The IFSO Global Registry

First IFSO Global Registry Report

2014

Prepared by

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Preface: Big Data demands Big Questions

The past 2 decades have seen the world engulfed by a pandemic of overweight and obesity, with the emerging economies as severely affected as the advanced [1]. Beyond the individual toll of disabling illness [2] and reduced lifespan [3] lies a major health-economic and socio-economic burden [4]: it is intuitive that the most severely affected individuals are the greatest contributors to this cost.

Surgical treatment demonstrably improves the health and life expectancy of those who suffer from Severe and Complex Obesity, a protean disease of civilisation. Surgeons and patients alike are convinced of this truth and few can contradict: over 340,000 operations were performed worldwide in 2008 [5].

Such a volume should yield really good information. Several good national registries have emerged, yet at the global level there is such diversity between patients, healthcare systems, preferences of patients and predilections of surgeons that the signal-to-noise ratio in this **Big Data** has hitherto been poor.

The present report is a bold and outstanding approach to processing this signal: diverse data from around the world have been painstakingly collated and filtered for their similarities. The *differences* uncovered are intriguing and themselves challenge to lateral thinking, but real persuasive impact comes from the *addition of the similar*, precisely because it speaks in spite of diversity.

The current project pilot breaks new ground: of course it demonstrates the ability of modern data systems and experienced analysts to filter the background noise of diversity and to offer more secure answers to old questions.

Beyond that however the upward shift in magnitude of data that, if collected, can be interrogated challenges to define the new questions that must now be asked.

These are interesting times for the global bariatric community and its representative body, IFSO.

Alberic Fiennes
President of the European Chapter of IFSO
Immediate Past President, British Obesity & Metabolic Surgery Society (BOMSS)
Foundation Chairman of the Data Committee, UK National Bariatric Surgery Registry (NBSR)

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Foreword

The epidemics of obesity and metabolic syndromes like type-2 diabetes are not sparing any part of the World. According to the World Health Organization (WHO), non-communicable diseases (NCD) kill more than 36 million persons each year, most before the age of 60; will the United Nations Millennium goal to decrease those estimates be reached? A recent National Institute of Health (NIH) study has reported that extreme obesity is shortening life expectancy in certain groups by 14 years. The economic burden of such health problems is estimated to be 190 billions of dollars *per* year in the United States alone (Harvard School of Public health, 2005) and rising rapidly in extremely populous countries like India and China. All efforts are needed to control NCDs, and since the WHO is developing a comprehensive global programme for monitoring prevention and control of non-communicable disease, surgical interventions should be counted.

Surgery is the only hope for this decade, and the early part of this century, to decrease this epidemic. We have decided to tackle this in a worldwide fashion, and since IFSO (International Federation For The Surgery of Obesity & Metabolic Disorders) is now 20 years of age, we need to know how extensive is the practice of bariatric and metabolic surgery across the globe, and how effective it is in different regions?

Lack of monitoring, the need for an accurate database from numerous countries, more specifically the outcomes and health systems responses have prompted IFSO to establish a registry. At the start of this project, within 4 months, 3 national registries were uploaded successfully (Sweden, United Kingdom and Russia), with the additions of individual centres and contributors, representing a total of 18 countries, with more than 100,000 patients. Although, at this time, IFSO is made up of 60 national Societies, it is expected that in the near future, this registry will encompass far more countries and a larger cohort of patients (>half a million to 1 million patients).

This was all permitted by a generous grant from Dendrite, under the leadership of Dr Peter Walton and his fantastic team. The Dendrite software technologies have enabled the merging of national, local and individual registries, into a unique merged dataset with intelligent analysis. In fact, the story started by solidifying a concept that took form after a meeting at the Royal Society of Medicine, in Wimpole street in London, on August 9, 2013, and presented to the executive board of IFSO in Istanbul at the end of the same month. By September 13, 2013, the industrious executive board of IFSO, under the presidency of Luigi Angrisani of Napoli, has approved the Dendrite Proposal to commence a Global IFSO Registry Pilot Project with a report to be presented at the 19th World Congress of IFSO in Montreal, Canada (August 26-30, 2014). After some discussion, the founding charter of the IFSO global registry was approved on January 22, 2014, and invitation letters were sent to worldwide participants on February 12, 2014, and data gathered until mid-June.

The present reported analyses, with the expertise of members of the Steering committee Richard Welbourn, Ingmar Naslund, Johan Ottosson, and Peter Walton with a special contribution from Robin Kinsman (Dendrite's Senior Data Analyst), have taken the data and presented it nicely for readers. With the First IFSO Global Registry report in hand, over 100 pages describe demographics, presence of comorbidities, and type of surgery, post-operative outcomes, and follow up data. We have some description of post-operative stay *per* country and region, as we know there are regional and cultural differences in this aspect. In addition, this report presents follow up data, outcomes on weight loss are given at 1 year (we know it is short, but it is the beginning!), as well as comorbidity resolution.

But, as the late Canadian economist John Kenneth Galbraith used to say:

> *Do not be alarmed by simplification, complexity is often a device for claiming sophistication, or for evading simple truths.*

Congratulations on the first report.

Michel Gagner

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Senior Consultant, Hopital du Sacre Coeur, Montreal, Quebec, Canada

President, Clinique Michel Gagner, MD, Inc.

Director of the IFSO Global Registry

President, IFSO 2014 - 19th World Congress of IFSO, Montreal, Canada

IFSO Global Registry: an Australian bariatric physician's perspective

Surgical registries have had an extraordinary impact on evaluating and positively influencing numerous areas of surgical care. Understanding trends, providing quality assurance, allowing timely evaluation of innovation, monitoring devices, and examining and understanding outliers are all vital roles of registries in delivering positive health outcomes and assuring public and stakeholder confidence. Unlike medical drug therapies, surgery is rarely subjected to large randomized controlled trials: innovation is often incremental, and not all in a positive direction, and long-term *post marketing* surveillance of surgery is not assured. For example, the collection of sufficient evidence to formally support the change in cholecystectomy from a routine open approach to a routine laparoscopic approach took 20 years from the time the original innovation was introduced [1]. The development cycle in bariatric-metabolic surgery is short, generating a need for timely assessment of trends and innovation.

Bariatric surgery provides specific challenges that increase the need for excellent long-term surveillance. Bariatric surgeons are not excising diseased or dysfunctional tissue; blocking, unblocking or repairing a bodily conduit; restoring dysfunctional or damaged anatomy; or implanting a device to restore function. They are treating a chronic metabolic disorder by targeting organs that are neither diseased nor necessarily dysfunctional. The responsibility to understand the consequences of what we are doing is critical to public confidence in this rapidly evolving area of surgery. We have the global challenge of rapidly increasing numbers of eligible patients with modest overall growth in bariatric surgery over recent years, but have many more bariatric surgeons, institutions and countries sharing the load [2-4]. The percentage of eligible patients undergoing bariatric surgery is very low, generally less than 2% annually in regions of greatest uptake, and trivial globally. Within countries, regional and socio-economic factors have a major influence on availability and uptake [5, 6]. At a public health level any effect would be negligible.

