Clinical and Health Economic Relevance of The Swedish Hip Arthroplasty Register

P. Herberts MD, PhD.
Professor
Acknowledgment to co-workers

Johan Kärrholm
Göran Garellick

&

The entire Register Staff
The idea of a national Register

_Serious consideration should be given to establishing a central register to keep a finger on the pulse of total implant surgery on a nation-wide basis_

_Sir John Charnley_
_Internal Publication No 39, 1972_
The Swedish Hip Arthroplasty Register - A Prospective Observational Study

- Started 1979 and has had a profound impact on the results of all THR surgery in Sweden.
- Owned by the Swedish Orthopaedic Society
- Supported by the National Board of Health and Welfare.
The Swedish Register
Internet address

• [http://www.jru.orthop.gu.se/](http://www.jru.orthop.gu.se/)

• All data collection and feedback through this site since Jan. 1st 1999.
The Mission

- To improve the general outcome of total hip replacement by outcome assessment
- To establish a continuous learning process
- To control quality with focus on the procedure – i.e. enables cost-utility analysis
- To give public information of results
Confidential and public feedback on-line and Annual Reports

Feedback of results is the most essential feature for compliance and will make continued clinical responsibility and accountability feasible

www.jru.orthop.gu.se
The Swedish THA Register
1979 - 2007

• 284,630 primary THR
• 27,690 revision THR
Two levels of Definition for Failure

- Traditional: *Revision of the implant (since 1979)*
- The patient not satisfied or low HRQoL at follow-up (2002)
Results after 30 years

The result of this continuous outcome assessment and dissemination of results back to the profession is a constant improvement of the 10-year survivorship on a nation-wide basis.
10-years survivorship

% survivors

10-year: 94%

time interval – index operation
Restriction of Implant Choice
One reason for improvement

- Survival statistics based on patient-and implant related factors.
- Kaplan-Meier and regression analysis.
- In 2007 more than 50% of the THRs were done with 3 cemented implant combinations.
Primary THR in Sweden 1979 - 2007

Cemented
Hybrid
Uncemented
Reversed hybrid
Resurfacing
All cemented THRs
256 689 primary THRs, 22 641 revisions, 1979-2007

RB 1979 – 2007: 8.1%
RB 1992 – 2007: 9.8%
Uncemented THRs
12,289 primary THRs, 2,569 revisions, 1979-2007

RB 1979 – 2007: 17.3%
RB 1992 – 2007: 20.3%
Reasons for revision 1998 - 2007
Improvement of surgical technique
Most important reason for improvement
Significant factors in regression analysis

- Pulsative lavage
- Distal femoral plug
- Proximal femoral seal
- Vacuum mixing
## Cementing technique
### OA and aseptic loosening

<table>
<thead>
<tr>
<th>Technique</th>
<th>Risk ratio</th>
<th>95% confidence limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulsatile lavage</td>
<td>0.72</td>
<td>0.66-0.79</td>
</tr>
<tr>
<td>Proximal femur seal</td>
<td>0.79</td>
<td>0.72-0.87</td>
</tr>
<tr>
<td>Distal femoral plug</td>
<td>0.87</td>
<td>0.80-0.94</td>
</tr>
</tbody>
</table>
Introduction of new technology
i.e. uncemented fixation

The problem is that surgeons by their nature are attracted to new ideas and concepts. New designs are used with very little supporting evidence.
Survival cemented fixation in blue
Survival uncemented fixation in red
(n=170,413  1992-2007)
Survival cemented fixation in blue
Survival uncemented fixation in red (n=115.959, 1998-2007)
Survival cemented fixation in blue
Survival uncemented fixation in red
Revised within 2 years (1998-2007)
Secur-Fit/Omnifit
All observations, 1979-2000

percent not revised

- Revision Cup: 8 y = 79.1%, n = 457
- Revision Stem: 8 y = 98.5%, n = 457

years postoperatively
CLS Spotorno
all diagnoses and all reasons

1992-2004, 12y = 97.6% (95.4-99.7), n = 551
1992-2004, 12y = 98.8% (97.6-100), n = 551
All other fixation methods

