No x-ray (usual care)</td>
</tr>
<tr>
<td></td>
<td>Population:</td>
<td>Low back pain of at least 6 weeks duration</td>
</tr>
<tr>
<td></td>
<td>Perspective:</td>
<td>SOCIETAL</td>
</tr>
<tr>
<td></td>
<td>Study type:</td>
<td>CEA</td>
</tr>
<tr>
<td></td>
<td>Methods:</td>
<td>RCT</td>
</tr>
<tr>
<td></td>
<td>Health valuations:</td>
<td>WTP/WTA</td>
</tr>
<tr>
<td></td>
<td>Cost components:</td>
<td>Direct NHS costs, indirect costs to patients and to society</td>
</tr>
<tr>
<td></td>
<td>Currency:</td>
<td>£</td>
</tr>
<tr>
<td></td>
<td>Cost year:</td>
<td>not stated</td>
</tr>
<tr>
<td></td>
<td>Time horizon:</td>
<td>3 and 9 months</td>
</tr>
<tr>
<td></td>
<td>Discount rate:</td>
<td>no discounting performed due to time horizon &lt;1 year</td>
</tr>
<tr>
<td></td>
<td>Results-cost:</td>
<td>£41.04 mean direct cost difference</td>
</tr>
<tr>
<td></td>
<td>Results-effectiveness:</td>
<td>2.1 units difference on Roland satisfaction score</td>
</tr>
<tr>
<td></td>
<td>Results-ICER:</td>
<td>£19.54 per one additional unit of satisfaction</td>
</tr>
</tbody>
</table>
Result-Uncertainty: At a WTP of £30 per unit change in Roland satisfaction score, there is a 90% chance of lumbar radiography being cost effective (when x-ray costs £40). The results of the CEAC are stratified for x-ray costs tiered at £20, £40 and £80).

Source Funding: Public

Comments: The trial found no significant difference in functionality and health outcomes between the two cohorts. At the same time, the x-ray intervention group did incur higher costs at 3 and 9 months follow up. As a result, the authors concluded that on a £/QALY (cost utility) basis the intervention would be dominated as it was not more effective on the EQ-5D dimensions whilst being significantly more costly. From a societal perspective, there was a significant difference in satisfaction scores between the cohorts. From an NHS perspective, health-related quality of life is the outcome measure used across clinical guidelines and therefore this result should be considered conclusive.

Moreover, the authors have performed a simple Cost Benefit Analysis. They found that patients valued the reassurance gained from radiography at £30 and the perceived risk of radiation at £43. “This indicates that lumbar spine radiography is associated with a net economic loss at 9 months follow up”.

No 235 Study Quality: The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial

Author: Kendrick D;Fielding K;Bentley E;Miller P;Kerslake R;Pringle M; 2001

Intervention: X-ray

Comparison: No x-ray (usual care)

Population: LBP >6 weeks

Perspective: SOCIETAL

Study type: CEA

Methods: RCT

Health valuations: NOT APPLICABLE

Cost components: NHS, patient and economic (productivity) costs

Currency: £
Cost year: not stated
Time horizon: 3 and 9 months
Discount rate: not applicable.
Results-cost: £41.04 cost difference between cohorts
Results-effectiveness: Difference between cohorts = 2.1 units satisfaction on satisfaction score. No improvements in health measurements.
Results-ICER: £19.54 per one additional unit satisfaction on satisfaction score
Result-Uncertainty: At a WTP of £30 per unit change in satisfaction score, there is a 90% chance of lumbar radiography being cost effective (when x-ray costs £40). There was no improvement in health outcomes. The results of the CEAC are stratified for x-ray costs tiered at £20, £40 and £80). See also comment below.
Source Funding: Public
Comments: This is the corresponding HTA to the paper by Miller et al. Therefore the findings are the same:

This paper spins off the 2001 HTA by Kendrick et al. (RM ID 92). The trial found no significant difference in functionality and health outcomes between the two cohorts. At the same time, the x-ray intervention group did incur higher costs at 3 and 9 months follow up. As a result, the authors concluded that on a £/QALY (cost utility) basis the intervention would be dominated as it was not more effective on the EQ-5D dimensions whilst being significantly more costly. From a societal perspective, there was a significant difference in satisfaction scores between the cohorts. From an NHS perspective, health-related quality of life is the outcome measure used across clinical guidelines and therefore this result should be considered conclusive.