Given the impressive results that we believe bariatric surgery provides, and that it is considered the best, or only, effective therapy available for a range of eligible patients, we must consider some important questions. Why is uptake so low? Why do we not have a group of patients where bariatric surgery would be recommended as responsible best care; a group that caring physicians would be obliged to offer a referral for a surgical opinion? When would not providing access be negligent? We all know of our responsibilities when confronted with patients with other serious chronic conditions, but somehow clinically severe obesity is different. There is clearly an issue of confidence. Those working in the bariatric surgical area may have misplaced confidence in the therapy provided, or a well justified confidence, but have they have not shared, or marketed, this effectively to healthcare providers. What is clear is that broader healthcare providers, payers, health practitioners, and patients do not share the confidence of those working directly in the bariatric surgical area. Our patients and their local stakeholders need to have confidence in bariatric-metabolic surgery, a confidence not derived from model practice in another country. Real world, local data in the context of the big picture is a valuable resource. Simply contributing to a surgical registry inspires confidence, demonstrates integrity, oversight, and quality assurance. Indeed, impressive local results may demonstrate the need for increased bariatric surgery capacity to accommodate a growing demand.

The First IFSO Registry Report has contributions from 18 countries and represents national data from the United Kingdom, Sweden and Russia. This first report clearly demonstrates:

- Commitment to move forward and provide an opportunity to engage the global bariatric community to contribute and share data. This is particularly important for countries and regions without registry access.
- Willingness for many nations to contribute to a global registry.
- Ability for the current registry software to upload data from multiple established sources and provide a data entry platform for those with no current database.
- Capacity to merge data and generate analyses of interest.

This is an exciting start to an important international journey; a commitment that will need to be flexible, innovative, provide leadership, and serve the needs of the global bariatric community in monitoring and improving patient outcomes.

Minimal dataset

Registries need to engage a minimum required dataset for each patient as part of entry. Bringing disparate datasets together has delivered an extremely minimal dataset, and this will need to change. The minimal dataset should only include fundamental elements needed to define critically important outcomes such as early morbidity

& mortality, surgical reoperations and revisions. The composition of any minimal dataset will be controversial, as today there is no consensus in presenting weight loss [7,8]. We also need to consider the value in collecting poor quality, for example non-objective, data on obesity-related comorbidity, when this quality data can be accurately sourced from a small sub-study. I commend the efforts of the England NHS-funded By-Band RCT study group for taking on the detailed task of developing a minimal dataset for reporting bariatric-metabolic surgery randomized controlled trials as this should provide excellent guidance for the global registry. A minimal dataset does not preclude collecting detailed data on a specific topic; for example, examining in detail the early outcomes of a newly-introduced gastrointestinal device or procedure.

There are limitations to the current data and analysis. Much of the data has been uploaded retrospectively; only limited countries can provide rigorous post-operative mortality data; and the method and integrity of data entry varies. However, this first report sets the scene, enables clear trends to emerge, and provides a roadmap for the future.

Observations from the current analysis

Publicly funded bariatric-metabolic surgery dominates in Europe with high levels of privately funded surgery in Asia, the Middle East and South America. Areas with high levels of public funding tend to operate on patients with a higher baseline BMI and are more likely to also report diabetes, hypertension, depression, musculo-skeletal pain and obstructive sleep apnoea. In Asia, BMI levels are generally lower and the proportion of patients with diabetes is higher, as might be expected given the greater propensity for diabetes at a lower BMI in Asian communities. European countries, specifically the United Kingdom, Germany and Spain, operate on a higher proportion of patients with a higher surgical mortality risk, probably reflecting prioritisation within publicly funded health services.

The three most commonly used procedures are almost always performed laparoscopically. There also appears to be extraordinary polarity with regard to procedure selection. In Sweden and the Netherlands the Roux-en-Y gastric bypass dominates (>90%) while in Peru and Saudi Arabia sleeve gastrectomy are performed almost exclusively. Of course, in some countries this may be related to the surgical practices currently contributing to the registry. There is a striking variation in the rate of reported re-operative surgery with 40% from France and less than 1% from Germany and Brazil. Clearly differences are likely to be related to bias generated by national reporting requirements, an issue which needs attention. However, the two large national contributors to the registry (the United Kingdom and Sweden) also have substantial differences in the proportion of re-operative surgery being performed.

Post-operative results

Weight loss results at one year demonstrate the overwhelming bias that BMI generates with percentage of excess weight loss. This reporting method, while distorted, implies a uniform *ideal weight* for all, but, this is not the case, as ideal BMI for mortality varies with age, ethnicity, and state of health [9]. Percentage weight loss provides a more comparable picture and thankfully demonstrates a lower percentage weight loss in those of lower baseline BMI & a trend for the highest loss in the *super obese*. The weight loss results are as expected from the published literature and provide a *real world* result that individual practices could use as a standard for one year following surgery.

Changes in the presence of comorbidity or medications used for comorbidity are also as reported in the literature but, speaking as a bariatric physician, we should be very cautious with this approach. All comorbidity must be measured objectively and there is no guarantee that patients who have stopped therapy for diabetes, hypertension, dyslipidaemia, depression, or obstructive sleep apnoea do not need their therapies. The aim of bariatric surgery should be to deliver better health, not to stop other highly effective therapy. There is clear evidence that post bariatric surgery remission of diabetes is not necessarily permanent; incident hypertension is not affected, with weight loss having a modest and variable effect on blood pressure; commonly-used procedures have small, if any, influence on total cholesterol or LDL-cholesterol; and obstructive sleep apnoea can be improved, but is rarely cured by bariatric surgery. Depression levels fall following bariatric surgery, but risk of suicide appears to increase with some modalities. In my view, monitoring comorbidity, while attractive, may not be a core role for bariatric registries. Registries do provide a platform to add on very detailed data collection on a specific topic or comorbidity, within a specific group, or in assessing innovation thereby providing excellent opportunities for high-quality clinical research.

Registries are of greatest value when the fundamental data are complete. Clearly, prospective data need to be sourced from all participating surgical practices on every patient. National registries are ideal and I would encourage all countries or regions to develop registries as a priority, and through these have their data seamlessly extended to the IFSO global registry. There will always be a need to provide direct access to the registry for

individual practices without an alternative. At this stage retrospective data entry from both individuals and registries has been valuable in providing clear evidence of successful data upload, integration and analysis; and is already providing a large enough caseload from many countries to generate interesting comparisons and trends.

In conclusion, I applaud this first report of the IFSO global bariatric surgery registry. It marks an historic first step in bringing together real world data from around the globe. It will provide essential support in understanding risk stratification, and refining those most likely to benefit from surgery. It will allow new procedures to be assessed, devices to be tracked, and provide information regarding surgical learning curves, and may define minimal surgical workloads for surgeons and their institutions. It will enable morbidity, mortality, complications and reoperations to be assessed, allow the development of clinical standards and benchmarks, detection of outliers, and provide valuable quality assurance locally and globally. Ultimately, it informs a broad range of stakeholders of the risk and benefits of surgery, while generating data to inform measurable improvement in the health outcomes of patients. The report strongly endorses the concept of a global registry. Now for extending its reach, refining the prospective data collection, and providing durability of the registry and data collection.

John Dixon

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Chairman's introduction

It is a privilege to present data on baseline obesity-related disease, operation types, operative outcomes and disease status after bariatric surgery in over 100,000 patients accumulated from 25 local and national databases and registries from all over the world. This initiative of IFSO, the first of its kind, could help the bariatric community establish essential benchmark knowledge about the patients we are operating upon, their age and gender distributions, body mass index (BMI) and disease burden, as well as track trends in surgery over time.

The data are presented not as the standard *Abstract*, *Introduction*, *Methods*, *Results*, *Discussion* and *Conclusions* format of a peer-reviewed publication. Rather, using a small and necessarily far from comprehensive dataset, we present the data as simple tables and graphs using usually 2 variables, one for each axis, plus a dedicated commentary for each. Even though this is a very basic presentation of data, many of the results demonstrate clear and important differences in bariatric practice between countries.

