Counterfactual for Revalidation

Report to the General Chiropractic Council

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1 INTRODUCTION

1.1 The purpose of this paper is to determine the counterfactual against which the costs and benefits of revalidation could be measured.

1.2 To this end, we analyse the various forms of adverse events, including sub-optimal outcomes, which occur in the chiropractic profession today and determine which of these might reasonably be affected by revalidation. Using the model we developed for the Department of Health, we estimate in monetised QALY terms the magnitude of adverse events and sub-optimal outcomes over the next 10 years in the absence of revalidation.

1.3 This report is structured as follows:

(a) Section 2 presents the results of our recent survey of the profession;

(b) Section 3 presents a brief outline of important assumptions used in the model;

(c) Section 4 presents quantitative results of the counterfactual scenario;

(d) Section 5 concludes; and

(e) Appendix 1 presents an overview of EQ-5D and QALYs, which are the basis of many quantitative estimates in this paper.

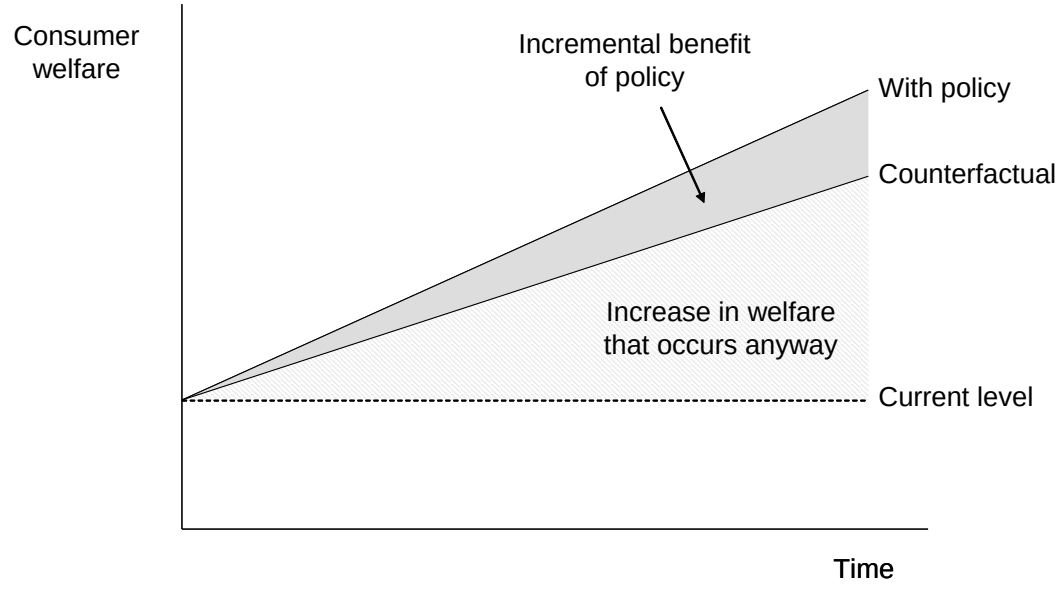
The Counterfactual

1.4 The counterfactual forms the basis of this report and hence it is important to clarify the definition of this term to economists.

1.5 The counterfactual is not the status quo, but the forecast of what would happen over the relevant period on the assumption of unchanged policies.

1.6 The importance of defining the counterfactual is illustrated by Figure 1.1, which takes the example of a policy which is aimed at increasing the welfare of users in a particular market. The diagram shows that welfare is expected to increase through time under the counterfactual scenario. In chiropractic, this might be because of increased use of the CPiRLS system, for instance, which could lead to an improved average patient experience. If the impact assessment were to ignore this and assume that any increase in welfare above its current level was attributable to the policy, then the benefits of the policy would be significantly over-estimated.

Figure 1.1: The Importance of Defining a Counterfactual



Source: Europe Economics

Definition of the counterfactual

1.7 To define the counterfactual it is necessary to complete each of the following steps:

(a) specify a period for the forecast;

(b) specify what are assumed as "unchanged policies";

(c) specify the factors to be forecast (depending on the nature of the policy option being considered). These will include health outcomes, adverse events, indications of severity of adverse events;

(d) specify and assess factors that are likely to influence factors to be forecast, e.g.:

- demographic
- market trends
- technology
- other

(e) forecast the numbers of users that might be affected; and

(f) forecast the number of events that might be affected.

Counterfactual quantification

1.8 The counterfactual will, where possible, be quantified in terms of QALYs lost as compared with no adverse incidents or outcomes below what would reasonably have been expected following treatment.

1.9 The comparison is not of what might be the outcome in a perfect world but what would be the outcome if everything went as well as could reasonably be expected. Treatments or care policies sometimes fail because the science is not perfectly understood but this is not a failure of regulation or of professional practice.

2 SURVEY OF THE PROFESSION

2.1 A survey of the chiropractic profession was undertaken between 9 April and 7 May 2010. The aim of this survey was to fill gaps in existing knowledge and to provide updated estimates of certain aspects of the profession.

Dissemination

2.2 The GCC provided Europe Economics with the contact details of all current registrants. Europe Economics circulated the survey by email wherever possible and requested that recipients respond (anonymously) to the questionnaire through the Survey Methods website. Hard copies of the questionnaire, together with a stamped addressed envelope, were sent to those for whom no email address was held. Hard copies were also sent where we received notification that our email had not been delivered to the recipient.

2.3 As the survey progressed, it became apparent that some chiropractors were unaware of the survey until they were contacted by their association or held talks with other chiropractors. The main explanations for this appear to have been that the chiropractor is using a different email address to that held by the GCC or the email went into the chiropractor's junk email folder and was automatically deleted (several chiropractors have informed Europe Economics that they found the survey in their junk folder). Copies of the survey were re-sent to all those that contacted Europe Economics stating that they had not received a survey.

Deadlines and Responses

2.4 An initial deadline for responding to the survey was set for 23 April 2010 and 361 responses were received prior to this date. The deadline was extended by a further two weeks and an additional 133 responses were received, giving a total of 494 responses prior to the final deadline (approximately 20 per cent of the profession).

2.5 The rationale for extending the deadline for responses was not only to try to increase the response rate but also to permit a statistical analysis of differences between samples to be undertaken.

2.6 Such an analysis is extremely important for any survey with a response rate below 100 per cent because it is possible that the characteristics of respondents differ from those of non-respondents. If this were the case, then extrapolating the results of a survey to the whole population would be inappropriate, since the population estimate based on a sample statistic would be biased.

2.7 By treating early- and late-respondents as separate groups, however, it is possible to use statistical tests to gain some reassurance that the characteristics of non-respondents are likely to be similar to those of respondents and hence that extrapolating results to the whole profession would be appropriate.

2.8 In particular, the test relies on the idea that if the characteristics of early-respondents differ from those of late-respondents then it is likely that the characteristics of non-respondents differ from those of either group of respondents. However, if the characteristics of early- and late-respondents can be treated as identical then we have no evidence to indicate that the characteristics of non-respondents are not identical also.

2.9 Following this approach, we have conducted 't-tests' on the results of the most basic quantitative survey questions, namely Q3, Q5, Q6, Q7 and Q8. In particular, we tested that the two samples are from the same population.[1] Separate results are presented below for a test in which the variance is assumed to be the same in both samples and a test in which it is assumed to differ. We have also conducted an F-test to test for differences in sample variance.

	t-test (p-value)	**F-test (p-value)**
Question 3	0.31	0.67
Question 5	0.74	0.20
Question 6	0.63	0.85
Question 7	0.71	0.52
Question 8	0.17	0.06

2.10 To interpret the table above, it is necessary to know that the null hypothesis that the samples are from different populations is conventionally rejected if the p-value is less than 0.05. None of the entries in the table above are less than 0.05 and hence in all cases it can be concluded that the sample of early respondents come from the same population as the sample of late respondents.

2.11 As a result of this finding, we have totalled and averaged results across the full sample of respondents and present only the results of the combined samples below.

Results

2.12 This section presents the results of the survey in the form of tables and charts, where appropriate. For quantitative questions, we present sample means wherever respondents

[1] Technical note: The t-test assumes that the data are normally distributed but it is obvious from the results presented below that distributions are non-normal. However, the Central Limit Theorem (which states that as the sample size increases, the distribution of the sample average approaches the normal distribution with mean equal to the population mean and variance equal to the population variance) guarantees that the test is valid for 'large' samples.

The definition of 'large' is not fixed, but can be as little as 30 observations per sample if the samples are approximately normally distributed. The greater the departure of the sample distribution from normality, the greater the number of observations required for a sample to be classified as 'large'. However, sample sizes of more than 100 observations are generally thought to be 'very large' and hence that the Central Limit Theorem would be valid. Given that we have more than 100 responses in both the before deadline and after deadline samples, we are permitted to invoke the Central Limit Theorem and use the t-test to test for differences between sample means.

were asked to specify a particular number or percentage, and present weighted averages wherever respondents were asked to specify one out of many possible ranges.

2.13 In this context, a weighted average is calculated by multiplying the mid-point of each range by the percentage of respondents that specified that particular range (hence the percentages are the 'weights' in the calculation). The resulting figures are then summed to give the weighted average.

2.14 We do not present a narrative of the results at this point, but will instead consider the most important results in subsequent sections of this report.

Question 1

Do you work in a practice with other chiropractors or are you the only chiropractor in your practice?

	Number of responses	**Percentage**
Only chiropractor in practice	206	41.8
Work with other chiropractors	287	58.2

Total number of responses to question: 493

Question 2

Do you keep electronic or paper patient records?

	Number of responses	**Percentage**
Paper records	336	68.2
Electronic records	33	6.7
Both	124	25.2

Total number of responses to question: 493

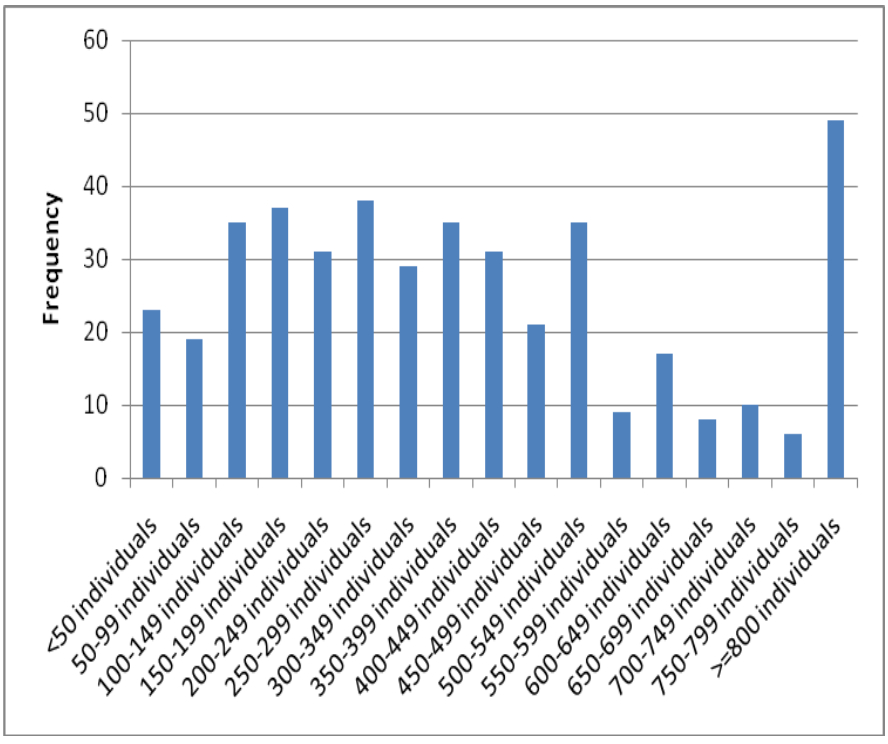
Question 3

We wish to estimate the total number of individuals that visit a chiropractor at least once during the course of the year. This could be a new patient, or an existing patient coming back for a repeat visit. Please estimate the number of different individuals that you provide care to each year on the basis of your most recent records.