Resurfacing
NARA
Nordic Arthroplasty Register Association
NARA history:

- Danish Hip Arthroplasty Register 1995
- Norwegian Arthroplasty Register 1987
- Swedish Hip Arthroplasty Register 1979
Material:

- A total of 280,201 THR:s
- Denmark 69,242
- Sweden 140,821
- Norway 70,138
Results 10-year survival:

9 596/280 201 revised

- Denmark 91.9% (91.5-92.3)
- Sweden 93.9% (93.6-94.1)
- Norway 92.6% (92.3-93.0)
Fig. 4 Survivorship curves (with 95% confidence intervals) for total hip arthroplasty implants in the United States, Sweden, and Norway.

Effect of Arthroplasty Registries

- The argument that information from a Registry is not as good as a well designed research study does not exist. They are different things.

- The fact that Registries are more effective at improving clinical outcomes than research studies is clearly established.
Register improvement since 2002
Increase the sensitivity for failure definition

- Since 6 years we capture PROM by use of EQ-5D – HRQoL, pain and satisfaction
- Web based registration and feed-back.
- It will enable a large scale of cost-utility studies.
The PROM instrument (patient related outcome measurement)

- Charnley classification (A, B, C)
- Pain – VAS (0-100)
- EQ-5D – HRQoL
- Satisfaction – VAS (0-100)
EQ-5D

- Self-reported health related QoL
- Five dimensions
- EQ-5D index from 0-1
The project implies Follow up for all primary THRs in Sweden

- Preop: questionnaire (10)
- 1 year: questionnaire (11)
- 6 years: questionnaire + X-ray
- 10 years: questionnaire + X-ray
Höftdispensär
Pilotprojekt inom Nationalregistret för höftledsplaster i Sverige.

- Registrering av patient

  Personnummer: 480301-5215  Sida: Höger  Tillfälle: Präoperativ

  Kliniskt protokoll:

  Via formulär  Via pekskärm

  Röntgenprotokoll:

  Via formulär

- Rapporter och resultat

  En sammanställning av klinikens utfall i jämförelse med hela landet
  Hämta klinikens data i Excel-format (version 4.0)
  Totalt antal registreringar per klinik:
  Antal registreringar per klinik 2005
  Antal registreringar per klinik 2004
  Antal registreringar per klinik 2003
  Antal registreringar per klinik 2002

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Har Du besvär från andra höften?

Ja

Nej

paperless – time saving
methodologically attractive
the patient is “forced” to answer all questions in order to go further
no missing values!
The outcome results-Specific gains for the clinic

• Every clinic can log in on-line
• Own results versus the country
• Pre and postop values for EQ-5D
• Pre and postop values for pain, satisfaction and Charnley category
EQ-5D index comparable with an aged and gender matched population (0.76 – 16 000 inhabitants)
Register gains with a standardized follow-up routine

- Patient reported outcome is present
- Increased sensitivity with a complementary failure definition.
- Decreased number of “unrecorded” failures.
Furthermore

• Since 2 years the National Board of Health and Welfare in Sweden desires inclusion of patient reported outcome in all Quality Registers

• …and “faster” performance indicators
Four outcome dimensions in the Register

- Patient related parameters: pain satisfaction QoL
- Reoperation @ 2 years
- Revisions @ 5 and 10 years
- Cost-effectiveness analysis
Re-op @ 2 year: dislocation/deep infection

- high patient morbidity
- technically demanding
- very expensive
- high failure rates
- often bad patient related outcome
Open variables from the Register per hospital on the home page:

- 5-year implant survival
- 10-year survival
- reoperation @ 2 year
- satisfaction
- pain relief
- EQ-5D gain @ 1, (6 and 10 year)
- 90-days mortality
- cost

1999
2005
2006
The Clinical Value Compass

Patient Satisfaction

Clinical Outcome

Cost and Utility

Functional Health
QoL

Batalden and Nelson,
Dartmouth Medical School.
Clinical Value Compass
THA surgery in Sweden - range of mean values (+/-1SD)
Patient Satisfaction