A comprehensive *Charter of ownership* has been set up regarding use and ownership of the accumulated and merged data, and contributors can be assured that we have steered well clear of attempting to make statistical comparisons between different units and countries, and that their submitted data will not be misused. We are also fully aware of the inherent problems of over interpretation and reading too much into the data (see page 25 for a discussion of the challenges of missing, incomplete or erroneous records). Statistical comparison and analysis between countries was not the purpose of data collection (see our aims on page 24) in this first iteration of the process.

If there are to be further developments and reports for the IFSO Global Registry, attractive aims could also include agreeing and developing models of risk stratification and the setting of international benchmarks for post-operative complications or mortality. The Registry could help in these aims by standardizing data collection. As it progresses, the data it contains might also be useful in influencing policy internationally and increasing service provision in countries where there is little or no bariatric surgery.

I encourage all key stakeholders in bariatric surgery (especially surgeons, providers and commissioners of care) to embrace this data collection and reporting process at individual clinics and hospitals, and onwards / upwards at both national and international levels. It will require widespread involvement and on-going commitment from all those involved in the care of the bariatric patient to ensure high-quality data can be collected, properly analysed and shared, so that we will be better able to understand shifts in disease patterns, practice and outcomes on a global scale.

Thank you to all those surgeons who have committed their data for inclusion in this first pilot report, your contribution is very much appreciated.

Richard Welbourn

Chairman of the IFSO Global Registry Database Committee

President, British Obesity & Metabolic Surgery Society (BOMSS)

Chairman of the Data Committee, UK National Bariatric Surgery Registry (NBSR)

Executive summary

This is the first comprehensive, international analysis of outcomes from bariatric (obesity) and metabolic surgery, gathered under the auspices of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

In overview

- 18 countries from 5 continents contributed 100,092 operation records, with 53,197 in the calendar years 2011-2013
- The number of operations contributed ranged from one individual centre that entered 24 operation records to over 34,000 each from two countries with established national registries (Sweden and the United Kingdom)
- The report details information on 65,636 gastric bypass operations (65.6% of the total operations submitted), 16,735 sleeve gastrectomy operations (16.7%) and 12,365 gastric banding operations (12.4%)
- Most database entries represented operations performed in the period 2011-2013 (53,197, 53.1% of the total) and therefore likely represent the current status of bariatric surgery in these countries

The dataset and completeness of data entry

- A simple dataset of only 30 (23 baseline / 7 follow up) variables was created.
- Overall more than 79.3% of the submitted baseline records were >80% complete, a remarkable achievement for the first iteration of an international collaboration in surgery.

Funding and gender inequality

- Overall 63.1% operations were funded by public health services of each contributor country and 36.9% were funded privately; there was wide variation in the rate of public funding (range: 0.0-100.0%), suggesting inequality of access to surgical services.
- There was also wide variation in the gender ratios of patients having surgery, ranging from 48.2% female patients in China to 80.7% female patients in the Netherlands.

Primary operations in the calendar years 2011-2013 and BMI range

- The average BMI of operated patients was 44.4 kg m^{-2} (inter-quartile range: 38.9-48.7 kg m^{-2}), the average age was 42.1 years (inter-quartile range: 34-76 years) and the average proportion of female patients was 74.4% (range: 47.3-80.8%).
- There was wide variation in the average initial body mass index (BMI) between different countries, ranging from 39.6 kg m^{-2} in Chile to 53.4 kg m^{-2} in Germany for male patients; and 36.1 kg m^{-2} in Peru to 49.1 kg m^{-2} in Germany for female patients.
- The centres submitting data from Mexico (92.2%), the Netherlands (94.0%) and Sweden (96.3%) had the highest proportion of gastric bypass operations and those submitting data from Peru (100.0%), Saudi Arabia (100.0%) and India (91.1%) had the highest proportion of sleeve gastrectomy surgery.
- A very large proportion of all operations (97.3%) were carried out laparoscopically and 91.2% of gastric banding patients were discharged by post-operative day 1; 91.6% of gastric bypass patients by day 3; and 88.3% of sleeve gastrectomy patients by day 3.
- The overall reported mortality for all operations was 0.03%.

Comorbidities

- Treatment for type 2 diabetes was reported more frequently in male patients (with the exception of France), but there was wide variation in reported rates. The average rate of diabetes was 30.5% for males (range: 5.4-57.1%) and 16.8% for females (range: 8.3-30.3%).
- Hypertension was more common in male patients in every country, but there was wide variation in reported rates. The average rate of hypertension was 46.9% for males (range: 21.4-67.9%) and 28.1% for females (range: 0.0-48.1%).

- Depression was more common in female patients (with the exception of Saudi Arabia), but there was wide variation in reported rates. The average rate of depression was 11.2% for males (range: 0.0-28.6%) and 19.3% for females (range: 0.0-41.7%).
- Musculo-skeletal pain did not show a significant gender difference, but there was wide variation in reported rates. The average rate of musculo-skeletal pain was 23.3% for males (range: 0.0-68.2%) and 25.1% for females (range: 0.0-48.1%).
- Sleep apnoea was more common in male patients (with the exception of Germany), but, again, there was wide variation in reported rates. The average rate of sleep apnoea was 29.4% for males (range: 3.8-86.5%) and 11.2% for females (range: 0.0-52.9%).

Stratification for operative risk

The Obesity Surgery-Mortality Risk Score (OSMRS) varied widely between the submitting countries. Operated patients in Peru, Chile and United Arab Emirates appeared to have least risk (OSMRS Groups B & C: 21.9%; 23.6%; and 26.2% respectively) while patients from Spain, Germany and the United Kingdom appeared to have the highest risk (OSMRS Groups B & C range: 54.8%; 57.7%; and 57.9% respectively).

Follow-up data derived from some 191,387 follow-up entries show

- One year after primary surgery performed in 2009-2013, the average percentage excess weight loss was 75.9% (inter-quartile range: 58.6-90.5%) for all operations; the equivalent percentage weight loss was 30.5% (range 25.3-36.5%).
- The available two-year data after primary surgery showed the average %EWL was 76.4% (inter-quartile range: 59.2-94.4%) for all operations; the equivalent % weight loss was 31.4% (inter-quartile range: 25.0-38.5%).
- For the severely obese patient these weight loss results are far better than can be achieved by dieting alone. For these people, medical therapy, lifestyle changes and attempts at dieting rarely succeed in maintaining long-term, clinically beneficial weight loss due to the hormonal effects of the obese state, dieting, energy balance and metabolic rate.
- One year after primary surgery 65.8% of patients recorded as taking medication for diabetes beforehand were no longer on medication, implying in practice, that they no longer were considered diabetic. There was no substantial gender difference in recovery in diabetes.
- The rate of diabetes one year after primary surgery was highly dependent on weight loss.
- One year after primary surgery, 46.0% of patients recorded as being on medication for hypertension initially were off medication; there seems to be a near linear relationship between the rate of patients still medicated for hypertension and weight loss.
- There were also reductions in recorded rates of depression (38.1% no longer medicated one year after surgery), musculo-skeletal pain (50.2% no longer medicated one year after surgery) and sleep apnoea (71.6% no longer treated using CPAP/ BiPAP one year after surgery).
- As an example of the type of analysis that can be done, %EWL and %WL at one and two years after gastric bypass were compared between the two largest contributors to the IFSO Global Registry (Sweden and the United Kingdom); there were no significant differences.

Implications for bariatric surgery

- A simple dataset and the willingness of many centres in different countries to contribute can lead to a large body of pooled and merged data.
- This first report quantifies the gender inequality evident worldwide and also shows inequality of access to surgery in many countries.
- For the first time on the scale of a large international collaboration, the data on improvement in diabetes demonstrate the profound treatment effect that bariatric surgery has on this disease.
- Therefore, this initiative may be useful in advancing the status and acceptability of bariatric surgery worldwide and suggests many international research projects that could be undertaken.

