

# Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty

A study of the Swedish Hip Arthroplasty Register

WHEN WE WANT YOUR OPINION  
WE'LL GIVE IT TO YOU



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UNIVERSITY OF GOTHENBURG

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*“It’s about  
doing the right thing,  
doing the thing right,  
and doing it at the right time”*



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# Abbreviations

<b>ASA</b>	American Society of Anesthesiologists
<b>AVN</b>	Avascular necrosis
<b>CHD</b>	Childhood hip disease (congenital or acquired)
<b>CI</b>	Confidence interval
<b>CPP</b>	Cost per patient
<b>EQ-5D</b>	The five dimension self-assessment tool from the EuroQol-group
<b>HRQoL</b>	Health-related quality of life
<b>IHD</b>	Inflammatory hip disease
<b>OA</b>	Osteoarthritis (osteoarthrosis)
<b>PRO</b>	Patient-reported outcome
<b>PROM</b>	Patient-reported outcome measure
<b>RCT</b>	Randomised clinical trial
<b>QALY</b>	Quality-adjusted life years
<b>RA</b>	Rheumatoid arthritis
<b>SD</b>	Standard deviation
<b>SEK</b>	Swedish currency kronor
<b>SF-36</b>	The 36-item Short-form Health Survey
<b>THA</b>	Total hip arthroplasty (synonymous with THR)
<b>the Register</b>	The Swedish Hip Arthroplasty Register
<b>TKA</b>	Total knee arthroplasty (synonymous with TKR)
<b>VAS</b>	Visual analogue scale
<b>WOMAC</b>	Western Ontario McMaster Universities Osteoarthritis Index
<b>WTP</b>	Willingness to pay





# Definitions

<b>Completeness</b>	Proportion of registered procedures at individual level to all procedures performed.
<b>Cost of illness</b>	Direct and indirect costs related to a defined illness.
<b>Cost-effectiveness analysis</b>	Evaluation that measures effects and consequences with disease specific tools.
<b>Cost-utility analysis</b>	Cost-effectiveness evaluation that combines utility measures with survival and cost data.
<b>Cost-effectiveness</b>	Efficient use of resources.
<b>Coverage</b>	Proportion of participating units to all units.
<b>Effectiveness</b>	Consequence of a treatment in everyday practice ('doing the right thing').
<b>Efficacy</b>	Consequence of a treatment under ideal/controlled conditions.
<b>Efficiency</b>	Comparison of the utility of a treatment with what can be achieved with the same consumption of resources ('doing the thing right').
<b>Direct medical costs</b>	Costs directly related to health-care interventions due to illness.
<b>Direct non-medical costs</b>	Non-medical costs directly associated with illness.
<b>Health economics</b>	The science of application of the economic theories, analyses and tools on circumstances and behaviour affecting people's health.
<b>Hip disease</b>	Collective term for any pathological condition of the hip joint.
<b>Incremental cost</b>	Additional cost an alternative intervention or therapy imposes over another intervention.
<b>Indirect costs</b>	Costs for production loss (e.g. due to sick-leave, disability pension) and premature death associated with illness.
<b>Intangible costs</b>	Cost of decreased health-related quality of life as a result of illness.
<b>Post hoc analysis</b>	Examining data for a hypothesis that came up after the data was collected.
<b>Regression analysis</b>	Statistical method for assessing the degree of correlation of a dependent variable adjusted to one or several independent variables.
<b>Re-operation</b>	Any surgical procedure related to a previous arthroplasty localised to the prosthesis joint.
<b>Response rate</b>	The proportion of respondents in relation to all patients who received the questionnaire.
<b>Revision</b>	A <i>re-operation</i> with extraction or exchange of all or parts of the implant.



# Abstract

## Background

The Swedish Hip Arthroplasty Registry collects prospective, observational, nationwide data on all total hip arthroplasties (THAs) in Sweden. Implant survival has been the most commonly reported outcome variable. However, the main indications for THA are pain and impaired health-related quality of life (HRQoL) due to hip disease. Therefore it is crucial to include patient-reported outcome measures (PROMs). Consequently, starting in 2002, the Registry introduced a PROM programme which has gradually expanded to include all units performing THA.

## Objectives

The present aims were to investigate the response rates to the PROM programme, to test an application for an Internet-based follow-up questionnaire for PROMs, to analyse patient-reported outcomes (PROs) and predictive factors for PROs in the Swedish THA population, and to estimate all costs related to hip disease in patients eligible for THA.

## Patients and methods

The PROM programme comprises a self-administered, ten-item questionnaire including Charnley category, a pain and a satisfaction visual analogue scale, and the generic HRQoL tool EQ-5D presented pre-operatively and at one, six and ten years post-operatively. An Internet application for collecting PROMs was developed.

The analyses were based on more than 40 000 THAs selected from the Registry according to predetermined criteria. A specific questionnaire to estimate cost of illness was completed by 2 635 patients prior to surgery.

## Results

Response rates to the PROM programme were appreciable but the Internet-based application for collecting PROMs did not give sufficient response rate to replace the pen-and-paper version. Patients eligible for THA reported poor HRQoL and considerable pain. The overall PROs were satisfactory, with an average increase in EQ-5D index of 0.37 one year after surgery. A non-negligible proportion did not respond satisfactorily to surgery one-year post-operatively. Musculoskeletal co-morbidity portended worse outcomes as did the presence of mental distress. The annual cost of illness for patients eligible for THA was SEK 58 600 (approximately € 6 000). Productivity loss was the major cost. Long wait for surgery was associated with increased costs.

## Conclusions

This study demonstrates the necessity of including PROM and societal cost data in a continuous, multidimensional assessment of THA. Thus the approach facilitates health-economic analyses and permits adequate monitoring and improvement of results.



# Introduction

Total hip arthroplasty (THA) is a successful intervention to decrease pain and to improve health-related quality of life (HRQoL) in patients with disabling end-stage hip disease<sup>1-3</sup>. Since the introduction of the modern THA by the innovative work of Sir John Charnley in the early 1960s the area of THA surgery has expanded tremendously<sup>4</sup>. The increasing life span of the patients, along with the advances in general medical practice and implant technology that now allows surgery on both younger and older patients, has lead to an increasing population of THA patients.

In the history of hip arthroplasty, innovations have often been more common than evaluations. Today there are, however, numerous long-term evaluations that document the outstanding survival of many implant designs. Therefore, the scope for further improvement of implant technology seems to be limited for most patient groups. In Sweden, orthopaedic health care complies with evidence-based methods and documented implants. This is to a large extent due to the continuous work by the Swedish Hip Arthroplasty Register.

Several years ago Robert Poss (1993) expressed concern about the future of hip arthroplasty<sup>5</sup>. He stated that “total hip replacement is threatened by its own success”. This concern remains, as widening indications place greater demands on the procedure, along with changes in people’s expectations and functional requirements due to generation shifts. Short-term economic interests may also threaten long-term results.

The rapid increase in the burden of musculoskeletal diseases in the past few decades is expected to continue<sup>6,7</sup>. Health-care spending in relation to the economy in general is constantly growing<sup>8</sup>. One fundamental prerequisite for understanding how to meet the changes in the demands on THA is to measure outcomes from patients’ perspectives. For this reason, patient-reported outcome measures (PROMs) are becoming increasingly important in the allocation of health care resources and the provision of guidelines for optimum care and management<sup>9</sup>.

The outcome of a medical intervention depends on biological, psychological, technical, educational, cultural, political, economic, religious factors, and on further equity issues. These factors have to be taken into account when considering alternative interventions and any alterations in current practice. This is particularly relevant in elective joint arthroplasty surgery.

The work reported in this thesis investigates and discusses some of these aspects with the aim of adding information on THA outcome and how this outcome should be maintained and even improved. *It is about doing the right thing, doing the thing right and doing it at the right time.* Thus, the indications for surgery should be correct for an individual, who will benefit from the operation to an extent that cannot be achieved with any other – and less costly – alternatives.



# Background

## Health-technology assessment in total hip arthroplasty

### The epidemiology of hip disease

The epidemiology of hip disease is difficult. The prevalence and incidence of the diverse pathological conditions of the hip joint are not easily studied and described. There are different ways of defining and diagnosing the various conditions. The diagnostic criteria may be based on symptoms, radiographic and other imaging technology findings, micro- or macroscopic changes, biochemical markers or a combination of these. For example, symptoms of osteoarthritis (OA) of the hip may be present without radiographic findings, radiographic findings may be present without symptoms and symptoms mimicking hip disease may be due to other conditions not related to the hip joint. This makes it problematic to study the epidemiology of hip disease in general and OA in particular. The prevalence of OA increases with age and with population ageing, the burden of hip disease has increased dramatically over the past few decades.

### Concerns about THA surgery

THA is an effective and cost-effective intervention for severe hip disease. It reduces pain and improves HR-QoL. In most countries the frequency of the procedure has increased steadily since the introduction of modern THA in the early 1960s. Although THA is very successful, there are concerns about the indications for and the assessment of the intervention. The EUROHIP project, initiated in 1997, resulted in a comprehensive publication with the title “Health Technology Assessment of Hip Arthroplasty in Europe”<sup>10</sup>. The authors shed light on the fact that a small proportion of the patients do not respond satisfactorily to surgery. They also conclude that there is no consensus about the indications for THA. Further, the frequency of the procedure has been increasing continuously and the demand for primary THA and revision surgery is expected to increase over time. There are large variations among different countries in Europe, and even within countries, in the care provided, implants used, costs for surgery, and clinical and patient-reported outcomes. Comprehensibly, there is an obvious call for a multidimensional outcome assessment concerning hip disease and THA surgery.

## On outcome measurements in the Register

### Prospective observational data since 1979

In the Swedish Hip Arthroplasty Register prospective observational data regarding all hip arthroplasty surgery in Sweden is continuously collected. The overall aim of the Register is to improve the outcome following THA<sup>11-17</sup>. Feedback of analysed data stimulates the participating units to reflect, improve and compete. Since the Register was initiated in 1979, its purpose has been to monitor technical issues related to surgery (e.g. surgical technique, the performance of different implants, prophylactic measures, environment in operation theatre) to minimise complications and adverse events related to THA.

### The stepwise introduction of new technologies

The introduction of new technologies in arthroplasty should follow a standardised protocol as described by Malchau in 1995<sup>18</sup>. Pre-clinical testing should be followed by small-scale randomised studies and later multi-centre studies. Finally, the intervention should preferably be monitored by a nationwide register study. This system uses the advantages of the respective methodologies.

### Prospective observational studies versus randomised clinical trials

A randomised clinical trial (RCT) is an experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism. This design is the gold standard for the study of effects of an intervention. The advantages include unbiased distribution of confounders, possibility to blind, and that the randomisation facilitates statistical analysis. RCTs measure *efficacy* under controlled circumstances. The disadvantages include the facts that RCTs are expensive and time-consuming and that they are not feasible or ethical for many research questions. RCTs could also be problematic because of volunteer bias. Moreover, for studying subtle differences between implant systems and rare adverse events there is a need to recruit very large numbers of patients to reach statistical power – and therefore RCTs are not suitable.

Observational studies such as register studies obtain data from groups who have been exposed, or not exposed, to



the new technology or factor of interest. No allocation of exposure is made by the researcher. This design is preferred for the study of effects of predictive risk factors on an outcome. The advantages of observational studies are that they are ethically safe and administratively easier and cheaper than an RCT. Further, subjects in an observational study can be matched, the eligibility criteria and outcome assessments can be standardised and the timing and directionality of events can be established. The disadvantages include difficulties to include controls, there may be hidden confounders, and blinding and randomisation are not possible. There are also difficulties for registers to achieve a high degree of completeness and response rate.

### The particular advantages of register studies

In particular, register studies have an advantage over controlled studies in that they are designed to assess *effectiveness*, i.e. the performance of an intervention or a device in everyday practice. Hence, performance bias is avoided and the results may be generalised. Register studies are especially desirable in populations where large numbers of subjects are needed e.g. to detect, monitor or analyse rare events. A limited data set is often a prerequisite for high coverage, completeness and response rate. Ideally, a continuous observational study from a register enables rapid feed-back to the profession and early detection of failures, which will then be urgently announced to all departments. However, the limited data set is often not sufficient for investigating the reason for failures or deteriorating results. Such in-depth analysis should preferably be performed locally.

### The definition of outcome quality

Traditional outcome parameters, such as implant survival, often fail to describe the patients' subjective outcomes<sup>19,20</sup>. The increasing focus on patient-reported outcome (PRO) as one major outcome measure following medical interventions has led the Registry to gradually implement a nationwide programme for measuring PROs in the THA population. In Sweden, as in many other countries, there are increasing demands to measure PROs. The Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Landsting, SKL) and the National Board of Health and Welfare (Socialstyrelsen) require the health-care quality registries to include PROs and to present the results publicly.

The rationale for measuring PROs was eloquently phrased by Berwick in a British Medical Journal editorial in 1997: "Sociologically, professions tend to reserve the right to judge the 'quality' of their own work. The

best route to the future is for the medical profession to externalise the definition of 'quality'. This is not to say that patients should, or would care to, choose their own drugs, diagnoses, or surgical procedures. It is to say that the ultimate measure by which to judge the quality of a medical effort is whether it helps patients (and their families) as they see it. Anything done in health care that does not help a patient or family is, by definition, waste, whether or not the professions and their associations traditionally hallow it."<sup>21</sup> To date, there are very few examples of PROMs being collected across an entire health system.

### Patient-reported outcome measures

There is a wide range of PROM instruments of varying quality and differing purpose. When selecting appropriate PROMs for a certain programme aiming at a specific disease or condition, there are several things to consider. First, the PROM instruments used need to meet basic methodological requirements on validity and reliability. Secondly, the set of instruments should combine generic and disease-specific PROMs to cover both the effect on a person's state of health or overall life and how the condition affects the functioning of a body part; or other particular limitations/problems that people can experience. It is particularly important to include a generic instrument so that the results can be compared across different patient and population groups. Thirdly, the number of questions in the survey must be dosed correctly to provide a high response rate. Lastly, the instruments used need to be responsive, i.e. reflect sensitivity to change and ability to detect changes when they are present.

PROMs should not be confused with patient-reported experience measures (PREMs). PREMs may provide useful indications of patients' perspective on their care. By their nature they reflect experience of the *process* rather than the outcome of care. Measures of experience are particularly useful for local improvement work but are not suitable for use in a national quality register.

### The PROM programme

A standardised protocol, including PROMs, was introduced stepwise in Sweden from 2002<sup>11-16,22</sup>. The programme adopted the Swedish name "Höftdispensären" (The Hip Dispensary) but in this thesis it is referred to as *the PROM programme*. All orthopaedic departments performing THA, except for one private unit, have now (2010) joined the follow-up programme<sup>17</sup>. The pre-operative questionnaire comprises generic and disease-specific PROMs, including Charnley's functional catego-

ries<sup>23</sup>, pain measured with a visual analogue scale (VAS), and the EQ-5D instrument of the EuroQol group<sup>24</sup>. At follow-ups at one, six and ten years post-operatively a VAS for satisfaction is added to the questionnaire.

The questionnaire has been adapted to an Internet-based touch-screen application for pre-operative use in hospital clinics. However, for logistic reasons, some units have chosen not to use the touch-screen questionnaire but use a conventional pen-and-paper questionnaire pre-operatively instead. Some units combine the two systems.

## Disease-specific and generic instruments used in the PROM programme

### Visual Analogue Scales

Disease-specific instruments used in the PROM programme are VAS' for pain and satisfaction. The VAS for pain ranges from 0 (no pain) to 100 (worst imaginable pain). The question addresses the average pain-experience from the current hip during the last month. The vertical line is supplied with subscale indicators and ordered response levels (between 0–20 no or slight pain, 20–40 mild pain, 40–60 moderate pain, 60–80 severe pain, 80–100 unbearable pain). The VAS addressing satisfaction with the outcome of the hip arthroplasty ranges from 0 (satisfied) to 100 (dissatisfied). This vertical line is also supplied with subscale indicators and ordered response levels (between 0–20 very satisfied, 20–40 satisfied, 40–60 moderately satisfied, 60–80 not satisfied, 80–100 dissatisfied). Thus, the VAS' used in the PROM programme are not orthodox; they are modified for two reasons. Firstly, the scales are used in different settings (in pen-and-paper forms, for touch-screen and Internet applications) and cannot be dependable on a specific length. Secondly, older patients tend to have difficulties understanding the traditional VAS. The modified VAS' have been tested internally for validity and reliability.

### Charnley's functional categories

In 1972, Sir John Charnley developed a simple clinical classification system<sup>23</sup> to allow for correction of scores because of different co-morbidity burdens associated with walking capacity (musculoskeletal co-morbidity). Category A comprises patients with unilateral hip disease, category B patients with bilateral hip disease and category C those with multiple joint disease or other major medical conditions impairing walking capacity. Originally, the classification was developed for categorisation by the interviewer. In the PROM programme

**Table 1 – The British EQ-5D tariff**

	No problems (1)	Moderate problems (2)	Severe problems (3)
Mobility	0	0.069	0.314
Self-care	0	0.104	0.214
Usual activity	0	0.036	0.094
Pain/discomfort	0	0.123	0.386
Anxiety/depression	0	0.071	0.236
Constant	0	0.081	0.269

Table 1. The EQ-5D index is calculated as 1 minus the respective coefficient for each dimension and minus the respective constant for any score of 1, 2 and/or 3.

the Charnley category is assigned by using two self-administered questions; 1) “Do you have any symptoms from the other hip?” and 2) “Do you have problems walking because of other reasons? (e.g. pain from other joints, back pain, angina, or any other medical condition impairing your walking capacity)”.

### The EQ-5D self-completion instrument

The EQ-5D<sup>24</sup> is a generic (non-disease-specific) HR-QoL/utility instrument developed by the EuroQol group (trademark of the EuroQol group). It is standardised for use as a measure of health outcome and has been scientifically translated into more than 120 languages. The EQ-5D evaluates patients in five dimensions, namely mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is divided into three levels of severity (1, no problems, 2, moderate problems and 3, severe problems) generating 243 possible combinations of response. The EQ-5D is presented as a health profile or as a global health index with a weighted total value. To adjust for cultural differences in response pattern, different national/regional tariffs are used when computing the index. Lacking a particular Swedish tariff, the Registry uses the British tariff<sup>25</sup> (table 1). The index ranges from minimum value -0.594 to maximum value 1.0. For health-economic calculation, negative values are set to 0. Negative values through 0 represent the worse possible health state and 1 represent the best possible health state. The questionnaire also includes a vertical EQ-VAS which assesses global health ranging from 0–100 (worst possible health state to best possible health state).

## Other frequently-used, disease-specific and generic PROM instruments

### WOMAC

The Western Ontario and McMaster Universities Arthritis Index (WOMAC<sup>TM</sup>) was originally introduced in 1982 and has since undergone several revisions and modifications<sup>26</sup>. This disease-specific instrument is self-administered and assesses pain, disability and joint stiffness in knee and hip OA using a battery of 24 questions. The latest version of the instrument (WOMAC<sup>TM</sup> 3.1) is available in 65 alternate language forms, and in most languages is available in both 5-point Likert and VAS formats. It is a valid, reliable and responsive measure of outcome, and has been used in diverse clinical and interventional environments. It has been adapted for touch-screen<sup>27</sup> use and a new cell-phone version is being developed<sup>28</sup>. The Swedish WOMAC has been tested for validity and reliability in the Swedish THA population<sup>29</sup>. However, the questionnaire is too comprehensive for large-scale use in a national register.

### Oxford Hip Score

The Oxford Hip Score (OHS) is a 12-item, disease-specific, patient-based questionnaire developed and validated specifically to assess function and pain after THA<sup>30,31</sup>. It was developed from patient interviews and validated against the generic SF-36. It has demonstrably reliable and responsive measurement properties for assessing outcomes of THA. It is a simple scoring and summing system that provides an overall scale for assessing outcome of THA. It has, in combination with the EQ-5D, been proposed for use in the British PROM programme recently initialised by the United Kingdom Department of Health<sup>9</sup>.

### Short-form 36

The most frequently used generic PROM instrument in clinical trials is the 36-item short-form health survey (SF-36) introduced by Ware et al<sup>32</sup> in 1992. It contains 36 items and measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. The SF-36 yields a score for each of these domains, as well as summary scores both for physical and mental health, and a single health utility index. The questionnaire is self-administered, either via pen-and-pencil or computer, or given by a trained interviewer to persons older than 14 years. It takes five to ten minutes to complete. The SF-36 health utility index cannot be

used for health-economic cost-utility analysis. However, the SF-6D is a preference-based classification which, derived from the SF-36, allows the analyst to obtain QALYs for use in cost-utility analysis<sup>33</sup>. The length of the questionnaire is one obvious disadvantage when used in large-scale observational studies because it jeopardises the quality of data through a high risk of insufficient response rates.

