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# Formation of the Scandinavian Obesity Surgery Registry, SOReg

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## **Abstract:**

**Background:** Obesity surgery is expanding, the quality of care is ever more important and learning curve assessment should be established. A large registry cohort can show long-term effects on obesity and its comorbidities, complications and long-term side-effects of surgery, as well as changes in health related quality of life (QoL). Sweden is ideally suited to the task of data collection and audit, with universal use of personal identification numbers, nation-wide registries permitting cross-matching to analyze causes of death, in-hospital care and health-related absenteeism.

**Method:** In 2004, the Scandinavian Obesity Surgery Registry (SOReg) was initiated and government financing secured. A project group created a national database covering all public as well as private hospitals. Data entry was to be made online, operative definitions of comorbidity were formed, and complication severity scored. Several forms of audit were devised.

**Results:** After pilot studies the system has been running in its present form since 2007. Since 15 January 2013 SOReg covers all bariatric surgery centers in Sweden. The number of operations in the database exceeded 40,000 (March 2014), with a median follow-up of 2.94 years. Audit shows that >98% of data are correct. All results are publicized annually on the Internet.

**Comments:** Using this systematic approach it has been possible to cover >99% of all bariatric surgery, cross-matching our data with nation-wide registries for in-hospital care, cause of death and permitting regular nation-wide audit. Several scientific studies have used, or are using, what seems to be the most comprehensive database in obesity surgery.

## **Background:**

Several factors speak in favor of establishing registries for obesity surgery. Obesity prevalence is rising, no effective non-operative means of treatment have been identified, and surgeons new to the field are driven to increased operative activity. It seems prudent to establish an instrument that can identify the quality of care given. At the same time data can be collected to find long-term effects on the underlying obesity and its comorbidities, any long-term side-effects of surgery and, not least, changes in perceived health related quality of life (QoL).

Sweden is ideally suited to this task, with central registries permitting cross-matching with nation-wide registries for in-hospital care, causes of death and health-related absenteeism. Furthermore a country such as Sweden, with only one Society for upper GI surgery (SFÖAK) can easily keep track of compliance with registration. Also, the different levels of hospitals are closely cooperating and a national infra-structure for governmental economic support of national quality registers exists.

The strengths of a design encompassing an entire country is that cohort data are registered, rather than a sample, and that numbers can be accelerated quickly. The Swedish personal ID-number permits specific scientific studies to utilize already existing registry data on demographics.

The aim of the present paper is to describe the formation of such a registry for Sweden, SOReg, which seems to be the most comprehensive existing database of obesity surgery.

## **Process and Method:**

A motion to build a registry for obesity surgery was made to the Swedish Surgical Society and the process was started in 2004. Financing was secured from a combination of the legal caregiver, the “Swedish Association of Local Authorities and Regions” (SKL), and from the government regulatory body, the “Swedish Board of Health and Welfare”.

An eight-member project group was put together, representing all geographic areas of Sweden. Once the registry was up and running, a steering committee was put in charge of overseeing its long term goals, and a director responsible for day to day running. The steering committee members represent all levels of hospitals, university, regional, county and private, as well as having representatives for the allied care professions.

The instructions were to create a national database covering all public as well as private hospitals. Patients are entered into the database either the operation is tax-financed or privately paid. The database design permits any separate research databases to be coupled to the basic data existing in the registry, covering demographics, comorbidity, outcome of surgery and follow-up data. Furthermore, regular audit of the database was included and annual cross-matches with the major official registries.

As with all Swedish surgical registries, a QoL instrument had to be included to secure government financing. It was furthermore stated that annual reports had to be made and publicized on the Internet, with identifiable hospitals. These annual reports (in Swedish, and in English can be found at [http://www.ucr.uu.se/soreg/index.php/arsrapporter\\_](http://www.ucr.uu.se/soreg/index.php/arsrapporter_)

In the choice between good compliance and thorough recording, the project group decided that a data input session per patient visit should take no more than three minutes and that data

entry should be made online. An example of parameters recorded is given in table 1, and recorded details for a gastric bypass operation are shown in table 2.

For each variable, a standard range was determined and shown as explanatory text for the cell. Any attempt at entering data outside this range yields an error message. Affirmative action can override this function. Variables were divided into mandatory and optional/ recommended variables. Great effort was put into making the registrations user-friendly and logical. Data entry cannot be concluded until all mandatory variables have been entered. This goes for baseline registration, as well as for the other time points. So the completion rate for mandatory variables is 100%. Optional variables are entered in 67% of all cases (SEM 6.1; i.q. range 51.3-82.4).

A set of rules for the operative definitions of comorbidity was formed following consultation with the medical societies for diabetes, sleep apnea etc. The principle was that comorbidity was recorded if it required continuous treatment. The year of onset of type 2 diabetes was noted; all other comorbidities were entered as they were present on the day of inclusion. Comorbidity is thus given in the registry as Yes/No, specific values are kept in medical records. Laboratory values can be added at all time points. The standard, optional parameters are given in table 1. Any number of user-defined extra values can be added by an individual department for research or other purposes. They are then visible only for that department.