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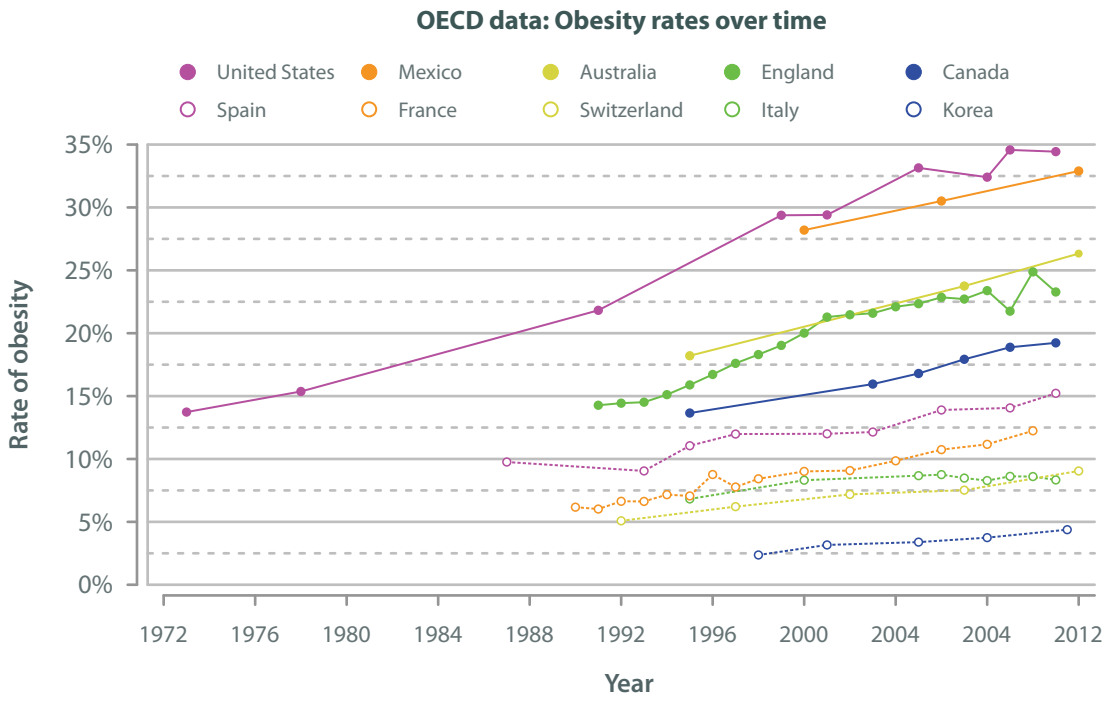
GLOBAL REGISTRY

Obesity across the world

Obesity and bariatric surgery

According to the World Health Organisation (WHO), worldwide obesity has nearly doubled since 1980 [1]. In 2008, 1.4 billion adults (aged 20 years and older) were overweight, with 200 million men and nearly 300 million women classified as obese. More recent research has claimed that the number of people in the world who are overweight or obese has almost tripled in the last 30 years, increasing from 857 million in 1980 to 2.1 billion (or one-third of the global population) by 2013 [2].



Since 1980, the number of adults (aged >20 years) who are overweight or obese has risen from 28.8% to 36·9% in men, and from 29.8% to 38.0% in women [2].

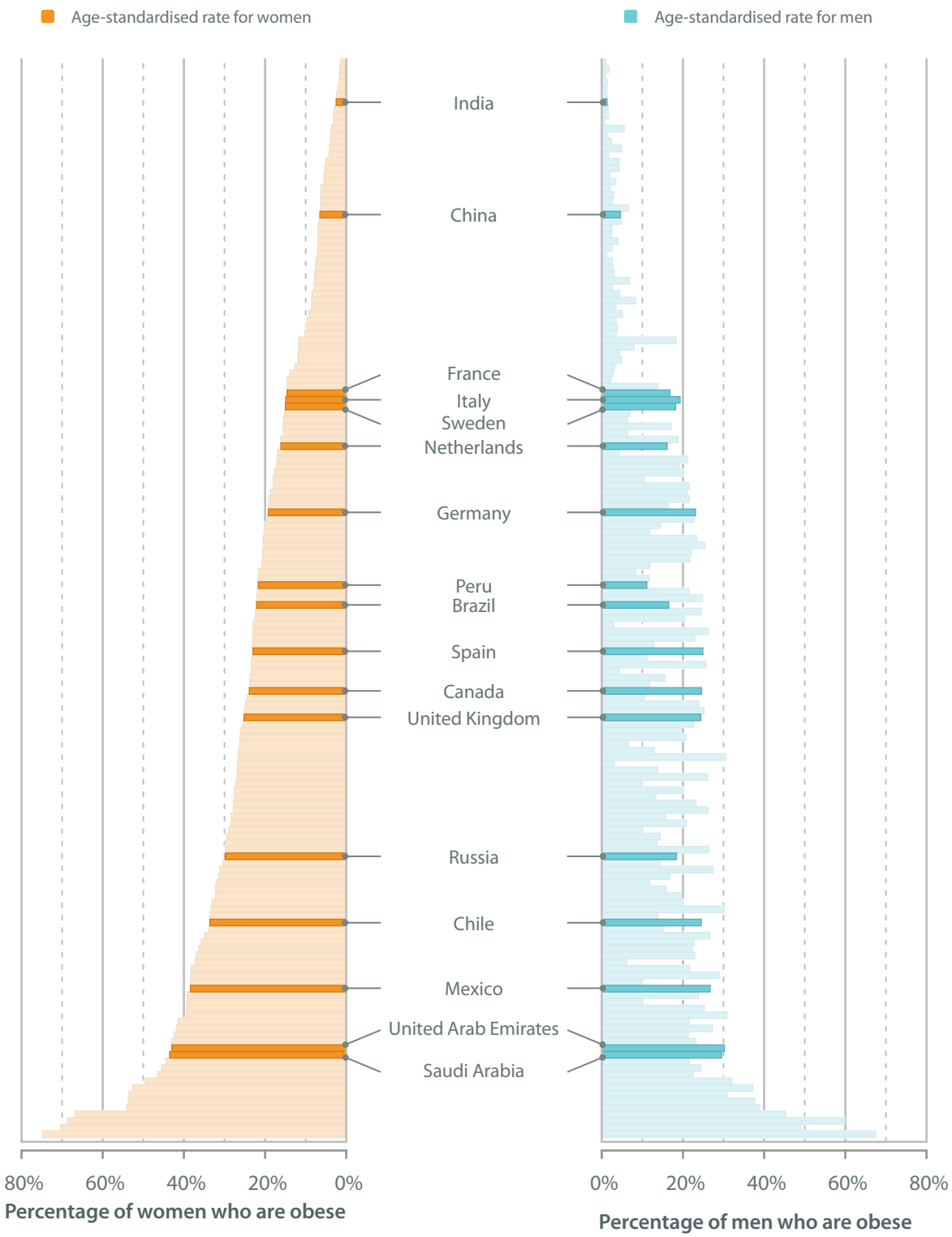
The highest estimated rates of overweight / obesity and obesity in males were in Tonga (83.5% and 52.4% respectively); the highest proportion of females who were overweight / obese (88.3%) was also in Tonga. The highest reported rate of obesity (69.1%) for women was in Samoa [2].

Of the countries featured in this report, Saudi Arabia had the highest rates for men and women (male overweight / obese 69%, male obesity 30%; female overweight / obese 74.4%, female obesity 44.4%).