	Number of responses	Percentage
<50 individuals	23	5.31
50-99 individuals	19	4.39
100-149 individuals	35	8.08
150-199 individuals	37	8.55
200-249 individuals	31	7.16
250-299 individuals	38	8.78
300-349 individuals	29	6.70
350-399 individuals	35	8.08
400-449 individuals	31	7.16
450-499 individuals	21	4.85
500-549 individuals	35	8.08
550-599 individuals	9	2.08
600-649 individuals	17	3.93
650-699 individuals	8	1.85
700-749 individuals	10	2.31
750-799 individuals	6	1.39
>=800 individuals	49	11.32

Total number of responses to question: 433; Median = 350-399 individuals

Weighted average = 387.7 individuals



Question 4

Please specify the amount of time in minutes you typically spend with a patient on the initial and subsequent visits.

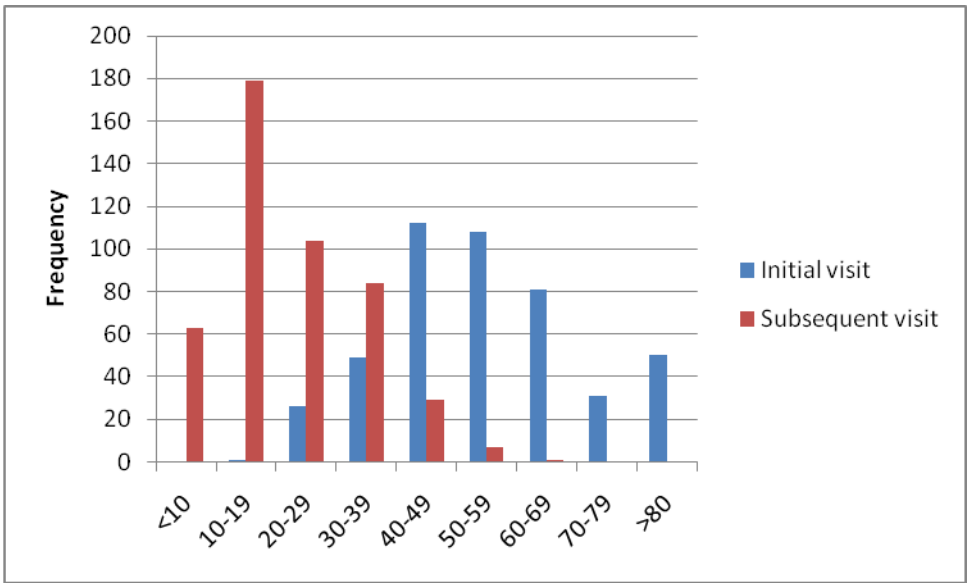
	Initial Visit		Subsequent visit	
Number of Minutes	**Number**	**Percentage**	**Number**	**Percentage**
<10	0	0.0	63	13.5
10-19	1	0.2	179	38.3
20-29	26	5.7	104	22.3
30-39	49	10.7	84	18.0
40-49	112	24.5	29	6.2
50-59	108	23.6	7	1.5
60-69	81	17.7	1	0.2
70-79	31	6.8	0	0
>80	50	10.9	0	0

Total number of responses to question: Initial visit – 458; Subsequent visit – 467;

Median: Initial visit –10-19 minutes; Subsequent visit – 50-59 minutes

Weighted average (initial visit) = 54.5 minutes

Weighted average (subsequent visit) = 21.5 minutes



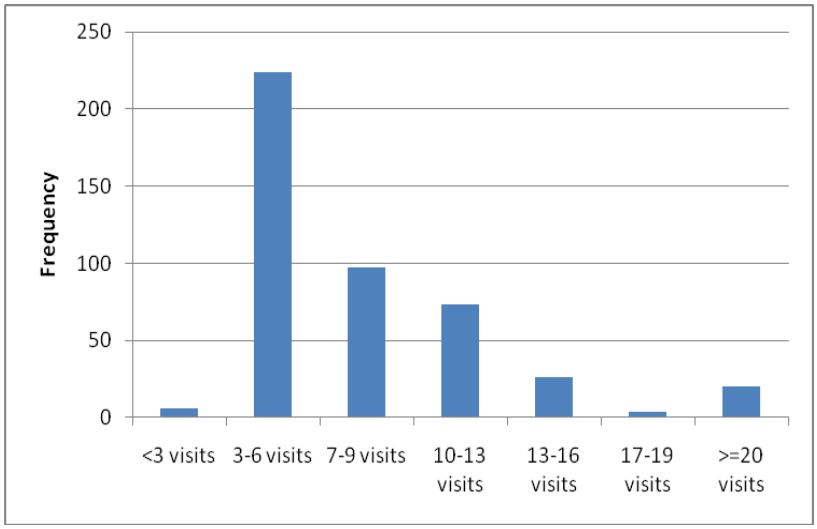
Question 5

Please estimate the typical number of treatment sessions you would provide for a programme of care for patients receiving symptomatic care (i.e. excluding those that receive ongoing/maintenance/asymptomatic care).

	Number of responses	Percentage
<3 visits	6	1.3
3-6 visits	224	49.8
7-9 visits	97	21.6
10-13 visits	73	16.2
13-16 visits	26	5.8
17-19 visits	4	0.9
>=20 visits	20	4.4

Total number of responses to question: 450. Median = 3-6 visits

Weighted average = 7.8 visits



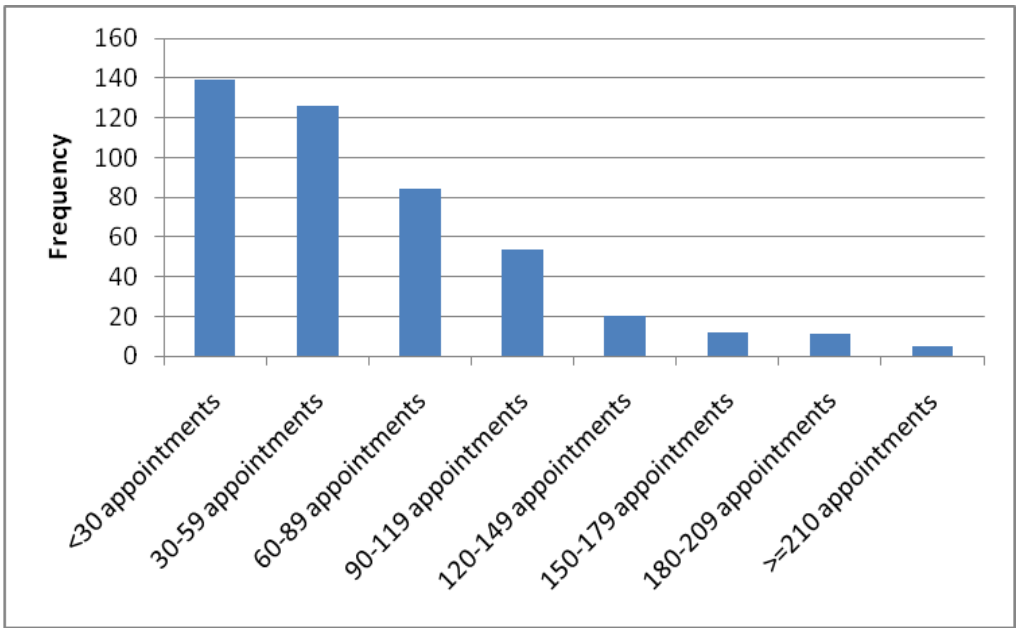
Question 6

Please estimate the number of appointments that you fulfil each week, on average.

	Number of responses	Percentage
<30 appointments	139	30.8
30-59 appointments	126	27.9
60-89 appointments	84	18.6
90-119 appointments	54	12.0
120-149 appointments	20	4.4
150-179 appointments	12	2.7
180-209 appointments	11	2.4
>=210 appointments	5	1.1

Total number of responses to question: 451. Median = 30-59 appointments

Weighted average = 61.4 appointments



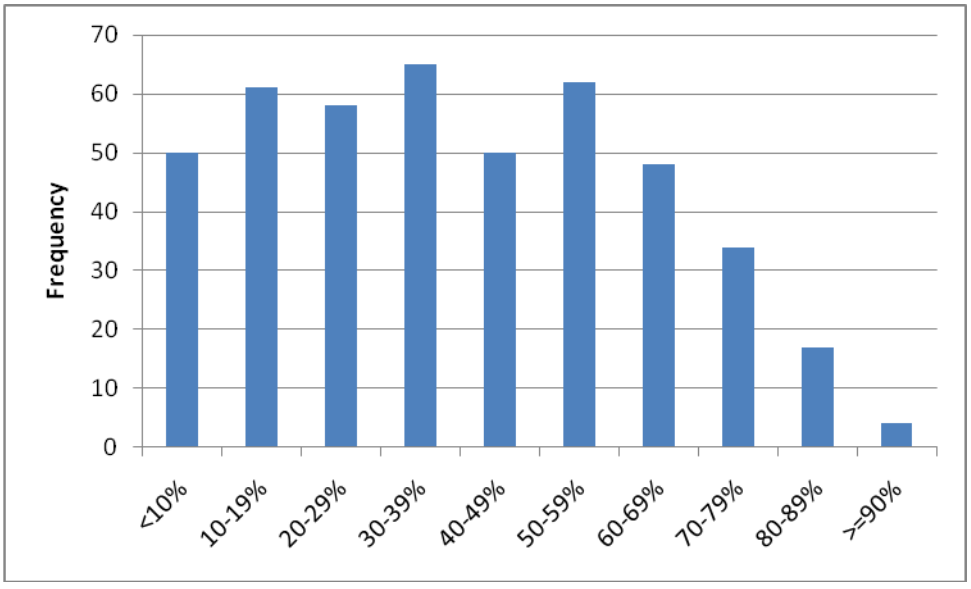
Question 7

Please estimate the percentage of your patients that receive ongoing/maintenance/asymptomatic care at any one time.

