

**Quality of Life during the Treatment of  
Gallstone Disease: Issues in the  
Development of Health State Descriptions.**

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## ABSTRACT

There are three main options for the treatment of gallstone disease, namely open cholecystectomy, laparoscopic cholecystectomy and extracorporeal shockwave lithotripsy. An economic evaluation of these was undertaken. Because the three options have serious but different effects upon the quality of life (QoL) the study design was a cost utility analysis (CUA). In such a design the output of each intervention is measured in quality adjusted life years (QALYs) or healthy year equivalents (HYEs). Measurement of these require the construction of valid health state scenarios. The objective of the present paper is to describe these scenarios and the issues arising from this. Other results and issues from the project are present in Street (1993), Cook and Richardson (1993), and Cook, Richardson and Street (1993a; 1993b).

In the paper a variety of methodological issues are discussed that are associated with the construction of the health state scenarios. First, an issue overlooked in the literature to date is that health state values change with the underlying perspective or value basis adopted by the researcher. This has typically been an *ex post* perspective in which the quality of life actually experienced is measured at a point in time. The alternative is an *ex ante* perspective in which the patient's anticipated outcome and considerations of risk aversion become relevant. Secondly (and to a greater or lesser extent in common with most economic analyses in the health sector) the patient experience cannot be inferred from the clinical outcome and, at present, the long run clinical consequences of the various treatments are uncertain. Thirdly, in the absence of a universally accepted method for constructing health states scenarios the conversion of qualitative and survey QoL information into scenarios appropriate for cost utility analysis remains problematic.

The paper outlines the three treatment options for gallstone disease. It describes the patient experience as obtained from interviews and a postal questionnaires and how the final health state descriptions were derived from this. It is concluded that there is a need for a general instrument which in the context of life and quality of life judgements about resource allocations itself is cost effective, as well as valid and sensitive to changes in quality of life factors across a wide range of diseases.

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# Quality of Life During the Treatment of Gallstone Disease: Issues in the Development of Health State Descriptions

## 1 Introduction

### 1.1 Outline of Treatment Options

The conventional treatment for gallstone disease is open cholecystectomy, the surgical removal of the gall bladder. It is one of the most common operations performed in Australia with about 25,000 procedures per year or 1500 per million population (Hailey & Hirsch 1991). The treatment causes significant post-operative morbidity. After surgery patients require narcotic analgesics to control the pain. The procedure requires an average length of stay in hospital of seven days for uncomplicated cases and a subsequent recovery time of up to six weeks. At the end of the third to fourth week there is normally a rapid recovery with a return to full health in four to six weeks.

In the last few years the treatment of gallstone disease has changed dramatically with the availability of two revolutionary new treatments: extracorporeal shock wave lithotripsy (ESWL) and laparoscopic cholecystectomy. ESWL was first used to treat biliary stones in 1986 by clinicians at the Klinikum Grosshadern in Munich. Gallstones are fragmented by externally generated shockwaves which are transmitted through a column of water to the patient's body. Because the procedure is non-invasive post treatment morbidity is minor and patients can leave the hospital on the same day. Consequently, the treatment can readily be scheduled around work and family commitments. To clear the fragments or 'sludge' from the gall bladder patients are given oral dissolution therapy until they are diagnosed as being 'stone free'. However, the therapy which can last for up to 18 months can cause significant diarrhoea and some nausea both of which may be controlled by a reduction in dosage. Because the gall bladder is left *in situ* the treatment may not be definitive and gallstones may recur. In a number of cases the failure of the procedure to relieve symptoms results in a rapid recourse to surgery.

Laparoscopic cholecystectomy was first used in France in 1987. It is a form of minimal

access surgery similar to the techniques used in gynaecological procedures for the last three decades. Post-operative morbidity is significantly reduced. Most patients are out of bed on the day after the operation and are able to return to normal activities two or three days after the operation. As with the alternative procedures there is a small probability of serious complications.

Because of the importance of the quality of life (QoL) during post procedural recovery, a cost utility analysis was selected as the appropriate framework for an economic evaluation of the three options. Cost utility analysis evaluates treatment outcomes, not simply in terms of the quantity of life obtained, but also in terms of 'quality of life' gained from the intervention. The desirability or otherwise of an intervention from the patient's point of view is measured by the number of 'QALYs' or, as we shall refer to them, 'healthy year equivalents' or (HYEs) that are 'produced' by the intervention.<sup>1</sup> HYE's incorporate both quality and quantity of life and provide a common unit by which different outcomes may be compared.

## **1.2 Approaches to Quality of Life Measurement**

In a prospective trial, QoL may be measured at different points in time following an intervention. Patients may be asked to evaluate their health state at each point using either a multi-attribute utility (MAU) scale - or a profile approach which may consist of a single health profile instrument or a battery of appropriately selected QoL instruments. If a MAU scale is used patients are asked to describe their health state on a number of separate dimensions which may include mobility, pain, emotional well-being and ability to carry out normal role function. A scale value for each set of health state attributes is then ascertained and a single utility value calculated according to the combination rule of the particular index. The battery approach was adopted in the Sheffield Biliary Lithotripsy Trial. Patient symptoms after treatment were rated using the McGill Pain Questionnaire, The Nottingham Health Profile and a visual analog scale. Neither of the above approaches is feasible in a study constrained to retrospective analysis of interventions. More fundamentally, both methods present a number of methodological limitations which limit their usefulness in an economic evaluation.

At present, none of the available MAU scales are sensitive to the important aspects which characterise the treatment outcomes of gallstone disease. Except at the most general level existing MAU scales are not sensitive to the differences in health outcomes between and within each of the procedures. By contrast, a multi-instrument strategy to measuring quality of life, unlike a MAU scale, can be highly sensitive to different aspects of the post treatment

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<sup>1</sup> We have adopted the term 'healthy year equivalents' to describe what is more commonly referred to in the literature as quality adjusted life years or QALYs. The term HYE's has earlier been used by Mehrez and Gafni (1989) to distinguish the conventional QALY (which assumes that different health states may be combined in an additive way) from a unit of outcome derived from the holistic evaluation of multi-stage scenarios. Our use of the term does not imply this approach but is predicated on the belief that the term HYE's more accurately describes the final unit of outcome.



health states if the appropriate indices are chosen. However, except in the case of absolute dominance - where one intervention is superior or equal to other alternatives on all dimension, including costs - the approach will not be capable of ranking procedures without subjective judgment about how to combine dimensions. That is, there is no method available for collapsing the descriptive data from the QoL scales into a single index of utility required for the calculation of HYE.