Complications were to be classified for etiology, and scored for severity using the Clavien-Dindo system [1, 2]. The operating department is primarily responsible for data entry, but can transfer the responsibility of follow-up data to another cooperating center after written notification.

Points in time for recording were chosen to be a base-line approximately one month before surgery and another at the day of surgery. It would then be possible to monitor any effects of

preoperative optimizing. Operation data entry was made hierarchal; variables depend on type of procedure used. The time of the first database recorded follow-up visit (six weeks) was chosen to facilitate recordings of 30-day morbidity. Standard demographic data and blood chemistry is collected at these time-points.

**QoL data:** At baseline and at 1, 2 and 5 years postoperatively patients fill out two questionnaires on paper. These are the Short form generic quality of life scale (SF-36) and the Obesity Problems scale (OP) [3]. Both of these scales have been widely used and are well validated in the Swedish language. The filled-out forms are then transported to the central facility of the SOReg and entered into the database using a specifically programmed scanner.

**Audit** and the addition of supplementary data (if needed) occur at regular intervals in several different ways: All records are cross-matched to the registries kept by the Swedish board of Health and Welfare; The Swedish population registry, each month for death or alive status and place of domicile; The Swedish in-hospital registry, collects data on a nation-wide basis, classified according to the ICD 10 system (Individuals that have previously been entered as bariatric operations can be identified if they have renewed admissions, regardless of cause); Swedish Death Registry, at least once a year; Swedish Cancer Registry, (planned for).

An independent observer visits all departments involved with bariatric operations. Records are thoroughly gone through if they show values outside predetermined levels for duration of hospital care. Also, a random sample of patient medical records from the center in question is examined for accuracy of recording.

As **research projects** we presently match registry data also against The National Prescription Drug registry, to study consumption before and after surgery, and to the Social insurance registry for data on employment status, absenteeism from work, levels of education, and annual income.

## **Results:**

**Number of patients in the SOReg database:** Pilot studies were made in 2005 with only a few departments participating. After an initial phase in 2007-2010 all data were transferred to the Uppsala Clinical Research center (UCR) platform. Controls showed that no data were lost. The database is up and running in its present form on the UCR platform, with comprehensive nation-wide data, since 2007. The characteristics of patients that make up the SOReg cohort are given in table 3. Patients are informed about the registry, and they may decline to have their records included. However, virtually no one does. Patients also have an option to withdraw their information from the registry, though to date it has only occurred in five cases.

Operative activity in Sweden has risen dramatically (fig 1) even though there is some levelling off during the last few years. With a present inclusion rate into SOReg of 99.1 %, the number of operations recorded in the database exceeded 40,000 in March 2014, making it the most comprehensive database in the field of obesity surgery. The cumulative rate of growth is illustrated in fig 2.

Median follow-up time is 2.94 years; with at present 6 834 / 43424 (15.7 %) operated patients followed in the system for more than 5 years.

**Data entering:** Blood chemistry data are delivered on-line from the laboratory. Nurses take anthropometric data and collect the applicable questionnaires. Data inputting can be performed only by persons registered with the system; all participating surgeons and one or two nurses in each center has such accreditation. They are specifically trained for the task, in nation-wide courses once or twice a year.



Base-line registration is in most centers performed by the surgeon; operative data are entered on-line in the OR, with the surgeon still present. Postoperative data for patients with no aberrations from the expected postoperative course are in most centers entered by a nurse at the follow-up appointment, but for patients with a suspected or confirmed complication, data are entered by a surgeon.

Time for entering data for one patient and one visit has been timed to take a mean of 1 min 20 seconds (range 1-5 minutes). Additional time for data entry by an experienced surgeon for patients with a complication was 4 min 30 sec per patient (range 1 min 40 sec – 8 min 30 sec).

**Waiting-lists and regional mobility:** The fact that patients often try to avoid waiting-lists by seeking care at several different hospitals made it desirable to include county of domicile as well as hospital; the former is achieved automatically by cross-matching with the population registry, the latter is also automatic and depends on the surgeon's log-in code to the registry. SOReg thus makes it possible to look for regional differences in tax-financed obesity surgery. By allowing only the hospital where surgery was performed to enter its data, it has been possible to preclude double registration. Cross-matching with official data bases enables a comparison of the number of operations per 100 000 inhabitants and year (Supplementary data, table S1). A more than fivefold difference is noted between counties with high activity, and those with low. No explanation can be found from population data on obesity for this difference.

It was found that 43 % of patients were operated elsewhere than at their county or regional hospital; the cost of the operation was tax financed in 91.3 %, by insurance in 1.5 % and by the patient herself in 7.3 %. The distribution of operations for different types of care-givers is presented in fig 1.