- Implant Survival 10 years
- Implant Survival 5 years
- Reoperations within 2 years
- 90 Days Mortality
- EQ-5D index Gained
- Pain Relief
- Costs
In this example, this hospital has worse outcome in five different dimensions (cardinals).
High volume central hospital

Sundsvall

Case mix
Reoperation @ 2 years varies: 0 – 4.8%
local analysis

improvement programme

no dislocation last year

saving: 5 X 20.000 €

this example shows the true mission of the Register

“I wasn’t aware of our high complication rate.”
The goal with open disclosure of clinical results is to initiate a local learning and improvement process at each department.
Clinical Value Compass Thinking

• It will improve the entire process
• THR is not an operation - it is a procedure
Comparisons are difficult

The Case-mix problem

The case-mix factor is the largest individual factor that leads to misinterpretations of register results.
The case-mix is defined by specific criteria:

- gender
- diagnosis
- age
- Charnley Category

"Case-mix"-variables
nation-wide mean values (percentage)

Charnley Category
A/B

females

OA

60 years or older
# Implant Survival per Hospital

**all diagnoses, all reasons for revision and all types of implants, 1992-2004**

<table>
<thead>
<tr>
<th>Cup (Stem)</th>
<th>Period 1)</th>
<th>Number 2)</th>
<th>OA 3) 60-75 yrs 4)</th>
<th>5 yrs</th>
<th>95% CL</th>
<th>10 yrs</th>
<th>95% CL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>University/Regional Hospitals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huddinge</td>
<td>1992-2004</td>
<td>2,619</td>
<td>64.5% 45.2%</td>
<td>95.3%</td>
<td>± 1.0%</td>
<td>87.6%</td>
<td>± 2.0%</td>
</tr>
<tr>
<td>Karolinska</td>
<td>1992-2004</td>
<td>2,287</td>
<td>56.8% 44.9%</td>
<td>94.9%</td>
<td>± 1.1%</td>
<td>87.4%</td>
<td>± 2.9%</td>
</tr>
<tr>
<td>Linköping</td>
<td>1992-2004</td>
<td>2,464</td>
<td>68.0% 44.4%</td>
<td>99.0%</td>
<td>± 0.5%</td>
<td>96.6%</td>
<td>± 1.4%</td>
</tr>
<tr>
<td>Lund</td>
<td>1992-2004</td>
<td>1,949</td>
<td>50.1% 40.5%</td>
<td>97.1%</td>
<td>± 0.9%</td>
<td>89.7%</td>
<td>± 2.2%</td>
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<tr>
<td>Malmö</td>
<td>1992-2004</td>
<td>2,831</td>
<td>51.9% 45.8%</td>
<td>96.0%</td>
<td>± 0.8%</td>
<td>88.1%</td>
<td>± 1.9%</td>
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<tr>
<td>SU/Sahlgrenska</td>
<td>1992-2004</td>
<td>2,595</td>
<td>60.9% 41.0%</td>
<td>97.7%</td>
<td>± 0.7%</td>
<td>91.5%</td>
<td>± 2.0%</td>
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<tr>
<td>SU/Östra</td>
<td>1992-2004</td>
<td>2,112</td>
<td>75.4% 49.7%</td>
<td>97.5%</td>
<td>± 0.8%</td>
<td>93.2%</td>
<td>± 1.7%</td>