The approach adopted in the present study was in part dictated by the study design and in part by the methodological shortcomings of the available techniques. As QoL data was not part of the protocol we were constrained to evaluate a number of representative or standard scenarios developed from a retrospective analysis of patient experience. These standard health states were designed to combine different levels of the major determinants of quality of life in such a way that they collectively covered the range of normal health state experiences for patients in the study. The treatment of complications is discussed in Cook, Richardson and Street (1993a; 1993b).

### **1.3 Issues in the Measurement of Quality of Life**

Three sets of issues arose during conduct of the QoL study. They relate to (1) the value system - *ex ante* or *ex post* - from which the evaluation is conducted; (2) the relationship between the patient and clinical experience and; (3) the decision about whose values should be used to scale health states.

The first issue, the distinction between an *ex ante* and *ex post* measurement perspective is a general issue which has not been resolved or indeed discussed in the literature. The remaining issues also have general application but are of particular significance in the present study.

#### **1.3.1 *Ex Post* Versus *Ex Ante* Measurement**

There are two fundamentally different value systems that can underlie the measurement of quality of life in CUA. The first step in measuring quality of life gains from an intervention should be to decide upon the particular value system or point of view from which to measure patient preferences. The first basis follows from the 'material welfare tradition' (Robinson 1986) or 'extra welfarism' (Culyer 1992). It seeks to measure the quality of life actually experienced after an intervention (*ex post*). This is the older tradition of Pigou and Marshall in which 'utility' is interpreted in terms of the satisfaction of physical needs and which, according to Robinson (1986) underlies cost effective analysis and its objective of maximising particular 'external' objectives - life, life years or objectively measured indices of health. Information about the probability of each outcome would not influence the utility value of that health state. The second basis, which follows from 'the new welfare economics' or 'welfarism' in Culyer's terms, is based on the libertarian premise that revealed preferences should be the gold standard for measurement and definition of utility. People's (*ex ante*) expectations and attitudes to risk are relevant as they will affect their revealed preferences even if these factors are unrelated to *ex post* experiences. This more recent tradition is the

mainstream view of economists who deny the possibility of interpersonal comparisons of subjectively determined preferences. In the view of many economists the *ex ante* perspective is the 'theoretically correct' perspective. It is more correct, however, to treat these two traditions as representing different sets of social values rather than as being theoretically 'right or wrong'. The two perspectives could result in significantly different values for the same health states - a point noted by Robinson.

In principle, policy makers must be clear on the particular perspective they wish to adopt and measurement could be adjusted to the required perspective. In practice, policy makers have not given clear guidelines and most CBA and CEA has adopted the earlier, *ex post* perspective in which the objective of measurement and evaluation is the outcome observed and experienced. The present study commenced with the intention of measuring outcomes from both perspectives. However for reasons discussed below it rapidly became apparent that the *ex ante* perspective would result in a serious problem of 'cognitive overload' - the number and complexity of the health states were so great that the presentation of the *ex ante* option (all possible outcomes and their probabilities) would result in invalid responses. However, prior research on patient preferences (Daly 1990) pointed to the fact that patients might prefer lithotripsy over cholecystectomy because it avoids the risk of the operation and associated morbidity. Consequently we carried out a 'partial *ex ante*' analysis. That is, in addition to measuring health state values *ex post*, we also measured respondents attitude to the risk of the operation and combined this with the other *ex post* values of the health states. In effect, we adopted an additive model in which the values or utility of risk and outcome are independent. In practice, these assumptions are very restrictive and, at best, would be expected to yield only an approximation of the true *ex ante* values that individuals would place upon the option which measured respondents attitude to the surgical intervention and its possible outcomes. (See Cook, Richardson & Street 1993a; 1993b for a detailed account of results.)

### **1.3.2 Patient vs Clinical Perspective**

An implicit assumption often made in the CUA literature is that the patient experiences is a function of the clinical state of the patient. That is, while it is emphasised that it is the patient experience, perspective and preferences that provide the relevant values for measurement of post treatment quality of life, these will vary systematically with the clinical state. If the assumption is unwarranted then the various health outcomes found in a clinical or randomised control trial may only be of limited assistance in the measurement of HYE's.

The initial work of Daly (1990) casts serious doubt upon the validity of the assumption in the case of gallstone disease. The conclusion was reinforced by the results at Sheffield (Nicholl et al. 1992). The Sheffield Biliary Lithotripsy study found that biliary pain experience after lithotripsy did not depend on whether or not stones were cleared. A further confounding factor and one well documented in the literature is the so-called post cholecystectomy syndrome. Long term follow up of cholecystectomy patients suggests that about 10 percent of patients continue to experience symptoms following removal of the gallbladder. In some cases these symptoms can be attributed to physical problems or complications of the

procedure. Where this is not the case and no physiological symptoms can be found the conditions is most often described as 'post cholecystectomy syndrome'.

Our approach to identifying patient experience following the three treatment options is discussed below in Section 3.

### **1.3.3 Whose Values**

A further question that needed to be addressed in this study was 'whose values should be used to measure post operative quality of life'. The issue has by no means been resolved in the literature. The important question underlying the debate is whether the use of different groups, (clinicians, patients or members of the general population) results in different health state values. The evidence is mixed (Froberg & Kane 1989). In this study values from those persons in the population who matched the age and sex profile of our patient population were used. It was postulated that this group represent the preferences of the potential client group for the three treatment options.

As our approach required assessment of different health states from respondents with no personal experience of the health state it was necessary to present respondents with descriptions of the health state as experienced by the typical patient. Two conflicting requirements arose, both of which may affect the validity of the approach. The first is that the health state descriptions should represent a full and correct statement of the QoL issues that concern patients. The second requirement is that the health state description should be sufficiently simple that respondents who have not experienced the health states can fully understand and assess the implications of the health states being described. This second requirement, in particular, makes use of complex and multi outcome 'scenarios' infeasible. In the literature there is no method described and generally accepted for the conversion of complex and differing individual experiences which are sensitive to context and prognosis into a simple scenario.

In the *ex post* approach adopted in this study many of the problems of the *ex ante* approach are minimised because health states are measured independently from the health states which precede or follow it. Health state values measured this way are combined, subsequently, in an additive way to represent the loss of utility of an entire post operative treatment episode. Our approach to translating the patient experience into health state descriptions for use by the general public is discussed in section 4, below.

## **2 STUDY DESIGN AND DATA**

The analysis was based upon a clinical trial of the three treatment options that was conducted at St Vincent's Hospital Melbourne where the first publicly owned lithotripter was put to clinical use in September 1989. While this trial was primarily conducted to evaluate biliary lithotripsy it resulted in the collection of information on a comparable sample of patients undergoing each of the treatment options, lithotripsy, open cholecystectomy and laparoscopic cholecystectomy.