Moreover, the authors have performed a simple Cost Benefit Analysis. They found that patients valued the reassurance gained from radiography at £30 and the perceived risk of radiation at £43. "This indicates that lumbar spine radiography is associated with a net economic loss at 9 months follow up".

No 234 Study Quality: Rapid magnetic resonance imaging for diagnosing cancer-related low back pain
Author: Hollingworth W; Gray DT; Martin B; Sullivan SD; Deyo RA; Jarvik JG; 2003

Intervention: Rapid MRI

Comparison: X-ray

Population: LBP patients with suspected causal malignancy

Perspective: THIRD PAYER

Study type: CUA

Methods: DECISION ANALYSIS

Health valuations: NOT STATED

Cost components: Screening costs (imaging and biopsy), treatment costs. Imaging includes personnel and equipment use time etc (refer to Gray, Hollingworth et al., RM ID 82 for details)

Currency: US$

Cost year: 2001

Time horizon: 20 years

Discount rate: 3% (0-7%)

Results-cost: $135 incremental cost per case detected of rapid MRI over x-ray
$128 incremental cost per QALY

Results-effectiveness: Incremental effectiveness 1: 0.00063 extra cases detected
Incremental effectiveness 2: 0.00043 extra QALYs generated

Results-ICER: ICER (cases detected): $213,927
ICER (QALY): $296,176

Result-Uncertainty: In univariate sensitivity analysis, the ICER was most sensitive to probability of x-ray induced cancers (no risk $2.8m/Qaly; high risk=19 in 100 000 $153,421/Qaly). Discount rate was also influential as these induced cancers only manifest after about 20 years. If not discounted, ICER $145,090/Qaly. Baseline prevalence and specificity and sensitivity changes in MRI scanning were also important: with higher specificity (0.97), ICER falls to $98,681/Qaly. If cancer prevalence is raised to 5%, rapid MRI scanning becomes cost effective ($8,816/Q).
Other parameters such as QoL, survival or treatment costs did not greatly influence the result.

Source Funding: Public

Comments: Concludes that routine use of (rapid) MRI is not to be recommended for cancer detection in LBP patients until further advances in accuracy of the test and diagnostic protocols are obtained.

No 232 Study Quality: Does early imaging influence management and improve outcome in patients with low back pain? A pragmatic randomised controlled trial

Author: Gilbert FJ; Grant AM; Gillan MC; Vale L; Scott NW; Campbell MK; Wardlaw D; Knight D; McIntosh E; Porter RW;

Intervention: Early imaging (CT or MRI as soon as practical)

Comparison: Delayed imaging (CT or MRI only if clear indication develops)

Population: Acute (21%), 3-12 months subacute (40%), chronic (38%) and unknown (1%) LBP patients of whom 92.6% had 'history of back pain', and who were referred by GP to orthopaedic specialist or neurosurgeon because of symptomatic lumbar spine disorders. Imaging modality (CT or MRI) at discretion of specialist.

Perspective: SOCIETAL

Study type: CUA

Methods: RCT (n=782)

Health valuations: TTO

Cost components: Patient management and costs to patients

Currency: £

Cost year: 1999/2000

Time horizon: 24 months

Discount rate: 6% discounted costs only

Results-cost: incremental costs early vs delayed £61
Results-effectiveness: incremental effect early vs delayed 0.07 Qaly

Results-ICER: ICER £870/Qaly

Result-Uncertainty: PSA: cost effectiveness acceptability curve: 90% cost effective at base case when WTP equals £30k. This result appears robust to changes of imaging costs: at £500 for CT or MRI, there is still about 80% chance that early imaging will be cost effective when WTP equals £20k and 84.4% if WTP £30k.