## The collection of PROMs

### How to collect PROMs

Traditionally, pen-and-paper questionnaires are used and data are collected, recorded and computerised manually. The administration of pen-and-paper forms is not only time-consuming and costly but also constitutes a risk of errors when entering data. Another disadvantage of pen-and-paper questionnaires is that missing values often compromise data quality. This is a problem in routine use in health-care quality registers as well as in trials managed by clinical research organisations<sup>34,35</sup>.

The development of information technology and software along with an exponential increase in the use of the Internet now allows new modalities for collecting PROMs, and these need to be compared to the traditional method<sup>36</sup>. Studies have shown comparable results between pen-and-paper versions and patient-administered computer versions of questionnaires in a variety of areas<sup>37-40</sup>.

### Collection of PROMs in the Registry's programme

The collection of prospective PROMs in the Register was introduced in 2002<sup>12</sup>. The idea originated in the mid-1990s but due to a volume problem it was not realised until safe Internet-based applications for data entry had been developed. Parallel with the introduction of the programme, the Registry developed an Internet-based touch-screen application for collecting the pre-operative PROM questionnaire for use in hospital clinics. This system has been tested internally for reliability and validity and is very effective. The advantages include immediate online access to the results, no missing values and decreased risk of systematic errors (e.g. illegible handwriting and incorrect manual registration). The system is also less laborious, with no need for manual registration of questionnaires. However, at follow-ups all questionnaires are mailed to the patients. Monthly, the Registry distributes lists of patients due to receive follow-up questionnaires to the orthopaedic departments and specially trained secretaries at the department are responsible for sending out questionnaires and reminders and entering data in the on-line PROM database.

Hence, the rationales for developing a self-administered Internet-application for the follow-up are economic and methodological.

**The increasing use of Internet worldwide**

According to recent reports from the World Internet Institute in collaboration with the Internet Infrastructure Foundation, 90% of Swedes older than 16 years had access to the Internet in 2008 and 81% were using it<sup>41,42</sup>. The largest increase in the past few years is among younger retired people (65–74 years). Similar observations have been made in other countries with high Internet use, e.g. Canada, Australia, New Zealand and the USA<sup>43</sup>. In summary, it appears that there are fair potentials to introduce an Internet-based method for collecting PROM data.

**Public reporting of register results**

**Reforming health care systems**

The Registry became web-based in 1999 and started, the same year, to publish annual reports on its homepage. Five- and ten-year implant survivals were the first openly-reported outcome variables at unit level. The number of publicly reported variables has increased in recent years and twelve such variables figured in the 2008 annual report, including three PROMs<sup>17</sup>. The goal of open reporting is not to point to individual departments but to initiate local analysis and in turn clinical improvement work. In *Redefining Health Care*<sup>44</sup> the authors emphasise that “...measurement and public reporting of patient results is the single most important step in reforming health care systems... because nobody wants to be worst in class in a value-based competition on results.”

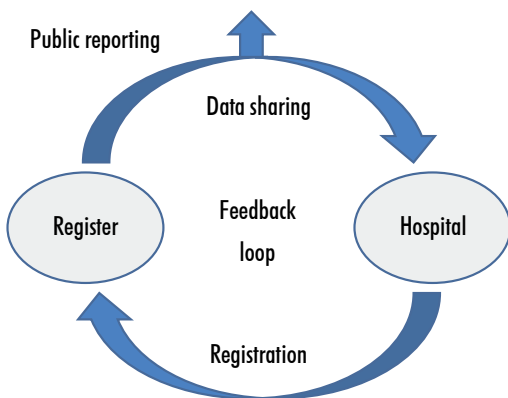


Figure 1. The feedback loop illustrates the possible benefits of rapid and public reporting of register results and the participating hospitals’ accurate and immediate registration of data.



Figure 2. The Clinical Value Compass according to Nelson et al<sup>47</sup>.

**The feed-back loop**

To speed up the implementation of best practice, it is important that the feedback loop between units and the registry is fast (figure 1). It is a balance for national quality registries to decide to what extent in-depth analyses should be published in annual reports instead of in peer-reviewed international journals. A disadvantage of the peer-review process, is a more slow feedback loop and consequently also a prolonged a transition time for a unit to shift to best practice.

The Registry has since many years worked with a compromise model, immediately publishing adverse results of an implant, a surgical technique or of clinical outcomes but also continually exploiting register analysis for scientific manuscripts.

The results after THA surgery in Sweden have gradually improved since the Registry started its activities, and on several international comparisons Sweden has the lowest reported revision rate<sup>45,46</sup>. There is no reason to believe that this is because Swedish orthopaedic surgeons are more skilled than their colleagues elsewhere, but is more likely due to many years of feedback from the Registry, creating a continuous national learning process.

**The Clinical Value Compass**

The Clinical Value Compass, developed by Nelson et al<sup>47</sup>, is a four-dimensional tool for evaluating the value of health care. It is useful for health-care providers to measure the value of health care for specific patient groups, to analyse processes related to different interventions or treatments, and to determine whether changes in processes lead to better outcomes and lower

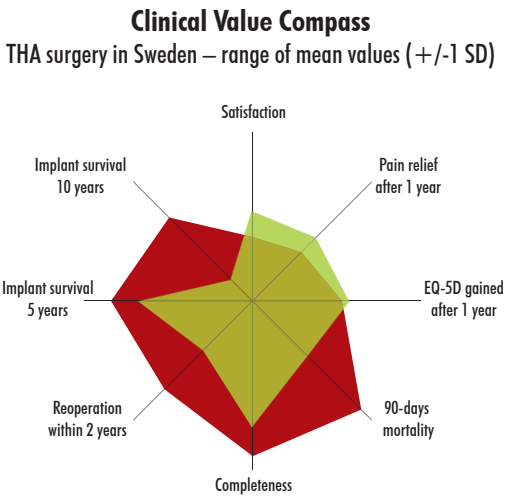


Figure 3. The modified Clinical Value Compass used in the Registry. The red area represents national mean values and the green area is an example of how the compass is used to visualise the results of a particular department. In this example the current department has worse outcomes regarding implant survival and re-operations, completeness, 90-days mortality but equal or better PROs compared to the average outcomes in Sweden.

costs. The compass shows clinical outcome and functional status, including HRQoL, patient satisfaction and costs (direct and indirect costs) as illustrated in figure 2.

### The Clinical Value Compass in the Register

The Registry has modified the clinical value compass to visualise outcomes for different units in Sweden. Currently, the model includes eight outcome cardinals (patient satisfaction, pain relief, change in HRQoL, 90-days mortality, completeness, re-operations within two years, and five- and ten-year implant survival) which are presented in the annual Register reports. As soon as valid and reliable cost data can be obtained for all hospitals it will be added to the compass. In the model the limit values are the largest and the smallest value of the variable in question plus/minus one standard deviation. This means that the standard values (red area) vary from year to year. The worst value (0.0) for the variables is given as origo and the best value (1.0) at the periphery. This expanded value compass could be regarded as a balanced score card. The larger the surface, the better the total result for each hospital. Figure 3 presents an example of results visualised in the modified clinical value compass from the overall results of THA in Sweden in the 2008 Annual report. The compass is used as a teaching aid to provide a quick overview of outcomes of participating units.

## Quality of register data

The relevance of a register analysis depends largely on the quality of data in the current registry's database. There are different dimensions of data quality such as:

- validity and reliability of metrics
- coverage and completeness of registration
- patients' response rate to questionnaires

### Validity

The Registry is continuously working on data validation by examining medical records from all re-operations. Once a year, all participating departments are requested to compare the Registry's figures to the local hospitals' patient administrative system. The Register online entry application has a built-in warning system for incorrect entries such as wrong personal identity number, operated side, and implants.

### Reliability

On construction of a register or introduction of new variables in an existing database, it is mandatory to use or test variables so that they meet methodological base requirements such as high reliability (i.e. consistency or precision of the measuring instrument).

### Coverage

Coverage is the proportion of participating units to all units. Many registries indicate their coverage based on the proportion of possible units that are actively participating in the registry's data capture. Such a specified percentage, however, gives little information on the register's "true coverage" on the individual procedure level. For this reason it is also necessary to analyse each unit's registration at individual level termed completeness of registration.

### Completeness

Completeness here depends on that of the respective participating unit's report at individual level<sup>17</sup>. The Register has been collaborating for years with the National Board of Health and Welfare which operates the National Patient Register based on the personal identity number. Departments are required by law to report all medical interventions to the Patient Register. Each year a linkage between the Swedish Hip Arthroplasty Register and the National Patient Register is performed. In this way the Registry's completeness is calculated at department and individual level. The Register has long been 96% to 98% complete. The figures are published



each year in the Annual Report, which has led to some out-liers rapidly improving their registration. Poor completeness may lead to flawed analyses and feedback will then be misleading.

### Response rate

For the PROM programme quality of data also depends on response rate. Response rates refer to the proportion of responders in relation to the number of patients who receive the questionnaire. However, it is often difficult to give an accurate picture of patients' true willingness to answer the questionnaire because for non-medical logistic reasons it does not reach all patients.

## Health-economic aspects

### Definition of health economics

Health economics is the science of application and development of economic theory, analyses and tools to circumstances and behaviour affecting people's health. Scarce resources and an infinite demand for health care constitute the health economic dilemma. The allocation of health-care services by a free market is not efficient for society, and this used to be referred to as market failure. The essence of health economics is to allocate limited resources optimally to provide maximum output within a given budget. In public health-care systems, al-

ternative interventions should be compared with regard to cost and utility as measured in improvement in HR-QoL. If the alternative intervention generates additional costs these costs should be considered with respect to improved utility and survival. If the alternative intervention generates lower costs, the intervention should be regarded as cost-saving if utility equals or exceeds the standard intervention. Measures combining utility and survival are described below.

### Health-economic evaluations

Resource allocation requires analyses of the consequences (costs and benefits) of interventions, diagnostic methods, and therapies in health care. Alternative treatments must be evaluated to prove the value for money for resource allocators. What type of economic evaluation should be used for a specific situation depends on the purpose or goal of the analysis. The *cost-minimisation* analysis is a simple type of economic evaluation that only compares the cost of an intervention assuming that the effects of the alternatives are equal. The *cost-effectiveness* evaluation analyses costs and consequences with disease-specific measures in terms of physical or natural units. This type of analysis is suitable for interventions with few outcome measures. It does not measure patients' preferences but it enables comparisons within the same disease or illness. In *cost-benefit* analysis not only the costs but also the values of the consequences are transposed to monetary units to facilitate direct comparison of benefits and costs. *Cost-utility* analysis is a form of cost-effectiveness evaluation that combines utility measures, such as selected HRQoL score, with survival and cost data. In the case of THA, the incremental cost of the intervention is compared with the benefits in utility, measured by improvement in HRQoL scores. The alternative interventions could be non-surgical or a different surgical method or implant.

### Utility measures

One frequently used outcome measure that combines HRQoL over a given time is the quality-adjusted-life-year (QALY). Thus, QALY is a measure that combines utility and survival and could be compared across borders of different areas in health care. Estimation of the utility of a particular health state should be based on preferences derived with *Standard Gamble* or *Time-Trade-Off* methods. Utility values range between 0 (dead) and 1 (full health; e.g. EQ-5D index 0.0–1.0)<sup>25</sup>. The QALY is estimated using standard area-under-the-curve calculations based on the utility values at different measuring times. Figures 4 and 5 present examples of alternative interventions and their respective utilities over time.



## Cost-per-patient

There are different ways of estimating or determining the cost of an intervention. For THA it is most common to use direct medical costs during hospital stay in conjunction with the operation. In Sweden a standardised system for assigning costs for individual patients (cost-per-patient, CPP) has been developed and is widely used. CPPs are collected from hospital databases. Currently, the CPP system has limitations because assessments at different hospitals may differ and not all hospitals have introduced it yet. However, there are continuous improvements of the CPP-system, and it is expected soon to be used nationwide; the assessments are also getting more uniform. The advantage of CPP is that individual costs can be assigned, so that the CPP is very useful when comparing costs for different patients within a hospital.

## Cost-utility calculation

Cost-utility is computed by dividing the incremental cost of the intervention compared to the alternative, by the difference in QALYs during the observation period.

Cost-per-QALY could be described as the cost for prolonging a perfectly healthy individual's life by one year.

$$\text{Cost-per-QALY} = \frac{\Delta \text{Costs}}{\Delta \text{QALYs}}$$

To calculate the cost-utility of THA in a general model, the hypothetical non-treatment alternative is set to the pre-operative HRQoL baseline level. Cost per QALY is an independent measurement that allows cost-utility comparisons of interventions in different medical fields.

## Willingness-to-pay and cost-per-QALY threshold

Willingness-to-pay (WTP) refers to preferences in the general public as to how much they would be prepared to pay to accrue a benefit or to avoid certain events. There are different methods to determine the WTP; it can be assigned by methods such as bidding games, risk/payment trade-off methods or conjoint analysis. One appropriate application for WTP is estimation of threshold values for cost-per-QALY. Although there are other methods of assigning threshold values – cost-effectiveness ratios, relations to gross national product

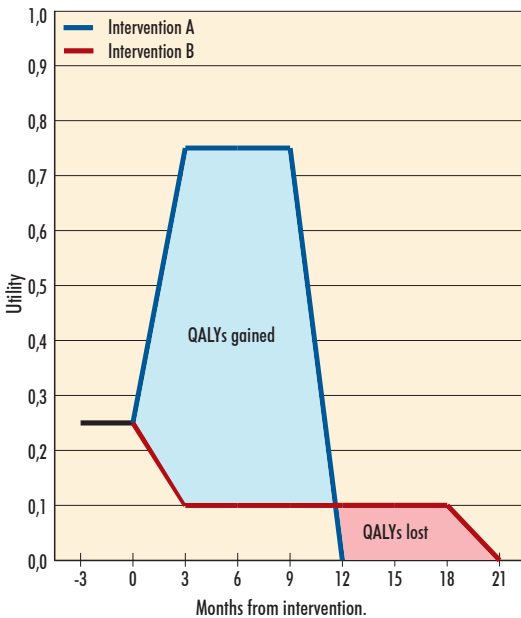


Figure 4. Comparing the utility derived from EQ-5D indices over time for two alternative interventions. The blue area between the curves during the first 12 months represents the QALYs gained in favour of intervention A (blue line). Intervention B (red line) is associated with longer survival but with a decrease in utility from the baseline. Therefore the pink area below the curve beyond 12 months represents the QALYs lost for intervention A compared to intervention B. From a utility perspective, intervention A provides better outcome than intervention B.

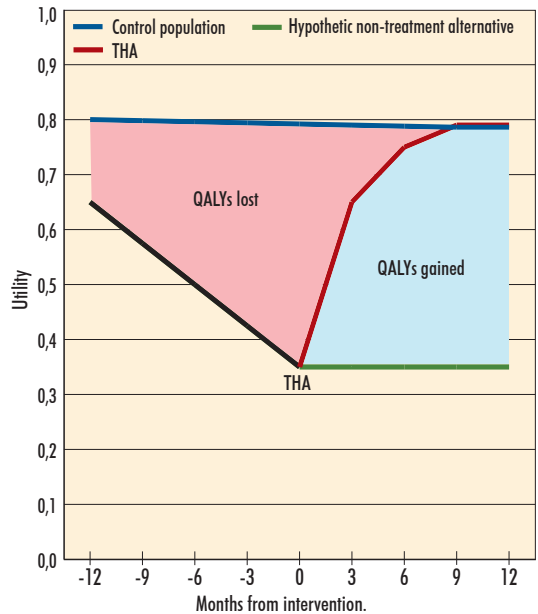


Figure 5. Hypothetic illustration of the decline in utility during the course of disease (black line) until THA and the improvement for those operated on (red line) compared to a hypothetical non-intervention group (green line) and a control population (blue line). The pink area represents QALYs lost due to hip disease compared to a control population. The blue area represents QALYs gained due to surgery compared to the hypothetical non-treatment alternative.

**Table 2 – Costs and economic consequences of health-economic evaluation of THA**

	<b>Cost/consequences of hip disease</b>	<b>Costs/consequences of THA</b>
<b>Direct medical costs</b>	Care visits Hospital admissions Diagnostics Non-surgical interventions Medication Physiotherapy Patient education Walking aid	Primary surgery Rehabilitation Complications Follow-up programme Re-operations
<b>Direct non-medical costs</b>	Household and home-help services Transport services Home modifications Change of accommodation Informal care Complementary medicine	Increased or reduced needs for direct non-medical resources as exemplified to the left
<b>Indirect costs</b>	Productivity loss Sick-leave Disability pension Premature death	Restored productivity capacity Mortality related to surgery or complications Prolonged life?
<b>Intangible costs/values</b>	HRQoL loss	HRQoL gain

*Table 2. Example of different costs and consequences of hip disease and THA.*

and thresholds based on past decisions or proposals from institutions – WTP is maybe the most suitable<sup>48</sup>. Cultural differences and economic conditions create diverse thresholds between countries. In Sweden the cost-per-QALY threshold is around SEK 500 000 to 600 000<sup>48-50</sup>.

### **Direct, indirect and intangible costs and values**

There are various costs of a specific disease. Direct medical costs are those associated with the medical treatment or diagnostics of the present condition. Direct non-medical costs are a variety of costs such as home-help service, transport and informal care. Indirect non-medical costs are those related to productivity loss, e.g. due to temporary sick leave or long-term disability pension, and costs related to premature death. Intangible costs or values are those related to HRQoL; they can be assigned with methods that aim to estimate WTP as described above.

### **The burden of hip disease**

Protecting people from the economic consequences of illness is a major concern for national health-care systems<sup>51</sup>. Increasing health-care spending makes a greater demand

on efficiency and equity in resource allocation. The GNP proportion of health care spending is constantly increasing according to health data from the Organisation for Economic Co-operation and Development (OECD). Over the past few decades the burden of hip disease has increased and is expected to continue to do so<sup>6,7</sup>. Cost-of-illness (COI) studies regarding hip disease and OA of the hip, in particular, have either investigated the direct medical costs incurred by the health-care system<sup>52,53</sup> or the direct expenditure incurred by patients<sup>52,54,55</sup>. Few studies have included the direct non-medical costs such as the value of informal care<sup>56</sup> and costs incurred by the municipality. Maetzel et al<sup>55</sup> reported an estimated annual COI for OA of the hip of \$ 4 900 and in a study by Gupta et al<sup>56</sup>, including the value of unpaid informal care, the annual COI was estimated to \$ 9 900. To our knowledge, no previous studies have investigated COI for patients eligible for THA in particular.

### **Cost and economic consequences of THA surgery**

A complete health economic evaluation of hip disease in general and THA surgery in particular requires numerous variables to be included in the analysis. Such



analysis should preferably apply a societal perspective, i.e. all costs and consequences should be included regardless of who incurs them. Firstly, all costs and consequences related to the hip disease need to be estimated as accurately as possible. Those costs serve as baseline data when evaluating the effects of THA. They are also useful for evaluating alternative ways to manage patients or groups of patients with hip disease. Secondly, the costs and consequences of the surgical intervention have to be determined. These data can be used for comparing economic outcomes of alternative interventions. In table 2 costs and consequences of hip disease and THA are exemplified and categorised to provide an overview.

The overall objective of thoroughly estimating all costs and consequences in a complete health-economic model is to optimise the management and use of resources for hip disease to maximise the outcomes and minimise the HRQoL loss. However, it is difficult to determine how far a certain cost or resource is related to the actual condition. For example, co-morbidities interact to create a need for resource utilisation at individual level.

## The Health-care Guarantee and waiting time

Reports conflict on how waiting time affects HRQoL and resource utilisation prior to surgery<sup>57-59</sup>. In many countries waiting time for different interventions is a frequently debated issue. In 2005 the Swedish government enacted a Health-care Guarantee prescribing a 90-day maximum waiting time for specialist physician consultation and a 90-day maximum waiting time for health-care interventions. When investigating the effects of the Health-care Guarantee, the National Board of Health and Welfare concluded in a recent report<sup>60</sup> that the overall proportion of patients waiting more than 90 days for any elective specialist care had decreased in both relative and absolute terms, which means that the average waiting time is likely to have become shorter. However, this decrease took place mainly in the latter part of 2009. The proportion of patients waiting longer than 90 days has become more evenly distributed across the different county councils. Inconsistencies in how the county councils report their waiting times, along with lack of individual data on waiting time, limit the Board's analysis. One important issue in this report is the potential conflict between county councils' short-term efforts to comply with the Guarantee and more sustainable investments in availability.