The data from the trial were augmented by data from two other sources; Firstly, in consultation with clinical staff at St Vincent's the probability of a significant clinical outcome was estimated based on St Vincent's clinical data and outcomes in other centres, particularly those centres which, at the time of the study, had more extensive experience with the new procedures. Secondly, a patient survey was conducted. In common with other economic evaluations of health care interventions, the patient experience could not reliably be inferred from the clinical outcomes. Consequently, interviews were conducted with a sample of lithotripsy and laparoscopic cholecystectomy patients to identify the essential components of their subjective experience of post treatment health states. Open cholecystectomy patients were not included in this initial data gathering phase because the procedure is well documented and well understood. Patients were surveyed, subsequently, via a postal questionnaire. The questionnaire was designed to validate the health state dimensions identified from the literature and the interviews. In addition, it provided information on the frequency, severity and duration of post treatment disability. This enabled categorisation of patients into treatment outcomes including transitional outcomes or health states.

### **2.1 The St Vincent's Hospital Trial**

The design of the St Vincent's trial is described in both the first interim report of the St Vincent's Hospital Biliary Lithotripsy Evaluation Sub-Committee (1991) and in Hailey and Hirsch (1991). A randomised control trial was not employed because of the difficulty in obtaining agreement from patients and referring specialists, doubts as to whether randomisation criteria would be consistently followed, and the potential difficulty with numbers of patients in each of the arms of the trial.

As a second best approach the clinical trial employed selection criteria to ensure that patients assigned to each arm of the trial were comparable, i.e. their prior medical condition would not bias the outcome of the trial. Patients in the lithotripsy arm of the trial were given the procedure if they had a functioning gall bladder, if they had no more than three stones with a total volume not exceeding 3 cm, and if they were willing to accept the treatment. Pregnancy, jaundice and the presence of acute cholecystitis, acute pancreatitis, and acute cholangitis were all contra-indications for the procedure. These criteria closely reflect those initially developed in the Munich lithotripsy trial which has become the de-facto gold standard (Sackmann et al. 1988). (A copy of the St Vincent's criteria is attached as Appendix 1). The application of these criteria result in about 15-20 percent of all patients presenting with

symptomatic gallstone disease being suitable for lithotripsy (Vellar 1993).

After laparoscopic cholecystectomy became available at St Vincent's Hospital at the end of 1990 patients were normally offered and selected the laparoscopic procedure as the treatment of first choice. As a consequence there have been few uncomplicated open cholecystectomy patients at the hospital since 1991. For comparative purposes only uncomplicated open cholecystectomy patients could be included in the trial. This meant that patients in the study were chosen retrospectively and pre-date laparoscopic patients by up to 30 months. The selected uncomplicated open cholecystectomy patients were matched as far as possible by age and sex to patients in the lithotripsy and laparoscopic cholecystectomy arms of the trial. Characteristics of the final patient samples are summarised in *Table 1*.

**Table 1**  
**Patients in the St Vincent's Hospital Trial**

<i>Procedure</i>	Male			Female		
	Open Cholecystectomy	Laparoscopic Cholecystectomy	Lithotripsy	Open Cholecystectomy	Laparoscopic Cholecystectomy	Lithotripsy
Sample size	25	26	128	74	72	326
mean age	53	47	53	46	49	49
median age	52	41	53	49	49	48
range age	(20 - 79)	(19 - 79)	(28 - 80)	(18 - 72)	(14 - 77)	(16 - 81)

While the selection criteria eliminated the most obvious sources of systematic difference between the three groups, the trial permits the possibility that patients undergoing the three procedures may have varied systematically in some respect. Results obtained throughout the present study were tested for differences associated with age, sex and stone size/type.

## 2.2 Interviews

Using the approach advocated by Glaser and Strauss (1987). Subjects were recruited into the study up to a point where each major outcome dimension was judged to be saturated. This resulted in a total sample of 20 lithotripsy patients. Unless patients wished otherwise the interviews were conducted in the patient's own home. The nature of the interview was largely unstructured to allow all aspects of the patient's experience to be explored.

A similar survey was conducted for laparoscopic patients. From a sample of 11 patients the typical post laparoscopic cholecystectomy health state was identified.

Because of the time since treatment it was not feasible to interview open cholecystectomy patients and the description of the immediate post-operative experience of the typical patient was based, in the first instance, on clinical advice. As the procedure has been established

for a long time and is well understood this was judged to be a reliable approach.

## 2.3 Postal Questionnaire

The patient postal survey had two objectives. First, it sought to validate the result of the interviews and to ensure that no major category of symptoms or patient experience had been overlooked. Secondly, as clinical data could not be used to group patients into the relevant outcome categories, it sought information on the distribution of patients between the major health states, including transitional health states. Patients were asked about the severity and frequencies of their symptoms after treatment including their ability to return to normal activities. In accordance with the principles of qualitative research open ended questions were provided to allow patients to convey any other post-treatment symptoms which had not been identified by the previous methods.

Since persons have imperfect recall the information collected in the survey was limited to the experience in the first six months after the procedure and in the one month immediately prior to receipt of the questionnaire. This latter information was designed to allow estimation of the prevalence of symptoms beyond the initial six months and up to the 18 months when bile salt therapy for lithotripsy ceased. If symptoms persisted beyond this initial period they were to be primarily attributed to post-cholecystectomy syndrome. Questionnaires were sent to all open cholecystectomy patients in the trial and to a sample of lithotripsy and laparoscopic cholecystectomy patients. Excluding those who were known to have died or for whom there was no current address, questionnaires were sent to 369 lithotripsy, 79 laparoscopic cholecystectomy and 89 open cholecystectomy patients.

As *Table 2* shows the response rate from the 3 groups was 73, 82 and 69 percent respectively giving an overall response rate of 74 percent from the 537 patients approached. The questionnaire is reproduced in *Appendix 2*.

**Table 2**  
**Response Rate of Patient Questionnaire**

	<b>Patients in Trial</b>	<b>Intended Sample</b>	<b>Achieved Sample</b>	
	<b>No</b>	<b>No</b>	<b>No</b>	<b>%</b>
Open Cholecystectomy	99	89	61	69
Laparoscopic Cholecystectomy	98	79	65	82
Lithotripsy	454	369	269	73

Respondents to the survey were tested against the age/sex profile of the patient cohort. For each procedure the age distribution of respondents were similar to that of the total patient population.