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<tr>
<td>Umeå</td>
<td>1992-2004</td>
<td>1,546</td>
<td>70.0% 48.7%</td>
<td>97.5%</td>
<td>± 0.9%</td>
<td>94.8%</td>
<td>± 1.5%</td>
</tr>
<tr>
<td>Uppsala</td>
<td>1992-2004</td>
<td>3,362</td>
<td>55.1% 39.0%</td>
<td>94.4%</td>
<td>± 1.0%</td>
<td>86.9%</td>
<td>± 2.0%</td>
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<tr>
<td><strong>Central Hospitals</strong></td>
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<tr>
<td>Borås</td>
<td>1992-2004</td>
<td>2,307</td>
<td>68.4% 48.8%</td>
<td>97.5%</td>
<td>± 0.7%</td>
<td>94.6%</td>
<td>± 1.5%</td>
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<tr>
<td>Danderyd</td>
<td>1992-2004</td>
<td>3,599</td>
<td>85.8% 43.8%</td>
<td>96.8%</td>
<td>± 0.7%</td>
<td>93.4%</td>
<td>± 1.4%</td>
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<tr>
<td>Eksjö</td>
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<td>2,232</td>
<td>83.5% 53.5%</td>
<td>96.6%</td>
<td>± 0.9%</td>
<td>93.4%</td>
<td>± 1.6%</td>
</tr>
<tr>
<td>Eskilstuna</td>
<td>1992-2004</td>
<td>1,814</td>
<td>59.8% 47.5%</td>
<td>97.9%</td>
<td>± 0.7%</td>
<td>95.8%</td>
<td>± 1.5%</td>
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<tr>
<td>Falun</td>
<td>1992-2004</td>
<td>1,833</td>
<td>82.9% 51.6%</td>
<td>96.0%</td>
<td>± 1.3%</td>
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<tr>
<td>Gävle</td>
<td>1992-2004</td>
<td>1,915</td>
<td>71.4% 47.6%</td>
<td>96.9%</td>
<td>± 0.9%</td>
<td>84.2%</td>
<td>± 6.5%</td>
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<tr>
<td>Halmstad</td>
<td>1992-2004</td>
<td>2,122</td>
<td>64.1% 48.0%</td>
<td>97.3%</td>
<td>± 0.8%</td>
<td>93.3%</td>
<td>± 2.0%</td>
</tr>
<tr>
<td>Helsingborg</td>
<td>1992-2004</td>
<td>1,905</td>
<td>72.9% 49.7%</td>
<td>96.4%</td>
<td>± 1.0%</td>
<td>86.6%</td>
<td>± 2.8%</td>
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<tr>
<td>Hässleholm-Kristianstad</td>
<td>1992-2004</td>
<td>4,209</td>
<td>83.3% 53.6%</td>
<td>97.9%</td>
<td>± 0.5%</td>
<td>93.9%</td>
<td>± 1.5%</td>
</tr>
<tr>
<td>Jönköping</td>
<td>1992-2004</td>
<td>2,100</td>
<td>79.8% 51.0%</td>
<td>97.5%</td>
<td>± 0.8%</td>
<td>95.2%</td>
<td>± 1.3%</td>
</tr>
<tr>
<td>Kalmar</td>
<td>1992-2004</td>
<td>2,287</td>
<td>65.0% 48.8%</td>
<td>98.3%</td>
<td>± 0.6%</td>
<td>95.3%</td>
<td>± 1.5%</td>
</tr>
</tbody>
</table>
The Case-Mix Problem

The Charnley classification is a highly significant predictor concerning patient related outcome – both for disease-specific and generic instruments.
Patient reported results

Charnley category C patients varies

Preop frequency: 31 - 55%
## Patient related outcome per clinic @ 1year 2002 - 2005