Of the estimated 671 million obese people in the world, more than 50% live in just ten countries: USA, China, India, Russia, Brazil, Mexico, Egypt, Germany, Pakistan, and Indonesia. The USA has 13% of the total worldwide obese population, with China and India jointly accounting for 15% [2].

The increase of overweight and obesity rates has occurred in both developing and developed countries. Interestingly, more men were reported to be overweight or obese in developed countries, whereas the opposite was true for women in developing countries [2].

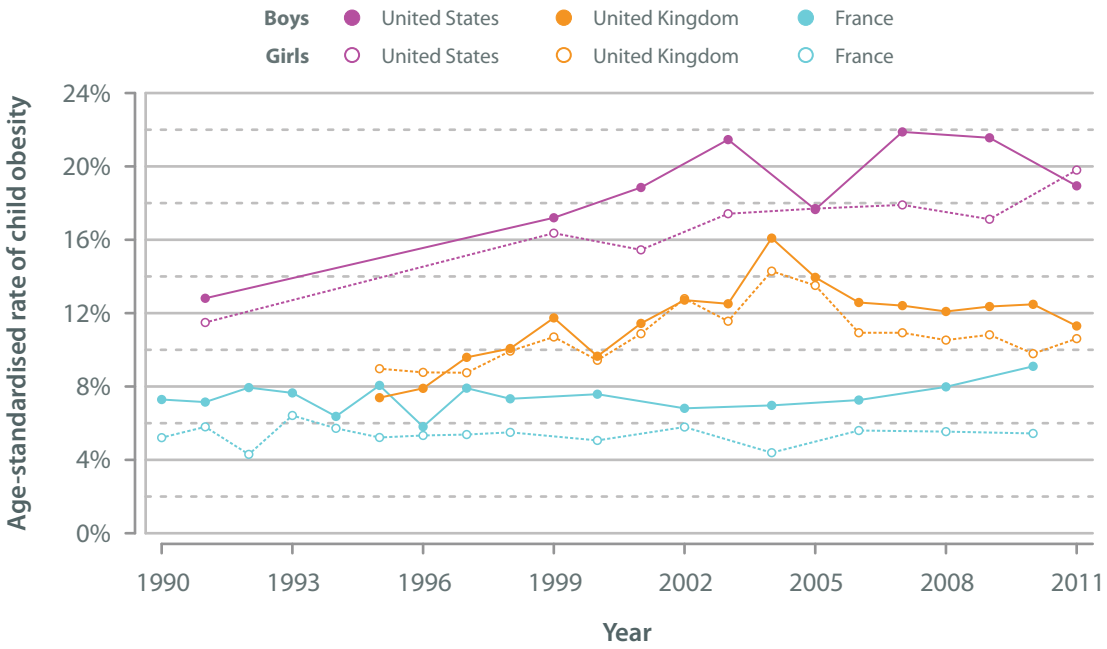
WHO data: Gender and obesity by country for those over the age of 20 years; 2008



Childhood obesity

Rates of overweight and obesity in children have risen more than in adults, increasing by 47% between 1980 and 2013 [2]. The main increase was found in developed countries with the overweight / obese rate increasing from 16.9% to 23.8% for boys and 16.2% to 22.6% for girls. Rates of overweight and obesity in children have also increased in developing countries, from 8.1% to 12.9% for boys and from 8.4% to 13.4% for girls.

OECD data: Changes in rates of childhood obesity in three countries; children aged 3-17 years



Future predictions

Data from the Organization for Economic Cooperation and Development (OECD) suggests that there is some evidence that overweight and obesity rates may have started to stabilise in Italy, England and the United States. Nevertheless, the increase still continues unabated in Mexico, Canada, Korea, Spain, Australia and Switzerland [3].

There is some addition evidence to support the notion that obesity rates may be slowing, or may have plateaued [3, 4, 5, 6, 7]. However, other research has predicted that overweight and obesity rates will continue to increase [8, 9].

A recent study forecast that most parts of Europe would see rising numbers of people carrying excessive weight by 2030 [8]. In almost all countries the proportion of overweight and obesity in males was projected to increase between 2010 and 2030 to reach 75% in United Kingdom, 80% in Czech Republic, Spain and Poland, and 90% in Ireland, the highest level calculated. The lowest male obesity prevalence was projected in Romania (10%).

The lowest projected levels of overweight and obesity were found in Belgium (44%), and the Netherlands (47%). Similar trends in overweight and obesity were projected in women, with Ireland showing the greatest proportion (84%).

In the United States, despite some reports to the contrary [4, 5, 6, 7], obesity rates are predicted to rise and by 2030, 42% of Americans will be obese and 11% of Americans will be severely obese [9].

Obesity and mortality

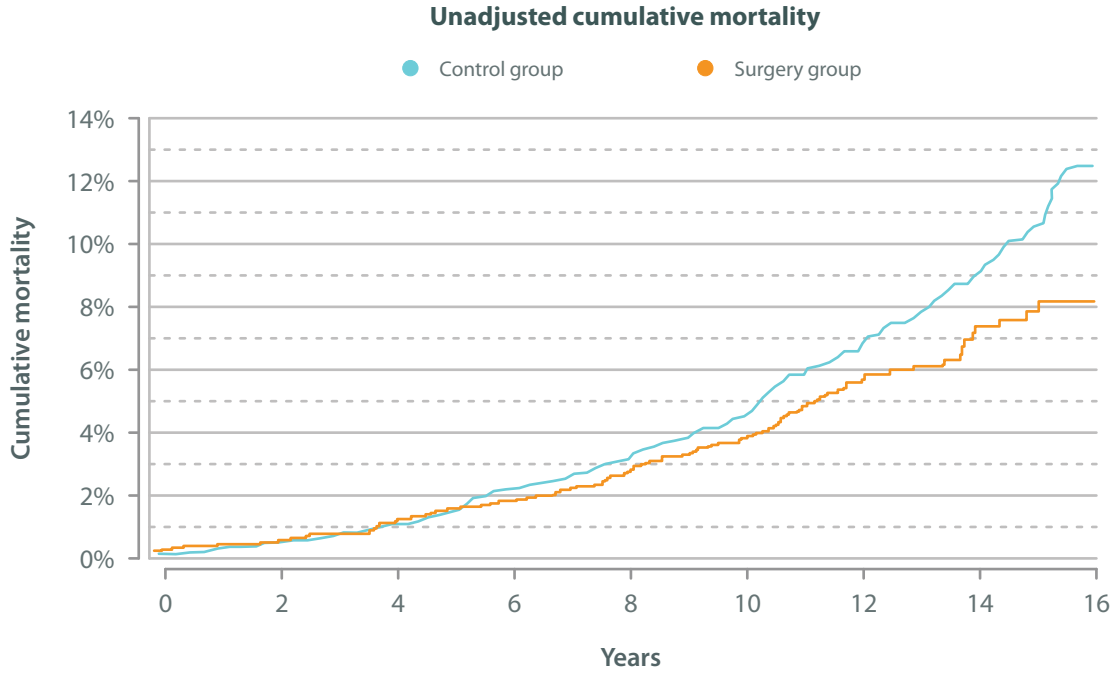
The World Health Organisation (WHO) claims that overweight / obesity is one of the leading risks for global deaths, accounting for some 3.4 million adult deaths annually. In addition, overweight / obesity also accounts for 44% of the diabetes burden, 23% of the ischaemic heart disease burden and between 7% and 41% of certain cancers [1].