Censoring: result sensitive to whether missing values were imputed or not. When imputed, the effect size almost halved to 0.04, being insignificant at 95% level (-0.015 to 0.10).

Source Funding: Public

Comments: Concludes early imaging may be cost effective when compared to delayed imaging however acknowledges uncertainty surrounding underlying assumptions as discussed under ‘uncertainties’. Highlighted necessity of judgement whether this small increment in QoL for this population compared to competing indications for the imaging resource used needed further consideration.
9 What is the effectiveness and cost effectiveness of performing X-ray compared with MRI to improve functional disability, pain or psychological distress?

No 233 Study Quality: Rapid magnetic resonance imaging vs radiographs for patients with low back pain: a randomized controlled trial

Author: Jarvik JG; Hollingsworth W; Martin B; Emerson SS; Gray DT; Overman S; Robinson D; Staiger T; Wessbecher F; Sullivan SD; Kreuter W; Deyo RA; 2003

Intervention: Rapid MRI

Comparison: X-ray

Population: LBP patients for whom a radiographic evaluation was ordered.

Perspective: SOCIETAL

Study type: CEA

Methods: RCT (n=380)

Health valuations: NOT APPLICABLE

Cost components: Health care services and societal

Currency: $

Cost year: 2001

Time horizon: 3 and 12 months

Discount rate: not used

Results-cost: For MRI - x-ray, there was an insignificant difference of $2121 - $1651 = $470 from health service perspective, and (insignif.) of $2380 - $2059 = $321 from societal perspective (bearing in mind that manual therapies are largely a private service that patients pay out of pocket and would therefore not be captured in health service perspective.

Results-effectiveness: No significant differences in clinical outcomes (Roland score, pain, SF-36)

Results-ICER: MRI appears more costly with unlikely incremental benefit (ratio statistic undefined)
Result-Uncertainty: High uncertainty, CE plane dispersion of bootstrap replications inconclusively wide

Source Funding: Public

Comments: Clinical trial outcomes are insignificant for the Roland scale, and even though there was some initial improvement at 3 months follow up, this disappeared by 12 months. All differences became even smaller when adjusted for baseline differences.

While intervention resulted in nearly identical outcomes for LBP patients, patients and physicians alike preferred MRI scanning to X-ray. However, since costs for MRI are likely to be higher than x-ray and there is a larger number of spine operations associated with MRI scanning, the authors do not recommend early MRI scanning until this interaction is better explained.

As for the diagnostic benefits, disk and facet joint degenerations were very common in both groups, there was no evidence of infection, tumor, inflammatory spondylitis in any one patient.
What is the effectiveness/cost effectiveness of general supervised exercise programmes or specific exercise training programmes (individual or group) compared with usual care on functional disability, pain or psychological distress?

No 616 Study Quality: United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: Cost effectiveness of physical treatments for back pain in primary care

Author: UK Back pain exercise and manipulation (UKBEAM) Trial Team; 2004

| Intervention: | Exercise programme |
| Comparison: | Best care |
| Population: | N = 1334 patients aged between 18 and 65 years who consulted their GP for simple low back pain. |
| Perspective: | NHS |
| Study type: | CUA |
| Methods: | RCT |
| Health valuations: | SG |
| Cost components: | Healthcare resources included: spinal manipulation package, exercise programme, hospital inpatient stay, outpatient attendance, general practice consultation. |
| Currency: | £ |
| Cost year: | 2000-2001 |
| Time horizon: | One year |
| Discount rate: | Costs not discounted because one year time horizon only |

Results-cost: Mean cost (Standard deviation) by treatment group: Best care in general practice = £346(602), best care+exercise=£486(907), best care +manipulation=£541(768), and best care+exercise +manipulation=£471(490).