## Indications and timing for total hip arthroplasty

### Variability in indications

A recent European prospective cohort study of patients with OA eligible for primary THA showed a great variability in the severity of the disease at the time of surgery<sup>61</sup>. The pre-operative scores of pain, stiffness and function, as measured with the WOMAC instrument, showed a great spread of disease severity with many patients reporting relatively mild disease, whereas others appeared to be more severely affected. This study was consistent with earlier findings that there is no correlation between symptoms and radiographic severity of the disease<sup>62-64</sup>. That study also found an association between the severity of symptoms at the time of surgery and differences in age, gender, BMI, co-morbidities, and socioeconomic status. Interestingly, these variations were not dependent on individual centres but appear to be present throughout Europe.

Although not fully coherent, reports of the pre-operative levels of pain and HRQoL seem to be associated with the absolute outcomes<sup>65-67</sup>. Patient-reported outcomes (PROs) for those with severely affected HRQoL pre-operatively do not reach the levels of those with mildly affected HRQoL, even after adjusting for other possible predictors. Some urge a re-evaluation of the traditional practice to delay surgery as long as possible, especially for older patients<sup>67,68</sup>. However, individual differences in patient characteristics, expectations and ability to benefit from non-surgical treatment make it difficult to create uniform and proper criteria for indications and timing for surgery.

### Criteria for priority and indications

Even though there is no consensus on indications for surgery, a recent study from OsteoArthritis Research Society International (OARSI) proposes guidelines for the management of hip and knee OA including indications for surgery<sup>69</sup>.

In Canada, efforts to develop uniform criteria for priority and indications have been made<sup>70,71</sup>. The Canadian instrument, including the EQ-5D index, has been translated and modified for use in Sweden in a recent study from the National Competence Centre for Musculoskeletal Disorders<sup>72</sup>. That study confirmed variations in indications for surgery between hospitals in Sweden. The authors concluded that a clinical priority criteria tool is a useful means of following changes in indications for

certain procedures, and that such a tool could contribute to explaining differences in case mix when evaluating clinical outcome and patient satisfaction. The use of this tool may feasibly contribute to less arbitrary indications, less variability in disease severity on surgery and improved and more uniform overall outcomes.

### Timing of surgery is a major future challenge

Several interacting factors make timing intricate: the risk of future revision surgery, life expectancy, the impact on HRQoL, cost-utility aspects, societal costs, and occupation. All these have to be taken into account when creating a model for optimal timing of surgery. However, there is insufficient knowledge to construct an instrument to assess the optimal time point for THA for an individual or for groups of patients. Some authors suggest that earlier intervention (with less pre-operative deterioration in HRQoL) may result in higher HRQoL levels, as measured with the EQ-5D index, compared with later intervention<sup>65,66,73</sup>.

### Better management of patients with osteoarthritis

The project “Better management of patients with OsteoArthritis” (BOA) is a collaboration between four

county councils in Sweden<sup>74</sup>. BOA was initiated during 2008, prompted by poor adherence to national guidelines for management of patients with OA of the hip and knee. Findings showed that only a minority of all patients who receive joint replacement had participated in physiotherapy at any time before surgery. Nevertheless patient education, exercise and weight control are core treatments of OA according to national as well as international guidelines<sup>69,75</sup>. The aim of BOA is to offer every patient with OA adequate information and physiotherapy according to the evidence-based recommendations, and that surgical interventions should be considered only if non-surgical treatment have been tried and shown not to be sufficient<sup>69,75</sup>. The goal is to reduce the need for health care and sick leave due to OA, as well as to increase HRQoL, level of independence and physical activity. Patients with OA should receive equal and optimal management on first contacting health care, regardless of where this first contact takes place. The project is currently being run as an interventional multi-centre study and all data is gathered in the BOA register.





# Aims

**The main objectives of the work presented in this thesis were:**

- to describe the development of the Swedish PROM programme for the THA population,
- to analyse the response rate and the non-respondents to the PROM programme,
- to investigate pre-operative and one-year-post-operative PROs in the Swedish THA population,
- to analyse factors predicting PROs following THA,
- to develop an application for an Internet-based follow-up questionnaire for PROMs, to test its reliability and to investigate the feasibility of its replacing the traditional pen-and-paper questionnaire,
- to estimate all costs related to hip disease in a Swedish population eligible for THA and to analyse predictive factors for costs related to hip disease, and
- to investigate costs and PROs related to one-stage bilateral THA.



# Patients

Patient information used in the different studies on which this thesis is based, is stored in the primary THA database of the Register. For *papers I, II and IV* data were retrieved from the Register according to different pre-determined selection criteria. In *paper III*, all patients at the 20 participating centres were asked to participate by

completing a questionnaire shortly prior to THA surgery. In *paper V* the study population of a randomised clinical trial was used<sup>76</sup> (32 patients; 64 procedures) together with a control population retrieved from the Register. Table 3 summarises the patients and procedures in the different papers, the time intervals and the selection criteria.

**Table 3 – Patients**

	Patients	Procedures	Year for primary THA	Comments and selection criteria
Primary THA database <sup>†</sup>	180 716	214 445	1992–2009	All THAs performed in Sweden ( $\approx 98\%$ completeness).
PROM database <sup>†</sup>	57 826	63 997	2002–2009	Surgery for acute hip fractures and malignancies included.
pre-operative	48 549	53 820		
one-year follow-up	39 487	43 987		
six-year follow-up	2 463	2 825		
<b>Paper I</b>				All registrations with complete pre-op and one-year post-op PROM protocol. Surgery for acute hip fractures and malignancies excluded.
main analysis	32 396	34 960	2002–2008	
response-rate analysis	11 901	12 300	2008	
six-year follow-up	2 831	3 272	2002–2004	
<b>Paper II</b>	2 258	2 290	2002–2003	Randomisation and stratification. Surgery for acute hip fractures and malignancies excluded in an “extra” four-year follow-up.
<b>Paper III</b>	2 635	2 698	2005–2007	Intention to include all elective THAs at the participating centres from 1 Oct 2005 to 31 Dec 2006.
<b>Paper IV</b>	6 158	6 158	2002–2006	All patients with OA and complete pre-op and one-year post-op PROM protocol.
<b>Paper V</b>	64	96	2000–2002	One group with one-stage bilateral THA and one matched reference group with unilateral THA.

<sup>†</sup> Registrations by 31 December 2009



# Methods

## The Swedish Hip Arthroplasty Register in Gothenburg

The Swedish Hip Arthroplasty Register was initiated in 1979<sup>22,77-82</sup>. All public and private orthopaedic units in Sweden that perform hip arthroplasties participate on a voluntary basis. Besides the information included in the personal identity number (date of birth and gender), individual data on diagnoses, laterality and detailed information on implants and fixation are reported. More recently, information about the American Society of Anesthesiologists' (ASA) classification of physical status<sup>83</sup>, height and weight has been added to the variables collected.

## Databases

There are six databases in the Registry:

- *Primary THA database*
- Re-operation THA database (revision and re-operation)
- Environmental/technical profile (aggregated data per unit)
- *Patient-reported outcome measure database*
- Primary hemi-arthroplasty database
- Re-operation hemi-arthroplasty database (revision and re-operation)

For the analyses of this thesis (*papers I-V* and the additional results) the *primary THA database* and the *PROM database* were used.

## The PROM programme

Intentionally all patients eligible for THA are asked to complete a questionnaire pre-operatively containing ten items, including Charnley's functional categories (A, B, and C)<sup>23</sup>, a VAS for pain (no pain (0) to unbearable pain (100), disease-specific question), and the generic EQ-5D instrument. The measurements are repeated at one, six and ten years post-operatively (no ten-year data are yet available). Supplementing the follow-up instrument, a VAS for satisfaction (satisfied (0) to dissatisfied (100), disease-specific question) is added. Satisfaction refers to the outcome of surgery. The PROM protocol is presented in the Appendix.

At the follow-ups at one, six and eventually ten years after the operation, the questionnaire is mailed to the patient with a cover letter and a stamped addressed envelope. Besides general information about the PROM

programme and the survey, the cover letter tells patient to contact their orthopaedic surgeon if he or she has hip problems. Non-respondents receive the first and only reminder after eight weeks. Once a month, the Registry distributes to the participating departments lists of all patients due to receive follow-up protocols. Each department is then responsible for the logistics including checking the current address, sending out questionnaires and reminders and manually registering the data in the on-line PROM database.

Data from the PROM database is used in all five papers.

## Minimally important difference

Minimally important difference (MID, also referred to as minimum clinically important difference) is used to interpret whether the observed change in a certain PROM is important from the patient's or clinician's perspective<sup>84,85</sup>. Increasingly, in health-outcomes research, the MID is based primarily on the patient's perspective with the clinician's viewpoint serving to confirm the findings. The MID has been defined as the smallest change in a PRO measure that is perceived by patients as beneficial or that would result in a change in treatment. The MID for EQ-5D index has been investigated by Walters et al<sup>86</sup> and determined to 0.074. For pain as measured with a VAS the reported MID values ranges from 9 to 15 mm<sup>87,88</sup>. The MID regarding EQ-5D index and pain measured with VAS are discussed in *paper I*.

## The COI questionnaire

The questionnaire in *paper III* was taken from a previous COI study<sup>89</sup> and modified for hip disease in collaboration with health economists. The questions covered civil status, housing, use of health care, medication, home-help services, home modification, transport services for the disabled, and informal care (i.e. care provided by proxy) due to hip disease, all during the previous twelve months. The questionnaire also included items about sick-leave due to hip disease and whether the patient was currently in work, retired, unemployed, on sick-leave or on disability pension. The coordinator at each hospital was asked to add information about when the patient had been referred to the orthopaedic department and when the orthopaedic surgeon listed the patient for surgery. The questionnaire is presented in the *appendix* (in Swedish).



## Costs

Costs included in *paper III* were direct costs (medical and non-medical), informal care, and costs for productivity loss due to sick leave and disability pension (indirect non-medical costs). Unit costs were assigned using official statistical sources or market prices. Costs were calculated at individual level by multiplying resource use with corresponding unit costs. Informal care was divided into time spent by caregivers during leisure time (value of lost leisure time) and time spent by caregivers absent from work for care-taking (replacement costing method).

In *papers IV and V* CPP databases were used for cost calculations. Individual CPP values considered only the total sum of direct medical costs during the hospital stay in conjunction with the operation and were collected from hospital databases. In *paper V* individual records from the Swedish Social Insurance Administration concerning the length and cost of sick leave to twelve months after surgery were collected.

## The Internet application – PIVI

In *paper II* an Internet application for performing online patient surveys, which was developed and named “Patient Information Via Internet” (PIVI), is presented. In this application, the database is implemented through a terms catalogue so that it can accommodate new questionnaire designs without programming or restructuring. It also permits re-use of standardised questions, helpful when using EQ-5D or other strictly standardised forms.

When entering the number of patients to be included, the application generates a list of serial numbers and corresponding passwords. This list is merged with patient data and constitutes the link between the PIVI-generated serial number and, in the Registry’s case, the personal identity number. The advantage of this approach is that the PIVI database contains only anonymous data. All sensitive data are managed offline.

The patient receives a printed letter with a web address and a password, together with instructions on how to open the questionnaire in the web browser, where the survey is outlined. The patient logs in with the enclosed password, answers the questions all on one page and submits the questionnaire. Any unanswered mandatory questions are marked with a red frame, clearly stating what needs to be corrected before the questionnaire can be saved. Once saved, the questionnaire cannot be updated by the patient.

Survey results can be retrieved continuously in many ways through the web service and merged with the rest



The PIVI-login.

of the patient data through the PIVI-generated serial number. Screen-shots of the PIVI-login and Internet questionnaire are presented in the Appendix.

## Ethical considerations

All the studies presented in this thesis conform to the Declaration of Helsinki. The Swedish Hip Arthroplasty Registry continuously collects nationwide prospective observational data regarding all hip arthroplasty surgery in Sweden. This collection is regulated by the Patient Data Act<sup>90</sup> and the Personal Data Act<sup>91</sup>. All data from the Register are presented in aggregated form so that no information can be traced to the individual. According to the Patient Data Act all patients must be adequately informed, in writing or orally, before registration. This information is normally given in writing pre-operatively in connection with all other information then provided. Written consent is not necessary but, regarding the PROM programme questionnaire, it is naturally up to the patient to fill it in. Patients may at any time, and without giving reasons, request that their data in the register should be erased.

The Registry holds general approval regarding the PROM programme from the Local Ethical Review Board in Gothenburg (decision S 067-02, 19 March 2002). Data from the PROM programme is used in *papers I to V*.

The clinical trial part of *paper V* study was approved by the Local Ethical Review Board in Gothenburg (decision S 257-00).

# Statistical methods

## Descriptive statistics

Data regarding categorical variables are generally presented using frequencies and proportions. For continuous variables, means and standard deviations (SD) are presented in most cases. In some cases 95% confidence intervals (CI<sub>95</sub>) or medians and ranges are used.

## Comparing the mean or proportions

For continuous variables with normal distribution the parametric paired *t* test was used to evaluate differences. For categorical variables the Chi-square test was used.

For continuous variables with an asymmetric distribution (not normally distributed) non-parametric tests such as the Wilcoxon signed ranks test or the Mann-Whitney *U* test were used. Fisher's exact test was used to evaluate differences regarding proportions.

Regression models were also used to evaluate differences as appropriate (see below).

Throughout the thesis two-tailed probability values less than 0.05 represent significant differences.

## Regression models

In *paper I* multivariate linear regression analyses where the differences between pre- and post-operative values of the outcome parameters and absolute value of satisfaction were used as the dependents. Independent variables included in the models are age, gender, Charnley category and diagnosis. Variables with more than two nominal values were sub-categorised. Results are presented as multivariate correlation coefficients (B) with the standard deviations (SD) around the regression function and CI<sub>95</sub> for B.

In *paper II* logistic regression models were used to analyse the differences in the content of the answers and the importance of age with regard to the two randomisation groups (dependents).

In *paper III* the cost of hip disease and some of its potential predictors were analysed in a multivariate regression model to permit control for confounding effects. Cost data were roughly gamma-distributed and a gen-

eralised linear model (GLM) with a log-link and robust standard errors to adjust for heteroskedasticity was used, as recommended in previous research<sup>92</sup> for healthcare cost data.

In *paper IV* multivariate linear regression models investigating the association between the five EQ-5D dimensions, Charnley categories, gender, age as independent variables and the VAS results (pain and satisfaction) as dependent variables were used. In the regression model concerning pain the VAS was regarded as a nominal scale and the change calculated as a percentage.

Multivariate linear or logistic regression models were also used in *paper V* to assign individual estimated values for CPP and sick leave in the patients with one-stage bilateral THA. The regression function from an analysis only including cases from the matched control group was applied to the one-stage subjects. CPP and sick leave were dependent variables and age, gender, Charnley category and diagnoses were independent variables. Thus, individual expected values for the costs could be assigned. This permitted estimation of costs for the theoretical two-stage model using data from the matched control cases.

## Tave's minimisation

In *paper II* randomisation was carried out with Tave's minimisation<sup>93,94</sup>. Minimisation is a method of assigning patients at random to different groups that ensures perfect balance between groups with regard to possible determinants. By determining known or susceptible prognostic factors in advance, imbalance between groups is minimised during the allocation process. The treatment allocated to the next participant enrolled in the trial depends on the characteristics of those participants already enrolled.

## Correlation

In *paper II* Spearman's correlation was used for reliability tests.

## Software

SPSS 14.0 later upgraded to 17.0 (©SPSS Inc, Chicago, IL) was used for most of the statistical analyses.



# Summary of papers

## Paper I

### Patient-reported outcomes in the Swedish Hip Arthroplasty Register – results of a nationwide prospective observational study

In this study the development and results of the nationwide, prospective, observational PROM programme is presented. These current analyses include 34 960 THAs with complete pre- and one year post-operative questionnaires. A separate response rate analysis was also performed.

## Results

### Response rates

The response rates for the pre-operative questionnaire and the one-year follow-up questionnaire among 12 300 patients operated on in 2008 were 86.1% and 90.2% respectively. Seventy-nine percent completed both questionnaires.

### EQ-5D

The pre-operative EQ-5D indices were distributed bimodally, one cluster having a median at 0.089 and the other at 0.69, (figure 6).

Post-operatively, 35.5% of the population reported no problems in any dimension. Figure 7 presents the tri-modal one-year post-operative distribution with a large group in the middle clustering at median 0.73 and a small group (7.3%) of “non-responders” clustering around median 0.089.

### Charnley category consistency

The consistency of the Charnley self-categorisation was examined. Forty percent reported Charnley A or B and twenty-eight percent reported Charnley C both pre-operatively and one year after surgery. Thirty-two percent were inconsistent, either shifting from A or B to C (15%) or vice versa (17%).

### Patient-reported outcomes one year post-operatively

One year post-operatively there were improvements in

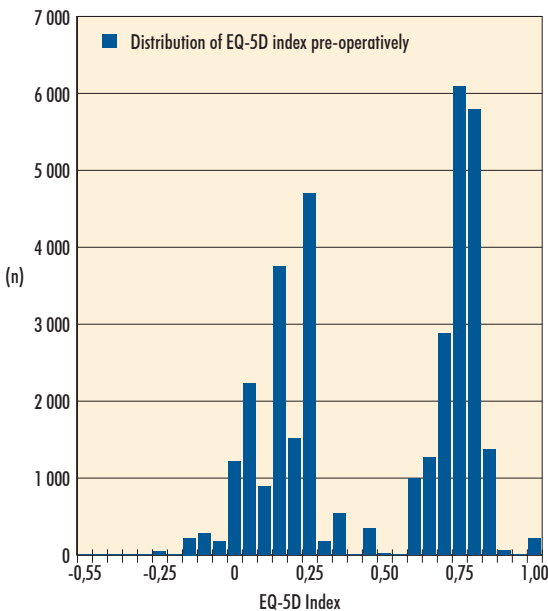


Figure 6. Histogram presenting the bimodal distribution of EQ-5D indices pre-operatively.

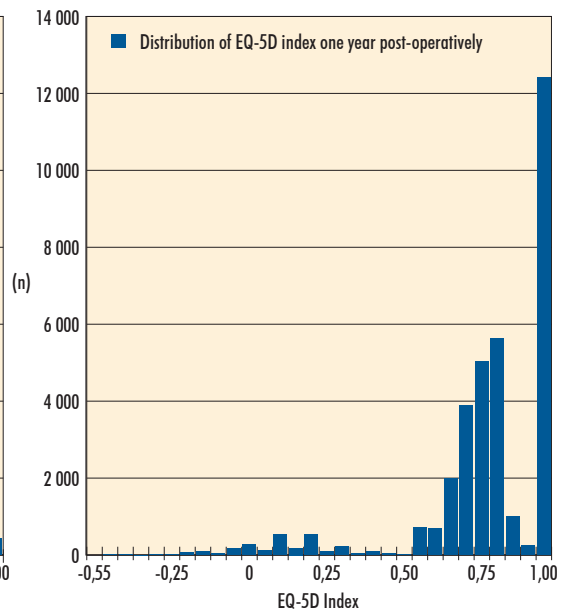


Figure 7. Histogram presenting the trimodal distribution of EQ-5D indices post-operatively.

**Table 4 – Patient-reported outcomes one year post-operatively**

		0 y	1 y	Δ	CI <sub>95</sub>
<b>EQ-5D Index</b>	All (n=34 960)	0.41	0.78	0.371*	0.368–0.375
	Females (n=20 220)	0.37	0.76	0.385*†	0.380–0.390
	Males (n=14 740)	0.45	0.81	0.353*†	0.347–0.358
<b>EQ-VAS</b>	All (n=34 890)	54	76	22.2*	21.9–22.5
	Females (n=20 159)	51	74	23.5*†	23.1–23.9
	Males (n=14 720)	57	78	20.4*†	20.0–20.8
<b>Pain-VAS</b>	All (n=34 953)	62	14	-47.4*	-47.2–-47.7
	Females (n=20 214)	64	15	-48.7*†	-49.0–-48.4
	Males (n=14 739)	59	13	-45.6*†	-46.0–-45.3

Table 4. Mean EQ-5D index, EQ-VAS and pain-VAS scores pre-operatively (0 y), one-year follow-up (1 y) and differences (Δ) between them. Last column shows 95% confidence interval (CI<sub>95</sub>) for Δ. The symbols represent significant differences within each group (\*) and between genders (†), (all p<0.001, Wilcoxon signed ranks test (\*) and the Mann-Whitney U test (†)).

HRQoL compared to pre-operatively (table 4): EQ-5D index, EQ-VAS and pain were significantly reduced (all p<0.001, Wilcoxon signed rank test). Females and younger patients (<60 years) reported lower EQ-5D index pre-operatively but they had a greater mean gain at the one-year follow-up than males and older patients (both p<0.001, Mann-Whitney U test). Mean satisfaction VAS score was 16.8 (CI<sub>95</sub> 16.4–17.2) and 88.6% reported a score of 40 or less (=satisfied). Males were slightly (mean difference 2.7 units) but significantly more satisfied (p<0.001, Mann-Whitney U test).