### 3 MAJOR DETERMINANTS OF QUALITY OF LIFE FOLLOWING TREATMENT

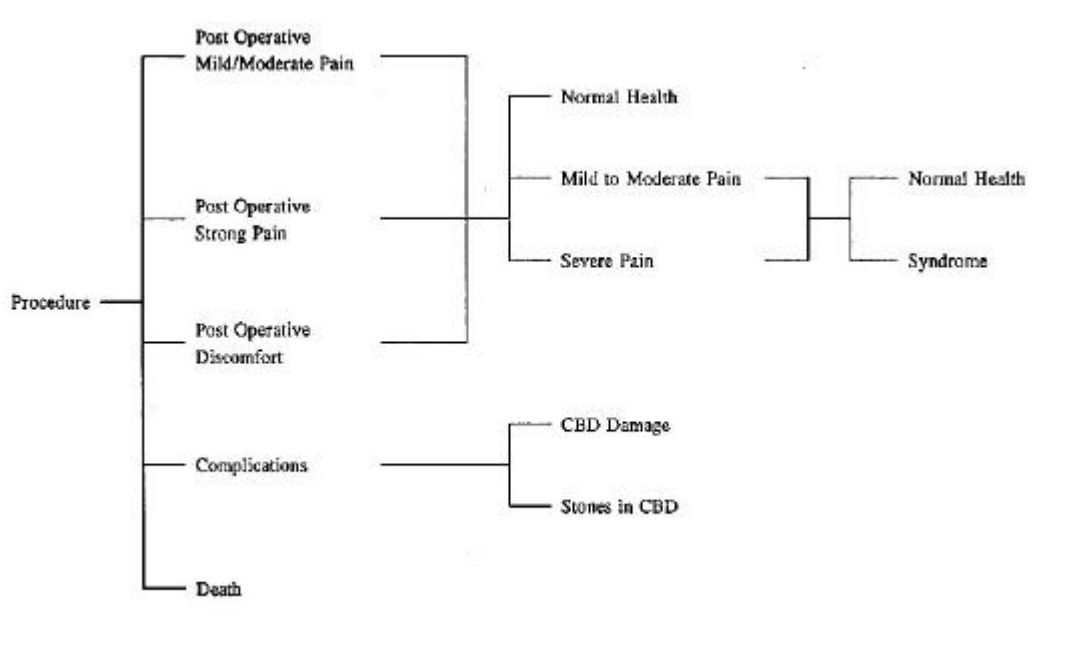
As noted previously, prior research indicates imperfect correspondence between the subjective patient experience and the clinical outcomes (ie stone clearance or removal of the gallbladder) after treatment. Quality of life differed significantly during the post procedural recovery in the case of laparoscopic and open cholecystectomy and the prolonged bile salt therapy following lithotripsy. As cost utility analysis must be based upon the patient experience a separate study was carried out to determine the perceived quality of life. The analysis was based upon three sets of data, namely, open ended interviews of patients, a questionnaire survey and selected patient information collected during the St Vincent's trial. These data were combined with clinical outcome data into the outcome trees in Figures 1-3.

#### 3.1 Pain, Diarrhoea and Nausea

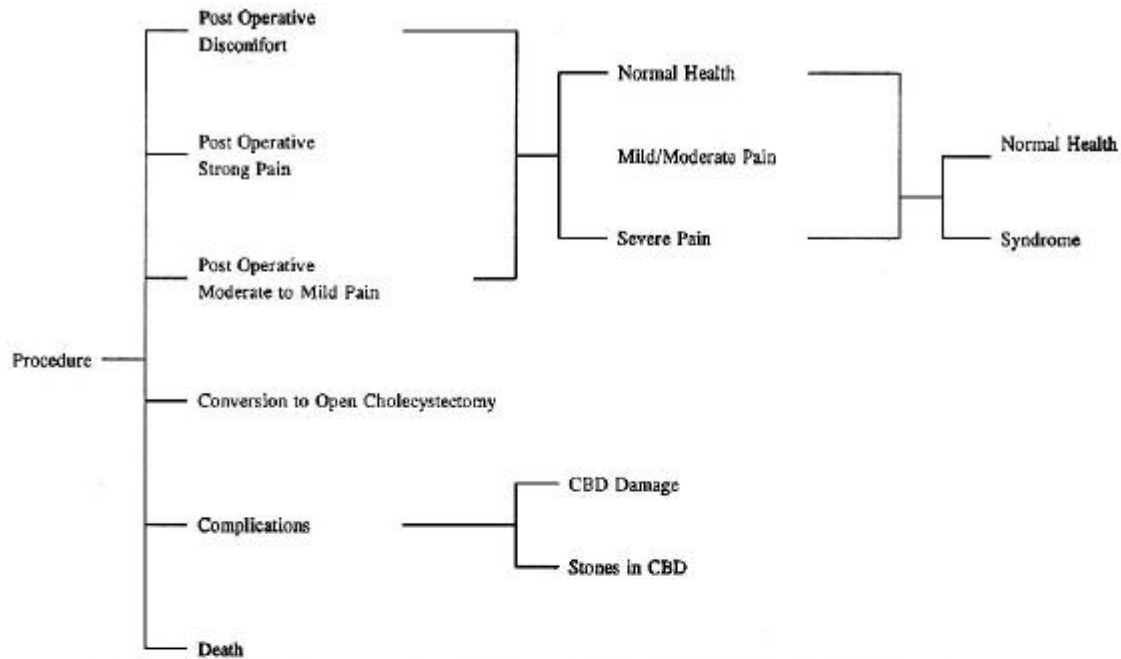
From the clinical data and the patient interviews it was established that pain, diarrhoea and to a lesser extent nausea were significant determinants for the quality of life after lithotripsy and that pain was the major determinant in the case of the surgical procedures. The data also demonstrated the variability of symptoms both between individuals and over time for individuals.

To ensure that no other major symptom group was excluded or indeed that the previously identified symptoms were appropriate, patients were also asked to comment on anything they thought important about their post-treatment health state.