Results-effectiveness: Mean (Standard deviation) QALYs over 12 months by treatment group: Best care in general practice=0.618(0.232), best care+exercise=0.635(0.245), best care+manipulation=0.659(0.241), and best care+exercise +manipulation=0.673(0.241).
care+exercise+manipulation=0.651(0.237).

Results-ICER:
Best care + exercise was dominated by combined treatment (best care+exercise+manipulation): that is, combined treatment cost less and gained more QALYs.
Best care+exercise+manipulation ICER was £3800 relative to best care.
Best care+manipulation ICER was £8700 relative to combined treatment (best care+exercise +manipulation).

Result-Uncertainty:
1) Excluding n=51 patients with health care costs more than £2000 (statistical outliers): best care+manipulation dominates other alternatives with a ICER of £3000 per additional QALY relative to best care..
2) Using private costs for manipulation that took place in private premises: combined treatment dominates best care+exercise with an ICER of £6600 compared with best care. Best care+manipulation then has an ICER of £8700 relative to combined treatment.
3) Using private costs for all manipulation in the trial: as for no. 2 best care+exercise is dominated and combined treatment has an ICER of £8600 compared with best care. Best care+manipulation has an ICER of £10,600 relative to combined treatment.

Source Funding:
Public

Comments:
The study acknowledges that it might have underestimated the benefits of exercise and manipulation therapies compared with “usual care” in general practice. This is because the study trained volunteer general practices in the active management of back pain, and provided trial participants with a copy of The Back Book. By using “best care” in general practice as the comparator, this reduces the opportunities for additional improvement.
What is the effectiveness/cost effectiveness of manual therapies compared with usual care on functional disability, pain or psychological distress?

Study Quality: United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: Cost effectiveness of physical treatments for back pain in primary care

Author: Manca A; 2004

Intervention: 1) Best care+exercise programme, 2) best care+spinal manipulation, and 3) best care +exercise + spinal manipulation combined.

Comparison: 4) Best care in general practice

Population: N= 1334 patients aged between 18 and 65 years who consulted their GP for simple low back pain.

Perspective: NHS

Study type: CUA

Methods: RCT

Health valuations: EQ-5D data mapped to EQ-5D single index

Cost components: Healthcare resources included: spinal manipulation package, exercise programme, hospital inpatient stay, outpatient attendance, general practice consultation.

Currency: £

Cost year: 2000-2001

Time horizon: One year

Discount rate: Costs not discounted because one year time horizon only

Results-cost: Mean cost (Standard deviation) by treatment group: Best care in general practice = £346(602), best care+exercise=£486(907), best care +manipulation=£54(768)1, and best care+exercise +manipulation=£471(490).

Results-effectiveness: Mean (Standard deviation) QALYs over 12 months by treatment group: Best care in general practice=0.618(0.232), best care+exercise=0.635(0.245), best care+manipulation=0.659(0.241), and best
Results-ICER:
Best care + exercise was dominated by combined treatment (best care+exercise+manipulation): that is, combined treatment cost less and gained more QALYs.
Best care+exercise+manipulation ICER was £3800 relative to best care.
Best care+manipulation ICER was £8700 relative to combined treatment (best care+exercise +manipulation).

Result-Uncertainty:
1) Excluding n=51 patients with health care costs more than £2000 (statistical outliers): best care+manipulation dominates other alternatives with a ICER of £3000 per additional QALY relative to best care.
2) Using private costs for manipulation that took place in private premises: combined treatment dominates best care+exercise with an ICER of £6600 compared with best care. Best care+manipulation then has an ICER of £8700 relative to combined treatment.
3) Using private costs for all manipulation in the trial: as for no. 2 best care+exercise is dominated and combined treatment has an ICER of £8600 compared with best care. Best care+manipulation has an ICER of £10,600 relative to combined treatment.