	Number of responses	Percentage
<10%	50	11.1
10-19%	61	13.6
20-29%	58	12.9
30-39%	65	14.5
40-49%	50	11.1
50-59%	62	13.8
60-69%	48	10.7
70-79%	34	7.6
80-89%	17	3.8
>=90%	4	0.9

Total number of responses to question: 449. Median = 30-39%

Weighted average = 40.2%



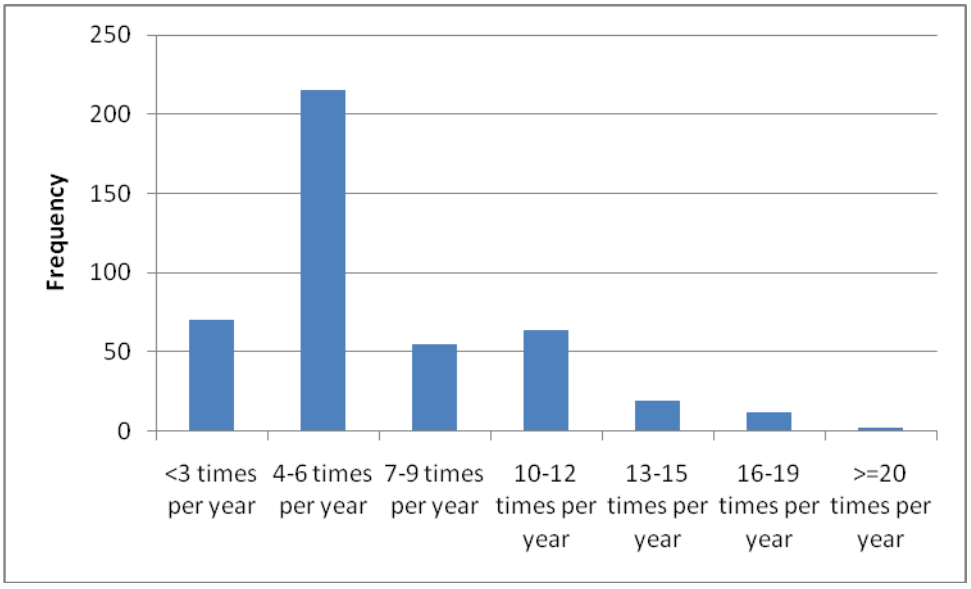
Question 8

We are interested in finding out roughly how many times per year you would see an individual patient who is attending for ongoing/maintenance/asymptomatic care.

	Number of responses	Percentage
<3 times per year	70	16.0
4-6 times per year	215	49.2
7-9 times per year	55	12.6
10-12 times per year	64	14.7
13-15 times per year	19	4.4
16-19 times per year	12	2.8
>=20 times per year	2	0.5

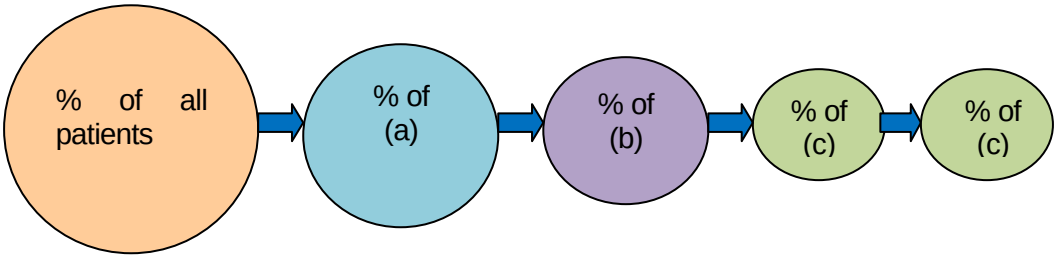
Total number of responses to question: 437. Median = 4-6 times per year.

Weighted average = 6.5 times per year



Question 9

This question explores the use of patient records in chiropractic. The purpose is to assess whether or not the quality of patient records has any impact on patient care. The question is structured in five steps where, other than step (e), each step considers a smaller pool of patients than the previous steps. The following diagram illustrates this idea:



	Other chiropractor is from…	
Percentage of your patients who will have had records of their assessment and care made by other chiropractors	**…within own practice**	**…different practice**
(a) Percentage of your patients that visited another chiropractor before seeking chiropractic care from you	9.8%	12.7%
(b) Percentage of patients identified in **(a)** for whom you based their chiropractic care on the patient records of the other chiropractor(s)	27.7%	4.5%
(c) Percentage of patients identified in **(b)** whose records were of poor quality	3.3%	7.7%
(d) Percentage of patients identified in **(c)** where the poor quality records had an impact on the quality of care you provided to the patient	2.1%	2.3%
(e) Percentage of patients identified in **(c)** where the poor quality records led to an increase in the time required for the appointment	10.9%	8.9%

Total number of responses to question: 336 (excludes entries such as N/A etc.)

The table above can be used to estimate the percentage of **all** patients where poor quality records of another chiropractor have had an impact on their care or led to an increased appointment time. The results of these calculations are shown in the table below.

	Other chiropractor is from…	
Percentage of your patients who will have had records of their assessment and care made by other chiropractors	**…within own practice**	**…different practice**
Percentage of all patients that visited another chiropractor before seeking chiropractic care from you	9.8%	12.7%
Percentage of all patients for whom chiropractic care was based on the patient records of the other chiropractor(s)	2.7%	0.6%
Percentage of all patients whose records were of poor quality, given that care was based on these records	0.1%	0.04%
Percentage of all patients where the poor quality records had an impact on the quality of care provided to the patient, given that care was based on the poor quality records	0.0019%	0.001%
Percentage of patients where the poor quality records led to an increase in the time required for the appointment, given that care was based on the poor quality records	0.01%	0.0039%

Question 10

Did you include locums in the "from within own practice" figures?

	Number of responses	Percentage
Yes	86	21.2
No	320	78.8

Total number of responses to question: 406

Question 11

What proportion of your own patients do you believe, on reflection, could have had a better outcome if their care had been managed and/or implemented differently?

Average = 4.15 per cent

Total number of responses to question: 482

Of the total number of 482 responses, 201 chiropractors specified that zero per cent of their patients have had a sub-optimal outcome and 281 specified a non-zero percentage. Responses to Question 12 were only included in our analysis if a non-zero response was given for Question 11.

Question 12

Please rank causes of sub-optimal outcomes in terms of importance, based on your experience with your own patients, where 1 represents most important and 8 represents least important. If you do not have a view of the importance of some of these causes please enter N/A and rank the remaining causes in order of importance.

Also, please estimate the percentage of sub-optimal outcomes that are accounted for by each cause listed in the table, again based on your experience with your own patients. We recognise that this will be an estimate and will not come from patient records. Note that zero is an acceptable response for any of the categories below but that the total should sum to 100%.

Cause of sub-optimal outcome	**Average Ranking**	***Implied rank order***	**Avg. percentage of sub-optimal outcomes**	***Ranking inferred from incidence of sub-optimal outcomes***
Delayed diagnosis	4.0	4	12.2	3
Missed diagnosis	3.2	1=	9.0	4
Delayed recognition of contra-indication	4.2	5	5.0	6
Missed recognition of contra-indication	3.3	3	3.1	7
Failure to refer in timely manner	4.8	6=	6.8	5
Failure to refer at all	4.8	6=	2.5	9
Inadequate care management	5.1	8	13.8	2
Patient non-compliance	3.2	1=	61.1	1
Poor record-keeping of other chiropractors	6.3	10	2.1	10
Your own poor record-keeping	6.1	9	2.8	8

Total number of responses to question: 178

Please note that responses to this question were only included where a percentage greater than zero was specified in Question 11 and where allocated percentages in Question 12 summed to 100%. As noted above, 201 chiropractors specified that zero per cent of their patients have had a sub-optimal outcome and 281 specified a non-zero percentage in Question 11. The responses to Question 12 summed to 100% for 216 chiropractors but summed to less than 100 per cent for 59 chiropractors.

Question 13

We are interested in learning about adverse events in chiropractic. What percentage of your patients do you believe have experienced an adverse event (i.e. suffered an unintended unfavourable outcome) through your chiropractic care, in the last 12 months? Please note that zero is an acceptable response if you believe that no patient has suffered an adverse event as a result of your care.

Average = 2.58 per cent

Total number of responses to question: 486

Please note that 261 chiropractors specified that zero per cent of their patients have had an adverse event and 225 specified a non-zero percentage. This distinction is important because responses to Question 14 were only included in our analysis if a non-zero response was given for Question 13.

Question 14

The entries in the left-hand column of the table below are possible causes of adverse events in chiropractic. Please rank these from 1 to 6 in terms of importance (based on your experience with your own patients), where 1 represents most important and 6 represents least important. Also, please estimate the percentage of adverse events that are accounted for by each cause listed in the table, again based on your own patients.

Cause of adverse event	**Rank (1-6, each number entered only once)**	***Implied rank order***	**Percentage of adverse events**	***Ranking inferred from incidence of adverse events***
Delayed diagnosis	3.1	3	23.4	2
Missed diagnosis	2.5	1	17.5	3
Delayed recognition of contra-indication	3.2	4	16.1	4
Missed recognition of contra-indication	2.8	2	10.7	5
Inadequate management	3.6	5	44.2	1
Poor record-keeping of other chiropractors	5.4	6	6.3	6

Total number of responses to question: 116

Please note that responses to this question were only included where a percentage greater than zero was specified in Q13 and where allocated percentages in Question 14 summed to 100 per cent. As noted above, 261 chiropractors specified that zero per cent of their patients have had an adverse event and 225 specified a non-zero percentage in Question 13. The responses to Question 14 summed to 100 per cent for 149 chiropractors but summed to less than 100 per cent for 35 chiropractors.

3 MODELLING ASSUMPTIONS

3.1 As noted above, the survey of the profession was designed to elicit information that would be useful in quantifying the counterfactual, i.e. in estimating the number of adverse events and sub-optimal outcomes that would occur over the next ten years in the absence of a revalidation scheme. As such, a number of assumptions presented are based directly on the basis of survey results.

3.2 However, a survey is not the most appropriate method of gathering certain types of information and hence numerous other sources have been used to inform modelling assumptions. For example, we have conducted wide-ranging reviews of the healthcare literature to uncover information on the QALY values attached to chiropractic care, best care in general practice, rib fractures and cancer. We have also reviewed scientific literature on dosage levels involved in exposure to ionising radiation in the context of chiropractic care and the risk of cancer attached to this.