## **Hospital category and case mix**

The design of data catchment permits sub-analyses of individual hospitals; numbers of the various procedures, operative time, and hospital time as well as complication rates are specified and are publicized annually with the hospitals named.

To permit a better understanding of the case mix, patients are scored for severity depending on the type and number of comorbidities. A full description of the method is given on the website, and the full tabular presentation (Suppl. Material, table S2) is taken from the most recent annual report. In summary, all units in Sweden are ranked for the proportion of patients they operate with the risk factors high age, high BMI, high waist circumference, male sex, presence of comorbidity, and previous gastric surgery. The quartile scoring highest in each category is given 4 points, and the lowest quartile is given 1 point. The maximum score possible is thus 24 points, and the lowest 6 points. In our annual report we also included the standard DeMaria score. The correlation between these two methods is very strong ( $r=0.89$ ;  $p=0,000$ ) a fact that is illustrated in part 1 of the 2013 SOReg annual report.

## **Audit**

All participating centers have now been audited at least once. At the time of data acquisition, 41 367 data recordings have been inspected, of which 40 022 were possible to audit (96.7 %). Complete audits were performed in 980 patient records; the accuracy was found to be 96.7 - 98.6% between hospitals for base-line data entry, and data for the different FU points were accurate in 98.6-100 %. Data that had been entered as falling outside the expected range was in 90% due to manual errors, and the appropriate changes could be instituted to the accepted value ranges in the database. A value outside a predetermined range now calls for affirmative action before entry is allowed.

## **Data ownership and Research projects**

Any individual department is the owner of its own data, which can at any time be downloaded from the data-base server, and used for quality control, local research projects or any other initiative. These reports include a full personal identification number.

A number of standard reports can be viewed on screen or downloaded. They include complications and development with time for any variable in the database. National averages are always given as comparison. These standard reports are aggregate data and no individual can be identified. Reports can be used for local quality control, and are frequently downloaded. Such reports have been downloaded on average 1287 times per year, corresponding to about 30 times for each participating department.

Any group wishing to use data from the entire registry can apply if they have approval from one of the six ethics committees of Sweden. The steering committee then decides whether or not the project is compatible with Swedish legislation, and not severely overlaps or influences other on-going projects. Information on this process is given on the registry home-page (<http://www.ucr.uu.se/soreg/>).

Already at the outset, SOReg was designed to be a data base also for add-on research projects, providing basic demographic and comorbidity data. Generating new knowledge was considered to be one of the main goals of the SOReg and the steering committee has actively encouraged such endeavors. SOReg has several ethics committee approvals of its own.

## **Data output and Results downloading**

Several standardized reports can be down-loaded by participating centers. These reports encompass both the effects on weight, calculated in several different ways, on comorbidity

resolution and on complication. The individual department is highlighted against a background of all participating departments. Another way is to download in database format all patient data for one's own department. Here filters can be applied to identify patients of interest. Complications are accounted and classified for severity using the Clavien-Dindo system. This means that reoperations/ICU care are covered under that heading.

Revision surgery is a factor in case-mix assessment. It is defined as an elective procedure performed due to shortcomings of the index operation. Revision surgery is further subdivided into modification of the original operation, such as lengthening of the alimentary limb. Or as changing the fundamental principle, such as when converting a band to a GBP. Any department can download their own data for revisional operations using the built-in filters of the database.

## Discussion

The introduction of a quality registry is justified when new technology is introduced, as well as when an existing method is increasingly used in several types of clinical settings. Obesity surgery corresponds well to both indications and this is reflected in the fact that registries have been created within several professional networks. Many scientific reports have been based on registry data but have been flawed by being sample-based and often represent data from a particular type of hospital or from a specialist center. SOReg was introduced to overcome these difficulties, as well as be independent of commercial interests in that it is wholly financed by tax money.

Norway with a health system with great similarities to the Swedish has joined in spring 2014 and after a pilot period all bariatric surgery units of the country is expected to start to use SOReg from January 2015. The Michigan collaborative covers 95% of bariatric surgery in the state and adds annually some 6500 new cases. This large registry has been used for scientific purposes [4-6]. The Bariatric Outcomes Longitudinal Database (BOLD) is another large database [7]. However participation in these projects is voluntary, and reflects mainly the production from centers of excellence, thus not necessarily reflecting the true panorama of outcomes. Registries can be based on a sample of patients from a given number of hospitals. The statistical analyses then apply to the population that these hospitals serve. However, such a sample based on select hospitals cannot predict accurately outside that population for several reasons. The most important may be that patient selection can vary between hospitals, that patients' disease patterns vary between catchment areas and that specialization of the hospital and its operative volumes are known to influence both complication rates and outcome. If however all hospitals can be included such as in SOReg, i.e. no selection bias, statistical validity improves greatly.