Source Funding:
Public

Comments:
The study acknowledges that it might have underestimated the benefits of exercise and manipulation therapies compared with “usual care” in general practice. This is because the study trained volunteer general practices in the active management of back pain, and provided trial participants with a copy of The Back Book. By using “best care” in general practice as the comparator, this reduces the opportunities for additional improvement.
What is the effectiveness/cost effectiveness of combined physical and psychological interventions compared with usual care/other interventions on functional disability, pain or psychological distress?

957 Effectiveness and cost-effectiveness of three types of physiotherapy used to reduce chronic low back pain disability: a pragmatic randomized trial with economic evaluation

No 957 Study Quality: Effectiveness and cost-effectiveness of three types of physiotherapy used to reduce chronic low back pain disability: a pragmatic randomized trial with economic evaluation

Author: Critchley DJ; Ratcliffe J; Noonan S; Jones RH; Hurley M; 2007

Intervention: Pain management (education and group exercise) and spinal stabilization physiotherapy

Comparison: Individual physiotherapy

Population: 212 people with 'chronic low back pain' were randomised. They had low back pain for longer than twelve weeks, with or without leg pain and were over 18 years old. They were excluded if they had previous spinal surgery, physiotherapy for low back pain in the last six months prior to trial or had specific medical conditions such as rheumatological diseases.

Perspective: NHS

Study type: CUA

Methods: RCT

Health valuations: TTO (EQ-5D)

Cost components: Treatment costs per protocol and all direct medical costs from individual resource utilisation.

Currency: £

Cost year: 2003/2004 (PSSRU, BNF and NHS reference costs)

Time horizon: 18 months

Discount rate: 3.5% for costs and outcomes

Results-cost: Total NHS costs (SD) per patient were £474 (£840) in the individual physiotherapy control group, £379 (£1040) in the spinal stabilisation intervention group, and £165 (£202) in the pain management/education intervention group.
Results-effectiveness: The QALY gains (SD) were 0.99 (0.27) in the individual physiotherapy control group, 0.9 (0.37) in the spinal stabilisation intervention group, and 1.00 (0.28) in the pain management/education intervention group.

Results-ICER: Pain management/education was less costly and marginally more effective than the other interventions, thus dominates. Relative to spinal stabilisation, individual physiotherapy is marginally more expensive and slightly more effective with a mean incremental cost effectiveness ratio of £1055 per QALY.

Result-Uncertainty: The CEAC show that across all presented WTP thresholds, pain management/education was most cost effective, with the curve sloping downwards as the imprtance of the cost advantage diminishes as WTP for a QALY increases. The probability that spinal stabilisation is cost effective was shown negligible throughout. Given a WTP of £30,000 per QALY, there is ~65% probability the pain management/education intervention will be cost effective, and ~35% that the usual physiotherapy is cost effective. Sensitivity analysis of missing values and outliers showed the rationale to be robust.

Source Funding: Public

Comments: 1. Authors stretch that pain management is not suitable for all patients, for example where multiple and complex problems or language difficulties are an issue. These results should thus not be interpreted as meaning that all patients with back pain should receive pain management.

2. Possible explanations for difference to BEAM results: pain management programme had a larger, structured, educational component specifically aimed at improving self management, which may explain lower health service utilisation in this study arm. Also, BEAM patients had back pain for shorter period of time. As psychological factors become increasingly important with chronicity, an intervention specifically addressing distress and beliefs may have been of greater benefit to the more chronic population.

3. There was an issue with drop outs across the groups, and it should be noted that this has an effect on the findings and interpretation. Attrition was highest in the pain management/education group, confirming patient reports that attending classes was difficult to some patients. 25% did not provide data at 18 months. Those remaining on trial were older, more likely to be female, less disabled. Most notably, there were pronounced differences in socioeconomic characteristics. Nonresponders were more likely to be off work due to back problems, in social housing and receiving state benefit.
What is the effectiveness and cost effectiveness of opioids compared with placebo, paracetamol, anti-depressants or oral NSAIDS on functional disability, pain or psychological distress?