A recent analysis concluded that mortality increases once individuals cross the overweight threshold [10]. For example, an obese person (with a BMI 40.0-44.9 kg m^{-2}) could have their life expectancy to be reduced by eight to ten years, compared with a person of normal weight (BMI 19.0-24.9 kg m^{-2}). A person with a BMI in the range of 55.0-59.9 kg m^{-2} would see their life expectancy reduced by almost 14 years.

The study also found that an overweight person of average height will increase their risk of death by approximately 30% for every 15 additional kilograms of weight. These reductions in life expectancy mirror the loss of life suffered by smokers, as obesity increases the risks of dying at a young age from cancer, heart disease, stroke, diabetes, and kidney and liver diseases [1].

There is currently no effective treatment for obesity other than general lifestyle advice to continue dieting. However, it is now accepted that the effects of dieting are modest: the 2014 NICE Public Health Guidance (PH53) indicates that people attending a lifestyle weight management programme only lose around 3% of their body weight, and accepts that weight loss of more than 5% is needed to gain substantial benefit, and this weight loss needs to be maintained life-long to keep the benefit [11]. Given that worldwide efforts to prevent or treat obesity have consistently failed, invasive techniques (surgery) need to be taken seriously.

This graph from the long-running Swedish Obese Subjects (SOS) studies [12] shows the cumulative mortality for 2,010 patients who chose to have bariatric surgery compared to 2,037 matched controls who did not have surgery. The difference in survival between the two groups was statistically significant (p=0.04). The patient groups were not randomised since in 1987, at the time the study began, only open surgery was available and it was not considered ethical to do a randomised study in bariatric surgery.



The potential role of bariatric surgery

Bariatric surgery is now established worldwide as an effective treatment for severe and complex obesity. It is estimated that more than 340,000 procedures were carried out by more than 6,700 surgeons worldwide in 2011 [13]. A systematic review of survival benefit, as well as 2 important studies in the New England Journal of Medicine, demonstrates that bariatric surgery provides survival benefit compared to no surgery [14, 15, 16]. In addition, scientific evidence is accumulating that bariatric surgery is far more effective than medical therapy and constant cycles of dieting at helping patients keep weight off in the long term, and effectively treats obesity-related disease such as type 2 diabetes. In long-term studies surgery patients maintain 25-30% weight loss at 10 years or more compared to 4.7 % at 8 years for Intensive Lifestyle Intervention [12, 17].

In practice, most patients having surgery will have spent a lifetime trying to diet with inevitable yo-yoing, recidivism and rebound weight regain up to a higher level, according to the hormonal effects of the obese state, dieting and consequent changes in energy balance and metabolic rate [18]. In one study, patients had dieted for an average of 22 years and had a net gain of 55 kg at the time of surgery, despite also losing 61 kg in multiple weight loss attempts in the intervening years [19].

The effect of bariatric surgery on diabetes and other obesity-related disease

The fact that type 2 diabetes can be effectively treated by an operation is still neither understood nor appreciated by most clinicians or commissioners. There is level 1 evidence (meaning randomised controlled trials, systematic reviews and meta-analyses) that surgery is superior to medical therapy in improving diabetes control and the metabolic syndrome [20]. Surgery reduces the number of hypoglycaemic medications required, including getting patients off insulin therapy. Simply considering the reduced costs of diabetes treatment, bariatric surgery pays for itself within 2-3 years. So, it is very important that priority is given to bariatric surgery as a treatment option purely from the economic perspective of the tax payer. Surgery can also put many patients into remission (normal HbA1c, normal fasting glucose, off all medication, relative risk 22.1) and markedly reduce incident diabetes compared to matched patients not having surgery [12, 21].

The gastric bypass has been called the equivalent of a free injection of GLP-1 for life. The International Diabetes Federation even recommends bariatric surgery as: an appropriate treatment for type 2 diabetes and [patients with] BMI ≥35 not achieving recommended treatment targets with medical therapy, especially where there is other obesity-related comorbidity [15].

It is also accepted that the BMI threshold for bariatric surgery may be reduced by 2.5 kg m^{-2} for Asian patients due to their greater susceptibility to diabetes and metabolic syndrome. Bariatric surgery is also very effective at reducing the number of anti-hypertensive medications required by patients, probably for several years, but the indications are that over time, as patients get older, they will eventually go back on treatment. All the other comorbidities associated with obesity show improvement, with patients stopping treatments [22]. Fertility is known to improve in those female patients with polycystic ovarian syndrome. Surgery also reduces the risk of cardiovascular events and the risk of gynaecological cancers [23]. It also restores functional capacity: in the First United Kingdom Registry Report to March 2010 on data from 8,000 patients with an average BMI of 47 kg m^{-2}, 70% were unable to climb 3 flights of stairs before surgery; one year later, half of these patients were no longer functionally impaired. Surgery in the United Kingdom is safe, with a mortality rate of around 1 in 1,000, according to external validation (Hospital Episodes Statistics data), which is less than many more common gastrointestinal procedures [23].

It is the remarkable effect of bariatric surgery on improving the metabolic syndrome (type 2 diabetes, hypertension, dyslipidaemia and polycystic ovarian syndrome) that spurred a change in emphasis away from the old-fashioned term weight reduction surgery, which carries social stigma and prejudice, to the current term metabolic surgery, (hence BOMSS, the British Obesity & Metabolic Surgery Society; and ASMBS, the American Society of Metabolic & Bariatric Surgery), indicating it is an intervention that happens to be an operation, and that treats and cures disease.

Different types of bariatric procedures

The 3 commonest bariatric procedures worldwide are Roux-en-Y gastric bypass (the commonest variety of this operation) at 46.6%, sleeve gastrectomy at 27.8%, and gastric banding at 17.8%. The bilio-pancreatic diversion with duodenal switch, an operation that works primarily through inducing malabsorption, comprises 2.2% of all bariatric surgery. Sleeve gastrectomy has increased in popularity from 5.3% in 2008 to 27.9% in 2011, and the rate of gastric banding has decreased from 42.3% to 17.8% in the same time period. The reasons for these trends are not known; however, the choice of operation appears to be largely determined by surgeon- and patient-preference, and the local expertise of each bariatric unit.

An illustration of each kind of surgery is shown below.