#### EQ-5D index one year post-operatively compared to the general population

Compared to the EQ-5D index of the general population (expected EQ-5D index), 86% reported a lower index pre-operatively. One year after surgery 67% reported EQ-5D index higher than the EQ-5D index of the general population.

#### Multivariate linear regression analyses

In a multivariate regression analysis Charnley category C, male gender and higher age were associated with less improvement in HRQoL (p<0,001).

**Table 5 – Response rates in age categories and different randomisation groups**

Age category	Number	Response rate after first reminder	Response rate with cross-over	Total response rate
<b>Pen-and-paper questionnaire</b>				
<50 years	293	88%	2%	90%
50–59 years	296	92%	1%	93%
60–75 years	287	97%	0%	97%
>75 years	275	91%	0%	91%
Total	1 151	92%	1%	93%
<b>Internet questionnaire</b>				
<50 years	294	71%	15%	86%
50–59 years	289	62%	27%	89%
60–75 years	288	37%	40%	77%
>75 years	268	23%	48%	71%
Total	1 139	49%	32%	81%

Table 5. Response rates after first reminder; with the cross-over opportunity, and with the combination of answering modes in different age categories according to stratification.

## Paper II

# Internet-based follow-up questionnaire for measuring patient-reported outcome after total hip replacement surgery – reliability and response rate

This randomised methodological study sought to test the reliability of an Internet questionnaire and investigate the differences in response rates between traditional pen-and-paper questionnaires and Internet questionnaires for measuring PRO after THA.

Two-thousand-four-hundred patients were chosen at random but stratified by age, gender and diagnosis for inclusion in an “extra” (i.e. not in the Registry’s ordinary routine) four-year follow-up using EQ-5D and VAS for pain and satisfaction. The patients were randomised to answer the follow-up model protocol either via a password-protected Internet questionnaire or via a mailed pen-and-paper questionnaire.

**Figure 8 – Age dependent probability of response in randomisation groups**

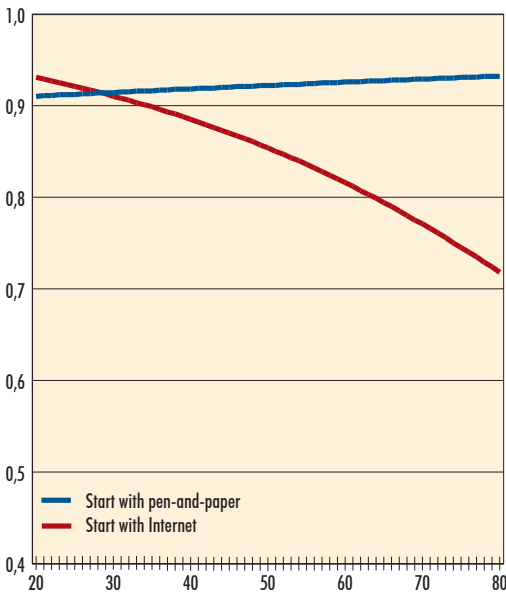


Figure 8. The graph illustrates the probability of final response based on a logistic regression model including age at operation and randomisation group. The curves for the probability to respond for the two different ways of administering the questionnaire cross at age of 28 years at operation.

## Results

### Response rate

Response rates are presented in table 5. After the first reminder, the 92% response rate in the pen-and-paper questionnaire group significantly differed from the 49% response rate in the Internet questionnaire group ( $p < 0.01$ , Fisher’s exact test). The total frequency in the Internet group rose to 81% when the non-respondents were offered the possibility to answer via the pen-and-paper questionnaire (“cross-over”). The difference in response frequency between four age groups was not significant in the pen-and-paper questionnaire group ( $p = 0.093$ , logistic regression) but *was* significant in the Internet group ( $p < 0.001$ , logistic regression). Response rates declined with increasing age in the Internet group. The gender differences in response rates in the two randomisation groups were not significant ( $p = 0.09$  and  $p = 0.74$  respectively, Fisher’s exact test). Adjusting from age-cohort grouping to normal age distribution in the Register, the Internet response rate was computed to 34% and the pen-and-paper version to 94%.

### Probability of responding

The probability of responding in any way for the two alternatives start with pen-and-paper questionnaire or start with Internet questionnaire, is further visualised in figure 8. The logistic regression model from which these probability curves were created includes age and randomisation group as dependent variables and any response as independent variable.

### Reliability test

To test the reliability of the questionnaire the 100 patients that answered the Internet questionnaire first were asked to re-answer it three weeks after the first mail was delivered. Seventy patients completed the retest form. Spearman’s correlation for the EQ-5D index was 0.82, for VAS pain 0.83 and for VAS satisfaction 0.63.

## Paper III

# Costs related to hip disease in patients eligible for total hip arthroplasty

This study was designed to estimate direct and indirect costs incurred by hip disease in patients eligible for THA. Prior to surgery, 2 635 patients from 20 hospitals completed a questionnaire regarding the use of resources and loss of productivity due to their hip disease during the previous twelve months. The mean time between

completing the questionnaire and surgery was 29 days (SD 49.7). Costs were assigned using official statistical sources or market prices. Individual data on waiting time were collected. A regression analysis was performed to investigate predictors of costs.

## Results

### Waiting time

The mean waiting time for orthopaedic consultation was 176 days (CI<sub>95</sub> 164.5–185.7, SD 246), and the median 104 days (range 0–3 786). The mean and median waiting times for surgery were 144 days (CI<sub>95</sub> 139.1–149.2, SD 129.5) and 115 days (range 0–2 786), respectively.

### Health Related Quality of Life

The PROM programme was completed in 2 304 cases (87.4%). Among these the mean EQ-5D index was 0.428 (CI<sub>95</sub> 0.415–0.441, SD 0.31) and VAS pain 60.4 (CI<sub>95</sub> 59.8–61.1, SD 16). Adjusting for age, gender, region (Northern or Western region) and Charnley category (A+B or C) lower pre-operative EQ-5D index at surgery was associated with shorter ( $p < 0.001$ ) waiting time.

### Productivity loss

Of patients not age-retired ( $n=880$ ), 48% had been home from work due to hip disease, and their mean duration of sick leave was 29.6 weeks (CI<sub>95</sub> 27.73–31.42, SD 18.5) during the previous 12 months. Twenty four percent ( $n=207$ ) were on disability pension but it was not clear from the questionnaire whether the reason was hip disease. Therefore, it was approximated that 50% of the costs incurred by disability pension was due to hip disease.

### Pharmaceuticals

Use of any medication for the hip disease was reported in 81% ( $n=2 146$ ) of the subjects. The mean cost of continuous medication was SEK 802 (CI<sub>95</sub> 752.5–852.0, SD 1303) and medication on demand SEK 149 (CI<sub>95</sub> 140.5–158.29, SD 232).

### Community services

The 4.0% who reported home-help services required on average 3.9 hours (CI<sub>95</sub> 2.89–4.99, SD 5.1) per week. The need for transport for the disabled averaged 1.6 occasions per week (CI<sub>95</sub> 1.33–1.87, SD 1.8) in 233 subjects (8.6%).

**Table 6 – Costs and resource utilisation 12 months before surgery**

Resource	Number	Mean utilisation (CI <sub>95</sub> )	Unit cost (SEK)	Reference
<b>Health care resources</b>				
<b>Outpatient care visit</b>				
General practitioner	$n=2 635$	1.77 (1.69–1.84) visits	1 345	95
Physiotherapist	$n=2 635$	3.84 (3.42–4.25) visits	743	95
Orthopaedic surgeon	$n=2 635$	1.44 (1.40–1.49) visits	2 155	95
Hospital inward care	$n=79$	18.2 (7.1–29.3) days	4 645	95
Pharmaceuticals	$n=2 146$	1 (NA) unit	1 176	96
<b>Municipality resources</b>				
Transportation for disabled	$n=227$	83.2 (69.1–97.3) transports	221	97
Home help service	$n=93$	204.9 (150.4–259.4) hours	350	98
Home modification	$n=1 127$	0,5 (NA) unit	11 617	99
<b>Informal care</b>				
Value of lost leisure time	$n=680$	676.3 (586.5–766.2) hours	28	100
Replacement costing method	$n=250$	77.6 (50.8–104.4) hours	141	101
<b>Productivity loss</b>				
Sick leave	$n=390$	30.24 (28.18–32.30) weeks	9 635	101
Disability pension	$n=207$	0,5 (NA) year	100 100	101
<b>Cost per patient</b>	$n=2 635$	<b>SEK 54 850 (51 250–58 500)</b>		

Table 6. The different resources, mean utilisation with 95% confidence intervals (CI<sub>95</sub>), unit costs in Swedish currency (SEK) and the aggregated mean cost per patient are presented in the table. Prices are adjusted to the 2005 consumer price index.

Use of any home modification (i.e. home elevator, removal of door thresholds, elevated water-closet or bed, bathroom adjustments) was reported by 43% (n=1 127).

### Informal care

Informal care was needed in 26.2% of whom 9.6% required this from caregivers who had to be absent from work. The mean time spent on informal care during leisure time was 13.0 hours (CI<sub>95</sub> 11.3–14.7, SD 20) per week and was 1.49 hours (CI<sub>95</sub> 0.98–2.01, SD 4.1) per week for informal care during caregivers' ordinary working time.

### Total costs

Resource utilisation frequency, unit costs and aggregated costs are presented in table 6. Total COI for patients listed for THA in this study amounted to SEK 54 850 (CI<sub>95</sub> 51 250–58 500, SD 94 875) during the year prior to surgery. Adjusting to the 2009 consumer price index this equals SEK 58 600. The distribution of costs is presented in figure 9.

**Figure 9 – Distrubtion of costs**

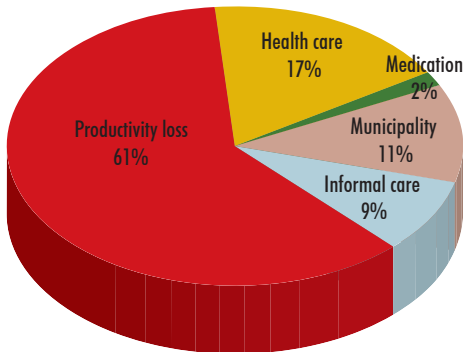


Figure 9. Distribution of cost-of-illness for patients eligible for THA.

### Regression model

The regression analysis of annual cost of hip disease (table 7) showed that patients below retirement age incurred markedly higher costs than older patients, other predictors of resource use controlled for. Women incurred 41% higher costs than men: there was no difference between the two geographical regions included and, as expected, Charnley category C was associated with higher costs. Waiting times above 90 days were associated with 20% higher annual costs of hip disease compared to shorter waiting times.

### Paper IV

## Variables determining outcome in total hip replacement surgery

In this study it was hypothesised that anxiety/depression, one of five dimensions in EQ-5D, could predict outcome after THA surgery. Pre-operative and one-year post-operative data from the Register, including 6 158 patients with primary OA, were analysed.

### Pre-operative

The pre-operative mean age of the cohort was 69 years (27 to 96, 57% women) and the distribution in Charnley categories was A (44%), B (14%) and C (42%).

The 3 597 patients classified in Charnley categories A and B reported lower mean values for pain (VAS 60, SD 16.2) and a higher mean pre-operative EQ-5D score (0.43, SD 0.31) compared to group C patients (n=2 561; VAS 64, SD 16; EQ-5D 0.34, SD 0.32) ( $p < 0.001$ , Mann-Whitney *U* test). Patients (n=198) who reported severe anxiety/depression also reported worse pre-operative pain than all other patients (VAS 71, SD 17) ( $p < 0.001$ , Mann-Whitney *U* test). A larger proportion of women (49%) than men (35%) reported pre-operative anxiety/depression.

**Table 7 – Predictors of costs of hip disease**

Variable	Relative cost	P-value	CI <sub>95</sub>
Charnley category (C vs. A + B)	1.44	<0.001	1.27–1.63
Region (Northern vs. Western region)	1.01	0.89	0.89–1.14
Gender (female vs. male)	1.41	<0.001	1.26–1.60
Age (below 65 years)	4.95	<0.001	4.42–5.55
Operation waiting time (above 90 days)	1.20	0.004	1.06–1.36

Table 7. Results from a logistic regression analysis with Charnley categories, regional affiliation, gender, age and waiting time as predictors in the same model. Total costs for hip disease constitute the dependent variable. Relative cost, p-values and 95% confidence intervals are presented.



**Table 8 – Patient-reported outcome measures pre-operatively and one year post-operatively**

Group	Anx/depr Pre-op	Number	Pain VAS mean (SD)			Satisf VAS mean (SD)		EQ-5D index mean (SD)		
			Pre-op	Post-op	Δ pain	Post-op	Pre-op	Post-op	Δ EQ-5D	
All patients	1	3 530	59 (16)	13 (17)	-47 (23)	15 (19)	0.49 (0.28)	0.82 (0.21)	0.32 (0.32)	
	2+3	2 628	65 (15)	17 (20)	-49 (24)	20 (22)	0.26 (0.30)	0.71 (0.26)	0.45 (0.36)	
Males	1-3	2 652	59 (16)	13 (17)	-46 (23)	15 (19)	0.44 (0.31)	0.80 (0.23)	0.36 (0.34)	
Females	1-3	3 506	64 (16)	15 (19)	-49 (23)	19 (22)	0.36 (0.31)	0.75 (0.25)	0.39 (0.35)	
Charnley A+B	1	2 214	58 (16)	11 (16)	-47 (22)	13 (17)	0.51 (0.28)	0.85 (0.19)	0.34 (0.31)	
	2+3	1 383	65 (15)	14 (18)	-51 (22)	17 (20)	0.29 (0.30)	0.74 (0.24)	0.48 (0.36)	
Charnley C	1	1 316	61 (16)	15 (19)	-46 (24)	19 (22)	0.46 (0.29)	0.75 (0.24)	0.30 (0.34)	
	2+3	1 245	67 (15)	21 (21)	-46 (25)	24 (24)	0.22 (0.30)	0.64 (0.27)	0.42 (0.37)	
Males	1	1 726	57 (16)	12 (17)	-45 (22)	14 (18)	0.52 (0.27)	0.83 (0.21)	0.31 (0.31)	
	2+3	926	63 (16)	16 (18)	-48 (23)	18 (20)	0.28 (0.31)	0.73 (0.25)	0.45 (0.37)	
Females	1	1 804	62 (16)	13 (18)	-49 (23)	17 (20)	0.47 (0.28)	0.80 (0.22)	0.33 (0.33)	
	2+3	1 702	67 (15)	17 (20)	-49 (24)	21 (23)	0.25 (0.30)	0.70 (0.27)	0.45 (0.36)	
All patients		6 158	61 (16)	14 (18)	-48 (23)	17 (21)	0.39 (0.31)	0.77 (0.24)	0.38 (0.35)	

Table 8. Mean values for pain (VAS) and EQ-5D index pre-operatively and mean values for pain (VAS), pain relief ( $\Delta$  pain), EQ-5D index and difference in EQ-5D index ( $\Delta$  EQ-5D) one year after surgery for different patient cohorts and subdivided into groups with or without anxiety/depression (anx/depr).

### Post-operative

Patients with musculoskeletal co-morbidity (Charnley category C) had worse outcome with regard to pain relief, satisfaction and EQ-5D index than did patients in Charnley categories A or B ( $p < 0.001$ , Mann-Whitney  $U$  test). Women had worse outcome than men in satisfaction and EQ-5D index ( $p < 0.001$ , Mann-Whitney  $U$  test). The mean differences in pain VAS and EQ-5D index are shown in table 8. The patients with a pre-operative anxiety/depression score of 2 or 3 had a higher increase in their EQ-5D index one year post-operatively ( $p < 0.001$ , Mann-Whitney  $U$  test) than those reporting no problems in the anxiety/depression dimension. However, mean EQ-5D index was 0.11 units lower for those reporting any anxiety/depression pre-operatively ( $p < 0.001$ , Mann-Whitney  $U$  test).

### Anxiety/depression and outcome

Adjusting for all dimensions of EQ-5D pre-operatively, Charnley category, age and gender, multivariate linear regression analysis showed that the degree of pain relief and satisfaction one year after surgery were related to pre-operative anxiety/depression in the fifth EQ-5D dimension and the Charnley category. As shown in figures 10 and 11, patients in Charnley category C reported an adjusted mean 5.6 VAS units (SD 0.53) in satisfaction and an adjusted mean 8.2 percentage points (SD 0.82)

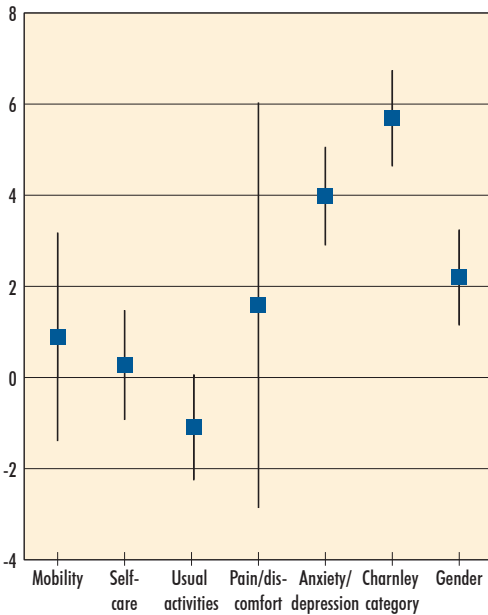
less pain reduction than patients in categories A and B ( $p < 0.001$ ). Patients with any pre-operative anxiety/depression reported an adjusted mean 4.0 VAS units (SD 0.55) lower in satisfaction and had 4.4 percentage points

**Table 9 – Satisfaction and pain relief at different levels of anxiety/depression pre- and postop**

Anx/depr Pre-op	Anx/depr Post-op	Number	Satisfact VAS mean (CI <sub>95</sub> )	Δ Pain VAS mean (CI <sub>95</sub> )
1	1	3 153	14 (13–14)	48 (47–49)
	2	356	30 (27–33)	36 (33–38)
	3	21	41 (26–56)	28 (18–39)
2	1	1 517	15 (14–15)	53 (52–54)
	2†	853	27 (26–29)	43 (41–45)
	3†	60	47 (38–55)	24 (17–30)
3	1	68	13 (9–18)	61 (56–66)
	2†	109	25 (20–30)	48 (43–53)
	3†	21	40 (25–56)	42 (27–56)
All patients		6 158	17 (17–18)	48 (47–49)

Table 9. Patient satisfaction and pain relief in VAS-units for different levels of EQ-5D dimension anxiety/depression pre- and post-operatively. Patients included in the 'persistent anxiety' group are indicated with †. 95% confidence intervals are presented (CI<sub>95</sub>).

**Figure 10 – Prediction of patient reported satisfaction**



**Figure 11 – Prediction patient reported percentage change in pain**

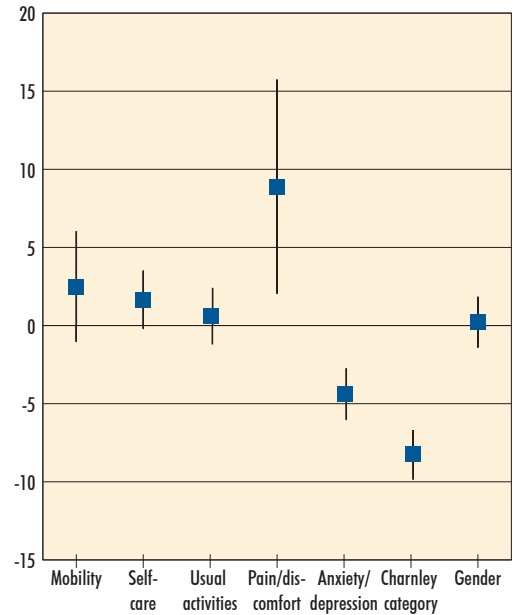


Figure 10. Prediction of patient-reported satisfaction. Graph showing multivariate linear regression analysis with all EQ-5D dimensions, Charnley categories, age and gender included in the model. The dependent variable is satisfaction as a VAS. The pre-operative EQ-5D dimensions are grouped into two categories: no problem and any problems (1 and 2 + 3). The pre-operative Charnley category is grouped into A + B and C. Scientific marks (\*) indicate the difference in the adjusted mean VAS score for satisfaction. Bars represent CI<sub>95</sub>. Pre-operative anxiety/depression, Charnley category C and female gender are associated with significantly higher VAS (less satisfied).