Intervention: Tramadol/paracetamol

Comparison: Immediate-release tramadol

Population: Lower back pain (3 CMA subacute LBP, 1 CUA moderate to severe LBP, lasting longer than 6 weeks)

Perspective: Health insurance perspective in CMA; perspective of CUA not stated.

Study type: Review of 4 models in LBP patients, 3 CMA and 1 CUA.

Methods: Not stated for CMAs, evidence review and panel data for CUA.

Health valuations: Not stated, see above.

Cost components: CMA: costs of 10 days worth of treatment with either regimen from the health insurance system. CUA: direct and indirect costs, perspective not stated.

Currency: EURO

Cost year: Not reported.

Time horizon: CMA: 10 days, CUA

Discount rate: Not reported.

Results-cost: The authors report a QALY gain from the Spanish CUA (which is a congress paper and has not been published), and explain this with lower adverse event rates and lower drop-outs.

Results-effectiveness: The intervention is thought to be cost-saving, and reasons reported were reduced costs for adverse events and fewer specialist referrals. The Dutch, Spanish and Austrian CMAs also report fewer costs for the intervention than the comparator, which seem to confirm this result.
The review concludes that the intervention Tramadol/Paracetamol dominates the comparator. An ICER has not been reported.

The authors claim that “sensitivity confirmed these benefits despite wide-ranging changes in the values of input parameters (usually 30% above or below baseline value)”.

Not stated.

This paper reviewed economic models. It reports the findings of three cost minimization studies and one cost utility study for LBP patients. Apart from these studies, which compared paracetamol/tramadol with immediate-release tramadol in patients with lower back pain, the review reports results for codeine/paracetamol combination in patients with post surgical pain, as well as NSAID comparator in osteoarthritis patients.

There are concerns with the methodology of this review. The assumption that if effectiveness results are insignificant in trials effectiveness is equal has led modellers in the past to conduct CMA. However, in these circumstances this assumption is today widely viewed as flawed.

Regarding the evidence base, only one of the four models cited and presented was actually published. Two CMA are internal documents of Gruenenthal GmbH, a manufacturer of a drug equaling the intervention. The CUA is a conference paper which has not been published, either.

Moreover, there was a lack of information regarding cost-components, perspective and sensitivity analyses performed.
What is the effectiveness/cost effectiveness of acupuncture (including PENS & neuroflexotherapy) compared with usual care or sham on functional disability, pain or psychological distress?

A randomised controlled trial of acupuncture care for persistent low back pain: cost effectiveness analysis

Author: Ratcliffe J;Thomas KJ;MacPherson H;Brazier J; 2006

Intervention: Acupuncture: ten individualised acupuncture treatments over 3 months

Comparison: Usual care: commonly entailed a mix of medication, physiotherapy and recommended back exercises

Population: The study included 241 patients between the ages of 20 and 65 years, whose current episode of back pain was at least of 4 weeks duration and no longer than 12 months.

Perspective: NHS

Study type: CUA

Methods: RCT

Health valuations: SF-36 trial data converted to a single index the SF-6D. (0=death, 1=perfect health)

Cost components: Healthcare costs included: Acupuncture, NHS visits including inpatient, outpatient and primary care contacts.

Currency: £

Cost year: 2002/2003

Time horizon: 24 months

Discount rate: Costs and QALYs discounted at NICE conventional 3.5% rates

Results-cost: Mean costs of acupuncture=£460
Mean costs of usual care=£345

Results-effectiveness: Mean QALY per acupuncture patient=1.453
Mean QALY per usual care patient=1.430

Results-ICER: Base case estimate of £4241 per QALY gained from acupuncture
Result-Uncertainty: 1) Imputing missing data relating to NHS costs or QALYs the ICER for acupuncture was £4209 at 24 mths
2) When patients who were permanently unable to work because of back pain were excluded (reason being that these patients would have higher costs and poorer outcomes) the ICER was £2104
3) By including lost productivity costs (from time off work with back pain) acupuncture treatment dominated usual care because of the overall cost savings from using acupuncture treatment.