The American Society of Metabolic and Bariatric Surgery (ASMBS) [8], The United Kingdom National Bariatric Surgery Registry [9] and the Veterans administration [10] also have data on medium to large number of patients. These series have either a low coverage, a short follow-up (FU) time or a low FU rate, even for an important variable such as mortality.

An on-going attempt at building a registry in Australia-New Zealand is expected to cover 95% of all bariatric surgery. This registry is very much like the design we have used, trying to achieve a full coverage on a national basis, and employing basically the same variables.

Several countries are currently planning to start national registers and IFSO is trying to start a global registry. The first results were given at the 2014 IFSO meeting. Their challenge is to reach full completeness, full accessibility and a measured high validity of data quality, much in the manner that SOReg has achieved.

Several single-center registries existed in a similar way in Sweden since the late 1980's.

Follow up rates were high and mortality rates could be ascertained by using the national death registry. The coverage was however only about 50% of the volume of bariatric surgery produced. Gray [11] has recently described the development of clinical registries as development tools, and stresses the importance of coverage and FU rates.

SOReg also makes detailed comparisons of complication patterns between different hospitals and these data are presented on the website

(<http://www.ucr.uu.se/soreg/index.php/arsrapporter>). Taken in conjunction with the data on differing operative activity (table S1-S2), department heads have thus been given a powerful tool in negotiations on how tax money is spent.

Also quality surveillance seems to benefit from the registry. Both weight loss data, resolution of comorbidities as well as complication rates have been regularly down-loaded from the

SOREg server about thirty times per year per participating department. These comparisons should yield more information than just a single center examining its own data.

In conclusion, the SOReg is presently the world's most comprehensive registry on bariatric surgery. It is also a cohort study, rather than a sample. Several research projects in Sweden are facilitated by using SOReg data for the basic variables. Registry data themselves have given rise not only to the annual reports, but also to scientific reports, as yet mostly on complications outcomes [12-15]. Using several different ethics approvals, other studies are in progress.

The gold standard for clinical research has always been the randomized control trial (RCT). The question of whether data from clinical registries are valid was discussed in two articles in NEJM. Concato et al [16] found that the results of well-designed observational studies, with either a cohort or a case-control design, do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic. Benson and Harts [17] concluded in their article that there seems to be no data to indicate that estimates of treatment effects differ between RCTs and registry-based research. Clinical research using large registries has indeed been shown to be fruitful. SC Chung and co-workers [18] analyzed > 500.000 cases of myocardial infarction and their management. After case mix standardization, they found differences with a lower mortality rate in Sweden than in the UK, and could identify the two factors that differed. Bhatt et al [19] compared registry and RCT patients in another cardiology study, and found registry data to be clinically useful. Orthopedic surgery has been on the forefront of using registries for scientific studies, an overview is found in Warwick et al [20].

Registers can be used to run large RCTs and SOReg has been used for such purpose in the Swedish study on closure or non-closure of mesenteric defects in laparoscopic gastric bypass

surgery. Here 2500 patients were included within 15 months. The Swedish way of using registries has been positively received [21].

The data quality of the SOReg registry is facilitated by several factors. One is the fact that central registries of deaths and of in-hospital care can be cross-matched with SOReg. Another is the fact all 44 departments of surgery performing bariatric surgery in Sweden are involved in this cohort study, making coverage and data auditing better.

The report from the recent NIH symposium [22] conclude that carefully designed observational studies is the most likely way of understanding outcomes from bariatric surgery. SOReg meets these criteria. At present 6 834 / 43 424 (15.7 %) patients have been followed up for five years or more. Over the next few years there will be a rapid rise in the number of patients followed up intermediate and long-term, since the rise in operative activity in Sweden started in 2010. Several interesting studies can then be based on this large cohort material, and new insight gained into the pros and cons of obesity surgery.



## References:

1.

Dindo D, Demartines N, Clavien PA

Classification of surgical complications

Ann Surg 2004; 240: 205-213

2.

Clavien PA, Barkun, J, de Oliveira M, Vauthey JN et al

The Clavien- Dindo classification of surgical complications: Five-year experience

Ann Surg 2009; 250:187-196.

3.

Karlsson J, Taft C, Sjöström L, Torgerson JS, Sullivan M

Psychosocial functioning in the obese before and after weight reduction: construct validity and responsiveness of the Obesity-related Problems scale

International Journal of Obesity (2003) 27, 617–630. doi:10.1038/sj.ijo.0802272

4.

Share DA, Campbell DA, Birkmeyer N et al

How A Regional Collaborative Of Hospitals and Physicians In Michigan Cut Costs And Improved The Quality Of Care

Health Affairs, 30, no.4 (2011):636-645

5.

Birkmeyer JD, Finks JF, O'Reilly A, et al for the Michigan Bariatric Surgery Collaborative  
Surgical Skill and Complication Rates after Bariatric Surgery  
N Engl J Med 2013; 369:1434–1442

6.