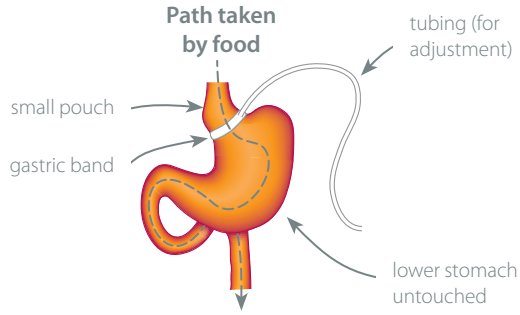


Fig. 1. Diagrammatic representation of a gastric band in place

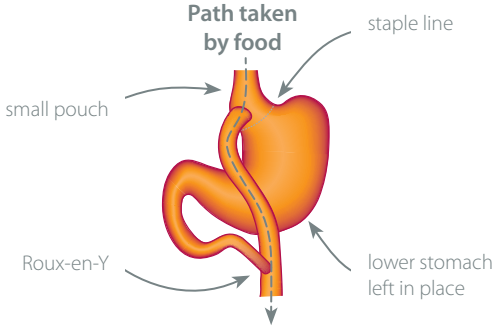


Fig. 2. Diagrammatic representation of a Roux-en-Y gastric bypass procedure

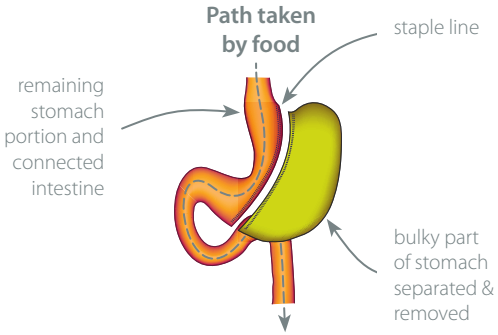


Fig. 3. The basics of a sleeve gastrectomy procedure

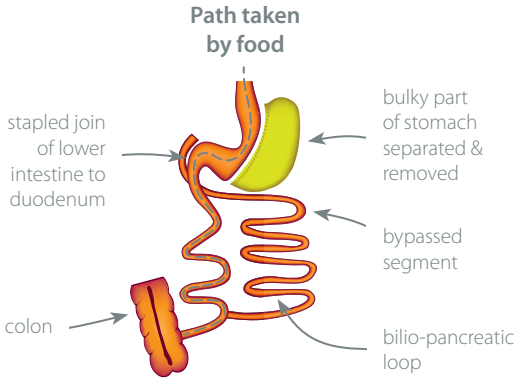


Fig. 4. Duodenal switch

There are many millions of patients worldwide who could benefit from bariatric surgery according to cost effectiveness analyses; however, the provision of surgery is a fraction of those even with a body mass index (BMI) over 40 kg m^{-2}, the upper thresholds according to the NIH, NICE and SIGN guidance.

Aims of this report

Bariatric surgery has great potential to improve health in a vast number of patients in a cost effective manner; however, it is made available to very few obese people who could benefit from it. Little is known internationally about which patients are being operated on, other than the worldwide survey of bariatric surgery undertaken by Prof Henry Buchwald [13]. Although we know from his surveys which operations are being performed, we do not yet know basic demographic data on variables such as gender distribution, starting BMI, and prevalence of comorbidities such as type 2 diabetes, hypertension and sleep apnoea. Nor do we have any data on surgical outcomes such as survival, length-of-stay or improvement in comorbidities on a registry level between different populations.

Therefore the aims of this project are to:

1. Establish that it is possible and feasible to combine large numbers of patient-records from different local and national database systems.
2. To demonstrate that the Dendrite Clinical Systems software is capable of providing a robust on-line data-capture platform and a parallel system for uploading data from a disparate collection of local and national database systems.
3. Establish that it is possible to analyse these data in a way that is meaningful, and that the results show important clinical differences that may be useful in promoting an increase in surgery provision.
4. Provide the basis for generating research questions for future investigation.

The data presented are not intended to be a definitive global representation of bariatric surgery, as data from many countries with large volumes of surgery are not yet included. However, the report is the start of a process that shows what can be achieved within the constituent countries of IFSO. For instance, the data could in future be used to estimate inequalities of provision of surgery internationally, and provide benchmarks for access to surgery to those people with specific obesity-related disease such as diabetes.

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Rationale for the IFSO Global Registry design

How it evolved and opportunities for future development

The Registry dataset came about as a result of a meeting between:

- Mr Richard Welbourn (representing the United Kingdom National Bariatric Surgery Registry; Chairman of the IFSO Global Registry Database Committee)
- Dr Ingmar Naslund (representing the Swedish Obesity Surgery Registry SOReg),
- Dr Johan Ottosson (representing the Swedish Obesity Surgery Registry SOReg),
- Dr Peter Walton (Managing Director of Dendrite Clinical Systems Ltd)
- Dr Robin Kinsman (Senior Data Analyst at Dendrite Clinical Systems Ltd)

held in England in November 2013. The dataset evolved from this meeting by e-mail conversation, in which Dr Michel Gagner (Director of the IFSO Global Registry) took an equal part.

Two guiding principles were adopted early in the design of the dataset:

1. It should be short and simple;
2. It should use variables most likely to be used already in existing national and local registries;

The intention was to maximise the appeal of contributing to the registry for different countries and centres, and to enhance the ease with which the uploading of data could be achieved.

The basic requirements for patient identification (generation of an anonymous patient number that is very likely to be unique) were date-of-birth (or age at operation), gender and date of operation. Clearly patient height and a weight (we decided on having initial weight on entry to the weight loss programme and as well as weight at the time of surgery to accommodate datasets where both were included) were likely to be universally recorded, as these are required for the calculation of the body mass index. The funding status appeared to be of interest, but we did not know if this was universally collected.

There was much discussion about which comorbidity data to include. Clearly type 2 diabetes status would be universally collected (we assumed); and hypertension and increased risk of deep vein thrombosis (DVT) and pulmonary embolus (PE) would be needed to calculate the Obesity Surgery-Mortality Risk Score: the only currently available risk stratification index. We did not include data on cardiovascular risk *e.g.,* a history of stroke, myocardial infarction, angina or peripheral vascular disease.

In order to keep the list short we added only 3 further variables: depression on medication, in order to encompass important baseline demographic information on psychological and psychiatric disease; musculo-skeletal pain on medication, as this is often a poorly-recognised aspect of severe obesity to our medical colleagues and public or insurance payers; and sleep apnoea, since the economic effects of this are considerable.

Rather than stratify the degree of each comorbidity (*e.g.,* impaired glucose tolerance or impaired fasting glycaemia, patients on oral hypoglycaemics or insulin and the duration of the disease for diabetes) we opted for a suite of simple yes / no responses. We hoped that this might still generate interesting clinical findings from a pooled and merged database representing information from many international centres. We specifically did not include laboratory measures of glycaemia *e.g.,* HbA1c, since the logistics of accumulating these data were thought to be far too complex and ambitious for the first iteration of such a project.

The dataset accommodated a wide range of bariatric operations so as to include many newer procedures, although it transpired that most operations recorded were gastric bypass, gastric banding and sleeve gastrectomy. It also seemed logical to collect information on the surgical approach (whether performed as a *laparoscopic* operation or as an *open* procedure or *converted* from laparoscopic approach to open procedure) and length of post-operative stay in hospital, as the latter has important implications for healthcare economists.

We chose to limit post-operative complications to those occurring after gastric bypass or sleeve gastrectomy (since 30-day complications are rare after gastric banding) and chose leak, bleeding and obstruction occurring within 30-days, recognising that for the recorded rates to be meaningful there would have to be evidence of follow up beyond 30 days. The follow up part of the dataset will need development in future iterations of the dataset, which needs to include the requirement of a specific alive / dead on discharge status button so that it is specified (rather than assumed) that the post-operative stay record refers to the patient leaving hospital alive.

In follow up we again chose to err on the side of simplicity, and used the same questions for comorbidity as were included in the baseline status section of the registry; in addition, the patient's current weight and the date of follow up were requested.

We would like to stress that the chosen dataset is **not** regarded by us as an ideal dataset, it was simply chosen as one that could be simple enough to achieve one of the goals of the IFSO Global Registry, that is it would attract large numbers of patient records, *i.e.,* it is a *lowest common denominator*, which is designed to help accumulate the maximum volume of data for analysis.

Another key goal was that it should be relatively easy to analyse the data, assuming that most or all contributing registries would have the same basic dataset. For future reports, the Registry Committee is likely to change and evolve the dataset to include, for instance, the duration of diabetes. Functional status is an important aspect of the disease state of severe obesity, but this is measured infrequently and recorded according to differing scales of disability where it is measured. This is an obvious example where some international agreement on the measurement and recording of data on comorbidity could help to standardise data across the world, which would then facilitate international analysis of resolution of this condition between groups of patients and over time. Bariatric surgeons also need to agree a standard way of measuring blood pressure and agreeing criteria for coming off medication for hypertension.

The validity and quality of registry data

The value of a registry rests largely on the quality of the data that it contains. The data need to be fit for purpose, and each data-point must be accurate and without bias.