Figure 11. Prediction of patient-reported change in pain (percentage). Graph showing linear regression analysis with all EQ-5D dimensions, Charnley categories, age and gender included in the model. The dependent variable is the percentage change in VAS. The pre-operative EQ-5D dimensions are grouped into two categories: no problem and any problems (1 and 2 + 3). The pre-operative Charnley category is grouped into A + B and C. Scientific marks (\*) indicate the difference in the adjusted mean percentage change in VAS score for pain. Bars represent CI<sub>95</sub>. Pre-operative anxiety/depression and Charnley category C are associated with a significantly lower percentage improvement in VAS for pain.

(adjusted mean SD 0.84) less pain reduction than patients not reporting anxiety/depression pre-operatively ( $p < 0.001$ ). The satisfaction outcome for women was 2.2 VAS units (adjusted mean SD 0.53) lower than for men ( $p < 0.001$ ), but there was no significant difference in the percentage of pain reduction in the linear regression analysis ( $p < 0.79$ ).

**Post hoc analysis**

The possible combinations and number of patients with respect to pre- and post-operative anxiety/depression in VAS units are shown in table 9. Patients with persistent anxiety/depression (1 043 patients) and patients (n=21) moving from no to severe anxiety had the poorest outcome for pain relief and patient satisfaction (table 9).

Linear regression analysis (adjusting for age, gender and musculoskeletal co-morbidity) showed that persisting moderate or severe problems in any of the EQ-5D dimensions were related to inferior results in the VAS for satisfaction and the degree of pain reduction, with the exception of the mobility dimension (all  $p < 0.001$ ). This analysis strengthened the relationship between anxiety/depression and a poor outcome.

**Paper V**

**One-stage bilateral total hip arthroplasty is cost-saving**

In this study a cohort of 32 patients with one-stage bilateral THA was prospectively followed for six years. A

matched cohort of 32 patients with unilateral THA was assembled. Medical records, individual data from the Register and the Swedish Social Insurance Administration, and local data on CPP, were used for the analyses. The study comprised costs, complications and PROs related to one-stage bilateral THA. The group with unilateral THA was used as a reference.

## Results

### Patient-reported HRQoL pre-operatively, one and six year post-operatively

The pre-operative EQ-5D index was 0.14 for the one-stage group and 0.31 for the unilateral group. Mean EQ-5D index gain was 0.77 for the one-stage group and 0.40 for the unilateral group at the one-year follow-up. The improvement was maintained at the six-year follow-up for both groups. For non-retired patients, the duration and costs for sick leave during the first post-operative year were similar in both groups. For the one-stage bilaterally-operated patients, complications occurred at a similar frequency and with similar severity to those of patients with unilateral THA.

### Costs

In table 10, medical costs in conjunction with the operation (mean CPP) were SEK 144 700 for one-stage bilateral surgery and SEK 90 600 for unilateral surgery. Mean sick-leave and social insurance administration costs were similar in both groups.

### Cost-utility aspects

A simple cost-utility analysis was conducted (table 10). QALYs and cost-per-QALY outcomes were superior for both the one-stage bilateral procedure and the unilateral procedure compared to the hypothetical non-treatment alternative.

### Cost-effectiveness model

On the assumption that a two-stage bilateral procedure would generate hospital costs equalling those of two unilateral operations, the one-stage bilateral procedure reduced hospital costs by 20% (table 11). In the model assuming a 90-day interval between staged procedures, reduction of sick-leave costs was estimated to 30%.

**Table 10 – Costs, sick-leave and QALYs**

	One-stage bilat				Matched control			
	mean	interquartile range	n	SD	mean	interquartile range	n	SD
Hospital costs SEK (CPP)	144 700	133 700–154 300	32	15 100	90 600	81 800–96 900	32	14 000
Total days off work 12 months	230	147–349	21	94	226	96–365	19	122
Social insurance administration costs SEK	100 300	57 900–148 400	21	53 200	99 800	53 800–133 800	19	61 000
QALYs gained at one year	0.56	-	32	0.18	0.28	-	32	0.26
Cost per QALY gained SEK first year	258 400	-	-	-	323 600	-	-	-
QALYs gained at six years	4.14	-	29	1.76	2.24	-	29	1.99
Cost per QALY gained SEK after six years	34 950	-	-	-	40 450	-	-	-

Table 10. Descriptive data regarding costs, sick-leave and QALYs for one-stage bilateral THA and for the matched control group. QALYs gained and cost per QALY refers to comparison to hypothetical non-treatment alternative (i.e. comparing to baseline data).

**Table 11 – Comparison between one-stage and two-stage model of bilateral THA procedures**

	Hospital costs mean (SD)	Sick leave costs mean (SD)	Total costs mean (SD)
One-stage bilateral THA*	144 700 (15 100)	65 900 (64 600)	210 500 (69 600)
Two-stage bilateral THA†	181 900 (6 800)	94 100 (80 000)	276 000 (91 600)
Wilcoxon signed rank test	$p < 0.001$	$p = 0.004$	$p < 0.001$

\*Based on observed individual values. †For each individual the expected costs were determined by applying regression functions as described in the Methods section.

## Additional results

All additional results are derived from the supplementary data of *paper I* from the PROM database.

### Distribution of fixation principles and different types of hospital

Among the 34 960 THA procedures in *paper I*, the distribution of different fixation principles was 78.6% all cemented, 9.9% all un-cemented, 2.4% hybrid, 6.6% reversed hybrids and 1.8% resurfacing prosthesis. The distribution of different types of hospital was 9.4% university or regional hospital, 35.7% central hospital, 50.1% rural hospital and 4.8% private hospital.

### Distribution of EQ-5D profiles and dimensions

Totally 181 of the possible 243 combinations were used (151 pre-operatively and 152 one year post-operatively). Pre-operatively, the ten most common EQ-5D combinations represented more than 70% of all answers. The most common combination was 21121 i.e. moderate problems in the “mobility” and the “pain” dimensions. Post-operatively, 35.5% of the population reported 11111, i.e. no problems in any dimension. The ten most common EQ-5D-combinations represented more than 84% of all answers. The ten most common combinations pre- and post-operatively are presented in table 12.

Figure 12 and table 13 demonstrate the distribution of answers in each dimension pre- and one year post-operatively. Unlike the EQ-5D index, which is bimodally distributed pre-operatively, the EQ-VAS is normally distributed as presented in figures 13 a and b. Also the EQ-VAS difference is normally distributed (figure 14). The pain and mobility dimensions are the most affected and consequently the most improved, see table 14.

### PROs in different time periods

To analyse changes over time, all patients who had surgery until 2005 and those operated later were compared. Results are presented in table 15. Mean absolute pre- and post-operative EQ-5D indices were higher in the later period but the mean difference was lower. Mean EQ-VAS differed in a similar way comparing the two periods but the mean difference was not significant. For pain, pre-operative VAS score was lower in the later period but the mean level post-operatively did not differ. Satisfaction measured with VAS was slightly but significantly better in the later period. No adjustments for confounders have been made. The patients operated on in 2002 to 2005 were mainly from the Western region since the project started off in this region. Patients operated on in 2006 to 2008 are more evenly distributed over the country.

**Table 12 – The ten most common EQ-5D combinations pre- and post-operatively**

Pre-operatively			One year post-operatively		
EQ-5D combination	EQ-5D index	Percentage	EQ-5D combination	EQ-5D index	Percentage
21121	0.73	15.7%	11111	1.00	35.5%
21221	0.69	11.8%	11121	0.80	13.9%
21231	0.16	7.4%	21121	0.73	11.3%
21222	0.62	7.0%	21221	0.69	5.9%
21232	0.09	6.7%	21222	0.62	4.9%
21122	0.66	5.2%	21122	0.66	3.8%
21131	0.20	5.0%	11122	0.73	2.6%
22232	-0.02	5.0%	21111	0.85	2.3%
22231	0.06	3.3%	22222	0.52	2.0%
11121	0.80	3.2%	11112	0.85	1.8%
Other	NA	29.7%	Other	NA	16.0%

Table 12. The ten most common EQ-5D-combinations pre- and post-operatively.

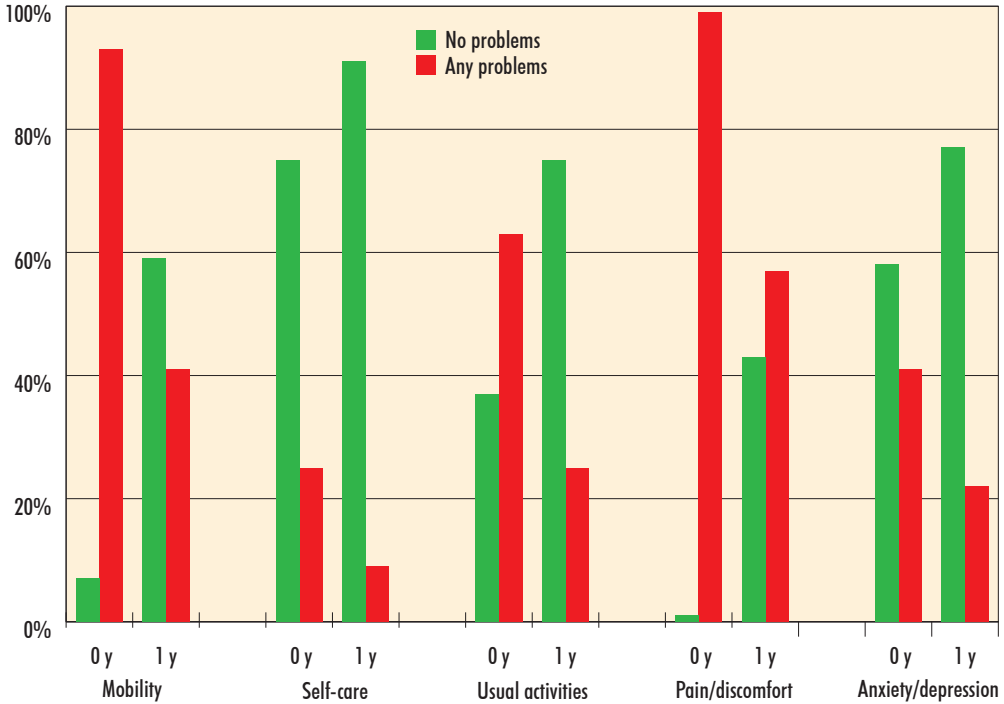


Figure 12. Distribution of responses (no problems or any problems) in the five EQ-5D dimensions pre-operatively (0 y) and at the one-year follow-up (1 y).

**Table 13 – Distribution of responses in EQ-5D dimensions**

Dimension	Time point	No problems	Moderate problems	Severe problems
Mobility	0 y	7%	93%	0%
	1 y	59%	41%	0%
Self-care	0 y	75%	24%	1%
	1 y	91%	8%	1%
Usual activities	0 y	37%	51%	12%
	1 y	75%	23%	2%
Pain/discomfort	0 y	1%	56%	42%
	1 y	43%	52%	5%
Anxiety/depression	0 y	58%	38%	3%
	1 y	77%	21%	1%

Table 13. Distribution of responses in all five EQ-5D dimensions pre-operatively (0 y) and post-operatively (1 y).

**Table 14 – Percentage change in different EQ dimensions at one-year follow-up**

	Mobility	Self-care	Usual activities	Pain/ discomfort	Anxiety/ depression
Worsened	2%	4%	6%	2%	7%
Unchanged	46%	81%	53%	34%	73%
Improved	53%	15%	41%	64%	20%

Table 14. The percentage of patients improving, worsening or reporting unchanged scores for each of the five EQ-5D dimension at the one-year follow-up.

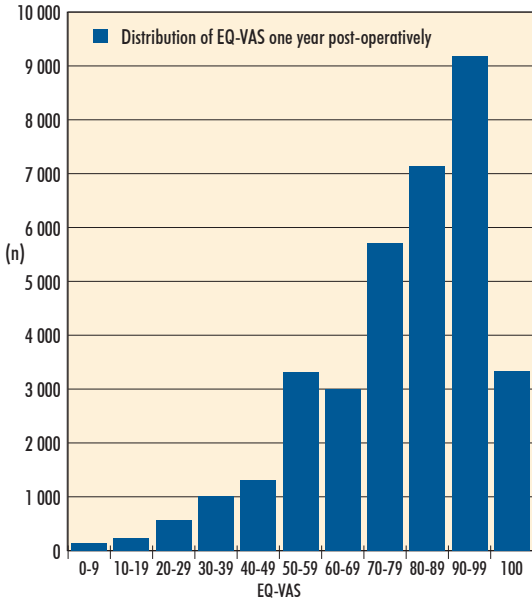


Figure 13a. Distribution of EQ-VAS post-operatively. VAS has been grouped to 0–9, 10–19 etc. 100 is all EQ-VAS 100

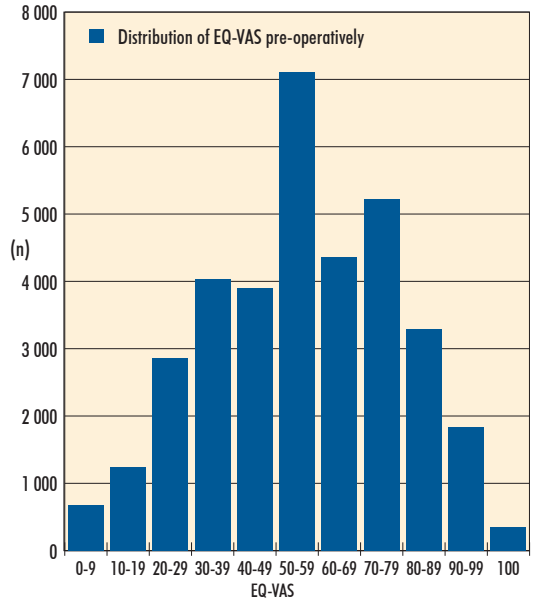


Figure 13b. Distribution of EQ-VAS pre-operatively. VAS has been grouped to 0–9, 10–19 etc. 100 is all EQ-VAS 100.

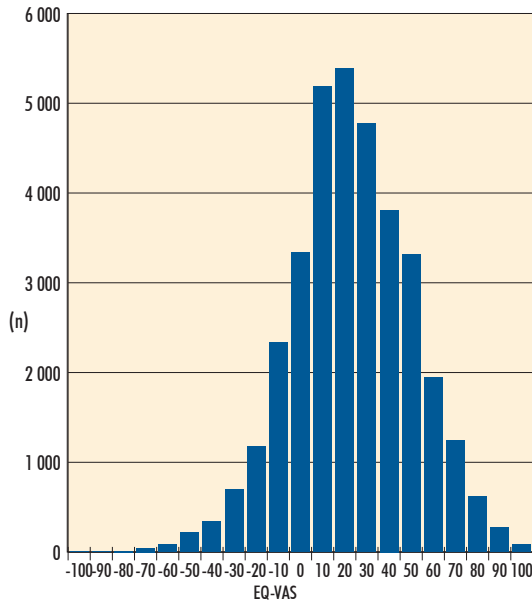


Figure 14. Distribution of differences in EQ-VAS between pre- and one year post-operative EQ-VAS clustered into differences in ten units on the VAS.

Table 15 – Changes in PROs over time

		2002–2005 (n = 10 094)	2006–2008 (n = 24 866)	p-value
EQ-5D index	0 y	0.39	0.41	<0.001
	1 y	0.77	0.78	<0.001
	Δ	0.38	0.37	0.001
EQ-VAS	0 y	52.6	53.8	<0.001
	1 y	75.1	75.9	<0.001
	Δ	22.5	22.1	0.29
Pain VAS	0 y	62.0	61.3	0.002
	1 y	14.1	14.1	0.86
	Δ	-47.9	47.2	0.012
Satisfaction VAS	1 y	16.7	16.5	<0.001

Table 15. PROs during 2002–2005 and 2006–2008. Pre-operative (0 y), one-year post-operative (1 y) and differences (Δ) are presented. P-values were calculated with the Mann Whitney U test.



# Strengths and limitations

## Large-scale prospective observational study

The general strength of the present work lies in the large number of patients collected from a nationwide, prospective, observational database. Consequently, performance bias, which can occur if patients are recruited from selected surgeons and centres, is avoided. The large numbers of registrations enable the detection of small differences among subgroups and over time but are limited for explaining the reasons for differences or changes.

## High completeness and response rate to the Register

Completeness as well as response rates to the Register are outstandingly high, which makes the data more reliable. The population in the PROM database is likely to be representative of the Swedish THA population.

## Concentrated set of PROMs

The concentrated set of PROMs may limit the range and depth of the analyses. Data on medical co-morbidities and detailed case-mix variables are not available.

## No patients lost to follow-up

The Swedish system, with a unique personal identity number, enables follow-up of all patients. The only exception to this is emigrating individuals. Via the personal identity number it is possible to link to other statistical databases and registers (this requires ethical approval).

## Recall bias and the relation between resource use and hip disease

Because the patients were asked to recall the use of resources due to hip disease during the previous twelve months, *paper III* is limited by recall bias. Furthermore, how far the use of a resource is due to hip disease is difficult to answer. Thus, the relationship between resource use and hip disease is uncertain even though patients were asked to indicate only resources used *mainly* because of hip disease. There are probably other resources such as complementary medicine that have not been included in the estimation of the total costs and that could be added.





## General discussion

### Health-technology assessment in total hip arthroplasty

There are increasing demands for and interest in routinely measuring PRO in different medical fields. Patients' subjective outcomes supplement traditional outcome measures and enable monitoring of the quality of the health care provided, local improvement work, and health-economic analyses. The monitoring also facilitates resource allocation and may reduce the number of routine follow-ups. The instruments used for measuring PRO must be valid and reliable, preferably both generic and disease-specific. When used routinely the number of items included in the questionnaire needs to be limited to provide sufficient response rates. A large-scale PROM programme requires structured organisation and effective and reliable IT solutions. The modalities used for collecting PROMs should be tested and non-respondents investigated. Multidimensional outcome assessment, combining traditional clinical outcome parameters with generic and disease-specific measures along with data on direct and indirect costs, will provide a more nuanced and complete assessment of the intervention.

### On outcome measurements in the Register

#### Predicting outcomes – the reasons for poor outcome

This thesis illustrates that implant survival as a single outcome parameter is too blunt an instrument to describe outcomes. One year after primary THA, implant survival is in most studies close to 100% while patient satisfaction in the Swedish THA population is barely 90% with this short follow-up. Even though THA overall has outstanding results compared to many other interventions, a considerable proportion do not respond or respond negatively to THA. The reasons for the poor outcomes need to be investigated further. *Paper IV* confirmed earlier findings that Charnley category C was associated with inferior results following THA and that female gender was associated with less pain reduction and lower absolute level of EQ-5D index at one year follow-up. It was also demonstrated that anxiety/depression was a strong predictor for worse PROs. This has not, to our knowledge, been demonstrated for THA

previously. However, in a recent study by Axford et al<sup>102</sup> the prevalence of mental anxiety or depressive disorders in patients with OA was examined using the Hospital Anxiety and Depression scale as a screening. They concluded that the strong relationship between mental health, pain and disability suggests a multidisciplinary management of OA, including psychological assessment and treatment. They also suggested that a pre-operative psychological evaluation of patients with OA of the hip or knee should be enforced. In *paper IV* 43% of OA patients eligible for THA reported anxiety/depression in the fifth dimension of the EQ-5D questionnaire prior to surgery and that pre-operative anxiety predicted inferior outcomes. A strong relationship between pain and mental distress was established. As did Axford et al<sup>102</sup>, we concluded that orthopaedic surgeons involved in the care of patients eligible for arthroplasty should be alert to the fact that mental health may influence the pain experience and PRO. An appropriate assessment of mental health and corresponding modifications in the management of these patients could improve their outcome.



#### Expectations and outcomes

In a recent study by Anakwe et al<sup>103</sup>, satisfaction correlated with post-operative functional scores, relief of pain, restoration of function and success in meeting patient expectations. They concluded that pain relief and expectation management are critical in maximising patient satisfaction after THA.

#### Discrepancy between EQ-VAS and EQ-5D index

Ostendorf et al<sup>104</sup> reported similar observations about the discrepancy between pre-operative EQ-VAS (patient-centred value) and EQ-5D index (social value) to

those in *paper I*. This pre-operative difference was explained by what they call “response shift”. Response shift is the change in internal standards, in values, or in the perception of HRQoL which are created by changes in health state. In clinical practice, this means that most patients perceive their HRQoL as being better than from the perspective of the general population. The remarkable inconsistency between the pre-operative EQ-5D index and the EQ-VAS, which was absent at the follow-up, raises questions about this algorithm (the tariff for calculation of the EQ-5D index)<sup>104</sup>. In other words, chronic pain in the hip may not influence HRQoL as much as the algorithm determines.