<table>
<thead>
<tr>
<th>Klinik</th>
<th>Preoperativt</th>
<th>Uppföljning efter 1 år</th>
<th>Vinst 3)</th>
<th>Kommentar</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antal</td>
<td>C-kat. 1)</td>
<td>EQ-5D</td>
<td>Smärta</td>
</tr>
<tr>
<td><strong>Universitets- och regionssjukhus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Huddinge</td>
<td>124</td>
<td>48%</td>
<td>0,28</td>
<td>64</td>
</tr>
<tr>
<td>Karolinska</td>
<td>79</td>
<td>46%</td>
<td>0,26</td>
<td>66</td>
</tr>
<tr>
<td>Linköping</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lund</td>
<td>653</td>
<td>49%</td>
<td>0,34</td>
<td>61</td>
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<tr>
<td>Malmö</td>
<td>390</td>
<td>43%</td>
<td>0,34</td>
<td>64</td>
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<tr>
<td>SU/Sahlgrenska</td>
<td>137</td>
<td>49%</td>
<td>0,28</td>
<td>67</td>
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<tr>
<td>Umeå</td>
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<tr>
<td><strong>Länssjukhus</strong></td>
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<tr>
<td>Borås</td>
<td>528</td>
<td>47%</td>
<td>0,41</td>
<td>59</td>
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<tr>
<td>Danderyd</td>
<td>43</td>
<td>44%</td>
<td>0,44</td>
<td>60</td>
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<tr>
<td>Eksjö</td>
<td>141</td>
<td>43%</td>
<td>0,43</td>
<td>62</td>
</tr>
<tr>
<td>Eskilstuna</td>
<td>40</td>
<td>50%</td>
<td>0,22</td>
<td>67</td>
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<tr>
<td>Falun</td>
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<td></td>
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<tr>
<td>Gävle</td>
<td></td>
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<tr>
<td>Halmstad</td>
<td>107</td>
<td>34%</td>
<td>0,36</td>
<td>65</td>
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<tr>
<td>Helsingborg</td>
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<tr>
<td>Hässleholm-Kristianstad</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Jönköping</td>
<td>184</td>
<td>22%</td>
<td>0,37</td>
<td>64</td>
</tr>
</tbody>
</table>
90-day mortality
primary THR 2003 - 2007

one tick - one unit
The Clinical Value Compass

Clinical Outcome

Patient Satisfaction

Functional Health QoL

Cost and Utility

Batalden and Nelson, Dartmouth Medical School.
Health economical evaluation:

*Alan Williams:*

"... It’s a waste of time to concentrate on disease and costs.

Cost-effectiveness or utility of intervention should be measured!..."
Health economy is controversial

- new scientific field
- decision makers often sceptical
  - no incentive for long-term results
  - not interested of total societal costs
  - ”our budget is in balance!”
Health economical evaluation

The most important "income" or profit in health care – is patient utility – quality of life improvement
Since 2004 cost is derived by

- linking with county databases concerning costs, resources, waiting lists …
Cost Per Patient = CPP data base

- most exact reimbursement system in Sweden
- 40 of 79 units
- nation-wide (as a standard) introduced 2009 - 2010
Nation wide mean costs:

- mean cost = 78 000 SEK (12 800 $)
- range = 56 000 – 147 000 SEK
Health economical evaluation

Costs (A – B)

gained HRQoL x duration

Costs/QALY gained

Quality Adjusted Life Years
Höftdispensär
En sammanställning av klinikens utfall i jämförelse med hela landet.

Dessa resultat bygger på vad som fanns i databasen 2008-08-07 och innefattar registreringar från 74 kliniker.

<table>
<thead>
<tr>
<th>Variabel</th>
<th>Din klinik</th>
<th>Hela landet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperativt</td>
<td>1-årsuppfölj.</td>
</tr>
<tr>
<td>Antal registreringar</td>
<td>738</td>
<td>902</td>
</tr>
<tr>
<td>Tillfredsställelse (VAS)</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>Smärta (VAS)</td>
<td>61</td>
<td>17</td>
</tr>
<tr>
<td>EQ-5D Index</td>
<td>0,35</td>
<td>0,69</td>
</tr>
</tbody>
</table>

Cost-utility: $78 000/(0,36 x 10)

QALY: 22 000 SEK (ca 3 540 $)