Finks JF, Kole KL, Panduranga Y, et al for the Michigan Bariatric Surgery Collaborative,  
Predicting Risk for Serious Complications with Bariatric Surgery: Results from the Michigan  
Bariatric Surgery Collaborative  
Annals of Surgery: October 2011 (254:4):633–640 doi: 10.1097/SLA.0b013e318230058c

7.

DeMaria EJ, Pate V, Warthen M, Winegar DA  
Baseline data from American Society for Metabolic and Bariatric Surgery-designated  
Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database  
Surgery for Obesity and Related Diseases 2010 Volume 6 (4): 347-355

8.

Mason EE, Renquist KE et al  
Bariatric surgery trends: an 18-year report from the International Bariatric Surgery Registry  
The American Journal of Surgery 192:5; 657-662, November 2006

9.

Welbourn R, Fiennes A

First NBSR Report April 2011 The United Kingdom National Bariatric Surgery Registry.

<http://www.nbsr.org.uk/>

10.

Hauser DL, Titchner RL, Wilson MA, Eid GM

Long-Term Outcomes of Laparoscopic Roux-en-Y Gastric Bypass in US Veterans

Obesity Surgery March 2010, Volume 20, Issue 3, pp 283-289

11.

Gray BH

Registries as a Knowledge-Development Tool: The experience of Sweden and England

July 2013; The Urban Institute Health Policy Center; [www.healthpolicycenter.org](http://www.healthpolicycenter.org)

12.

Sundbom M, Hedberg J, Wanhainen A, Ottosson J

Aortic injuries during laparoscopic gastric bypass for morbid obesity in Sweden 2009-2010; a nationwide survey

SOARD 2013; 10(2):203-7

13.

Stenberg E, Szabo E, Ågren G, Näslund E, Boman L, Bylund A, Hedenbro J, Laurenius A,

Lundegårdh G, Lönroth H, Möller P, Sundbom M, Ottosson J, Näslund I

Early Complications after Laparoscopic Gastric Bypass Surgery: Results from the

Scandinavian Obesity Surgery Registry

Ann Surg 2014; 260(6):1040-7

14.

Anderin C, Gustafsson U, Heijbel N, Thorell A

Weight loss before bariatric surgery and postoperative complications. Data from the Scandinavian Obesity Surgery Registry

Ann Surg 2014 DOI:10.1097/SLA.0000000000000839

15.

Stenberg E, Szabo E, Näslund I

Is Glycosylated hemoglobin A1C associated with increased risk for severe early postoperative complications in non-diabetics after laparoscopic gastric bypass.

SOARD 2014; 10(5):801-7

16.

Concato J, Shah N, Horwitz RI.

Randomized, controlled trials, Observational studies, and the hierarchy of research designs

N Engl J Med 2000;342:1887-92

17.

Benson K, Hartz AJ

A Comparison of Observational Studies and randomized controlled trials

N Engl J Med 2000; 342:1878-86.

18.

Chung SC, Gedeberg R, Nicholas O, et al

Acute myocardial infarction: a comparison of short-term survival in national outcome registries in Sweden and the UK

The Lancet, Volume 2014 (383) 12 April: 1305 - 1312.

19.

Bhatt DL, Bertrand ME, Berger PB, et al

Meta-analysis of randomized and registry comparisons of ticlopidine with clopidogrel after stenting

J Am Coll Cardiol. 2002;39 (1):9-14.

20.

Warwick D, Agnelli G, Cushner F, Friedman RJ, FitzGerald G, Gallus A,

GLORY Publication Committee: Lessons learned from the global orthopedic registry: study design, current practice patterns, and future directions

Am J Ortop 2010 Sept; 39 (Suppl 9):29-31

21.

Larsson S, Lawyer P, Silverstein MB

From concept to reality; Putting value-based Health care into practice in Sweden

Boston Consulting group; <http://www.bcg.com/documents/file64538.pdf>

22.

Courcolas AP, Yanovski SZ, Bonds D, et al

Long-term Outcomes of Bariatric Surgery: A National Institutes of Health Symposium

JAMA Surg 2014; 149(12):1323-9; doi:10.1001/jamasurg.2014.2440

**Table 1: Standard variables.**

M denotes mandatory; O = optional (recommended).