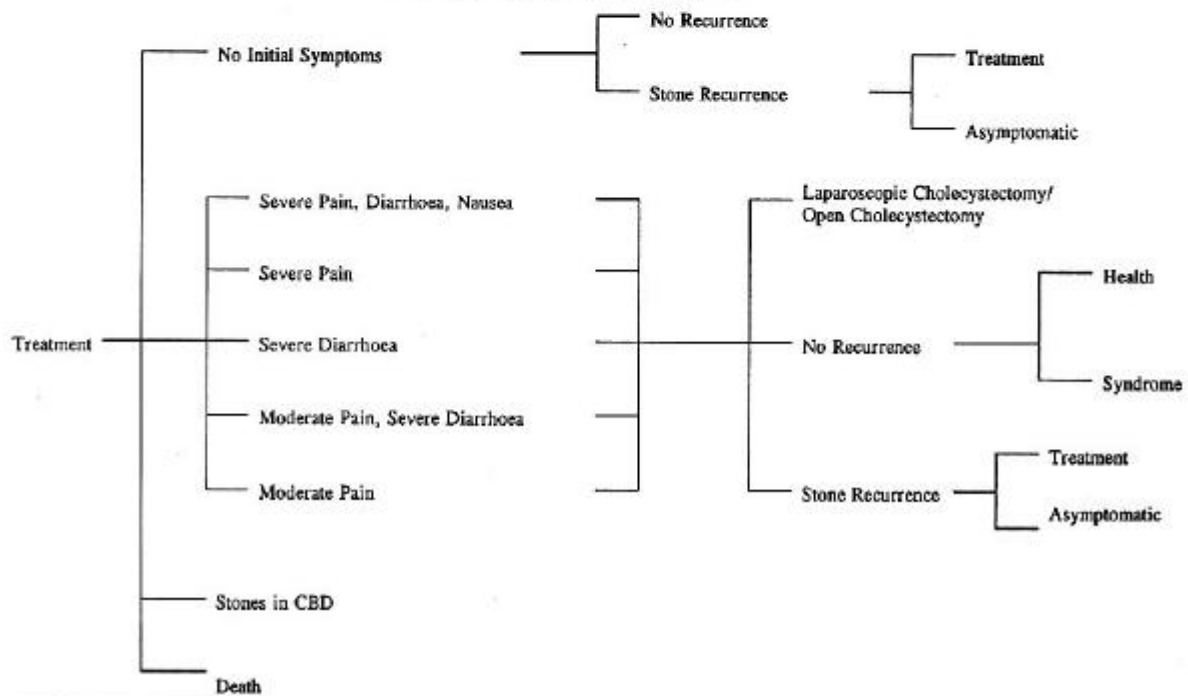
**Figure 1**  
**Open Cholecystectomy (Patient Perspective)**



**Figure 2**  
**Laparoscopic Cholecystectomy (Patient Perspective)**



**Figure 3**  
**Lithotripsy (Patient Perspective)**





The percentage of patients commenting on symptoms are given in *Table 3* below. *Table 3* reveals that for each of the treatment options respondents nominated pain most often in the open ended question. Thirty six percent of open cholecystectomy patients , 28 percent of laparoscopic cholecystectomy patients and 21 percent of lithotripsy patients commented on pain after treatment. As expected, diarrhoea was reported most frequently by lithotripsy patients - 19 percent of lithotripsy patients commented upon diarrhoea as compared with only 3.1 percent of laparoscopic cholecystectomy patients. No open cholecystectomy patient reported diarrhoea. Nausea appears to be less important for all treatment options with only 6 percent of both laparoscopic cholecystectomy and lithotripsy patients nominating this symptom. Nausea was not listed by open cholecystectomy patients. The lack of comment on diarrhoea and nausea after open cholecystectomy is most likely to be due to the time since treatment which was greatest for this group of patients and to diarrhoea and nausea, if they are present at all, being minor symptoms relative to pain.

To enable categorisation of patients into relevant outcome groups the questionnaire included a number of questions about the frequency and intensity of symptoms identified through the interviews as being important for the specific treatment. That is, all patients were asked to report experience with pain and, in the case of lithotripsy, with diarrhoea and nausea following treatment. Since no other major symptom group emerged from the survey as being quantitatively important it is reasonable to conclude that the outcomes patients felt most strongly about had been correctly identified in the previous interview.

*Table 3*  
**Percentage of Respondents Who Volunteered Symptoms  
Using Open Ended Questions**

Procedure	Pain	Diarrhoea	Nausea	Other
Open Cholecystectomy	36.1	-	-	26.2
Laparoscopic Cholecystectomy	27.7	3.1	6.2	16.9
Lithotripsy	21.2	19.0	5.9	17.5

For each of the procedures an immediate post-procedural time period was defined on the basis of the clinical evidence - to ensure that the questions about post treatment quality of life were presented to patients in the most meaningful way. This was the period during which the most severe symptoms would typically be experienced. For open and laparoscopic cholecystectomy and lithotripsy these periods were one month, two weeks, and two months respectively as shown in *Table 4*. As discussed previously, patient interviews and clinical data indicated a significant variability in the patients experience and the questionnaire data supported this finding.

**Table 4**  
**Percentage of Respondents Reporting Symptoms**

### Following Direct Questioning\*

	Pain Percent	Diarrhoea percent	Nausea percent
Open Cholecystectomy			
0 - 1 month	68.9	-	-
2 - 6 months	52.9	-	-
Months prior to survey	19.7	-	-
Laparoscopic Cholecystectomy			
0 - 0.5 months	61.5	-	-
0.5 - 6.5 months	33.8	-	-
Month prior to survey	23.1	-	-
Lithotripsy			
0 - 2 months	58.0	53.5	31.6
4 - 6 months	43.1	42.0	21.9
Month prior to survey	24.5	18.6	13.4

*Note: Only lithotripsy patients were asked direct questions about diarrhoea and nausea. Prior interviews demonstrated that diarrhoea and nausea were not significant aspects of the post treatment period for open and laparoscopic cholecystectomy patients.*

### **Pain**

When asked about pain 69 percent of open cholecystectomy, 62 percent of laparoscopic cholecystectomy patients and 58 percent of lithotripsy patients reported pain in the immediate post treatment period. However, for a large proportion of respondents pain persisted beyond the immediate post treatment period. As expected, the percentage of patients experiencing pain up to 6 months after treatment was highest for open cholecystectomy patients. The difference between the treatment groups becomes insignificant when pain persisted over a longer period of time. This result was also found in the Sheffield trial.

### **Diarrhoea and Nausea**

Slightly more than half of the lithotripsy patients reported diarrhoea for the two months after treatment lithotripsy with 42 percent experiencing continuing symptoms for the next four months. About one third of lithotripsy patients reported nausea after treatment reducing to one fifth for the next 4 months. Again diarrhoea and nausea persisted for a small percentage of patients beyond the initial 6 months period.

## Frequency and Severity of Symptoms

Table 5 reports on the severity and frequency of pain following treatment. The majority of open cholecystectomy patients who reported pain post-operatively also reported this pain to be frequent. For laparoscopic patients the post-operative pain experience is more varied. Although the majority of those who had severe pain reported this to be frequent, of the 65 percent who said they had moderate pain, 35 percent had frequent moderate to mild pain and 30 percent infrequent moderate to mild pain. Lithotripsy patients, on the other hand, most often reported infrequent pain after treatment. This result is also consistent with clinical evidence. Patients who have biliary colic in the first 2 months following lithotripsy usually have 1 or 2 attacks of biliary colic as small fragments of gallstone leaving the gallbladder.