3.3 Table 3.1 below presents the key assumptions that have been used in our model.

Table 3.1: Key assumptions

Variable	Assumed value	Rationale
QALY gain through chiropractic care	0.083	UK BEAM trial
QALY gain through best GP care	0.032	UK BEAM trial
Value of QALY	£30,000	NICE recommendation
Number of patients per chiropractor	388	Europe Economics survey of profession
Increase in number of chiropractors per annum	100	Based on trend between 2004 and 2008
Percentage of patients with sub-optimal outcome (central estimate)	4.5%	Europe Economics survey of profession
Duration of sub-optimal outcome	2.5 months	Based on Europe Economics survey of profession
Incidence of cancer in whole population (not chiro-specific)	294,000 p.a.	Cancer Research UK
Unjustified exposures to ionising radiation per year	3.25	PCC findings
Cancer risk from X-ray	Approx. 1 in 12,000	ICRP
QALYs lost through cancer	4.1	Calculated from WHO estimates
Poor conduct (instances per annum)	74	Association complaints statistics (doubled)
Rib fractures per annum	4	CPiRLS and BCA statistics
QALYs lost through rib fracture	0.017	Kanis et al. (2004)
Poor record keeping has impact on patient care (within practice)	0.0019%	Europe Economics survey of profession
Poor record keeping has impact on patient care (outside practice)	0.001%	Europe Economics survey of profession
Poor record keeping increases appointment length (within practice)	0.01%	Europe Economics survey of profession
Poor record keeping increases appointment length (outside practice)	0.0039%	Europe Economics survey of profession
Cost of chiropractic adjustment	£35.00	Expert Group agreement
Cost of initial appointment	£87.50	Based on Expert Group costing of repeat appointment and survey response for appointment duration

3.4 The majority of these assumptions are discussed greater detail in the following section but as the UK BEAM trial is a crucially important source of information in the context of the counterfactual, it is discussed in detail below.

The UK BEAM Trial

3.5 The UK BEAM trial, published in the British Medical Journal (BMJ) in 2004, sought to assess the effectiveness and cost-effectiveness of spinal manipulation, exercise or spinal manipulation plus exercise to "best care" in general practice.[2] It is one of few studies of care for low back pain to quantify the impact of interventions in QALY terms. It is therefore an extremely important study in the context of our project.

3.6 The authors recruited 1,334 participants for the trial, of which 1,287 were included in the effectiveness and cost-effectiveness analysis. Participants were randomly allocated to one of four groups, one of which received only "best care" in general practice, one of which received spinal manipulation in addition to best care, one of which participated in a class-based exercise programme in addition to best care and one of which received both spinal manipulation and an exercise programme in addition to best care in general practice. The group which received best care in general practice represented the control group or 'counterfactual' in this study, i.e. observations of this group showed the change in QALYs that would have occurred in the absence of manipulation or exercise.

3.7 The spinal manipulation package was agreed by the UK chiropractic, osteopathy and physiotherapy professional associations. Within each group designated to receive spinal manipulation, patients were randomised into a group that received spinal manipulation in NHS premises and a group that received the treatment in private premises. The primary clinical study outcome was the patient's improvement on the Roland disability questionnaire after three months and 12 months.

3.8 The clinical study found that all groups improved over time, and that adding exercise, manipulation or both exercise and manipulation to best care in general practice resulted in a greater improvement as measured by the Roland disability questionnaire. The greatest improvement at both three and 12 months was noted in the manipulation plus exercise group, although the improvement observed in the manipulation group was only slightly less. Exercise led to a greater improvement than best care at three months but no difference was observed at 12 months. No difference in outcome was observed between the groups that received manipulation in NHS premises and those that received manipulation in private premises.

3.9 Based on these results, it appears that outcomes for patients would be superior in cases where the chiropractor recommends an exercise package in addition to providing spinal manipulation and hence lends some support to the importance of the whole package of chiropractic care, not just spinal manipulation.

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[2] UK BEAM Trial team, "United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care", BMJ (2004) and "United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care", BMJ (2004)

3.10 The corresponding economic paper from the UK BEAM trial considers the general health benefits of care in contrast to the clinical paper which measured benefits specific to back pain.

3.11 Relative to best care in general practice, the cheapest treatment is exercise plus manipulation. The reason for this is that whilst treatment costs are greater, subsequent hospital inpatient, hospital outpatient and general practice consultation costs are lower than for either exercise alone or manipulation alone.

3.12 In order to assess the benefits, the economic study proceeds as follows. At baseline, before treatment began, the mean QALYs reported by all groups are reasonably similar, at 0.597, 0.556, 0.592 and 0.596.

3.13 Having adjusted the pre-treatment QALY score so as to take account of initial QALY differences between groups, the authors calculate the mean QALYs experienced by members of each group over the following twelve months. The 'best' treatment is defined as that with the greatest mean QALYs over a period of twelve months, and the effectiveness of this treatment is defined as the difference in mean QALYs between this treatment and best care in general practice.

3.14 This approach differs from that employed in the accompanying clinical paper, which compares the change in Roland disability score obtained in best care with the change obtained through each of the additional interventions at three months and twelve months. The decision by the authors of the economic paper to average QALYs results in an information loss and, we believe, leads the authors to a surprising conclusion, namely that "manipulation alone probably gives better value for money than manipulation followed by exercise".[3]

3.15 We think that the same approach should be used to determine 'effectiveness' (the outcome of the clinical paper) and 'cost-effectiveness' (the outcome of the economic paper) and that a sounder conclusion is reached by using the clinical report approach.

3.16 The clinical approach measures improvements at both three and 12 months, whereas the economic approach relies solely on an average of the two. At three months, manipulation alone gives the better results, whereas at 12 months the better results are from combined exercise and manipulation, perhaps because exercise has taken more time to be effective. Whatever the reason, more weight should be given to the longer-term measure, as this is likely to be the best indicator of what will happen thereafter.

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[3] UK BEAM Trial team, "United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care", BMJ (2004), Page 1 (Abstract)

3.17 Using our preferred approach of comparing QALYs gained at three and 12 months rather than mean QALYs, the results of the cost-effectiveness analysis are as presented in Table 3.2.

Table 3.2: Results of the UK BEAM Trial

	Best care in general practice	Best care plus exercise	Best care plus manipulation	Best care plus manipulation and exercise
Baseline QALYs	0.597	0.556	0.592	0.596
Change in QALYs at three months	0.029	0.064	0.083	0.064
Change in QALYs at 12 months	0.032	0.062	0.072	0.083
Change in QALYs relative to best care at three months	N/A	0.035	0.054	0.035
Change in QALYs relative to best care at 12 months	N/A	0.030	0.040	0.051

Source: Based on "United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care", BMJ (2004), Page 3, Table 3

3.18 Table 3.2 shows that the greatest improvement in QALYs over twelve months occurs in the combined treatment group. Given that this is also the cheapest of the three interventions, it is clearly the most cost-effective treatment package. Indeed, the cost effectiveness ratio is £2,451 per QALY, comfortably within the limit of £30,000 commonly employed by NICE.

3.19 This finding stands in contrast to the results reported in the UK BEAM report economic paper, based on a comparison of mean QALYs over twelve months. By that measure the greatest improvement in QALYs is observed for those receiving spinal manipulation in addition to best care without exercise. However, as noted above, we do not believe that this is the appropriate measure of QALY improvement and hence we depart from the conclusions of the UK BEAM economic paper in its statement that "manipulation alone probably gives better value for money than manipulation followed by exercise". Our analysis clearly shows that there is value in augmenting best care in general practice and spinal manipulation with the exercise programme. This lends further support to the value of the chiropractic approach.

4 QUANTITATIVE COUNTERFACTUAL ESTIMATES

4.1 In this section we estimate, in quantitative terms, the monetary cost of adverse events and sub-optimal outcomes in chiropractic. As noted above, quantification focuses on those events which might potentially be addressed through revalidation.

4.2 We define the counterfactual in the context of chiropractic using the framework presented in paragraph 1.7.

Specify a Period for the Forecast

4.3 The forecast period for this study is 10 years.

Specify what are Assumed as "Unchanged Policies"

4.4 Revalidation is, by definition, not in place in the counterfactual. However, there are a number of policy developments that are likely to affect chiropractors in the next 10 years and hence must be taken into account in defining the counterfactual.

4.5 First, in May 2009, NICE recommended a course of manual therapy, including spinal manipulation, as an effective treatment for persistent non-specific low back pain. It is possible that, as a result of this recommendation, GPs and/or the public might become increasingly aware of chiropractic and hence there may be increased demand for such treatment. However, during our interview programme chiropractors were sceptical about the likely magnitude of impact arising from the NICE guidelines.

4.6 Second, usage of CPiRLS might be expected to increase over time as chiropractors become increasingly aware of its existence and gain confidence in its security, anonymity and the fact that no reprisals will follow from reporting an incident. This could lead to a reduction in the number of adverse events even in the absence of revalidation, though much depends on usage levels of the system. At this moment in time, it is not possible to estimate how great (or minor) the impact of CPiRLS might be.

4.7 The GCC introduced a new Code of Practice and Standard of Proficiency from 30 June 2010 but we have been unable to identify any significant changes relative to the versions previously in force.

4.8 We assume in the counterfactual that there will be no other major changes to the system of regulation.

Specify the Factors to be Forecast

4.9 So as to estimate the monetised value of adverse events in chiropractic in the absence of revalidation, it is necessary to forecast the evolution of a range of factors over the next 10 years. Specifically, we must forecast the following:

(a) Numbers of chiropractors

The percentage growth rate of the number of chiropractors has slowed in recent years as the profession has matured in the UK. Between 2004 and 2008, the number of chiropractors increased by approximately 100 per year on average.

If chiropractic were to become available to NHS patients, it is possible that the growth rate of the number of chiropractors may increase. Chiropractors currently practising appear to have little appetite for securing contracts with the NHS and hence there is an argument that a different 'type' of chiropractor would enter the profession were NHS funding to become available and this could augment the current growth rate of the profession. In such a scenario, however, a countervailing factor might be that fewer chiropractors enter private practice each year such that the net increase in the number of chiropractors remains the same as in recent years.

On this basis, we assume in the counterfactual that the number of chiropractors will continue to increase by 100 per annum over the next 10 years.

(b) Balance of chiropractic techniques used

Based on discussions with chiropractors and experts in the field, there appears to be no reason to believe that the balance of techniques used in chiropractic treatment would change from that offered at present.

Therefore, we assume that the balance of chiropractic techniques will remain constant over the next 10 years.

(c) Patient numbers and characteristics

Question 3 of our survey found that, on average, chiropractors see approximately 388 different patients each year. Given that 2,590 chiropractors were registered as practising with the GCC in 2009, this implies that a total of approximately 1,005,000 patients saw a chiropractor in 2009.[4] Based on the assumption that the number of chiropractors will increase by 100 per annum over the next 10 years, this implies that *the number of patients will increase by approximately 38,800 per annum*.

Support for such an increase in the number of patients is twofold. First, there may be an increased number of referrals from GPs and greater awareness of chiropractic as a consequent of the recent NICE guidance for the treatment of persistent non-specific low-back pain. Second, it is possible that individuals currently aged less than 45 might be more aware of and open to receiving chiropractic care than older generations. On this basis, as these individuals enter the phase of their life in which back pain is more prevalent, there might be an increase in the patient numbers.

[4] The number of registrants is taken from the contact details provided by GCC for dissemination of the survey.

We expect that the typical age of a chiropractic patient will not change over the next 10 years and do not anticipate that the male/female split will change.