Area		Base-line/at inclusion	6 w postop	1, 2 and 5 y postop
Demographics	Height	M	automatic	automatic
	Weight	M	M	M
	Abdominal circumference	O		O
	Age (automatic)	M		
	Sex (automatic)	M		
Hospital (automatic)	M	M	M	
County of residence (automatic)	M			
Presence of comorbidity	T2DM (+since)	M	M	M
	Hypertension	M	M	M
	Sleep apnea	M	M	M
	Dyslipidemia	M	M	M
	Depression	M	M	M
	Diarrhea	M	M	M
	Dyspepsia	M	M	M
Complication	Musculo-skeletal pain	M	M	M
	During previous period (yes/no)		M	M
	If yes – yes/no for 16 specified complications*		M	M
	If yes – severity**		M	M
Readmission	Since previous registration		M	M
Surgery	Since previous registration		M	M
Laboratory test	HbA1c	O		O
	fP-glucose	O		O
	HDL	O		O
	LDL	O		O
	TG	O		O
	Haemoglobin	O		O
	Creatinine	O		O
	Vitamin D	O		O
	Parathyroid hormone	O		O
Systolic and diastolic BP	O		O	
Substitution	with different vitamins and minerals		O	O
Quality of life	SF-36	O	O	O
	Obesity Problems Scale (OP)	O	O	O

\*Leakage, bleeding, deep infection, abscess, wound rupture, other infectious wound complication, obstruction, band-related complication, port-related complication, stomal ulcer, cardiovascular complication, DVT, PE, pulmonary complication, urinary tract infection, other (specify)

\*\* As defined in the Clavien-Dindo system

**Table 2: Additional variables at operation, example given is for gastric bypass**

<i>Area of question</i>	<i>Type of answer/Specifications/Comments/free text</i>
Previous gastric surgery	Yes/no
- If yes	Specified previous method and year
- If yes	Indication for present surgery
Preop intentional weight loss	Yes/no
Access route	Laparoscopic/open/converted/endoscopic
- If conversion	Reason for conversion
Method used	9 predefined options (Gastric bypass, sleeve gastrectomy etc.)
Accidental lesions to organs	Yes/no
- If yes	specified
Anti-thrombotic prophylaxis	If yes: specified
Prophylaxis with antibiotic	Yes/no
Intra-operative test of leakage	Yes/no
Operating time	minutes
<b>Procedure specific variables for gastric bypass</b>	
Division of greater omentum	yes/no
Position of A-limb	Antecolic/retrocolic
Length of A-limb	cm
Method for gastrojejunostomy	Number of cartridges and height of staples/ hand sewn, type of suture material
Length of B-limb	cm
Length of division of mesentery	cm
Method for entero-enterostomy	Number of cartridges and height of staples/ hand sewn, type of suture material
Length of common channel (optional)	cm
Closure of mesenteric openings	Yes/no for Petersen's, E-A and mesenteric
-if yes	details of closure

**Table 3: Patients in the SOReg, September 2014**

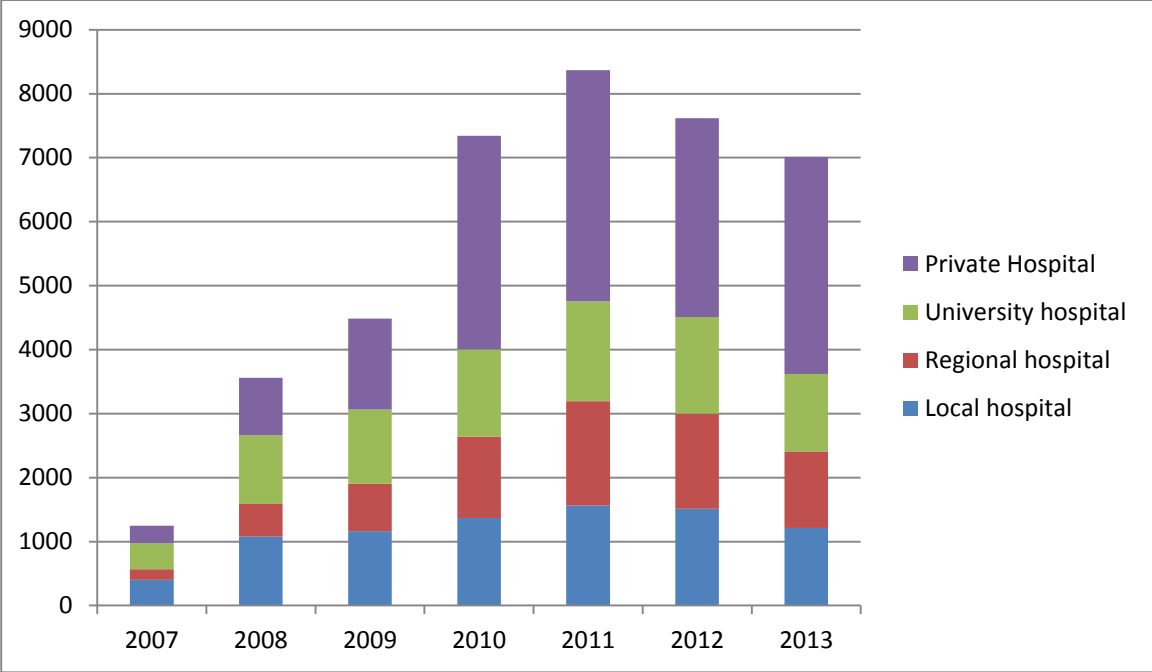
	Number of patients	Age at op.	BMI at op.	One or more comorbidities (%)
Total	43424	41.2	42.4	51.1
Men	10 475	43.0	43.5	61.9
Women	32 949	40.6	42.0	47.6