**Table 5**  
**Severity and Frequency of Pain Following Treatment**

	Severe Pain *		Moderate/Mild Pain	
	Frequent percent	Infrequent percent	Frequent percent	Infrequent percent
Open Cholecystectomy				
0 - 1 month	35.7	11.9	33.3	19.0
2 - 7 months	12.5	9.4	9.4	68.7
Months prior to survey	-	25.0	-	75.0
Laparoscopic Cholecystectomy				
0 - 0.5 months	30.0	5.0	35.0	30.0
0.5 - 6.5 months	9.1	18.2	13.6	59.1
Month prior to survey	-	13.3	-	86.7
Lithotripsy				
0 - 2 months	9.9	41.4	5.4	42.8
2 - 6 months	6.3	40.5	8.1	45.0
Month prior to survey	7.7	18.5	15.4	58.5

\* Frequent: 2 or more episodes of pain per week.

Table 6 reports on the severity and frequency of diarrhoea and nausea following lithotripsy. The majority of respondents who stated they had severe diarrhoea also reported frequent diarrhoea while the majority of those who reported mild diarrhoea indicated it to be infrequent. It is conceivable that respondent's perception of the severity of diarrhoea may have been influenced by its severity.

Nausea appears to be the least important symptom. The majority of patients reported it to be infrequent.

**Table 6**  
**Severity and Frequency of Diarrhoea and Nausea**  
**Following Lithotripsy**

	<b>Severe *</b>		<b>Frequent Moderate/Mild</b>	
	<i>Frequent percent</i>	<i>Infrequent percent</i>	<i>Frequent percent</i>	<i>Infrequent percent</i>
Diarrhoea				
0 - 2 months	37.8	20.3	14.0	28.0
2 - 6 months	31.5	10.2	18.5	39.8
Month prior to survey	23.9	8.7	13.0	54.3
Nausea				
0 - 2 months	11.8	20.0	17.6	50.6
2 - 6 months	10.3	12.1	10.3	67.2
Months prior to survey	15.8	15.8	5.3	63.2

\* *Frequent: 6 or more episodes per month.*

### 3.2 Ability to Carry Out Normal Duties

From the interviews it became apparent that patients considered the extent to which the treatment interfered with their normal activities to be an important aspect of the treatment outcome. The best aspects of lithotripsy were most frequently cited as avoidance of surgery, avoidance of a general anaesthetic and the need for recovery time as well as avoidance of the need for time off normal activities.

The average laparoscopic patient was also pleased to recover quickly and to be free from pain. Most were able to go home 2 to 3 days after the operation and return to work between 1 and 3 weeks later.

Consequently, patients were asked about their ability to carry out normal activities after treatment. *Table 7* demonstrated that lithotripsy is the least disruptive procedure to normal role functioning - well over 80 percent of patients reported little, if any, interruption to normal activities in the first 6 months after treatment. This compares with 32 percent of open cholecystectomy patients and 49.2 percent of laparoscopic cholecystectomy patients in the immediate post treatment period and 70 percent of open cholecystectomy patients up to 6 months following treatment.

**Table 7**  
**Ability to Carry Out Normal Duties**  
**Following Treatment**

	All or Most of the Time percent
Open Cholecystectomy	
0 - 1 month	32.1
1 - 7 months	70.7
Month prior to survey	92.6
Laparoscopic Cholecystectomy	
0 - 0.5 months	49.2
0.5 - 6.5 months	83.1
Month prior to survey	87.7
Lithotripsy	
0 - 2 months	83.4
2 - 4 months	87.6
Month prior to survey	93.8

Our approach to translating the patient experience identified in this way is discussed in *Section 4* below.

## **4 HEALTH STATE SCENARIOS**

In cases where the patient experience is highly variable in relation to clinical outcome and also variable through time it is not feasible to construct and measure each possible health state. When general population values are used to assess consumer preferences for the health outcomes a large number of interviews are needed to convert scenarios into utility values. It is unlikely that such a research strategy would be cost effective in relation to the value of the final results. Cognitive overload is an additional factor limiting the number of health states that can be evaluated by respondents at any one time. To overcome these constraints, selected standard health states were constructed which combined different levels of the major symptoms in such a way that these health states collectively spanned the full spectrum of health states experiences. Consequently, health states which were not directly measured could be readily mapped to a measured health state.

### **4.1 Translating the Patient Experience into Health State Scenarios**

In this study standard health states were developed by combining pain with degrees of diarrhoea and nausea. Pain, if it exist, was the most persistent and important symptom and it was the pre-cursor to subsequent treatment. Diarrhoea can be, and was, controlled over time through a reduction in the dosage of bile salts reinforced by the ability of the body to adjust to the drug therapy.

Standard states were used, subsequently, to estimate 'base values' for each of the treatment options. The results were subjected to extensive sensitivity analysis to ascertain where and when numerical changes in the utilities produce changes among the preferred options (Cook et al. 1993a; 1993b)

The health states were described, in the first instance, using patient terminology from the interviews in the case of laparoscopic cholecystectomy and lithotripsy. The health state scenario for open cholecystectomy was developed from discussions with clinical staff at St Vincent's Hospital and from questionnaire data.

Health state descriptions used the modal values of symptoms reported by patients.

### **4.2 Presenting the Health States to Respondents**

There is no generally agreed format on the way in which health state are presented to respondents. The important principle is that the description is readily understood by respondents and that important aspects of the health state are included clearly and explicitly. Cognitive burden increases with the number of attributes included in the health state descriptions (Fisher, 1979) and is exacerbated by the number of health states which are to be evaluated at any one time. Measurement validity therefore depends upon simplicity of the presentation.

As discussed above, the terminology and phraseology used to describe the health state scenarios was, in the first instance, based upon the typical descriptions given by patients. During the subsequent piloting of the interview with the general population, it became clear that respondents had difficulty in making comparisons between the health states descriptions

initially presented to them. The narrative style of the scenarios resulted in cognitive overload. From discussions with respondents it was ascertained that they were seeking a series of 'matching attributes' for each pair of scenarios they were asked to compare. This suggests that even when the multi-attribute or decomposed approach to health state measurement is not used explicitly it can provide a useful framework for constructing holistic health state description. Consequently, the description of the health states was restructured as a series of statements on each of the important attributes but with varying levels ranging from 'normal' to 'most severe', as required. In addition, the number of statements were kept to a minimum to reduce the cognitive burden. Only the most important aspects of the health states were stated explicitly. The resulting health state scenarios are reproduced in *Table 8*.