*Not adjusted for inflation, aging, death and reoperations!*
<table>
<thead>
<tr>
<th>Intervention</th>
<th>£/QALY at 1990 prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol testing and diet therapy (all adults aged 40–69)</td>
<td>220</td>
</tr>
<tr>
<td>Neurosurgical intervention for head injury</td>
<td>240</td>
</tr>
<tr>
<td>GP advice to stop smoking</td>
<td>270</td>
</tr>
<tr>
<td>Neurosurgical intervention for subarachnoid haemorrhage</td>
<td>490</td>
</tr>
<tr>
<td>Antihypertensive treatment to prevent stroke (ages 45–64)</td>
<td>940</td>
</tr>
<tr>
<td>Pacemaker implantation</td>
<td>1,100</td>
</tr>
<tr>
<td>Hip replacement</td>
<td>1,180</td>
</tr>
<tr>
<td>Valve replacement for aortic stenosis</td>
<td>1,410</td>
</tr>
<tr>
<td>Cholesterol testing and treatment (all adults aged 40–69)</td>
<td>1,480</td>
</tr>
<tr>
<td>Docetaxel (as opposed to paclitaxel) in treatment of recurrent metastatic breast cancer</td>
<td>1,890*</td>
</tr>
<tr>
<td>CABG (left main-vessel disease, severe angina)</td>
<td>2,090</td>
</tr>
<tr>
<td>Kidney transplantation</td>
<td>4,710</td>
</tr>
<tr>
<td>Breast cancer screening</td>
<td>5,780</td>
</tr>
<tr>
<td>Heart transplantation</td>
<td>7,840</td>
</tr>
<tr>
<td>Cholesterol testing and treatment incrementally (all adults aged 25–39)</td>
<td>14,150</td>
</tr>
<tr>
<td>Home haemodialysis</td>
<td>17,260</td>
</tr>
<tr>
<td>CABG (one-vessel disease, moderate angina)</td>
<td>18,830</td>
</tr>
<tr>
<td>Hospital haemodialysis</td>
<td>21,970</td>
</tr>
<tr>
<td>Erythropoietin treatment for anaemia in dialysis patients</td>
<td>54,380</td>
</tr>
<tr>
<td>(assuming 10% reduction in mortality)</td>
<td></td>
</tr>
<tr>
<td>Addition of interferon-α2b to conventional treatment in newly diagnosed multiple myeloma</td>
<td>55,060$</td>
</tr>
<tr>
<td>Neurosurgical intervention for malignant intracranial tumours</td>
<td>107,780</td>
</tr>
<tr>
<td>Erythropoietin treatment for anaemia in dialysis patients</td>
<td>126,290</td>
</tr>
<tr>
<td>(assuming no increase in survival)</td>
<td></td>
</tr>
</tbody>
</table>

* Adjusted to 1990 prices using Hospital and Community Health Service Pay and Prices Index, Unit Costs of Health and Social Care. PPSSRU, 1996.
\(2,431 \div 200.7 \times 155.6 = 1,890\).

$ Translated into 1990 prices, as above.
Costs/QALY gained

- even better if all societal costs were known
Waiting time mean costs

2 700 patients:

- 73 000 SEK /1 year (12 000 $)
- 14 000 X 73 000 = 1 bil SEK!
Health economical evaluation

THR is not only one of the best operations ever introduced but also one of the most cost-effective
We can and need to monitor and describe our current and changing practice continuously, and then provide this information public to all parties.
Advantages of a National Registry

- Independent
- Prospective data
- Comparative outcomes
- Simultaneously compares all treatments
- Very large numbers
- Provides data that is not available from any other source
- Describes and Monitors current/changing practice
- Able to identify outcome outliers
Advantages of a National Registry

• Includes all centers, no performance bias
• Wide applicability and relevance
• Can be used to answer multiple questions
• Answers questions not possible to do in any other way
• Hospital, Regional and International comparisons
• The information they provide improves performance
• Result in considerable savings / very cost effective
• Hypothesis generation
Improvement of the Arthroplasty Registries

- Establish a mechanism with the purpose of ensuring and maintaining continual quality improvement
- Provide hospital and community based comparative outcomes data
- Establish a mechanism for continuous public reporting of outcome measurements
Thank You for Your Attention
Conclusion

• Outcome assessment through the Register has had a profound impact on total hip replacement care in Sweden.
• These efforts must be a continuous process – a steady state situation will never develop.
• Enormous potential for clinical research
Conclusion

• For the healthcare providers— large economic savings and public information of results
• For the patient optimal treatment modalities identified and described on the web
• For the orthopaedic community outcome facts are present - confidential and public