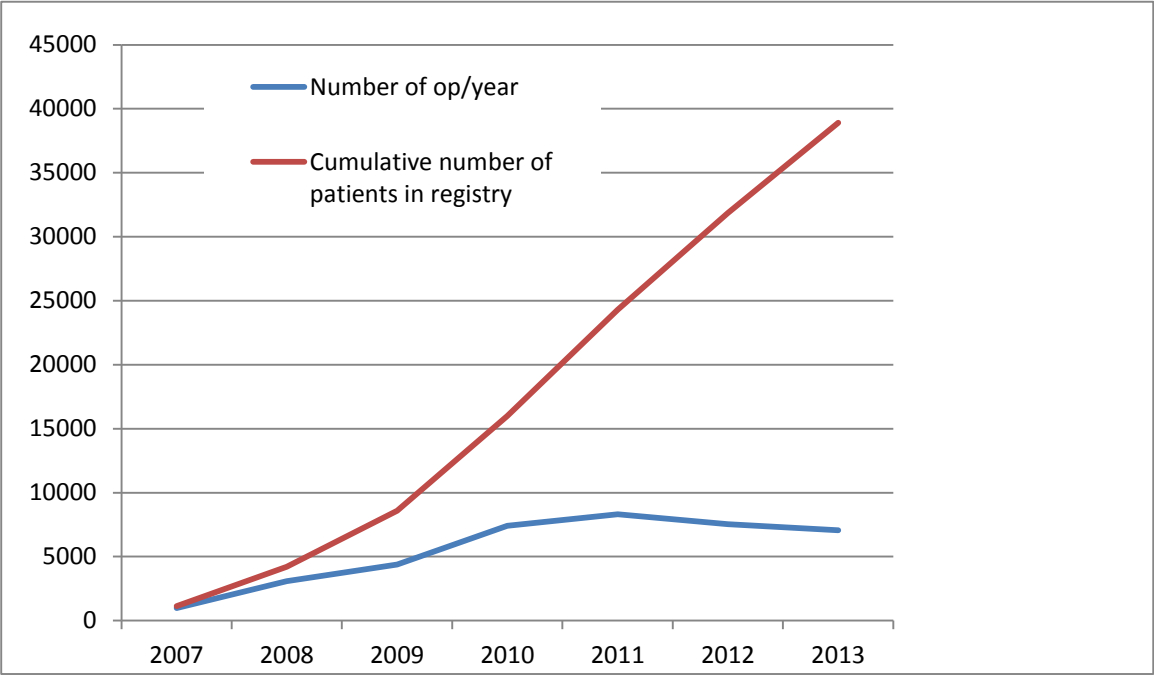
**Fig 1: The number of bariatric operations per year, for type of hospital.**

Note that also private hospitals are tax financed.

Sweden has a population 9.8 million.



**Fig 2: The growth of the SOReg database**



Supplementary material:

**Table S1: Operative activity in the counties of Sweden; number of operations per 100 000 inhabitants and year. Bottom line indicates national average.**

	<b>2011</b>	<b>2012</b>	<b>2013</b>
Stockholm	85,4	76,7	72,8
Uppsala	69,4	59,7	55,0
Södermanland	53,9	67,3	51,5
Östergötland	95,8	75,6	97,5
Jönköping	84,9	54,3	53,6
Kronoberg	81,2	94,7	91,4
Kalmar	93,1	88,6	93,2
Gotland	85,5	21,0	14,0
Blekinge	68,6	69,6	65,5
Skåne	93,8	115,1	137,0
Halland	68,6	84,8	59,6
Västra Götaland	81,0	58,2	58,4
Värmland	97,2	75,4	78,5
Örebro	154,5	127,9	68,3
Västmanland	100,7	76,1	69,5
Dalarna	58,6	69,4	121,9
Gävleborg	89,8	87,1	56,5
Västernorrland	94,6	63,2	50,8
Jämtland	74,4	54,7	32,4
Västerbotten	87,4	84,5	72,8
Norrbottn	125,5	94,9	72,2
<i>National average</i>	<i>87,4</i>	<i>79,0</i>	<i>77,8</i>

**Table S2: Case-mix score 2009-13 (left) for different hospitals and details for some factors for 2013 (right). Bottom line indicates national average. (n.a. = not available)**