### The selection of PROM instruments

The PROMs included in the follow-up instrument were carefully selected. The follow-up instrument was introduced to a limited number of departments in 2002. It has gradually been adopted and is now used in all THA departments except one to monitor all patients undergoing THA in Sweden. To maintain a high response rate, the number of questions needs to be limited. The generic EQ-5D corresponds to hip-disease-specific questionnaires such as the WOMAC<sup>105</sup>. The EQ-5D creates a utility index used to assess the benefits in terms of QALYs, which makes it very useful. The high response rates indicate the adequate dosage of questions. Adding a more comprehensive set of PROM instruments to the Register’s follow-up programme would jeopardise the response rates. Such surveys could be done in samples to enable in-depth analysis.

### The limitations of the EQ-5D instrument

The EQ-5D instrument has limitations regarding capability to detect small changes in HRQoL. This is especially so in the “normal” population because of a ceiling effect (a large proportion of a general population scores EQ-5D index of 1.00). However, a newer version of the instrument has recently been introduced by the EuroQol group offering five levels within each dimension (EQ-5D-5L)<sup>106,107</sup>. This instrument is intended to be more sensitive to changes in HRQoL and could be useful for the Registry in the future.

### The gender perspective

*Papers I and IV* showed that females report lower pre- and one-year post-operative EQ-5D index and more pain. Females’ mean age at operation is more than two years above males’. These findings lead us to question whether we are more conservative about the indications for females than for males. However, females have greater improve-

ment in HRQoL and greater pain reduction than males. Moreover, females improve to a significantly higher level above the EQ-5D index level of the normal population, than males do. The fact that females report lower HRQoL than males across countries and age groups both in the general population<sup>108,109</sup> and in the THA population, as reported in *papers I and IV*, illustrates the necessity of prospective studies instead of cross-sectional.

## The collection of PROMs

### Patient information via Internet – PIVI

The PIVI study (*paper II*) showed that the Internet questionnaire is not at present sufficient to replace the pen-and paper form for the THA population. However, a combined system, where the patients may answer either via Internet or in the traditional way, is feasible. The continuous increase in Internet use suggests a future improved response rate among the THA population using an Internet application. Even at limited Internet response rates, the combined answering system appears cost-saving for a large volume of respondents. The response rates do not differ among gender and the introduction of an Internet option to answer the PROM questionnaire seems unproblematic from a gender perspective.

### Generalisation of the results of the Internet questionnaire study

The results of *paper II* are probably not specific to the THA population and the specific PROM protocol used. It is feasible to generalise the results to an age-matched general population in Sweden. Therefore, when designing new programmes or altering present ones aiming at collecting PROMs one should be aware that response rates will probably be considerably lower in the elderly population if Internet applications are used solely.



Moreover, the results are less likely to be representative of the study group because non-respondents to the Internet questionnaire tend to differ more from the respondents than the corresponding difference using the traditional pen-and-paper questionnaire.

### Stepwise introduction of new technologies

The stepwise introduction of new technologies, as Malchau suggested in his thesis in 1995<sup>18</sup>, could partly also apply to the introduction of new modalities of measuring PROs. Consequently, the introduction of the Internet-based follow-up programme was started with a pilot test among volunteers (pre-clinical testing). As presented in *paper II*, a randomised study (clinical step I) to investigate the response rates was performed. Since the new method alone gave insufficient response rates, adjustments to the protocol (choice of answer method) will be made before introducing it to a larger THA population (clinical step II). Currently (October 2010), such a study is in preparation. The final step would be to adopt a modified programme for follow-up to all patients with THA surgery (clinical step III).

## Public reporting and value of register results

### Rapid feedback loop resulting in clinical improvement work

One main feature for the Registry is to feed back analysed data to the participating departments in an open manner. This initiates local analyses and implementation of best clinical practice, i.e. improvement work. For example, the Registry's sensitive monitoring of implant performance could detect early warning signs of implant failure and thus rapidly alert the profession. Measuring PROM in a nationwide prospective programme also enables national and local improvement work such as refining indications and reforming care programmes. Differences in PROs between participating units often reflect diverse demography, and distribution of diagnoses and medical co-morbidities in the patients (case-mix).

### The value of register studies

When presenting or submitting results of register studies, questions such as "How were patients recruited?" and "What were the inclusion and exclusion criteria for the study?" often arise from journal reviewers. Unfortunately, there seems to be a deep-seated lack of knowledge about register studies. In a comprehensive but interim report of the QoLA-project<sup>10</sup> (Quality of Literature in Arthroplasty) initiated by the European Federation of National Associations of Orthopaedics and

Traumatology (EFORT), the research group expresses concern about the reproducibility of results published in clinical sample-based studies. Thus in this thorough review fewer than half of clinical implant studies from the United States were reproducible in average patient treatment. These studies are often overly positive and, not surprisingly, often associated with the inventor of the product investigated. Register studies can essentially support the evaluation of outcome data and serve as a benchmark in verifying the reproducibility of clinical studies. The registries are useful for patients, surgeons, health care providers and researchers.

### Registries and personal integrity

Critics argue that, with the extensive activities of the many quality registries in Sweden, there is a risk that personal integrity could be compromised. However, a recent amendment to the Patient Data Act<sup>90</sup> increases protection of integrity and provides better support for the quality registries. For example, the Act requires a higher degree of authentication than heretofore. Although this authentication is not fully implemented yet, it may be accomplished by using e-ID or smartcards when medical staff enter data into registries. However, this will also affect the possibilities for future methods of collecting PROMs, discussed in the thesis under *The future*. Here there is a delicate balance between integrity and the benefit to both patient and society. The world-leading results of THA in Sweden, which may largely be accredited to the Registry, constitute a strong argument for not requiring written consent before patients are included in the registers.

## Quality of register PROM data

### Response rate in general

Pre-operatively there seem to be difficulties in presenting the PROM questionnaire to all THA patients. This is probably partly because the PROMs from patients with acute conditions such as femoral neck fracture or pathological fracture are difficult to collect in the emergency situation. Even when these patients are excluded from the response rate analysis, as presented in *paper I*, the response rate pre-operatively is lower than at the one-year follow-up. This reflects different local logistical problems in presenting the questionnaire to all patients eligible for THA, simply because there are different paths and entrances to surgery. Post-operatively the response rate is exceptionally high compared to that in most questionnaire studies. Still there are approximately 10% non-respondents, which could be due to e.g. invalid address, patients moving abroad and various human errors in sending out questionnaires.

Thus the true response rates are uncertain. It is not possible to register how far patients are offered the pre-operative questionnaires and it is not known how many patients actually receive the one-year follow-up.

## Health-economic aspects

### Effectiveness, costs and cost-effectiveness of joint arthroplasty

In his thesis, Pekka Rissanen explored the area of costs and cost-effectiveness of major joint arthroplasties<sup>111</sup>. Rissanen investigated outcomes in relation to costs for hip and knee arthroplasty and examined variations in effectiveness and cost-effectiveness between different groups of patients. He found that both THA and TKA were very effective in reducing pain and improving HR-QoL with superior results for hips compared to knees. THA was also more cost-effective than TKA. Remarkable variations in PROs and cost-effectiveness were reported within the different procedures and among hospitals. Therefore, Rissanen concluded that allocation of resources to either THA or TKA should not be based on tentative league tables because this fails to allocate fairly and efficiently. Both interventions have outstandingly low cost per QALY gained when compared to the hypothetical non-treatment alternative (comparing to baseline data). This fact and the large variations in results make ranking between the interventions inappropriate. Instead, focus should be on optimising the outcomes within the particular intervention.

Can health economic analysis help us to decide best clinical practice for areas within THA where there is no consensus? *Paper V* is an example of how data from the PROM programme can easily be combined with cost data to calculate the cost-utility for one-stage bilateral THA surgery compared to a hypothetical non-surgical alternative. In *paper V* a model for estimating costs for a simulated two-stage bilateral THA procedure was cre-

ated using cost data from unilateral surgery in a matched control group. This was basically a type of simulated cost-minimisation analysis comparing observed cost of the one-stage procedure and calculated costs for two-stage procedures assuming 90 days between procedures. In this case we conservatively assumed similar outcomes for the two alternatives, then there was a 30% reduction in sick-leave costs and 20% reduction in hospital costs of performing one-stage bilateral procedures compared to two-stage procedures. Thus one-stage bilateral THA surgery is cost-saving.

### Cost-of-illness

In *paper III* base-line COI data from a societal perspective for patients with hip disease eligible for THA is presented. The aggregated estimates of the cost of hip disease in this study are in parity with those in other studies examining OA of the hip and including both direct and indirect costs<sup>55,56</sup>. It was recognised that females incur greater mean costs related to their hip disease. A similar observation was reported by Gupta et al<sup>56</sup>.

When examining COI it is important to apply a broad perspective in order to recognise treatments that reduce costs, as opposed to shifting them from one party to another. An open dialogue on health-care policy requires knowledge of the full costs of care.

The principal cost attributable to hip disease was due to loss of production, as presented in *paper III*. It may not be well-known that about one-third of all patients undergoing THA are of working age. For many occupations, the capability to work is not usually affected by hip disease to an extent that requires sick-leave if the patient is attending a non-surgical treatment programme. Longer periods of sick-leave should be avoided since longer sick-leave is associated with decreased return to work<sup>112</sup>. Probably, pre-operative resource utilisation is related to remaining needs, which suggests a pre-operative emphasis on preventing the arousal of needs. It is reasonable that such efforts should be made early during the course of the disease. All these factors stress the importance of implementing patient education and physiotherapy in clinical practice. An important question impossible to answer from these findings alone is how far these hip-disease-related costs are reduced after THA, or whether e.g. community costs and costs for productivity loss will persist if once manifested. Currently, the results of the one-year follow-up of this study are being analysed.

One weakness of *paper III* is the long recall period of twelve months. Sick-leave may be particularly sensitive to recall bias. For this reason validation of the patient-



reported sick-leave and data reported from the Swedish Social Insurance Administration will be conducted. This estimate of COI at baseline, including both direct and indirect costs, is necessary for investigating the health-economic consequences of the surgical intervention.



### Equity, efficiency and allocation of resources

According to Swedish law<sup>113</sup> there are two main principles for priority in health care, which are hierarchically ordered. The first principle is that of human dignity stating that all humans are equal and have equal access to the health care provided. The second principle is that those who have the greatest need should receive priority. These principles are also common in other countries with public health-care systems. Decisions about allocation of resources to health care often also consider the principle of cost-effectiveness. But continuous medical interventions, along with scarce health-care resources, place increasing demands on decision-makers to allocate resources not only efficiently but also with consideration to equity. The dimension of equity is not commonly reflected in cost-effectiveness analyses, and consequently there are discrepancies between economic evaluations and health policy. However, Stolk concludes in her thesis that economic models can incorporate equity and efficiency concerns by using an application of equity weighting<sup>114</sup>. This could be accomplished by estimating the sacrifice to efficiency (equity-efficiency trade-off) to achieve a fair distribution of resources. However, methods for achieving this are in their infancy. The results of *paper IV* could be misinterpreted: patients with mental distress seem to have poorer PROs and thus compromise the cost-utility of the intervention. It is crucial to point out that this finding should not be used for resource allocation purposes. These patients should

not, by any means, be excluded from surgery because of inferior cost-effectiveness. However, the decision about THA surgery may be obscured by the influence of mental health on pain and HRQoL. Individual interventions, or combinations of other interventions such as educational programmes, physiotherapy and psychotherapy, could prevent or delay the need for THA and improve the outcomes following surgery.

## Health-care Guarantee and waiting times

### Accessibility and the Health-care Guarantee

A Health-care Guarantee was introduced late in 2005. The Guarantee was a political decision not based on medical evidence. Health-care discussions during the past few years have focused much on accessibility. In the Health-care Guarantee, accessibility is practically always assessed as a time variable. However, accessibility must be subject to quality assurance, with outcome both in the short-term and in the long-term, before it can be invoked as an improvement. Hence optimal accessibility for patients with hip disease should include:

- adequate and rapid appraisal by primary care,
- access to patient education and physiotherapy (complete non-surgical treatment),
- when orthopaedic specialist assessment is indicated – short waiting time before appointment,
- when surgery is indicated – short waiting time before surgery,
- standardised follow-up, preferably by the operating surgeon.

### Steadily increased procedure frequency

The steady increase in procedure frequency in Sweden over the years is presented in figure 15, published in the Register Report of 2009. What are the reasons for the continuous increase? Are there other explanations than population ageing, general progress in health care and improvements in implant technology? Is there a pent-up demand for THA? Even though incoherent, are indications also too wide? Do economic interests and political decisions affect the indications? The Health-care Guarantee seems to have increased the accessibility to THA assessed as a time variable. It may also have contributed to the widening of the indications.

The frequency of the procedure differs markedly in different county council areas in Sweden, as presented in figure 16. No major demographic variations can explain the differences. Note that the illustration represents the



production and not the consumption of THA. Thus, one explanation of the large differences between county council areas is that patients are often referred to hospitals in other county councils for surgery as a result of the Health-care Guarantee.

### Can political decisions influence outcomes of THA?

National and local alterations in PROs over time may reflect various changes in the management of THA patients. One example is the introduction of the Health-care Guarantee discussed above. As demonstrated in table 15 (Additional results section) the pre- and post-operative EQ-5D index comparing patients undergoing primary surgery until 2005 (before the introduction of the Health-care Guarantee) with those operated on later showed higher pre- and post-operative levels of HRQoL during the later period. However, the mean improvement was lower. It is important to emphasise that the differences are subtle and the results should be interpreted cautiously because there are confounders. In *paper III* an association between waiting times above 90 days and higher annual costs incurred by hip disease was found.

Even though this thesis provides some support for the Health-Care Guarantee Act, there are still many concerns about its effects. For orthopaedic surgery in general, and joint arthroplasty in particular, the Act means that patients are offered surgery at another hospital, of-



ten far from home, if the local hospital is unable to offer surgery within 90 days. Those who are severely impaired by the hip disease or medical co-morbidities may be less inclined to accept surgery at a hospital far away, which suggests inequities in the legislation.

Furthermore, the guarantee brings focus on ultimate interventions, such as surgery, and not on the primary and fundamental non-surgical interventions. This may negatively affect society's and the general practitioner's view of the importance of an early and thorough non-surgical treatment programme.

### Primary total hip arthroplasty in Sweden

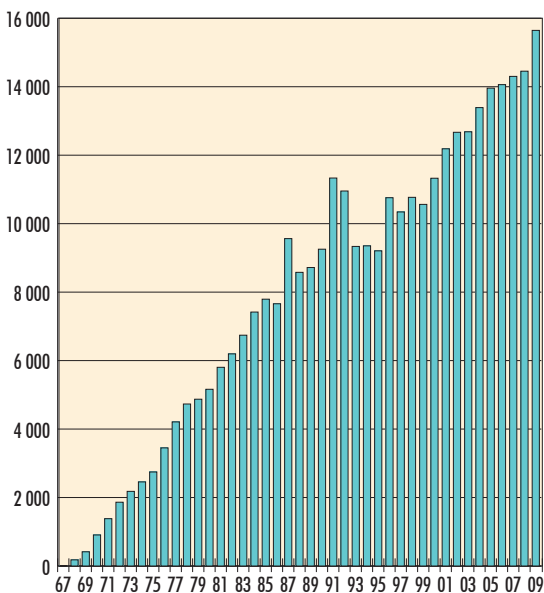


Figure 15. Numbers of THA in Sweden from 1967 through 2009.

## Indications and timing for total hip arthroplasty

### Indications for surgery

The indications for THA surgery recommended by OARSI<sup>69</sup>, are insufficient control of symptoms (pain, functional impairment, decreased HRQoL) despite adequate non-surgical treatment. Similar recommendations have been proposed by the National Institute for Health and Clinical Excellence (NICE)<sup>75</sup>. As reported in *paper III*, it was discouraging to find that no more than 35% stated they had visited a physiotherapist for their hip disease prior to surgery. This indicates that non-surgical treatment before THA is unsatisfactory. Thus, the indication for surgery often seems to be quite arbitrary in Swedish practice. This finding is confirmed by another study from the Register (in manuscript) where only 11% of patients undergoing THA had followed a full non-surgical treatment programme pre-operatively. This was one of the reasons for initiating the BOA project.

The high proportion of patients with rather moderate problems pre-operatively presented *paper I*, raises the question of whether these patients underwent surgery too early during the course of their disease. Perhaps, for some patients, non-surgical treatment options would have been sufficient to maintain adequate control of symptoms for a time. On the other hand, the results imply that the timing of surgery is generally relevant since patients' HRQoL is on average restored to above the expected level.

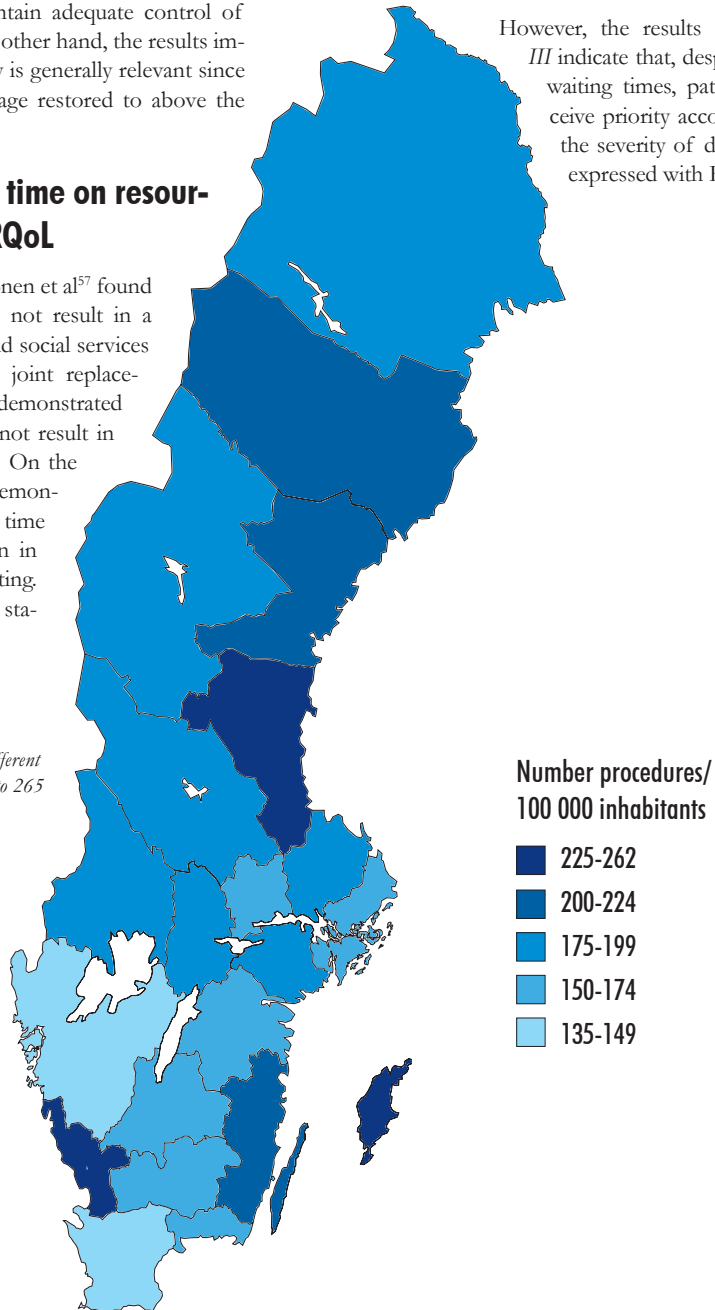
### The effect of waiting time on resource utilisation and HRQoL

In a randomised study, Hirvonen et al<sup>57</sup> found that longer waiting time did not result in a higher utilisation of health and social services before admission for major joint replacement. Hirvonen et al<sup>58</sup> also demonstrated that longer waiting time did not result in worse pre-operative HRQoL. On the other hand, Fielden et al demonstrated that longer waiting time for THA led to deterioration in physical function while waiting. Those with poor initial health sta-

tus showed greater improvement on WOMAC and EQ-5D measures six months after surgery. Coherent with the findings in *paper III* Fielden et al<sup>59</sup> also showed that longer waiting time for THA caused greater economic costs.

However, the results of *paper III* indicate that, despite long waiting times, patients receive priority according to the severity of disease as expressed with EQ-5D.

Figure 16. Procedure frequency in different counties in Sweden ranges from 135 to 265 procedures per 100 000 inhabitants.