(d) Health benefits of chiropractic

Chiropractic is an established healthcare profession which utilises techniques that have changed little over time. *We do not anticipate that, over the next 10 years, the potential health improvement that can be achieved through chiropractic care will change for the better or for the worse.* In particular, we anticipate that the findings of the UK BEAM trial will remain applicable during the period of the counterfactual forecast and hence *the combination of spinal manipulation and exercise would, as shown in Table 3.2 above, lead to an average QALY gain of 0.083 per patient relative to baseline, irrespective of the year in which treatment is administered. Using a value of £30,000 per QALY this implies that the per-patient benefit is worth almost £2,500.*

Specify and Assess the Factors that are Likely to Influence Factors to be Forecast

4.10 Given that low-back pain is most prevalent in individuals in the second half of their working life, demographic change could have an important impact on the prevalence and incidence of such pain and hence on the number of individuals seeking chiropractic care. The Office for National Statistics (ONS) has produced population projections based on the population of the UK during 2006 for the period 2006-2081.[5] Estimates are provided for every fifth year after 2006 (i.e. for 2011, 2016, 2021 and so on).

4.11 ONS estimates that the UK population will increase from 60.6m in 2006 to 67.2m in 2021. Between these dates, the number of individuals aged 45-49 is expected to increase until 2016 and fall thereafter such that the number of individuals in this age group will be lower in 2021 than in 2006. In contrast, the number of individuals aged 50-54 is expected to increase in each five-year period. The number of individuals aged 55-59 is expected to increase between 2006 and 2021, as is the number of people aged 60-64. This demographic change implies that the number of chiropractic patients might increase over the next 10 years.

4.12 We assume for the purpose of this paper that normal economic trends will resume over the next 10 years and hence do not expect that a significant increase or decrease in the number of chiropractic patients or the number of chiropractors will arise as a result of economic conditions.

4.13 *We do not anticipate any significant technological change that would affect the safety or effectiveness of chiropractic*. Chiropractic most commonly employs manual techniques

[5] Office for National Statistics, "National Population Projections, 2006-based", 2008, Series PP2 No 26, available at http://www.statistics.gov.uk/downloads/theme_population/pp2no26.pdf

and patient interaction techniques and hence there is relatively limited scope for technological developments. *One exception to this rule relates to the use of X-rays. In particular, it is possible that alternatives to X-rays (such as ultrasound) may be applied more commonly in the future and this could lead to a reduction in the risk of developing cancer through exposure to ionising radiation. It is also possible that new, safer imaging techniques will be developed*.

Sub-optimal Outcomes

Forecast number of patients that might be affected and the number of events

4.14 Question 11 of the survey we sent to chiropractors asked registrants to state what proportion of their patients could have had a better outcome if their care had been managed and/or implemented differently. It was emphasised that zero was an acceptable response.

4.15 Based on responses to this question, we have calculated through use of a weighted average that 4.15 per cent of patients experienced a sub-optimal outcome in 2009. The most common reason for the sub-optimal outcome was stated to be patient non-compliance (61.0 per cent of sub-optimal outcomes, on average) followed by inadequate care management (13.2 per cent of sub-optimal outcomes, on average).

Sensitivity analysis — number of events

4.16 The central estimate of loss due to sub-optimality is based on the survey responses that, on average, 4.15 per cent of patients experience a sub-optimal outcome. Of course, we do not assume that the statistic calculated from survey responses is completely accurate — all surveys with a response rate below 100 per cent are subject to some potential inaccuracy, and there is always a possibility that some individual replies may not be entirely correct. Therefore, in addition to calculating QALYs lost based on an estimate of 4.15 per cent of patients experiencing sub-optimal outcomes we will also utilise upper-bound and lower-bound estimates. As discussed with the Expert Group, the central estimate of the proportion of patients experiencing sub-optimal outcomes will be adjusted upwards and downwards by 10 per cent to give an upper bound of 4.565 per cent and a lower bound of 3.735 per cent.

Total loss of QALYs attributable to preventable failings

4.17 To quantify the impact of a sub-optimal outcome, we first use the results of the UK BEAM trial to estimate the pre-treatment EQ-5D score of chiropractic patients.

4.18 To estimate the loss suffered by these patients as a result of the sub-optimal outcome it is necessary to know the gain that could have been made had their care been optimal. For the purposes of quantification we assume that patients experiencing a sub-optimal outcome still derive some benefit of their chiropractic care, but that this benefit is lower than it would otherwise have been. In particular, we assume that patients experience a QALY gain equal to that which would be achieved through best care in general practice,

but that they do not obtain the 'added value' experienced by most patients that receive chiropractic care. Hence, we assume the QALYs lost through the sub-optimal outcome is equal to the difference between QALYs gained by the group which received best care in general practice in the UK BEAM trial and the group that received a package of care which included spinal manipulation and exercise.

4.19 It is also necessary to have an estimate of the typical amount of time over which a patient would experience a sub-optimal outcome. We fully acknowledge that some sub-optimal outcomes could be experienced for short periods (for example if a patient receiving symptomatic care visits their chiropractor the following week and the chiropractor resolves the issue) whilst others could be experienced for far longer (for example if the sub-optimality is 'hidden' to both chiropractor and patient). However, the Revalidation Working Group agreed that, for the purposes of this work, it would be reasonable to assume that the sub-optimality is typically experienced by the patient for a period of one month (i.e. 0.083 of a year).

Sensitivity analysis — duration of sub-optimality

4.20 The central estimate of loss due to sub-optimality is based on an assumption, agreed with the Revalidation Working Group, that sub-optimal outcomes would typically persist for one month. Of course, in some cases the sub-optimality would be resolved more quickly that this, whereas in other cases the sub-optimality may take longer to be resolved and, in the extreme, may never be resolved. As a result of the uncertainty in our central assumption, we wish to consider what the potential losses would be under different assumptions. On the advice of the Working Group, we therefore also calculate the loss on the assumptions that the sub-optimality would persist for two weeks (i.e. 0.038 of a year) and alternatively that the sub-optimality might persist for six weeks (i.e. 0.115 of a year).

4.21 Given the estimate derived above that 4.15 per cent of patients might experience a sub-optimal outcome, in 2009 the central estimate of QALYs lost as a result of this event is:

QALYs lost = Number of patients (1,005,000)
**Percentage of patients with a sub-optimal outcome (4.15%)*
**Missed improvement in QALYs through sub-optimality (0.051)*
**Duration of sub-optimality in years (0.083)*
= 177 (rounded to nearest QALY)

Sensitivity analysis — number of events

4.22 Using the lower bound estimate of the proportion of patients that experience a sub-optimal outcome, the number of QALYs lost is 159. Using the upper bound, the figure is 194 QALYs lost.

Sensitivity analysis — duration of sub-optimality

4.23 Using the lower estimate of the duration of sub-optimality discussed above, the number of QALYs lost is 81. Using the higher figure, the figure is 245 QALYs lost.

Monetary value of QALY loss

4.24 NICE does not have a threshold or a cut off point above which no treatment will be approved and has been clear that this is not the case. Each treatment is considered on a case-by-case basis. Generally, however, if a treatment costs more than £20,000-30,000 per QALY, then it would not be considered cost effective. Consequently, *the following estimates of the monetised value of adverse events and sub-optimal outcomes in chiropractic are based on a value of £30,000 per QALY.*

4.25 Quantification of this risk assumes that, as an upper bound, 4.565 per cent of patients experience a sub-optimal outcome each year. As a lower bound, we assume that 3.735 per cent of patients are affected in this way. It is assumed that the number of patients will increase by approximately 38,800 per annum over the next 10 years and hence the number of sub-optimal outcomes increases by between 1,455 and 1,804 per annum.

4.26 Based on these assumptions, the central estimate of the annual monetised QALY cost of sub-optimal outcomes rises from £5.46m in 2010 to £7.12m in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £51.86m.

Sensitivity analysis — number of events

4.27 As an upper bound, the present value of the cost of this risk over 10 years is approximately £58.21m whilst the lower bound estimate is approximately £47.63m.

Sensitivity analysis — duration of sub-optimality

4.28 As an upper bound, the present value of the cost of this risk over 10 years is approximately £71.86m whilst the lower bound estimate is approximately £23.74m.

Ionising Radiation

4.29 There are two potential risks associated with the use of ionising radiation within chiropractic premises. First, there is a potential risk that chiropractors may breach the requirements of the Ionising Radiation Regulations (1999), which are enforced by the Health and Safety Executive (HSE).

4.30 Second, there is a risk that chiropractors might take X-rays that cannot be clinically justified under IR(ME)R either because of an adherence to a mode of practice that makes routine use of X-rays or because of a personal interest in ionising radiation.

4.31 These issues are discussed in greater detail in the following paragraphs.

Potential breaches of the Ionising Radiation Regulations (1999)

4.32 The HSE Radiation Team has identified four areas of concern in relation to chiropractic practices that have x-ray equipment:

(a) lack of understanding of the role of the HSE and the powers of its inspectors;

(b) poor standards of training in radiation protection;

(c) failure to designate radiation controlled areas; and

(d) poor quality assurance of x-ray equipment.

4.33 According to the HSE:

> "the IRR99 and thus the HSE is principally concerned with the exposure of employees and other persons. These 'other persons' are often members of the public but not those actually undergoing medical examination or treatment. The only time the HSE really gets involved in patient exposure levels is when dealing with equipment maintenance and QA [Quality Assurance] issues."

4.34 A number of risks to the practitioner and the patient have been identified under the IRR99, including:

(a) a risk of excessive radiation dose for those receiving and providing x-rays if Quality Assurance is poor;

(b) all practitioners and patients visiting a practice could be at risk of receiving radiation from a faulty machine; and

(c) a risk of all patients and practitioners, whether they are x-rayed or not, receiving a radiation dose if a radiation controlled area has not been designated.

4.35 According to the HSE, in each of the above cases, the exposures that could be received range from above background to those which could be large enough to cause short and long term health effects.

Incidence

4.36 We have reviewed the HSE website to determine the number of chiropractors that have been issued enforcement notices or prosecuted by HSE under the IRR99. We identified two instances of chiropractic practices being issued with Improvement Notices during 2008.

4.37 However, HSE has informed us that this statistic underestimates the incidence of non-compliance with IRR99 at chiropractic practices because in the majority of cases HSE chooses not to serve Notices. Rather, the Executive sends a letter to the practice which outlines the issues and areas for improvement and this generally leads to the issues being resolved. It has not been possible for HSE to provide firm statistics concerning the number of letters that have been sent to chiropractors.

Valuation

4.38 It is not possible to place a monetary value on the loss to patients that has arisen as a result of non-compliance with IRR99. The primary reason for this is that a typical effect size (in terms of radiation dose received) cannot be estimated for non-compliance with IRR99, given HSE's statement that there is a wide range of possible exposure levels. In addition, there is no hard evidence concerning the incidence of breaches of IRR99. Therefore, this is treated subsequently as a non-quantifiable risk.