Department	Total score					N:o	Results 2013					
	2009	2010	2011	2012	2013		Age	Proportion males	BMI	Waist circumference	Co-morb	Rev.surgery
							mean	%	mean	mean	%	%
Sahlgrenska, Gbg	21	22	21	23	24	127	43,9	40,9	43,7	131,0	67,7	7,9
Lund/Landskrona	24	23	18	23	22	158	42,9	27,8	42,5	132,2	55,7	22,8
Falun	9	13	20	22	21	89	45,8	29,2	42,0	126,3	74,2	5,6
Norrköping	23	23	23	22	21	165	43,8	27,9	42,3	127,2	54,5	9,1
Sunderby, Luleå	21	20	18	17	21	160	42,8	28,1	43,0	133,1	56,9	1,9
Västervik			11	17	18	36	40,9	30,6	43,5	129,7	38,9	8,3
Eksjö		12	18	16	18	68	44,6	25,0	41,7	129,0	52,9	2,9
Sundsvall	15	17	14	16	18	116	41,1	23,3	44,0	129,4	44,0	8,6
Torsby	15	11	16	13	18	199	40,8	28,1	42,3	126,7	58,8	1,0
Växjö		14	12	13	18	56	41,7	32,1	42,1	n.a.	67,9	5,4
Uppsala	23	16	18	18	17	255	41,5	25,5	44,8	n.a.	63,9	3,5
Lycksele	18	23	21	17	17	177	40,8	24,9	42,4	125,2	58,2	2,8
Västerås	19	17	17	17	17	77	42,6	24,7	43,6	131,5	48,1	1,3
Danderyd, Sthlm	18	15	16	16	17	369	42,5	24,9	40,9	121,2	72,9	11,1
Nyköping	17	15	17	18	16	49	43,3	10,2	39,7	121,9	63,3	22,4
Östersund	19	16	17	18	16	36	37,1	36,1	44,6	129,9	50,0	0,0
Skövde	15	19	17	16	16	211	39,1	28,4	44,0	123,0	44,1	2,4
SU/Östra				14	16	141	38,8	27,0	42,8	131,1	53,9	0,7
Ersta, Sthlm	17	17	14	16	15	685	42,3	26,4	40,7	129,9	45,3	2,5
Mora			15	16	15	79	44,0	19,0	41,3	128,5	65,8	0,0
Trollhättan		16	15	16	15	70	40,1	24,3	43,8	137,6	48,6	0,0
Aleris, Skåne		16	19	14	15	947	40,4	24,8	41,9	122,0	71,8	0,2
Västra Frölunda			13	12	15	45	40,0	24,4	43,1	128,5	53,3	0,0
Kalmar	17	10	9	10	15	176	40,1	25,0	41,3	126,0	54,5	4,5
Borås		16	18	14	14	86	38,6	25,6	42,4	130,0	43,0	0,0
Värnamo	11	17	13	13	14	91	37,2	23,1	43,1	130,0	41,8	0,0
Gävle	18	17	15	16	13	58	37,2	13,8	43,0	133,1	43,1	0,0
Capio S.t Göran, Sthlm	11	10	13	11	13	267	42,3	22,8	40,8	122,4	51,3	0,0
Södersjukhuset, Sthlm	15	15	9	15	12	66	43,5	22,7	39,8	124,5	47,0	0,0
Örebro/Lindesberg	18	17	17	14	12	192	40,1	20,3	41,7	115,1	49,0	1,6
Hudiksvall		16	15	13	12	72	40,2	18,1	41,4	122,1	55,6	1,4
Södertälje	13	13	12	11	12	121	39,3	25,6	41,7	118,0	41,3	6,6
Carlanderska Gbg	8	8	8	8	12	135	44,5	20,0	37,3	112,9	48,9	1,5
Ljungby		13	12	16	11	112	39,2	19,6	40,3	130,2	37,5	3,6
Varberg	12	15		14	11	59	41,6	27,1	40,7	n.a.	40,7	3,4
Aleris, Motala			12	10	11	152	41,1	13,8	40,4	121,7	52,6	0,0
Norrtälje	8	8	9	9	11	111	40,8	28,8	41,4	n.a.	39,6	0,9
Bar. Cent. Skåne	7	13	16	9	10	227	38,5	16,7	41,1	127,6	37,0	0,9
Axess Med., Simrish.					10	476	38,3	17,2	41,2	136,5	37,2	0,0
CFTK, Sthlm					10	236	41,4	13,1	35,5	113,2	37,7	2,1
Bar.Centr.Sophiah., Sthlm	10	11	11	8	8	332	40,8	19,9	40,3	120,7	36,4	0,6
Blekinge-Karlshamn	10	7	8	8	8	86	38,0	19,8	40,5	121,3	26,7	1,2
Österlenkirurgin, Simrish.					8	103	42,5	10,7	35,6	112,5	31,1	0,0
<i>National average</i>		<i>17</i>	<i>17</i>	<i>16</i>	<i>14</i>	<i>7508</i>	<i>41,0</i>	<i>23,4</i>	<i>41,4</i>	<i>124,7</i>	<i>52,1</i>	<i>3,2</i>