# Conclusions

- Nationwide implementation of a PROM programme requires a structured organisation and effective and reliable IT solutions. The PROM programme allows continuous monitoring and improvements in outcomes locally as well as nationally.
- Patients' response rates to the Swedish Hip Arthroplasty Registry PROM programme in 2008 were 86 and 90 percent pre-operatively and one year post-operatively, respectively, which is considerable. Except for minor differences in distribution of diagnoses and ASA classification, the non-responders were representative of the Swedish THA population.
- The overall PROs of THA surgery in Sweden are satisfactory, with an average increase in EQ-5D index of 0.36 at the one-year follow-up. Charnley category C, male gender and higher age are associated with less improvement in HRQoL. However, a non-negligible proportion of the patients do not respond satisfactorily to surgery and the reasons for these short-term failures need to be investigated further.
- The pre-operative EQ-5D anxiety/depression dimension is a strong predictor of pain, pain relief and patient satisfaction. Orthopaedic surgeons involved in the care of patients eligible for THA should be aware that mental health may influence pre- and post-operative pain and HRQoL. An appropriate assessment of mental health may enable a modification in the way these patients are managed so as to optimise the outcome after THA.
- Using the Internet for patient-administered questionnaire does not give sufficient a response rate in the THA population to replace the pen-and-paper questionnaire. However, the system is reliable and could be used at present for measuring PRO if supplemented with traditional pen-and-paper questionnaires for Internet non-respondents.
- The burden of disease for patients eligible for THA is extensive, and loss of productivity is the major cost. Annual COI during the year preceding THA was estimated to SEK 58 600 (SEK 100 ≈ € 10 ≈ \$ 15). Longer waiting time, female gender, musculoskeletal co-morbidity and age below 65 years are associated with higher costs. The baseline cost data, presented in this thesis, will be useful for further health-economic analyses and could provide guidance for health care decision-makers.
- One-stage bilateral THA surgery is associated with 24 percent lower combined hospital and sick-leave costs and a shorter total sick-leave compared to a two-stage model assuming 90 days interval between procedures. For economic reasons, one-stage bilateral THA should be considered in healthy patients with indication for surgery on both hips.



# The future

## Ongoing projects

In an ongoing project a large-scale merging of databases (approximately 200 000 procedures) from the Register, Statistics Sweden (SCB) and the National Board of Health and Welfare will permit confirmation of findings in this thesis as well as to extend knowledge by the identification of new factors predicting outcome in THA. This project focuses on PROs and early failures such as re-operations with respect to socioeconomic and health-related factors. The objective is to identify preservative factors and risk factors so that pre-operative management may be altered to optimise the results after THA.

## New modalities for collecting PROMs

A feature for further research is to test new modalities for collecting PROMs to the Register. The combination of alternatives to answer the PROM questionnaire could also include a mobile phone application. Such an application has recently been developed and tested for the disease-specific WOMAC questionnaire<sup>28</sup>.

When completing the pre-operative questionnaire, patients could be asked to indicate their preferred way of answering the follow-up questionnaires. Then they may enter a valid phone number or e-mail address. Those who prefer traditional pen-and-paper questionnaires sent out by ordinary mail should be encouraged to reconsider their choice in the forthcoming follow-ups. The system could be automated to send out reminders by ordinary mail to all non-responders because of uncertainty whether the e-mail address or phone number is correct. In view of the general development of Internet use in Sweden, it is feasible that the population registry of the Swedish Tax Agency will in the future include

e-mail addresses. Such information would be very useful for all national quality registries. Internet-based questionnaires are methodologically superior, enable real time feed-back and are likely to be less costly.

In Sweden a recently introduced e-service “Healthcare Contacts” lets individuals communicate with their caregiver via Internet. There are currently two login options: either with an e-ID or with the personal identity number and a password. Different registries’ PROM programmes could be incorporated in this e-service in the future.

## The feasibility of a decision-making instrument

One improvement in THA would be to develop an instrument for decision-making regarding indications and timing for surgery and to infuse realistic expectations prior to surgery. Such an instrument would aim to produce a document that could be used when discussing risks and expected outcomes. The instrument could use different data from the Register and other relevant databases to make an individual prediction regarding many outcome measures. The results of this thesis and ongoing projects are the cornerstones of this application. Input data could include basic demographics, diagnoses and co-morbidities, body mass index, smoking and drinking habits, the PROM protocol, anxiety/depression scores, socioeconomic factors, intended implants, surgical approach and the technical profile for the hospital in question. It could also take into account how far the patient had participated in a non-surgical treatment programme pre-operatively. Output information could include the individual’s expected implant survival, risks of various complications, expected HRQoL, expected disease-specific outcomes, recommendations about the timing for surgery, recommended implant, and a health-economic profile including absolute costs of surgery, cost of follow-up programme, cost of productivity loss, predicted costs of complications, and cost-per-QALY. It would not be mandatory to enter all input data, but the more input data the more accurate the forecast. From the results of this thesis the framework of this new feature can be outlined.

## Five ingredients for optimising outcomes and cost-utility following THA

At national level, the recipe for optimising outcomes following THA includes widespread use of a thorough non-surgical treatment programme, uniform and simple



to use criteria for surgery, the use of well-documented implants and surgical techniques, an extensive follow-up programme and continuous monitoring of results in a national quality register.

### **How to improve things for all patients with or at risk of developing hip disease**

The overall goal is not only to optimise the outcomes of THA. A wider perspective is necessary, including all patients with or at risk of developing hip disease so as to minimise suffering, HRQoL-loss and the economic consequences of hip disease. This broad perspective

opens up great opportunities for improvement that could make substantial differences. One step is the newly-started BOA project<sup>74</sup> which aims at becoming a national registry for *all* patients with OA (and associated diseases) of the hip or knee. Hopefully, the medical profession in Sweden can prosperously collaborate to improve outcomes for hip and knee arthritis during the entire course of disease. This may be accomplished by gathering all orthopaedic registries under a common portal, as recommended by the Ministry of Health and Social Affairs in a recent report based on a thorough survey of the national quality registries.

## Summary in Swedish

### Patientrapporterat utfall och hälsoekonomiska aspekter på höftproteskirurgi

#### Introduktion

Höftprotesoperation är en mycket effektiv åtgärd för att minska smärta och öka livskvaliteten för patienter med invalidiserande höftledssjukdom. Sedan den moderna höftproteskirurgin introducerades i början av 1960-talet har området expanderat enormt. Ökad medellivslängd hos befolkningen jämte generella medicinska framsteg och förbättrade proteser tillåter kirurgi på både yngre och äldre patienter, vilket har lett till att antalet patienter som får och som har en höftprotes har ökat.

Idag finns det åtskilliga studier som visar enastående resultat för många protestetyper när det gäller protesens överlevnad. Utrymmet för avgörande tekniska förbättringar av proteserna förefaller vara begränsat för flertalet patientgrupper. Svensk ortopedi i allmänhet håller sig till metoder och proteser som har bra vetenskapligt stöd och god dokumentation, vilket avspeglas i världsledande resultat. En starkt bidragande orsak till de goda resultaten är Svenska Höftprotesregistrets kontinuerliga arbete.

Det har dock uttryckts oro över framtiden för höftproteskirurgin. Generationsskiften förändrar och ökar människors förväntningar och funktionella krav, samtidigt som indikationerna har vidgats, vilket ställer högre krav på åtgärdens prestanda. Det finns också kortsiktiga ekonomiska intressen som kan hota de långsiktiga resultaten.

Den snabba ökningen av kostnaderna för rörelseorganens sjukdomar som skett under de senaste decennierna väntas fortsätta att öka. Sjukvårdens kostnader i förhållande till bruttonationalprodukten ökar stadigt. En grundläggande förutsättning för att förstå hur man ska möta de förändrade kraven på höftproteskirurgin, är att mäta resultat från patientens subjektiva perspektiv. Patientrapporterat utfall blir allt viktigare för att fördela sjukvårdsresurser och för att fastställa riktlinjer för god vård.

Resultatet av en medicinsk åtgärd är beroende av en mängd olika faktorer. Utöver de rent medicinska aspekterna måste kulturella, sociala, politiska, ekonomiska, psykologiska och utbildningsrelaterade faktorer beaktas

när man överväger alternativa åtgärder och eventuella förändringar i nuvarande praxis. Detta är särskilt relevant när det gäller planerade protesoperationer.

I denna avhandling och dess delarbeten studeras och diskuteras några av dessa aspekter i syfte att öka kunskapen om och förbättra resultaten efter höftprotesoperationer. Att göra rätt saker, att göra saker rätt, och att göra dem vid rätt tidpunkt är centrala frågor. För varje individ måste indikationen för protesoperation vara korrekt; den förväntade nyttan av operationen skall inte kunna uppnås med något annat och mindre kostsamt alternativ.

#### Delarbete I

### Patientrapporterat utfall i Svenska höftprotesregistret

#### Höftdispensärens utveckling

Traditionella variabler som används för att mäta utfall efter höftprotesoperation såsom hur länge proteser sitter kvar och frekvensen av komplikationer ger en ofullständig bild av nyttan av operationen för individuella patienter. I strävan att inkludera patienters subjektiva upplevelse i registeranalysen introducerades "Höftdispensären" som ett pilotprojekt i Västra Götaland 2002. Successivt har fler och fler kliniker anslutit sig och nu deltar alla höftprotesopererande enheter, med enstaka undantag, i Höftdispensären.

#### Hälsorelaterad livskvalitet och smärta

I avhandlingens första studie ingår 34 960 höftprotesoperationer, där patienterna fyllt i dispensärens enkäten såväl före operationen som ett år efter operationen. Dessa patienter opererades under åren 2002–2008. Operationer på grund av akut höftfraktur eller malignitet ingick inte i analysen. Under första året efter operationen förbättrades den hälsorelaterade livskvaliteten. Medelvärde för livskvalitet mätt med EQ-5D steg från 0.41 till 0.78 där 0 representerar sämsta tänkbara hälsa och 1 bästa tänkbara hälsa. Kvinnor hade lägre EQ-5D index men hade i genomsnitt en större livskvalitetsvinst jämfört med män. Samma förhållande gällde för smärta som mättes med en 100-gradig skala. Vid uppföljningen angav patienterna tillfredsställelse med operationen på en liknande 100-gradig skala, som går från nöjd (0) till missnöjd (100). Medelvärde för tillfredsställelse var 17.

### EQ-5D index i olika åldersgrupper jämfört med normalbefolkning

Vid befolkningsundersökningarna "Hälsa på lika villkor" under åren 2006–2008 samlade man i Västra Götalandsregionen in ett referensmaterial för EQ-5D index avseende normalbefolkningen. Med data från denna undersökning kunde man bestämma ålders- och könjusterade EQ-5D index för varje individ som ingår i den aktuella analysen av dispensärsdatabasen. Denna jämförelse visade vid ettårsuppföljningen att patienter under 40 år i medeltal inte når samma EQ-5D nivå som normalbefolkningen. I övriga åldersgrupper är den hälsorelaterade livskvaliteten bättre än normalbefolkningens ett år efter operationen.



### Svarsfrekvens

En särskild undersökning av i vilken utsträckning patienterna har svarat på Höftdispensärsprotokollet utfördes också. Alla höftprotosesoperationer under 2008, som utfördes vid de kliniker som var anslutna till Höftdispensären den 1 januari 2008, ingick i analysen. Analysen omfattar 12 300 operationer. Före operationen svarade 86 procent och vid ettårsuppföljningen svarade 90 procent. Det var 79 procent som svarade på båda formulären. Att svarsfrekvensen före operationen är lägre reflekterar sannolikt olika lokala problem med att fånga upp alla patienter. Dessutom är hela distributionsprocessen av ettårsuppföljningen inklusive påminnelser organiserad så att formuläret sannolikt når fler patienter.

### Nytan med Höftdispensären

Resultaten från Höftdispensären kompletterar de traditionella utfallsmåtten och utgör en viktig kvalitetsindikator. Registret har nu en så gott som rikstäckande uppföljning med patientrapporterade utfallsmått med god svarsfrekvens.

Tidigare forskning har visat att den minsta skillnaden i EQ-5D index, som har klinisk relevans för den enskilda individen, är  $\pm 0.074$ . Om man använder den definitionen så är EQ-5D index oförändrat för en femtedel av patienterna och fem procent har till och med försämrats vid ettårsuppföljningen. Motsvarande definition för smärta uppmätt med den 100-gradiga smärtskalan visar att 90 procent rapporterar förbättring. Vidare var 89 procent nöjda med operationen. Utifrån dessa resultat kan man dra slutsatsen att det finns en betydande andel av de höftprotoserade som inte får den eftersträvade effekten av operationen. Det här leder till reflektion beträffande indikationer för kirurgi, kvaliteten av icke-kirurgisk behandling under sjukdomsförloppet, den information patienten får inför operationen, diskussionen om patientens förväntningar på ingreppet och kirurgisk teknik. När det gäller dessa områden finns sannolikt stort utrymme för förbättringar av omhändertagandet av patienter med höftledsjukdom.

### Delarbete II

## Jämförelse av Internetenkät och traditionell pappersenkät för att mäta patientrapporterat utfall

### Randomiserad studie

Den andra studien i avhandlingen är en randomiserad studie, vars syfte är att undersöka skillnader i svarsfrekvens mellan traditionell pappersenkät och Internetenkät vid uppföljning efter höftprotosesoperation. Höftprotosesregistret har utvecklat en pekskärmfunktion, som är kopplad till registrets databas. Peksärm används på många kliniker för att låta patienterna fylla i höftdispensärenskäten före operationen. Den här funktionen är mycket effektiv och har visat sig stämma överens med det traditionella pappersformuläret. Vid uppföljning ett, sex och tio år efter höftprotosesoperation får patienterna en pappersenkät med ordinarie post. Eftersom arbetet med att manuellt mata in uppgifter är resurskrävande är det önskvärt att utveckla metoder för Internetbaserad datainsamling. Det finns säkra tekniska lösningar för att utföra sådana undersökningar via Internet. Sverige är det land i världen med högst Internetanvändning. Det gäller särskilt i de äldre befolkningsgrupperna och mycket talar för en fortsatt ökad användartäthet.

### Studiens upplägg

2 400 personer ur Registret valdes slumpmässigt ut men stratifierades med avseende på ålder och diagnos för att ingå i en fyraårsuppföljning. De delades upp i kohorter

med 600 patienter vardera i åldergrupperna under 50 år, 50–59 år, 60–75 år och över 75 år, hälften kvinnor och hälften män. Patienterna randomiserades till att svara på dispensärsenkäten via Internet eller via en traditionell pappersenkät. Påminnelse skickades ut vid uteblivet svar till båda grupperna efter två månader. En ny påminnelse utgick efter ytterligare en månad och då växlade man svarsförfarande så att pappersenkätgruppen fick möjlighet att svara via Internet och vice versa.

### **Internetenkäten gav låg svarsfrekvens**

Svarsfrekvensen i pappersenkätgruppen var 92 procent och i Internetsvarsgruppen 49 procent. Svarsfrekvensen steg till totalt 83 procent när Internetsvarsdeltagarna erbjöds att svara via pappersenkät. Skillnaden i svarsfrekvensen mellan de fyra ålderskohorterna var marginell i pappersenkätgruppen medan den skiljde sig signifikant i Internetsvarsgruppen. I åldersgruppen under 50 år var svarsfrekvensen 71 procent, 50–59 år 62 procent, 60–75 år 37 procent och över 75 år 23 procent.

### **Möjligheter att kombinera svarsmetoder**

Internetenkäten för uppföljning av patientrapporterat utfall gav inte tillräckligt hög svarsfrekvens för att ersätta den traditionella pappersenkäten. Själva Internetfunktionen och enkäten visade dock god pålitlighet. Dessutom har systemet ekonomiska och metodologiska fördelar såsom att man förhindrar att det saknas värden, att felaktiga data matas in på grund av oläslig handstil eller på grund av andra mänskliga faktorer. Resultaten talar för att det går att kombinera svarsmetoderna, så att patienten får möjlighet att svara på det sätt som han eller hon föredrar.

### **Delarbete III**

## **Kartläggning av sjukdomsrelaterade kostnader före höftprotosoperation**

### **Enkätundersökning av sjukdomsrelaterade kostnader i Västra Götaland och Norrland**

En komplett hälsoekonomisk analys kräver att alla konsekvenser och kostnader som kan relateras till en viss sjukdom är kända. I syfte att identifiera de kostnader som genereras av höftledssjukdomen genomförde Registret en enkätundersökning i Västra Götaland och Norrland under tiden oktober 2005 till december 2007. Cirka 3 500 patienter ombads besvara en enkät strax före planerad protosoperation. Frågorna avsåg hän-delser och omständigheter som genererar kostnader för patienten, anhöriga eller samhället och som kan relateras till sjukdomen. Enkäten skickades ut av koordinatörerna

för operationsväntelistan på respektive sjukhus. De rapporterades också uppgifter om väntetiden från det att remissen till ortopederna skrevs till dess de bedömdes och sattes upp på väntelista för operation samt väntetiden för operation. Medelåldern bland de 2 635 patienter som besvarade enkäten var 69 år varav 56 procent var kvinnor. En tredjedel av populationen var i arbetsför ålder. Den genomsnittliga väntetiden från det att patienten remitterades till ortoped och mottagningsbesöket var 176 dagar och väntetiden till operation var 144 dagar.

### **Resursförbrukning**

Av dem som var i arbetsför ålder hade 48 procent varit sjukskrivna på grund av höftbesvär och för dessa var den genomsnittliga tiden för sjukskrivning 30 veckor under de tolv månaderna som föregick operationen. 24 procent var sjukpensionerade men det framgick inte av enkäten om skälet för sjukpension var höftledssjukdom. Därför gjordes uppskattningen att hälften av de kostnader som uppkom på grund av sjukpension berodde på höftsjukdomen. 81 procent använde läkemedel på grund av höftsjukdomen. Den genomsnittliga kostnaden för kontinuerlig medicinering uppgick 951 kronor. Fyra procent behövde hemtjänst på grund av sina höftbesvär och de krävde i genomsnitt 3,9 hemtjänststimmar per vecka. Behovet av färdtjänst uppgick till 1,6 gånger per vecka hos nio procent. Behov av någon typ av bostads- eller handikappanpassning förekom hos 43 procent av patienterna. 26 procent av patienterna krävde anhörighjälp i varierande omfattning på grund av höftledssjukdomen. Officiell statistik, marknadspriser och uppgifter från tidigare forskning och rapporter användes för att bestämma enhetskostnader för all resursförbrukning som kunde hänföras till höftledssjukdomen. De totala kostnaderna uppgick i genomsnitt till 58 600 kronor under året före höftprotosoperationen för patienterna i vår studie.

### **Justering för ålder, kön, diagnos och samsjuklighet (enligt Charnley)**

En regressionsanalys visade att personer i arbetsför ålder hade markant högre kostnader än de ålderspensionerade. Kvinnor hade 41 procent högre kostnader än män. Som väntat var högre grad av samsjuklighet associerat med högre kostnader. Väntetid till operation mer än 90 dagar var associerad med 20 procent högre kostnad.

### **Resultaten ger grund för vårdgaranti**

Studien bekräftar att den huvudsakliga sjukdomsrelaterade kostnaden för höftprotoskandidater utgörs av produktionsbortfall. Året före protosoperationen kostar i genomsnitt nästan lika mycket som själva protosopera-



tionen. Eftersom längre väntetid än 90 dagar var associerat med större resursutnyttjande ger studien också en grund för vårdgarantin när det gäller höftproteskirurgi. Trots att vårdgarantin hade införts då undersökningen påbörjades, var väntetiden för bedömning och operation oacceptabelt lång. Med hänsyn till att sjukgymnastik ingår som basbehandling i nationella vårdprogram för höftledsartros är de anmärkningsvärt att endast 35 procent av personerna i studien angav att de hade träffat en sjukgymnast någon gång under året som föregick operationen. Att känna till kostnaderna för en höftleds-sjukdom hos patienter som väntar på en protesoperation är en förutsättning för att kunna avgöra om åtgärden minskar behovet av olika resurser.

#### Delarbete IV

### Patientrelaterade faktorer som har betydelse för utfallet efter höftprotesoperation

#### Svårigheter med indikationen för höftprotesoperation

Indikationen för en höftprotesoperation är nedsatt hälsorelaterad livskvalitet och smärta på grund av höftleds sjukdomen. Sambandet mellan symptom och undersökningsfynd, det vill säga röntgen och fysikalisk undersökning, är dock lågt. Däremot vet vi att den individuella upplevelsen av smärta är starkt kopplad till mental hälsa. Därför kan det i vissa fall vara svårt att avgöra om indikation för operation föreligger. I den här studien användes data från Höftdispensären för att testa hypotesen att ångest/depression, som är en av de fem dimensionerna som ingår i EQ-5D instrumentet, kan förutsäga resultatet efter höftprotesoperation. I studien analyserades 6 158 patienter med höftartros. För att undersöka sambandet mellan ångest/depression och utfall med avseende på smärta och tillfredsställelse användes regressionsanalyser.