Potential taking of X-rays not justified under IR(ME)R

4.39 Since the year 2000, chiropractors practising in the UK have been subject to the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R), the purpose of which is to ensure that the public are protected as far as possible from potential adverse consequences of excessive radiographic exposure. Some chiropractors may, however, breach IR(ME)R guidelines and place their patients at unnecessary risk of adverse consequences. For example, some chiropractors might use X-rays more than justified by IR(ME)R because of a personal interest in radiography whilst others might adhere to a mode of practice that routinely uses X-rays.

4.40 Patients can only be at risk of a chiropractor using unjustified X-rays if the chiropractor has an on-site X-ray machine. Where patients are referred for X-rays, the relevant practitioner (who may or may not be another chiropractor) must justify the X-ray under IR(ME)R and hence the referring chiropractor cannot choose to use X-rays excessively.

Risk of cancer from spinal radiographs

4.41 The most serious possible adverse consequence of radiographic exposure is the development of a terminal cancer. There is a significant amount of debate surrounding the impact of radiation on the chance of suffering from cancer, based on differing beliefs concerning radiation-induced carcinogenesis. The linear no-threshold theory states that if 1 millisievert (mSv) of radiation gives a cancer risk R, the risk from 10 mSv is 10R and the risk from 100 mSv is 100R and hence the cancer risk is greater than zero regardless of how small the exposure. Cohen (2002) argued, however, that risk estimates in the low-dose region of radiation exposure based on the linear no-threshold theory are grossly exaggerated meaning that the cancer risk from diagnostic radiography may be zero.[6]

4.42 In January 2007, the International Commission on Radiological Protection (ICRP) stated that:

> "Although there are recognised exceptions, for the purposes of radiological protection the Commission judges that the weight of evidence on fundamental cellular processes coupled with dose-response data supports the view that in the low dose range, below

[6] Cohen, B.L., "Cancer Risk from Low-Level Radiation", American Journal of Roentgeneology (2002),179:1137-1143

> around 100 mSv, it is scientifically reasonable to assume that the incidence of cancer…will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues."[7]

4.43 The ICRP therefore holds the view that the linear no-threshold model is valid for low dosage levels and states that this view is also held by United Nations Scientific Committee on the Effects of Atomic Radiation, National Council on Radiation Protection & Measurements and National Research Council. Given the consensus amongst important international institutions, we consider it appropriate to employ this assumption in our work.

4.44 The amount of radiation received during a radiograph is typically measured as the effective dose. According to Fazel et al. (2009), the effective dose is a measure designed to represent the overall detrimental biological effect of a radiation exposure and hence accounts for the effect of radiation on the body as a whole rather than just in the area radiographed.[8] The Radiological Society of North America states that the effective dose of a radiograph of the lumbar spine is 1.5 mSv, which is comparable exposure to average background (naturally occurring) radiation in the USA for a period of six months.[9]

4.45 It has been argued that the distance of the X-ray device from the patient is usually greater in chiropractic use than in medical use and that, consequently, chiropractic patients would experience an effective dose of less than 1.5 mSv. A Radiation Protection Adviser confirmed, however, that an assumption of 1.5 mSv per X-ray would be reasonable and hence no adjustment needs to be made to account for differences in distance of chiropractic patients from the X-ray unit.

4.46 Given the evidence on the amount of radiation received during a typical spinal radiograph, the next step in quantifying the risk to the patient requires us to estimate the risk of cancer per unit of radiation received. The ICRP estimated in 2007 that the detriment-adjusted risk of cancer from X-ray radiation is 0.055 per sievert for the whole population.[10] This estimate takes into account differences in the risk between men and women for some cancers (e.g. breast cancer), differences in the severity of cancer in terms of lethality and quality of life and numerous other factors and remains the best available estimate.

4.47 Multiplying the radiation dosage by the detriment-adjusted risk of cancer from X-ray radiation shows that the risk of cancer from a single radiograph of the lumbar spine is $(0.0015*0.055) = 8.25x10^{-5}$, i.e. approximately 1 in 12,100.

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7 "Draft Recommendations of the International Commission on Radiological Protection", January 2007, available at http://www.icrp.org/docs/ICRP_Draft_Recommendations_12_January_2007.pdf, Page 21. Others have taken a similar view.

8 Fazel, R. et al., "Exposure to low-dose ionizing radiation from medical imaging procedures", New England Journal of Medicine (2009), 361:9:849-857

9 Radiological Society of North America (2009), "Safety: Radiation Exposure in X-ray Examinations", available on the RadiologyInfo.org website

10 "Draft Recommendations of the International Commission on Radiological Protection", January 2007, available at http://www.icrp.org/docs/ICRP_Draft_Recommendations_12_January_2007.pdf, Page 25, Table 1
'Detriment' is a measure of impact of radiation, where impact is defined as mortality for cancer and severity for genetic effects.

4.48 Although ionising radiation carries a (very low) cancer risk, it will be beneficial to the patient if it helps the chiropractor to improve his or her treatment, or uncovers a contraindication for spinal manipulation that may not have been found otherwise or identifies a condition that requires referral to another healthcare practitioner.[11]

Number of unjustified exposures

4.49 There is a view that the number of unjustified X-ray exposures in the field of chiropractic is zero because no instances involving chiropractors have been reported direct to the Care Quality Commission, the enforcement agency for IR(ME)R, or its predecessors. However, the GCC has found some chiropractors guilty of unacceptable professional conduct because X-rays were taken without justification. All these GCC findings have been reported to the relevant enforcement agency.

4.50 IR(ME)R requires that the employer reports incidents of exposure to ionising radiation to an extent much greater than intended as a result of a malfunction or defect in radiation equipment (Regulation 32(6)) or other than as a result of equipment malfunction or defect (Regulation 4(5)).

Forecast number of patients that might be affected and the number of events

4.51 The GCC has investigated a number of chiropractors for taking X-rays that could not be clinically justified under IR(ME)R. To date, the Professional Conduct Committee has found 26 instances of unjustified exposure to ionising radiation proved involving 12 patients and eight chiropractors.[12] The hearings spanned a period of approximately eight years and hence, on average, there have been 3.25 instances of unjustified exposure to ionising radiation each year. This means that approximately 0.000323 per cent of patients were unjustifiably exposed to ionising radiation in 2009. These figures are used in our work to estimate the lower bound of the number of unjustified exposures to ionising radiation.

4.52 Based on the ICRP risk coefficient discussed above, the detriment-adjusted risk of cancer from a typical spinal radiograph is $8.25e^{-5}$ (approximately 1 in 12,000).

4.53 On this basis, the proportion of chiropractic patients that develop cancer as a result of unjustified ionising radiation is $((8.25e^{-5} * 3.23e^{-4}\,\%) = 2.75e^{-8}$ per cent.

Total loss of QALYs attributable to preventable failings

4.54 According to Cancer Research UK, approximately 294,000 people were diagnosed with cancer during 2006, the most recent year for which figures are available, whilst 2m people

[11] There is literature relating to the possible benefits of X-rays, which we do not discuss here because the focus of our research is upon identifying potential risks in chiropractic, not to present a cost-benefit analysis of the value of X-rays

[12] The conduct hearing of one additional chiropractor also considered the issue of X-rays, but this did not relate to justification under IR(ME)R and hence has been excluded from the figures.

in the UK remain alive having been diagnosed with cancer in the past.[13] The former statistic is the annual 'incidence' of cancer whilst latter statistic is referred to as the 'prevalence' of cancer and includes both individuals that have recovered and those that continue to suffer from cancer.

4.55 The World Health Organisation (WHO) has estimated that 1.2m disability adjusted life years (DALYs) were caused by cancer in the UK during 2004.[14] This estimate could be interpreted as the total number of DALYs incurred by individuals diagnosed with cancer in a particular year. The estimate includes both time lived with disability and the time lost due to premature mortality and hence dividing the total number of DALYs in a given year (1.2m) by the annual incidence of cancer (294,000) provides an estimate of the average number of DALYs per cancer patient (4.1).

4.56 A DALY can be seen as an inverse QALY — both are measured on a scale of zero to one, but whilst one represents full health on the QALY scale it represents death on the DALY scale.[15] Although converting between the two is a non-trivial task, (since DALYs include an age-weighted component whereas QALYs do not) as an approximation we propose to treat one DALY gained as equal to one QALY lost. This approach has been used in previous studies. On this basis, an average of 4.1 QALYs are lost by each cancer patient in the UK.

4.57 Given the estimate derived above that $2.75e^{-8}$ per cent of patients will develop cancer from unjustified exposures to ionising radiation, in 2009 the total QALYs currently lost as a result of taking X-rays in the course of chiropractic treatment can be calculated as follows:

QALYs lost through X-rays = *Number of patients (1,005,000)*
**Proportion of patients that develop cancer (*$2.75e^{-8}$ *%)*
**QALYs lost through cancer (4.1)*
= 0.0011

Monetary value of QALY loss

4.58 Quantification of this risk assumes that $2.75e^{-8}$ per cent of patients will develop cancer from ionising radiation. It is assumed that the number of patients will increase by approximately 38,800 per annum over the next 10 years and hence the number of unjustified exposures increases by approximately 0.00001 per annum.

4.59 Based on these assumptions, the lower bound estimate of the annual monetised QALY cost of unjustified exposure to ionising radiation rises from approximately £35 in 2010 to

[13] Cancer Research UK, "Latest UK Cancer Incidence and Mortality Summary – numbers", July 2009, available at http://info.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@sta/documents/generalcontent/crukmig_1000ast-2735.pdf

[14] World Health Organisation, Global burden of Disease, Death and DALY estimates for 2004 by cause for WHO Member States, Persons, all ages, available at http://www.who.int/healthinfo/global_burden_disease/gbddeathdalycountryestimates2004.xls

[15] See, for instance, Robberstad, B., QALYs vs DALYs vs LYs gained: What are the differences, and what difference do they make for health care priority setting?", Norsk Epidemiologi (2005), 15:2:183-191

£47 in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £340.

Conduct Issues

Forecast number of patients that might be affected and the number of events

4.60 Approximately one-third of the complaints received by the British Chiropractic Association (BCA) between January 2008 and early September 2009 related to the conduct of chiropractors. Applying this percentage to the total number of complaints received by the BCA and annualising the figures results in an estimate of 36 complaints of poor conduct per year. The McTimoney Chiropractic Association did not receive any complaints about poor conduct between January 2007 and October 2009; the Scottish Chiropractic Association has not received any complaints about poor conduct; and the United Chiropractic Association (UCA) received five complaints categorised as "patient complaints/treatment" during 2009, of which three progressed to the GCC. The UCA has categorised one of these complaints as referring to poor conduct by the chiropractor. This gives a total of approximately 37 complaints of poor conduct per annum.

4.61 Presumably there are other cases that are not reported, but there is no basis for assessing this. As agreed with the Expert Group, we assume that half of all cases are reported and hence that there are approximately 74 instances of poor conduct per annum.