As noted in the introduction, this study was concerned with the distinction between *ex ante* (anticipated) and *ex post* (realised) health states. One of the major (but not the only) distinction between the two perspectives on health status measurements is risk attitude and particularly risk of death. Two health states were constructed to convey to respondents the risk to be undertaken during surgery. These 'health states' or scenarios are reproduced as HS8 and HS9, in *Table 8*. (Results are discussed in Cook et al. 1993a; 1993b.)

## 5 DISCUSSION

The procedures adopted in this study to construct health state scenarios correspond closely with those described in the literature. However, these procedures leave unanswered an important methodological issue. At present, instrument validity depends upon the process by which health state descriptions are constructed and this may or may not be satisfactory. The process of combining data from different sources and its simplification into a form that is easily understood during an interview results in a simplified health state scenario that necessarily differs from the richer and more diversified description that is obtained from qualitative research. A simpler scenario will omit some of the aspects of the health state that may be highly significant for some patients. In sum, the validity of the instrument may be reduced because of either of two conflicting requirements, first, that the content of the health state description should be a comprehensive and accurate representation of patient feeling and, secondly, that the health state description should be easily comprehended and appreciated. The unanswered issue is the means by which the scenarios can be validated. This latter point relates to the purpose to which they are being used.

The chief defect in the health state scenarios outlined here is that in the process of their construction there was a significant loss of information about context and prognosis. This could, potentially, invalidate the instrument but only if the *ex ante* basis for health state measurement represented the value system to be incorporated in resource allocation decisions. With this approach we must reproduce full information including the context of the decision, disease state, alternative treatments, all the likely outcomes, prognosis and probabilities. That is, the gold standard for measuring 'utility' is the strength of preferences for future treatments in the light of all relevant information. It is the anticipated not the realised health state which is being measured. This difference is reflected in the resulting health state values; as the object of measurement changes so does the value of the index used to measure relative quality gains of the competing alternatives. However, the application of the *ex ante* approach is likely to be severely limited and, in the present study, the diversity of outcomes made its full application infeasible.



**Table 8**  
**Health State Scenarios**

<b>Health State</b>	<b>Category</b>	<b>Scenario</b>
<b>1</b>	Open Cholecystectomy (normal)	You have had a successful operation. You get tired very easily and you don't sleep very well at night. The wound gives you a continuous dull sort of pain. You find that you cannot carry out most of your normal activities.
<b>2</b>	Laparoscopic Cholecystectomy (normal)	You have had a successful operation. You feel a little tired. It is uncomfortable for you to move. You cannot exercise or lift heavy things. You find that you can do most of your normal activities.
<b>3</b>	Severe pain Severe diarrhoea Nausea	You are having specialist medical treatment. Your treatment gives you 2 or 3 attacks of continuous agonising pain in your chest and back. The pain can last from half an hour to 4 hours. You can do nothing to relieve the pain. When the pain goes you can return to your normal activities. The treatment also gives you uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful. About once a week you feel a bit nauseous for a few hours.
<b>4</b>	Severe pain (periodically)	You are having specialist medical treatment. Your treatment gives you 2 or 3 attacks of continuous agonising pain in your chest and back. The pain can last from half an hour to 4 hours. You can do nothing to relieve the pain. When the pain goes you can return to your normal activities.
<b>5</b>	Severe diarrhoea	You are having specialist medical treatment. You have uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful.
<b>6</b>	Moderate pain Sever diarrhoea	You are having specialist medical treatment. The treatment gives you an uncomfortable heavy feeling in your stomach most of the time. About once a month you also have a cramping in your chest and back. You have uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful.
<b>7</b>	Moderate pain	You are having specialist medical treatment. The treatment gives you an uncomfortable heavy feeling in your stomach most of the time. About once a month you also have a cramping in your chest and back.
<b>8</b>	Operation 1	You will have an operation. Your doctor has told you that there is a very small risk of dying (about one person in every 1,000 dies). After the operation you will return to full health straight away.
<b>9</b>	Operation 2	You will have an operation. Your doctor has told you that there is a very small risk of dying (about one person in every 1,000 dies). After the operation you will be in hospital for one week and you will: have a dull gnawing sort of pain all of the time; feel sick and want to vomit most of the time; find coughing and moving painful; have constipation and will be given an enema; have trouble sleeping.

By contrast, many of these difficulties and the associated problem of validity are mitigated if

the *ex post* approach to measurement is considered to be the appropriate value basis. With this the utility of QoL index *should not* be a function of contextual factors and prognosis but should be an accurate description of a point in time state of health. This is in effect equivalent to the various multi-attribute including MAU approaches which are point in time measurements. In the *ex post* approach health states are measured independently from the health states which precede or follow it and are combined in an additive fashion to represent changes in health status during the course of a particular treatment. Measured in this way health state utility values are used to weight life years such that they reflect an average disease free life year. In principle, policy makers should determine the value basis for resource allocation. In practice, virtually all CUA has been based upon the *ex post* approach for measurement. While, as noted, this avoids some of the issues of content validity it leaves unresolved the issue of validating the *ex post* health state description which arises in a specific study.

The need to construct our own health state scenarios in the gallstone disease study was predicated on the fact that none of the existing MAU scales are sensitive to the QoL factors associated with gallstone disease. More importantly, there is serious doubt about their validity in relation to the objective of resource allocation (Nord et al. 1992). This dilemma highlights the need for a revised instrument for measuring quality of life which in the context of life - and quality of life judgements about resource allocation is cost effective, valid and sensitive to changes in quality of life factors across a wide range of diseases.

### **Selection Criteria for Lithotripsy and Laparoscopic Cholecystectomy Patients into the St Vincent's Trial**

#### **LITHOTRIPSY**

##### ***Inclusion Criteria***

- . Patients must be suffering from symptomatic gallstones.
- . The gall bladder must be functioning.
- . There must be no more than three stones.
- . The stones must not be heavily calcified.
- . No stone must be greater than 3 cm in diameter or less than 5-6 mm in diameter.
- . The volume of multiple stones must not exceed that of a 3 cm single stone.

##### ***Exclusion Criteria***

- . Pregnancy (all female patients within the child bearing age group must be tested for pregnancy).
- . Jaundice.
- . The presence of acute cholecystitis, acute pancreatitis or acute cholangitis.
- . Stones that are too big, too small or too numerous.
- . A non-functioning gall bladder.
- . The presence of a pacemaker.
- . Cysts or aneurisms which would be in the path of the shockwave during ESWL.