Source Funding: Public

Comments: There is a modest health gain from acupuncture compared to usual care and the extra cost to the NHS is minor. The cost per QALY gained from acupuncture is £4241. Inclusion of patient costs and the costs of lost productivity due to low back pain further strengthens the economics of acupuncture.
What are the indications for referral for surgery based on the effectiveness/cost effectiveness of surgical treatments compared with non-surgical treatment or no treatment on functional disability, pain or psychological distress

<table>
<thead>
<tr>
<th>No</th>
<th>Study Quality:</th>
<th>Surgical stabilisation of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: cost utility analysis based on a randomised controlled trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author:</td>
<td>Rivero AO;Campbell H;Gray A;Fairbank J;Frost H;Wilson MJ; 2005</td>
<td></td>
</tr>
<tr>
<td>Intervention:</td>
<td>Surgical stabilisation of the spine</td>
<td></td>
</tr>
<tr>
<td>Comparison:</td>
<td>Intensive rehabilitation</td>
<td></td>
</tr>
<tr>
<td>Population:</td>
<td>N=349 patients aged 18-55 with chronic low back pain of at least one year’s duration who were considered candidates for spinal fusion.</td>
<td></td>
</tr>
<tr>
<td>Perspective:</td>
<td>NHS</td>
<td></td>
</tr>
<tr>
<td>Study type:</td>
<td>CUA</td>
<td></td>
</tr>
<tr>
<td>Methods:</td>
<td>RCT</td>
<td></td>
</tr>
<tr>
<td>Health valuations:</td>
<td>TTO</td>
<td></td>
</tr>
<tr>
<td>Cost components:</td>
<td>NHS resources including: initial treatments, other back pain related hospital inpatient and outpatient visits, primary care contacts, and prescribed items of medication.</td>
<td></td>
</tr>
<tr>
<td>Currency:</td>
<td>£</td>
<td></td>
</tr>
<tr>
<td>Cost year:</td>
<td>2002/2003</td>
<td></td>
</tr>
<tr>
<td>Time horizon:</td>
<td>24 months</td>
<td></td>
</tr>
<tr>
<td>Discount rate:</td>
<td>Annual rate of 3.5%.</td>
<td></td>
</tr>
<tr>
<td>Results-cost:</td>
<td>£7830 (SD=£5202) for surgical patients  £4526 (SD=£4155) for intensive rehabilitation  Difference = £3304 (£2317 to £4291, p&lt;0.001)</td>
<td></td>
</tr>
<tr>
<td>Results-effectiveness:</td>
<td>For surgical patients QALYs at 24 months =1.004 (SD=0.405)  For intensive rehabilitation patients QALYs at 24 months =0.936(SD=0.431)</td>
<td></td>
</tr>
</tbody>
</table>
Difference = 0.068 (-0.02 to 0.156)

Results-ICER:
Incremental cost per QALY of using surgery immediately as opposed to intensive rehabilitation = £48,588 (-£279,883 to £372,406)

Result-Uncertainty:
1. If patients who had surgery had least expensive technique incremental cost per QALY = £35,338 (-£188,876 to £410,404)
2. If patients who had surgery had most expensive technique incremental cost per QALY = £60,765 (-£420,210 to £617,081)
3. If QALY difference between the two groups was maintained at four years then incremental cost per QALY = £25,398 (£13,121 to £75,916)
4. If patients in the study continued to receive both treatments in years three, four and five at the rates observed in years one and two, the incremental cost per QALY = £16,824 (-£156,358 to £138,911)
5. If patients in the study continued to receive both treatments in years three, four and five at half the rates observed in years one and two, the incremental cost per QALY = £31,838 (-£407,056 to £283,783)

Source Funding:
Public

Comments:
This economic evaluation took a pragmatic approach in that patients were not denied alternative interventions for their back pain. At 24 months there were more patients in the intensive rehabilitation group who had both treatments (n=38) than in the surgical group (n=7). If this difference were to continue it would substantially affect the cost effectiveness of surgery.