4.62 Therefore, based on our estimate of the number of chiropractic patients in 2009, the percentage of patients experiencing an incident of poor conduct is (74 / 1,005,000)*100 = 0.0074 per cent.

Total loss of QALYs attributable to preventable failings

4.63 It is not possible to quantify the impact of conduct issues in QALY terms. Instead, we will quantify the impact of this issue by valuing the monetary loss to the patient as the cost of a chiropractic treatment session. Details of the quantification procedure for this risk are discussed in more detail below.

Monetary value of QALY loss

4.64 As it is not possible to quantify the impact of conduct issues in QALY terms, we value the monetary loss to the patient as the cost of a chiropractic treatment session. In particular, given an estimate of the typical cost of a chiropractic treatment session, *we assume that where a chiropractor exhibits poor conduct the loss to the patient is equal to the cost of the treatment session*. The Expert Group advised that it would be reasonable to assume that the cost a typical non-initial treatment session is £35.

4.65 Inherent in this assumption is that patients experience only a short-term loss from poor conduct, a notion which is appropriate given that we include in the counterfactual only the least serious conduct issues. If we were also considering issues such as breach of

professional boundaries, the adverse event might be of greater duration. Also inherent in the assumption is that each patient experiences poor conduct only once.

4.66 In some cases, valuing the loss as the full cost of a treatment session is probably an overestimate since patients may benefit from chiropractic treatment even if the conduct of the chiropractor is poor. However, for some patients, the consequences of the adverse event might be of longer duration and hence the cost of a treatment session and duration of effect are somewhat balancing factors.

4.67 We estimated above that approximately 0.0074 per cent of patients experience poor conduct each year in the chiropractic profession and hence the annual monetary loss as a result of poor conduct can be calculated as follows:

2009 monetised loss through poor conduct = Number of patients (1,005,000)
**Chance of poor conduct event (0.0074%)*
**Cost of treatment session (£35.00)*
= £2,603

4.68 It is assumed that the number of patients will increase by approximately 38,800 per annum over the next 10 years and hence the number of adverse events increases by approximately 3 per annum.

4.69 Based on these assumptions, the annual cost of instances of poor conduct rises from approximately £2,700 in 2010 to £3,600 in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £26,000.

Fractured Ribs

Forecast number of patients that might be affected and the number of events

4.70 The BCA received five complaints that chiropractic care had caused a fractured rib in the period January 2008 to September 2009. We also note that since CPiRLS was introduced in spring 2009, three incidents of rib fracture have been reported through the system. In each of these cases, the practitioner believes that their actions/inactions were "likely" to be the responsible for the incident, suggesting that there may be a causal link between some inappropriately administered chiropractic techniques and fractured ribs.

4.71 Given the evidence from the BCA's complaints and CPiRLS, we include the risk of fractured ribs in the counterfactual.

4.72 For the purposes of quantification, we assume that the number of instances of rib fracture per annum is four, i.e. the average of the number of complaints received by the BCA and the number of CPiRLS reports of rib fracture received during its first year of operation. This means that approximately 0.000398 per cent of patients experience a rib fracture each year.

4.73 Given that CPiRLS was introduced only in Spring 2009, it is possible that the number of reports in the first year would be lower than the number of reports received in subsequent years as usage levels increase. However, it is equally possible that some of the reports refer to events that took place in years prior to 2009 and hence that the figure for the first year is an overestimate of the true incidence. Given uncertainty about which of these arguments applies, we treat the 2009 figures as central estimates.

Total loss of QALYs attributable to preventable failings

4.74 To quantify this risk, we reviewed the healthcare literature to obtain an estimate of the utility loss (measured by EQ-5D score) suffered as a result of a rib fracture. Our review of the literature identified a very small number of studies that have considered the QALY loss which arises from rib fracture — the majority of studies of fracture focus on hip fracture. This may be because rib fractures are typically less problematic and typically recover in a shorter period of time than do other types of fractures.

Our review has shown that the health impact of a rib fracture is relatively small and equivalent to the adverse health impact arising from a distal forearm fracture.[16] Indeed, one paper has estimated that for a clinical forearm fracture, a utility loss of 0.017 was incurred and stated that it would be valid to assume that the same utility loss is incurred by patients experiencing a rib fracture.[17] We use this estimate in our analysis. It is assumed that a rib fracture takes six weeks to heal.

QALYs lost in rib fracture = Number of patients (1,005,000)
**Proportion of patients that have rib fracture ($3.98e^{-4}$%)*
**QALYs lost through rib fracture (0.017)*
= 0.067

Monetary value of QALY loss

4.75 Quantification of this risk assumes that $3.98e^{-4}$ per cent of patients will experience a rib fracture each year. It is assumed that the number of patients will increase by approximately 38,800 per annum over the next 10 years and hence the number of rib fractures increases by approximately 0.15 per annum.

4.76 Based on these assumptions, the annual monetised QALY cost of rib fractures rises from approximately £2,119 in 2010 to £2,828 in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £20,382.

[16] National Osteoporosis Foundation (1998) Osteoporosis: review of the evidence for prevention, diagnosis and treatment and cost-effectiveness analysis. Status report. Osteoporosis 8:S4:S1–S88

[17] Kanis, J. A. et al. (2004), "The risk and burden of vertebral fractures in Sweden", Osteoporosis International 15:20-26

Poor Record-keeping

Forecast number of patients that might be affected and the number of events

4.77 Based on responses to Question 9 of the survey we distributed to chiropractors, internal poor record-keeping had an impact on the quality of care for 0.0019 per cent of all patients and poor record-keeping by a chiropractor in another practice impacted on the quality of care received by 0.001 per cent of all patients. Internal poor record-keeping had an impact on appointment duration for 0.01 per cent of all patients and poor record-keeping by a chiropractor in another practice impacted on appointment duration for 0.0039 per cent of all patients.

4.78 Given the number of individuals that visited a chiropractor in 2009, this implies that there were 19 cases where within-practice poor-record keeping had an impact on the quality of care provided to the patient and 10 cases where poor quality records were received from another practice. The figures also suggest that there were 101 cases where within-practice poor-record keeping had an impact on appointment duration and 39 cases where poor quality records were received from another practice.

Total loss of QALYs attributable to preventable failings

4.79 The precise impact of poor record-keeping on the quality of care is not clear and is likely to differ significantly between cases. Therefore, we do not consider that it would be reasonable to attempt to quantify the impact of poor record-keeping on the quality of care. This impact is hence considered to belong to the category of non-quantifiable risks.

4.80 However, we consider that it would be reasonable to attempt to quantify the impact of poor quality records on appointment duration. It is not possible to quantify the impact of in QALY terms and hence quantification is based on the idea that the monetary loss to the patient is related to the cost of a chiropractic treatment session. Details of the quantification procedure for this risk are discussed in more detail below.

Monetary value of QALY loss

4.81 Where poor quality records had the effect of lengthening appointment duration, it is assumed that the duration increases from that of a typical subsequent appointment to a typical initial appointment. Responses to our survey showed that the weighted average initial appointment duration is 54.5 minutes and the weighted average subsequent appointment duration is 21.5 minutes. The expert group has informed us that it would be reasonable to assume that the cost of a typical subsequent appointment is £35. For the purposes of quantification, we assume that the cost of an initial appointment is 2.5 times this, i.e. £87.50, since the typical initial appointment duration is just more than 2.5 times that of subsequent appointments. Hence, the increased cost of the appointment is £52.50.

2009 monetised loss – internal poor records = Number of patients (1,005,000)

**Chance of poor records increasing appt. duration (0.01%)*
**Increased cost of appointment (£52.50)*
= £5,276

2009 monetised loss – external poor records =Number of patients (1,005,000)
**Chance of poor records increasing appt. duration (0.0039%)*
**Increased cost of appointment (£52.50)*
= £2,058

4.82 Based on these assumptions, the annual monetised cost of increased appointment duration due to poor record-keeping by chiropractors from within the same practice rises from approximately £5,480 in 2010 to £7,313 in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £52,700.

4.83 The annual monetised cost of increased appointment duration due to poor record-keeping by chiropractors from different practices rises from approximately £2,137 in 2010 to £2,852 in 2019. The present value of the cost of this risk over 10 years, calculated with a real discount rate of 3.5 per cent, is approximately £20,600.

Total Costs

4.84 Table 4.1 shows the total cost of adverse events and sub-optimal outcomes in chiropractic if it is assumed that a sub-optimal outcome typically persists for one month.

Table 4.1: Total cost of sub-optimal outcomes and adverse events in chiropractic (central sub-optimal outcome duration assumption)

Risk	2010 Instances	2010 Cost (£)	2019 Instances	2019 Cost (£)	Present Value 2010-19 (£)
Sub-optimal outcomes (low incidence)	38,988	4,951,000	52,029	6,607,000	47,628,000
Sub-optimal outcomes (central incidence)	42,996	5,460,000	56,037	7,116,000	51,863,000
Sub-optimal outcomes (high incidence)	47,649	6,051,000	63,591	8,075,000	58,212,000
Radiation-induced cancer	0.00028	35	0.00038	47	340
Poor conduct	77	2,700	103	3,600	26,000
Rib fracture	4.1	2,119	5.6	2,828	20,382
Poor internal records lead to longer appointments	104	5,480	139	7,313	52,700
Poor external records lead to longer appointments	41	2,137	54	2,852	20,560
Total (low incidence)	39,214	4,963,000	52,331	6,624,000	47,748,000
Total (central incidence)	43,222	5,473,000	56,339	7,133,000	51,983,000
Total (high incidence)	47,875	6,064,000	63,893	8,092,000	58,332,000

4.85 In addition to the adverse events and sub-optimal outcomes listed in the table above, it should be noted that there are additional risks that were impossible to quantify with the data and information available to us. In particular, we were not able to quantify the cost of breaches of IRR99 or costs arising from poor-record keeping that had an impact on the quality of care provided to the patient.

4.86 Tables 4.2 and 4.3 below show, respectively, the total cost of sub-optimal outcomes in chiropractic, under the lower and upper assumptions concerning the amount of time over which a sub-optimal outcome is experienced.