#### **LAPAROSCOPIC CHOLECYSTECTOMY**

- . The majority of patients with symptomatic gallstones are suitable for laparoscopic (percutaneous) cholecystectomy.
- . Relative contra-indications include previous upper abdominal surgery and acute cholecystitis.
- . Absolute contra-indications include jaundice, a bleeding tendency and cirrhosis of the liver with portal hypertension.
- . Pregnancy is usually regarded as a contra-indication to laparoscopic cholecystectomy. Certainly the enlarged uterus in pregnancy may be damaged by the Verres needle or by the trocars.
- . Jaundiced patients may have the obstructing stone(s) removed by ERCP sphincterotomy and after recovering from this, may have the gall bladder removed by laparoscopic (percutaneous) cholecystectomy.

## APPENDIX 2

### Questionnaire for Patients who have had Treatment for Gallstone Disease.

Respondent Number: Ch

*Please answer every question. If you are not sure or cannot remember the exact details,*

*please make a guess.*

#### SECTION TWO

##### INSTRUCTIONS

In the following section we would like you to tell us how you felt after your operation.

We are asking you to think about three separate time periods:

- how you felt in the first month after your operation;
- how you felt in the next six months; and
- more recently, how you have been feeling during this last month.

Of course we only want to know about symptoms you think were related to your gallstone illness or to the

treatment you had received.

(Please \_ appropriate boxes.)

	IN THE FIRST MONTH AFTER YOUR OPERATION	IN THE NEXT 6 MONTHS	DURING THIS LAST MONTH
QUESTION 10			
How many episodes of pain did you have?	_____ episodes	_____ episodes	_____ episodes
About how long did a typical pain episode last?	_____ hours	_____ hours	_____ hours

How would you describe this pain?	<input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild	<input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild	<input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild
<b>QUESTION 11</b>			
Where you able to do everything you normally do?	<input type="checkbox"/> All the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> Hardly ever	<input type="checkbox"/> All the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> Hardly ever	<input type="checkbox"/> All the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> Hardly ever

<b>QUESTION 12</b> Is there anything else you would like to tell us about how you felt after your operation?	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
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<b>QUESTION 13</b> Did you have any treatment for gallstones before your operation? (Please _ appropriate box.)	<input type="checkbox"/> <sub>22</sub> No <input type="checkbox"/> <sub>23</sub> Yes (please specify) _____ _____ _____
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Respondent Number: La

## QUESTIONNAIRE FOR PATIENTS WHO HAVE HAD TREATMENT FOR GALLSTONE DISEASE

*Please answer every question. If you are not sure or cannot remember the exact details,*

*please make a guess.*

### SECTION TWO

#### INSTRUCTIONS

In the following section we would like you to tell us how you felt after your operation.

We are asking you to think about three separate time periods:

- how you felt in the first two weeks after your operation;
- how you felt in the next six months; and
- more recently, how you have been feeling during this last month.

Of course we only want to know about symptoms you think were related to your gallstone illness or to the

treatment you had received.

*(Please \_ appropriate boxes.)*

	IN THE FIRST 2 WEEKS AFTER YOUR OPERATION	IN THE NEXT 6 MONTHS	DURING THIS LAST MONTH
<b>QUESTION 10</b>			
How many episodes of pain did you have?	_____ episodes	_____ episodes	_____ episodes
About how long did a typical pain episode last?	_____ hours	_____ hours	_____ hours
How would you describe this pain?	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild

QUESTION 11			
Where you able to do everything you normally do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	All the time	All the time	All the time
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Most of the time	Most of the time	Most of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Some of the time	Some of the time	Some of the time	Some of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hardly ever	Hardly ever	Hardly ever	Hardly ever

<p><b>QUESTION 12</b></p> <p>Is there anything else you would like to tell us about how you felt after your operation?</p>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
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<p><b>QUESTION 13</b></p> <p>Did you have any treatment for gallstones before your operation? (Please _ appropriate box.)</p>	<p><input type="checkbox"/> 45 No</p> <p><input type="checkbox"/> 46 Yes (please specify) _____</p> <p>_____</p> <p>_____</p>
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Respondent Number: Li

## QUESTIONNAIRE FOR PATIENTS WHO HAVE HAD TREATMENT FOR GALLSTONE DISEASE

*Please answer every question. If you are not sure or cannot remember the exact details,*

*please make a guess.*

### SECTION TWO

#### INSTRUCTIONS

In the following section we would like you to tell us how you felt after your lithotripsy treatment.

We are asking you to think about three separate time periods:

- how you felt in the first two months after your first treatment;
- how you felt in the next four months; and
- more recently, how you have been feeling during this last month.

Of course we only want to know about symptoms you think were related to your gallstone illness or to the

treatment you had received.

*(Please \_ appropriate boxes.)*

	IN THE FIRST 2 MONTHS AFTER YOUR FIRST TREATMENT BY LITHOTRIPSY	IN THE NEXT 4 MONTHS	DURING THIS LAST MONTH
<b>QUESTION 10</b>			
How many episodes of pain did you have?	_____ episodes	_____ episodes	_____ episodes
About how long did a typical pain episode last?	_____ hours	_____ hours	_____ hours
How would you describe this pain?	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild



<b>QUESTION 11</b>			
How many episodes of diarrhoea did you have?	_____ episodes	_____ episodes	_____ episodes
About how long did a typical diarrhoea episode last?	_____ hours	_____ hours	_____ hours
How would you describe this diarrhoea?	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild
<b>QUESTION 12</b>			
How many episodes of nausea did you have?	_____ episodes	_____ episodes	_____ episodes
About how long did a typical nausea episode last?	_____ hours	_____ hours	_____ hours
How would you describe this nausea?	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild	<input type="checkbox"/> Severe  <input type="checkbox"/> Moderate  <input type="checkbox"/> Mild
<b>QUESTION 13</b>			
Where you able to do everything you normally do?	<input type="checkbox"/> All the time  <input type="checkbox"/> Most of the time  <input type="checkbox"/> Some of the time  <input type="checkbox"/> Hardly ever	<input type="checkbox"/> All the time  <input type="checkbox"/> Most of the time  <input type="checkbox"/> Some of the time  <input type="checkbox"/> Hardly ever	<input type="checkbox"/> All the time  <input type="checkbox"/> Most of the time  <input type="checkbox"/> Some of the time  <input type="checkbox"/> Hardly ever

<p><b>QUESTION 14</b></p> <p>Is there anything else you would like to tell us about how you felt after your lithotripsy treatment?</p>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
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<p><b>QUESTION 15</b></p> <p>Have you had surgery for gallstones since your lithotripsy treatment? (Please _ appropriate box.)</p>	<p><input type="checkbox"/> 86 Yes Date of surgery _____</p> <p><input type="checkbox"/> 87 No</p>
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