#### Ångest/depression kan förutsäga utfall efter höftprotesoperation

Det visade sig att ångest/depression var starkt associerat med lägre smärtlindring och sämre tillfredsställelse vid ettårsuppföljningen. Vid förekomst av ångest/depression både före och ett år efter operationen påverkades det patientrapporterade utfallet ytterligare i negativ riktning.

Härav dras slutsatsen att man bör vara observant på att patientens psykiska hälsa kan påverka smärtupplevelsen före operationen och att risken för sämre resultat efter operationen är större vid förekomst av ångest och de-

pression. Det är rimligt att anta att en grundlig bedömning av patientens hälsorelaterade livskvalitet och smärta i relation till den psykiska hälsan kan medföra förändringar, som leder till ett förbättrat omhändertagande av patienter med höftleds sjukdom.

#### Delarbete V

### Operation av båda höfterna på samma gång sparar resurser

#### Dubbelsidig höftprotesoperation i en seans

Många patienter med höftleds sjukdom lider av besvär från båda höfterna. Av alla dem som opereras med höftprotes får cirka 20 procent proteser i båda höfterna någon gång under livstiden. Omkring fem procent av alla som ska opereras med höftprotes uppfyller kriterierna för att opereras i båda höftlederna i samma seans. Dubbelsidig höftprotesoperation i en seans är dock ovanlig, sannolikt på grund av patientens eller ortopedens rädsla för komplikationer och besvärligare rehabilitering. De flesta studier visar alltså att det inte förelig-



Animerad bild av en cementerad total höftprotes.

ger någon riskökning hos friska patienter som opereras dubbelsidigt i en seans. Det femte arbetet i avhandlingen genomfördes i syfte att undersöka patientrapporterat utfall och kostnadseffektivitet i samband med operation av båda höftlederna i samma seans.

### Studiens genomförande

32 patienter som opererades dubbelsidigt med enseansförfarande följdes under sex år. En grupp på 32 patienter som opererades ensidigt vid samma sjukhus och med samma protesdelar användes som kontroll. Denna kontrollgrupp matchades med avseende på kön, ålder och diagnos. Patienternas subjektiva utfall undersöktes med livskvalitetsformulär (EQ-5D) och hundrageradiga skalor för smärta och tillfredsställelse användes. Genom systematisk genomgång av journaler inhämtades uppgifter om komplikationer och rehabiliteringsförlopp. För kostnadsberäkning användes sjukhusets kostnader-patient-databas. Uppgifter om sjukskrivning ett år efter operationen kom från Försäkringskassan.

### Exceptionell förbättring i hälsorelaterad livskvalitet

Patienterna som opererades i båda höfterna samtidigt hade mycket låg hälsorelaterad livskvalitet (EQ-5D index var 0.11) före operationen och de rapporterade mycket hög smärtnivå. EQ-5D index vid ettårsuppföljningen visade enastående förbättring, vilket även höll i sig efter sex år. Smärta minskade mer i gruppen som opererades dubbelsidigt än för dem i den kontrollgrupp som opererades i en höft. Tillfredsställelsen var hög i båda grupperna.

### Modell för att simulera dubbelsidig operation i två steg

För att undersöka om det är ekonomiskt fördelaktigt att operera båda höfterna samtidigt, skapades en modell i vilken kostnadsdata från dem som opererats i en höft utnyttjades. Genom en sk regressionsanalys användes dessa kostnadsdata på dem som opererats dubbelsidigt. På så sätt uppskattades kostnaden för operationer i två seanser med nittio dagars intervall. Modellen visade att den sammanlagda sjukhuskostnaden i samband med operationen och kostnaden för den efterföljande sjukskrivningsperioden var 24 procent lägre vid dubbelsidig operation i en seans jämfört med tvåseansförfarandet.

## Sammanfattning

### Multidimensionell utvärdering

Kraven på att rutinemässigt mäta patientrapporterat utfall inom olika medicinska områden ökar samtidigt som intresset för sådan uppföljning blir större. Patienternas subjektiva resultat kompletterar traditionella utfallsmått och möjliggör övervakning av kvaliteten av vården, lokalt förbättringsarbete och hälsoekonomiska analyser. Det ger också förutsättningar för resursfördelning och för ett rikstäckande program som kan följa upp och minska antalet rutinemässiga återbesök. De instrument som används för att mäta patientrapporterat utfall måste uppfylla basmetodologiska krav och man bör använda både generiska och sjukdomsspecifika instrument. Vid rutinemässig användning är det viktigt att antalet frågor begränsas för att svarsfrekvensen ska vara hög. Ett omfattande uppföljningsprogram kräver en strukturerad organisation och effektiva och tillförlitliga IT-lösningar. De metoder som används för att samla in data behöver utvärderas. Ett multidimensionellt utvärderingsverktyg, som kombinerar traditionella kliniska variabler med generiska och sjukdomsspecifika utfallsmått samt uppgifter om direkta och indirekta kostnader, möjliggör en mer nyanserad och fullständig analys av interventionen.

### Receptet för att optimera resultaten efter höftproteskirurgi

Receptet för att optimera resultaten efter höftproteskirurgi innehåller följande huvudsakliga ingredienser. Utbredd användning av ett grundligt icke-kirurgiskt behandlingsprogram, enhetliga operationsindikationer, användning av väldokumenterade protestyper och kirurgiska tekniker samt ett omfattande uppföljningsprogram i ett nationellt kvalitetsregister.

Dock är det övergripande målet inte bara att optimera resultaten efter höftprotesoperation. Det är nödvändigt att ha ett bredare perspektiv som inkluderar alla patienter som har eller löper risk att utveckla höftledssjukdom. Detta breda perspektiv öppnar upp stora möjligheter för förbättringar. Ett steg i den riktningen är det nystartade BOA-projektet (Bättre Omhändertagande av patienter med Artros) som siktar på att bli ett nationellt kvalitetsregister för alla patienter med besvär i höft- eller knäled. Förhoppningsvis kan den medicinska professionen i Sverige samarbeta för att minska lidandet och de ekonomiska konsekvenserna av höft- och knäledssjukdomar under hela sjukdomsförloppet. En åtgärd som potentiellt kan bidra till den utvecklingen är att samla alla ortopediska register under en gemensam portal, vilket rekommenderas i en färsk rapport från Socialdepartementet.





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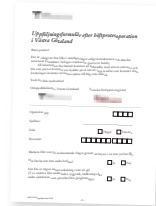
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# Appendix

## 1. The PROM protocol



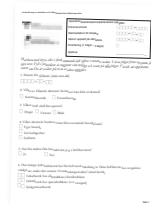
## 2. The PIVI login website



## 3. The PIVI PROM protocol



## 4. The pre-operative cost-of-illness questionnaire





## *Uppföljningsformulär efter höftprotesoperation i Västra Götaland*

Bäste patient!

Det är viktigt att Du fyller i samtliga frågor enligt instruktionen och därefter returnerar formuläret i bifogat svarskuvert (portot är betalt).

All information Du lämnar kommer att behandlas med största sekretess och Du som person kommer att skyddas på så sätt att inga resultat som kommer ifrån forskningen kommer att kunna spåras till Dig som individ.

Tack för Din medverkan!

Ortopedklinikerna i Västra Götaland

Svenska Höftprotesregistret



Operation (år):

Sjukhus: \_\_\_\_\_

Sida:

 Höger  Vänster

Personnr:

       -    

Markera Ditt svar på nedanstående frågor genom att kryssa i en ruta (så här ):

Har Du besvär från andra höften?

 Ja  Nej

Har Du av någon annan anledning svårt att gå?  
(T ex smärtor från andra leder, ryggvärk, kärlkramp eller  
andra sjukdomar som påverkar Din gångförmåga.)

 Ja  Nej



### Skala 1

**Smärta**

Sätt ett kryss på det *streck* som Du tycker motsvarar Din genomsnittliga smärtupplevelse från den aktuella höften under senaste månaden:



### Skala 2

**Tillfredsställelse**

Sätt ett kryss på det *streck* som Du tycker motsvarar hur nöjd Du är med operationsresultatet:





Markera, genom att kryssa i en ruta i varje nedanstående grupp (så här ☑), vilket påstående som bäst beskriver Ditt **allmänna hälsotillstånd** i dag (ej enbart beroende på den aktuella höften).

### Rörlighet

- Jag går utan svårigheter
- Jag kan gå men med viss svårighet
- Jag är sängliggande

### Hygien

- Jag behöver ingen hjälp med min dagliga hygien, mat eller påklädning
- Jag har vissa problem att tvätta eller klä mig själv
- Jag kan inte tvätta eller klä mig själv

### Huvudsakliga aktiviteter (*t ex arbete, studier, hushållssysslor, familje- och fritidsaktiviteter*)

- Jag klarar av mina huvudsakliga aktiviteter
- Jag har vissa problem med att klara av mina huvudsakliga aktiviteter
- Jag klarar inte av mina huvudsakliga aktiviteter

### Smärtor/besvär

- Jag har varken smärtor eller besvär
- Jag har måttliga smärtor eller besvär
- Jag har svåra smärtor eller besvär

### Oro/nedstämdhet

- Jag är inte orolig eller nedstämd
- Jag är orolig eller nedstämd i viss utsträckning
- Jag är i högsta grad orolig eller nedstämd

**Jämfört med mitt allmänna hälsotillstånd de senaste tolv månaderna är mitt hälsotillstånd idag:**

- (kryssa endast i en ruta)
- Bättre
- Oförändrat
- Sämre



Till hjälp för att avgöra hur bra eller dåligt ett hälsotillstånd är, finns den termometerliknande skalan till höger. På denna har Ditt bästa tänkbara hälsotillstånd markerats med 100 och Ditt sämsta tänkbara hälsotillstånd med 0.

Vi vill att Du på denna skala markerar hur bra eller dåligt Ditt hälsotillstånd är, som Du själv bedömer det. Gör detta genom att dra en linje från nedanstående ruta till den punkt på skalan som markerar hur bra eller dåligt Ditt nuvarande hälsotillstånd är.

**Ditt  
nuvarande  
hälsotillstånd**

*OBS!*  
Dra en linje från den svarta rutan till den punkt som Du tycker motsvarar Ditt nuvarande allmänna hälsotillstånd.

Bästa  
tänkbara  
tillstånd



Sämsta  
tänkbara  
tillstånd



Patientadministrerad enkät för  
**Uppföljning av Höftledsoperation**  
från Nationalregistret för Höftledsplastiker



Detta är en enkät som syftar till att avgöra hur Du som patient mår efter din höftledsoperation. Enkätundersökningen genomförs av Nationalregistret för Höftledsplastiker som sedan 1979 löpande har samlat in uppgifter om alla höftledsoperationer som utförs i Sverige, i syfte att utveckla och förbättra den vård vi ger Dig. Registret är ett nationellt medicinskt kvalitetsregister och är finansierat av Socialstyrelsen och Sveriges Kommuner och Landsting. Vill Du veta mer om registret kan du besöka vår [webbplats](#).

Enkäten består av **14 frågor** och tar cirka fem minuter att besvara. Dina svar skickas i krypterad form till registrets webbplats, så det är inte möjligt för obehöriga att se vad du svarar. I registrets databas kommer sedan uppgifterna att bearbetas vidare och ställas samman i olika statistiska resultat. **Notera att Du som enskild individ inte kommer att kunna identifieras i några av de resultat som härrör från denna undersökning.**

Vi är tacksamma för Din medverkan!

Överläkare Göran Garellick  
Ansvarig för enkätundersökningen.

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Ange nedan det lösenord som finns i Ditt brev:

Till enkäten

*På denna webbplats används en så kallad sessionscookie. Cookien används för att hantera din inloggning. Denna typ av cookie försvinner när du stänger Din webbläsare. Din webbläsare behöver också vara inställd på att acceptera sessionscookies för att enkäten skall fungera.*

Patientadministrerad enkät för  
**Uppföljning av Höftledsoperation**  
från Nationalregistret för Höftledsplastiker



Då en del statistiska bearbetningar kommer att göras på de svar Du anger är det särskilt viktigt att Du besvarar samtliga frågor i enkäten. Tänk inte för länge på varje fråga utan ange det svar Du kommer att tänka på först.

### Frågor om Din datoranvändning

---

**1. Använder Du egen dator för att svara på dessa frågor?**

- Ja  
 Nej

**2. Vad använder Du för typ av internetanslutning?**

- Bredband  
 Telefonmodem  
 Vet ej

**3. Patientinformation via internet**

Allt mer information hämtas och lämnas idag via internet, så även inom sjukvården (tidsbeställningar, kallelse till undersökningar, med mera). Hur tryggt upplever Du att det är att lämna information om Dig själv som patient via internet under förutsättning att informationen skickas och hanteras på ett säkert sätt?

- Mycket tryggt  
 Ganska tryggt  
 Ingen uppfattning  
 Inte särskilt tryggt  
 Inte alls tryggt

### Frågor om Din höftledsoperation

---

**4. Har Du besvär från andra höften?**

- Ja  
 Nej

**5. Har Du av någon annan anledning svårt att gå?**

(till exempel smärtor från andra leder, ryggvärk, kärlkramp eller andra sjukdomar som påverkar Din gångförmåga.)

- Ja

### 6. Smärtupplevelse

Markera Din genomsnittliga smärtupplevelse under **senaste månaden** genom att klicka på linjen nedan. Linjen är en skala där ett kryss längst till vänster innebär mycket liten smärta och ett kryss längst till höger innebär värsta tänkbara smärta. Genom att klicka på lämplig plats på skalan visar Du hur mycket smärta Du har.



### 7. Operationsresultat

Markera hur nöjd Du är med operationsresultatet genom att klicka på linjen nedan. Linjen är en skala där ett kryss längst till vänster innebär mycket nöjd och ett kryss längst till höger innebär missnöjd. Genom att klicka på lämplig plats på skalan visar Du hur nöjd Du är med din operation.



### 8. Rörlighet

- Jag går utan svårigheter
- Jag kan gå men med viss svårighet
- Jag är sängliggande

### 9. Hygien

- Jag behöver ingen hjälp med min dagliga hygien, mat eller påklädning
- Jag har vissa problem att tvätta eller klä mig själv
- Jag kan inte tvätta eller klä mig själv

### 10. Huvudsakliga aktiviteter

(till exempel arbete, studier, hushållssysslor, familje- och fritidsaktiviteter.)

- Jag klarar av mina huvudsakliga aktiviteter
- Jag har vissa problem att klara av mina huvudsakliga aktiviteter
- Jag klarar inte av mina huvudsakliga aktiviteter

### 11. Smärtor/besvär

- Jag har varken smärtor eller besvär
- Jag har måttliga smärtor eller besvär
- Jag har svåra smärtor eller besvär

### 12. Oro/nedstämdhet

- Jag är inte orolig eller nedstämd
- Jag är orolig eller nedstämd i viss utsträckning

Jag är i högsta grad orolig eller nedstämd

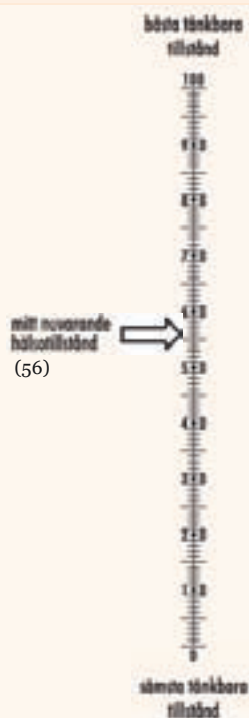
### 13. Jämfört med mitt allmänna hälsotillstånd de senaste tolv månaderna är mitt hälsotillstånd idag...

- Bättre  
 Oförändrat  
 Sämre

### 14. Nuvarande hälsotillstånd

Till hjälp för att avgöra hur bra eller dåligt ett hälsotillstånd är, finns den termometerliknande skalan till höger. På denna har Ditt bästa tänkbara hälsotillstånd markerats med 100 och Ditt sämsta tänkbara hälsotillstånd med 0.

Vi vill att Du på denna skala markerar hur bra eller dåligt Ditt hälsotillstånd är, som Du själv bedömer det. Gör detta genom att klicka på lämplig plats på skalan.



Skicka svar

Undersökning av vårdbehov och hälsotillstånd före höftledsoperation



Operationskoordinators/planerarens uppgifter:

Personnummer       -

Remissdatum till ortoped     -   -

Datum uppsatt på väntelista     -   -

Prioritering (1 högst – 3 lägst)

Sjukhus \_\_\_\_\_

Markera med kryss eller i förekommande fall siffror i rutorna nedan. I vissa frågor finns utrymme för egen text. Fyll i formuläret så noggrant som möjligt och svara på alla frågor. Försök att uppskatta svaret om Du är osäker på vissa exakta uppgifter.

1. Datum för ifyllande (åååå-mm-dd)

-   -

2. Vilket av följande alternativ beskriver bäst Ditt civilstånd?

Sammanboende  Ensamboende

3. Vilken höft skall Du operera?

Höger  Vänster  Båda

4. Vilket alternativ beskriver bäst Din nuvarande boendeform?

Eget boende  
 Servicelägenhet  
 Sjukhem

5. Har Du ändrat Din boendeform p g a höftbesvären?

Ja  Nej

6. Hur många sjukvårdsbesök har Du haft med anledning av Dina höftbesvär hos respektive vårdgivare under den senaste 12-månadersperioden? (antal besök)

Läkbesök hos allmänläkare/distriktsläkare  
  Läkbesök hos specialistläkare (t ex ortoped)  
  Sjukgymnastbesök

## Undersökning av vårdbehov och hälsotillstånd före höftledsoperation

7. Har Du varit inlagd på sjukhus på grund av Dina höftbesvär under den senaste 12-månadersperioden?

Ja  Nej (om nej gå vidare till fråga 9)

8. Hur många gånger och sammanlagt hur många dagar har Du varit inlagd på sjukhus på grund av Dina höftbesvär under den senaste 12-månadersperioden? (ej i samband med operation)

gånger inlagd på sjukhus

dagar sammanlagt

9. Använder Du läkemedel på grund av Dina höftbesvär?

Ja  Nej (om nej gå vidare till fråga 11)

10. Vilken eller vilka mediciner använder Du på grund av höftbesvär? Ange medicinens namn, styrka och dosering.

<i>Medicinens namn</i>	<i>Styrka</i>	<i>Antal tabl</i>	<i>Dagl</i>	<i>Vid behov</i>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>

11. Har Du haft kommunal hemtjänst under den senaste 12-månadersperioden där behovet i huvudsak beror på Dina höftbesvär?

Ja  Nej (om nej gå vidare till fråga 14)

12. Vilken är omfattningen av Din hemtjänst?

timmar per vecka

13. Hur länge har Du haft hemtjänst?

månader

Undersökning av vårdbehov och hälsotillstånd före höftledsoperation

14. Har Du färdtjänst där behovet i huvudsak beror på Dina höftbesvär?

Ja  Nej (om nej gå vidare till fråga 17)

15. Hur ofta använder Du färdtjänst?

gånger/vecka

16. Hur länge har Du haft färdtjänst?

månader

17. Har anhöriga tagit hand om Dig den senaste 12-månadersperioden till följd av Dina höftbesvär?

Ja  Nej (om nej gå vidare till fråga 21)

18. Hur många timmar per vecka har anhöriga i genomsnitt tagit hand om Dig den senaste 12-månadersperioden?

timmar/vecka

19. Förvärvsarbetar någon av de anhöriga som tagit hand om Dig den senaste 12-månadersperioden?

Ja  Nej (om nej gå vidare till fråga 21)

20. Hur många timmar per vecka har anhöriga i genomsnitt tagit ledigt från arbete för att ta hand om Dig den senaste 12-månadersperioden?

timmar/vecka

21. Har Du någon eller några av följande handikappanpassningar i bostaden eller i anslutning till bostaden?

Borttagna trösklar

Toalettstolsanpassning

Annan badrumsanpassning

Annan handikappanpassning \_\_\_\_\_ (ange vad)

Nej

Undersökning av vårdbehov och hälsotillstånd före höftledsoperation

22. Hur ser Din arbetssituation ut idag? Kryssa i det alternativ som stämmer bäst överens.

- Arbete heltid 100%
- Arbete deltid  % av heltid
- Arbetslös
- Sjukskriven 100%
- Sjukskriven deltid %
- Sjukpensionär
- Ålderspensionär
- Annat \_\_\_\_\_ (ange vad)

23. Har Du varit sjukskriven eller fått sjukbidrag/sjukpension p g a Dina höftbesvär under den senaste 12-månadersperioden?

- Ja  Nej (om nej hoppa över fråga 24)

24. Hur många veckor har Du varit sjukskriven den senaste 12-månadersperioden till följd av Dina höftbesvär?

- veckor

*Tack för Din medverkan!  
Är alla frågorna besvarade?*







*“...it’s a waste of time to  
concentrate on disease  
and costs, cost-effectiveness  
or utility of intervention  
should be measured...”*

*Alan Williams 1927–2005*