Table 4.2: Total cost of sub-optimal outcomes and adverse events in chiropractic (low sub-optimal outcome duration assumption)

Risk	2010 Instances	2010 Cost (£)	2019 Instances	2019 Cost (£)	Present Value 2010-19 (£)
Sub-optimal outcomes (low incidence)	38,988	2,267,000	52,029	3,025,000	21,806,000
Sub-optimal outcomes (central incidence)	42,996	2,500,000	56,037	3,258,000	23,744,000
Sub-optimal outcomes (high incidence)	47,649	2,770,000	63,591	3,697,000	26,651,000
Total (low incidence)	39,214	2,279,000	52,331	3,042,000	21,926,000
Total (central incidence)	43,222	2,512,000	56,339	3,275,000	23,865,000
Total (high incidence)	47,875	2,783,000	63,893	3,714,000	26,772,000

Note: Other risks have been omitted from this table but feed into the totals presented

Table 4.3: Total cost of sub-optimal outcomes and adverse events in chiropractic (high sub-optimal outcome duration assumption)

Risk	2010 Instances	2010 Cost (£)	2019 Instances	2019 Cost (£)	Present Value 2010-19 (£)
Sub-optimal outcomes (low incidence)	38,988	6,860,000	52,029	9,154,000	65,990,000
Sub-optimal outcomes (central incidence)	42,996	7,565,000	56,037	9,860,000	71,858,000
Sub-optimal outcomes (high incidence)	47,649	8,384,000	63,591	11,189,000	80,655,000
Total (low incidence)	39,214	6,872,000	52,331	9,171,000	66,111,000
Total (central incidence)	43,222	7,578,000	56,339	9,877,000	71,978,000
Total (high incidence)	47,875	8,396,000	63,893	11,205,000	80,775,000

Note: Other risks have been omitted from this table but feed into the totals presented

5 CONCLUSION

5.1 This paper has defined the counterfactual against which the benefits of revalidation could be measured. We have focussed on adverse events and sub-optimal outcomes that might potentially be addressed through revalidation — for the purposes of this project there is little benefit in devoting resources to quantifying risks that could not be addressed through revalidation.

5.2 We included several risks in the counterfactual: sub-optimal outcomes; non-compliance with IRR99; non-compliance with IR(ME)R; poor conduct; rib fractures; and poor record-keeping. Using the model we developed for the Department of Health, we estimated in QALY terms the magnitude of adverse events and sub-optimal outcomes over the period 2010-2019 in the absence of revalidation. Table 5.1 shows the total cost of adverse events and sub-optimal outcomes in chiropractic.

Table 5.1: Total cost of sub-optimal outcomes and adverse events in chiropractic (central sub-optimal outcome duration assumption)

Risk	2010 Instances	2010 Cost (£)	2019 Instances	2019 Cost (£)	Present Value 2010-19 (£)
Sub-optimal outcomes (low)	38,988	4,951,000	52,029	6,607,000	47,628,000
Sub-optimal outcomes (central)	42,996	5,460,000	56,037	7,116,000	51,863,000
Sub-optimal outcomes (high)	47,649	6,051,000	63,591	8,075,000	58,212,000
Radiation-induced cancer	0.00028	35	0.00038	47	340
Poor conduct	77	2,700	103	3,600	26,000
Rib fracture	4.1	2,119	5.6	2,828	20,382
Poor internal records lead to longer appointments	104	5,480	139	7,313	52,700
Poor external records lead to longer appointments	41	2,137	54	2,852	20,560
Total (low)	39,214	4,963,000	52,331	6,624,000	47,748,000
Total (central)	43,222	5,473,000	56,339	7,133,000	51,983,000
Total (high)	47,875	6,064,000	63,893	8,092,000	58,332,000

5.3 Based on these results, it is clear that by far the most costly risk in chiropractic is sub-optimal outcomes. Indeed, based on the central duration assumption, the estimated monetised loss of between £4.96m and £8.09m in QALYs each year as a result of sub-optimal outcomes is significant and hence a revalidation policy designed to target this risk could deliver great benefits to chiropractic patients. We do note, however, that not all sub-optimal outcomes could potentially be affected by revalidation. An important example of

this might be cases where the sub-optimal outcome results from patient non-compliance, unless there is some mechanism within revalidation that could ensure that chiropractors are doing all that they can to ensure that patients comply with, say, their prescribed exercise and treatment regime.

5.4 In order to provide a sense of scale for the value of lost QALYs due to adverse events, it is necessary to estimate the health benefit delivered to patients through chiropractic care. We are aware that the package of care is generally tailored to the patient's needs, but it is not possible to form an estimate of the benefit of chiropractic care unless we base our analysis on the results of a clinical trial.

5.5 Formulating such an estimate hence requires a reasonably crude assumption to be made concerning the chiropractic techniques administered to the patient. In particular, we assume that all chiropractic patients receive the combination of spinal manipulation and exercise described in the UK BEAM trial.

5.6 Using the estimate of QALYs gained by patients from the UK BEAM trial and applying a value of £30,000 per QALY as recommended by NICE, the value of chiropractic care to patients (relative to baseline) in 2010 is approximately £2,500m. On this basis the loss as a result of sub-optimal outcomes in 2010 is less than 1 per cent of the overall benefit of chiropractic care to patients.

APPENDIX 1: EQ-5D AND QALYS

A1.1 The calculation of the benefit, in monetary terms, of a particular intervention requires an assessment of the health state of a patient both before and after intervention. Health status is measured by the QALY score on a scale in which a score of one indicates perfect health. A QALY provides an indication of how many extra months or years of life of a given level of quality a person might gain as a result of treatment and hence the QALY takes into account both the quantity and the quality of life generated by healthcare interventions.

A1.2 This was developed by the National Institute for Health and Clinical Excellence (NICE) and has been the standard measure used in healthcare cost-benefit analyses for many years now.

A1.3 The QALY concept can also be applied to an analysis of the 'missed' benefits of treatment given a sub-optimal outcome and to the reduction of QALYs arising from an adverse event. Therefore, in the present paper we employ QALY analysis so as to quantify the 'loss' attributed to sub-optimal outcomes and adverse events in the field of chiropractic in the absence of revalidation.

A1.4 QALYs are constructed from first principles through use of patient questionnaires such as EQ-5D.

EQ-5D

A1.5 EQ-5D is a questionnaire used to create a descriptive system of health-related quality of life states, consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each of which can take one of three responses.

A1.6 The responses to EQ-5D record three levels of severity (no problems, some or moderate problems, extreme problems) within a particular EQ-5D dimension. The levels of severity in each of the dimensions are illustrated in the table below.

Table A1.1: Scores for the EQ-5D

Mobility	1. No problems walking about.
	2. Some problems walking about.
	3. Confined to bed.
Self-care	1. No problems with self-care.
	2. Some problems washing or dressing.
	3. Unable to wash or dress.
Usual activities (work, study, homework, leisure activities)	1. No problems in performing usual activities.
	2. Some problems in performing usual activities.
	3. Unable to perform usual activities.
Pain/Discomfort	1. No pain or discomfort.
	2. Moderate pain or discomfort.
	3. Extreme pain or discomfort.
Anxiety/depression	1. Not anxious or depressed.
	2. Moderately anxious or depressed.
	3. Extremely anxious or depressed.

Source, Philips/Thompson, "What is a QALY?" (2001)

A1.7 The digits for five dimensions can be combined in a five-digit number, which describes the respondent's health state. Three digits (or severities) across five dimensions create 245 possible health state utility scores via the EQ-5D, once "unconscious" and "dead" are added to those states which can be yielded by completion of EQ-5D.

A1.8 Researchers have used a random sample of 3,000 people in the UK to convert each of these 245 possible health states into QALY terms.[18] Two approaches were used to this, of which NICE has implied the Time Trade-Off (TTO) approach to be preferable for economic evaluations.[19] The UK TTO value set is illustrated in the table below.

[18] Dolan, P. et al., "A Social Tariff for EuroQol: Results from a UK general population survey", September 1995

[19] See "EQ-5D Value Sets", EuroQol Group Monographs Volume 2,Springer, 2007, Page 42.

Table A1.2: EQ-5D Scores and QALYs

UK TTO Value Set		Example: the value for health state 21232	
Full health (11111)	1	Full health	1
At least one 2 or 3 (constant)	-0.081	Minus constant	-0.081
At least one 3 (N3)	-0.269	Minus N3	-0.269
Mobility=2	-0.069	Minus MO level 2	-0.069
Mobility=3	-0.314		
Self care=2	-0.104	Minus SC level 1	-0.000
Self care=3	-0.214		
Usual activities=2	-0.036	Minus UA level 2	-0.036
Usual activities=3	-0.094		
Pain/discomfort=2	-0.123		
Pain/discomfort=3	-0.386	Minus PD level 3	-0.386
Anxiety/depression=2	-0.071	Minus AD level 2	-0.071
Anxiety/depression=3	-0.236		
		State 21232	=0.088

Source: EQ-5D Value Sets", EuroQol Group Monographs, Page 69

Using EQ-5D in this study

A1.9 We have found it difficult to obtain evidence concerning the change in QALYs following a course of chiropractic treatment. From the UK BEAM trial it has been possible to obtain an estimate of the baseline characteristics of patients, in terms of their QALY score, receiving a care package for back pain.

A1.10 The UK BEAM trial found that, prior to treatment, the average QALY value for patients was approximately 0.59 and this is used as the basis for our estimate of pre-treatment QALY value for the purposes of this study. Based on the UK TTO Value Set presented above, the closest approximation to a value of 0.59 is obtained if it is assumed that chiropractic patients before treatment on average have a health state 21222, i.e. that they have some or moderate problems with mobility, usual activities, pain/discomfort and anxiety/depression. This yields a QALY score of 0.62.

A1.11 Given this baseline assumption, the analysis presented above has estimated the (negative) change in QALYs as a result of adverse events and the difference in QALYs between actual outcome and potential outcome in the case of sub-optimal outcomes.

Monetary valuation of QALYs

A1.12 NICE does not have a threshold or a cut off point above which no treatment will be approved and has been clear that this is not the case.[20] Each drug is considered on a case-by-case basis. Generally, however, if a treatment costs more than £20,000-30,000 per QALY, then it would not be considered cost effective.[21] Consequently, we suggest attributing a value of £30,000 to each QALY in our risk-based regulatory model.

A1.13 Other valuations have sometimes been used. For example, we understand that the Department of Health has applied a threshold of £36,000, specific to a risk sharing agreement with the pharmaceutical industry over the provision of disease-modifying drugs for people living with multiple sclerosis.[22] Our model allows a different valuation than £30,000 to be used, but £30,000 is the recommended 'default' value.

A1.14 Shepley Orr presented a paper to the London Health Economics Group in January 2010 which reviews the fact that the problem of how to determine the monetary value of a QALY is a central concern in health economics. The paper notes that one approach used to infer the monetary value of a QALY has been to derive values from the value of preventing a statistical fatality (VPF) figure as used by the Department for Transport. Orr's paper examines the VPF-QALY relationship both by inferring the value of a QALY from the VPF, and the possibility of inferring the value of the VPF from the monetised value of a QALY. Orr investigates whether either approach is acceptable and, in particular, asks whether the monetised value of health should value only the stream of health provided (i.e. QALYs gained) or whether life itself should be valued.

A1.15 It is clear that the issue of how best to attach a monetary value to a QALY is a matter of intense academic debate at present and is likely to continue to be so.

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[20] http://www.nice.org.uk/archivedsite/publications/healthselectcommitteeinquiry2002/2002_005_nice_present_evidence_to_health_select_committee.jsp

[21] http://www.nice.org.uk/newsevents/infocus/MeasuringeffectivenessandcosteffectivenesstheQALY.jsp

[22] Health Service Circular 2002/004, *Cost Effective Provision of Disease Modifying Therapies for People with Multiple Sclerosis,* (21 November 2005)