The structure of a registry determines the database's relevance, *i.e.,* the way the variables are constructed and their under-pinning definitions. The way that the software functions is also important: for example, will the database front-end allow the user to add conflicting information at the time of data entry? To illustrate this point, the software must prevent users adding follow up data that are dated before the date of the patient's operation; it is important to try and prevent these kinds of errors at the coal-face. Users are also greatly assisted by on-screen prompts that alert them to unlikely / improbable values that they might have entered; an example here might be a bariatric surgery patient whose body mass index is calculated as less than 20 kg m^{-2}; this would suggest that either the patient's height or their weight have been entered incorrectly. A common request from users is for a user-friendly application. A piece of software that is easy to use is more likely to produce good long-term results than something that is difficult to navigate.

The ideal situation is to have a registry where data are collected prospectively; data collected in this way tend to have the highest validity. From the beginning of this IFSO Global Registry project, it was decided that adding retrospective, historic data should be allowed as a first step forward, until a time is reached when all registries have prospective data entry.

There are aspects of registry data that need to be scrutinized, like completeness, accessibility, and missing data.

Completeness: at the outset, it is important to define clearly the scope of the registry: which operations should be included? Are all the operations performed entered into the registry? Some databases aim to accumulate information on all the different surgical procedures in a particular country (Sweden and the United Kingdom), others represent a collaboration that covers a region within a country, some are hospital resources and others represent the hard work of individual surgeons who keep a record of their own practice. Having an understanding on a registry's underlying population and the degree to which the fields are complete has an impact on the interpretation of data analysis based on those data.

Accessibility: how many of the hospitals / surgeons covered by the registry actually actively contribute to the database? Many countries have some sort of compulsory reporting, mandated by government, specialist surgical societies or other bodies, which could be used to validate to the coverage of the registry. Knowing the administrative / organizational structures in which the registry sits can have an impact on the way in which its results are interpreted.

Missing data: this is relatively simple to assess. It is much more important to look for the reasons why data-items are missing, especially if they are missing systematically. Is there any selection bias in data entry; for example, patients who have complications after surgery do not always follow standard protocols for follow up, and so the surgeon might not be aware of the patient's situation throughout the follow up period, and so data on these patients might be missing from the registry.

Some of the local databases can differ from the central registry in terms of both content and definitions. This sort of variation is important, and any data that do not conform exactly to the format and definitions of the central registry should not be submitted for merging with data from other contributors. To illustrate: if a local database only assesses complications within the patient's hospital stay, and the central registry holds data on 30-day outcomes, then the local database should not forward their data on complications to the central registry, as the two types of data are incompatible, and cannot be analyzed together in any meaningful way.

Any registry project that incorporates long-term aims to add to the body of knowledge on obesity and its surgical treatment must include attempts to measure the validity of the registry. Typically this involves comparing the data in the patient's hospital record with the data in the registry. Completing this task for every single entry in the database would be impossible, in terms of both the time that it would take and the funding that would be required to support all the associated personnel. Sampling is the answer to this problem: some entries are selected from the database at random and compared to the patient's hospital records. Statisticians can do a *power calculation* to determine the minimum number of records that need to be checked in this way.

The future

A registry with high data validity can add to our knowledge about morbid obesity and its surgical treatment. A good database is a resource that can be used to assess health systems [1]. A registry demonstrates what is going on in the real word, whereas a randomized trial is more of a laboratory situation with selection bias [2]. A good registry could be used as a tool in an intervention study, where inclusion could be expedited, and both the intervention and follow up protocols could be standardized; this is the so-called register-Randomized Controlled Trial (RCT).

By constantly focusing on data quality and data validity, the IFSO Global Registry has great potential for improving the care of patients with morbid obesity and metabolic disorders on a global scale.

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Data collection methodology

This First IFSO Registry Report has been designed principally to test whether or not there is the political will to collect and share data from bariatric surgery centres around the world, and to test the capability of the Dendrite *Intellect Web* database technology platform to enable the process of uploading, merging, analysing and publishing data.

While in future years it is planned for the Registry to be open to all-comers, in this first round pilot project a short-list of just 48 invitees from around the globe were approached. Centres and national registries from the following geographical areas were approached:

- North America
- South America
- Europe
- Middle East
- Africa
- Asia
- Australasia

The 48 invitees ranged from individual centres with a known interest in collecting data to established bariatric surgery national registries. Purposefully, centres were chosen that operated a range of generic database systems (usually based on Microsoft Excel™ or Microsoft Access™) or commercially available bariatric surgery database systems such as Dendrite Clinical Systems, LapBase and ManaThea.

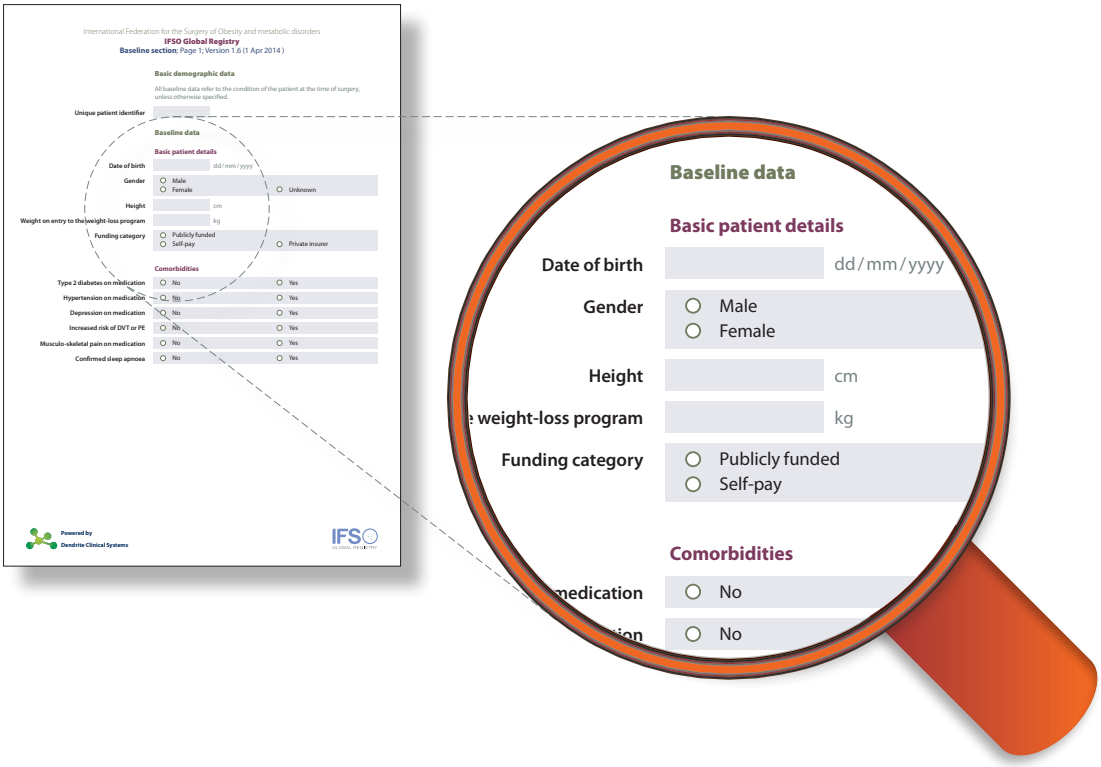
In the first quarter of 2014, each invitee was sent a formal letter of invitation asking them to join the project and around 80% (38) replied expressing a positive interest to join the project. Each of these responders were then sent a *Charter* document that outlined / explained:

- Aims of the Pilot Dendrite / IFSO Global Registry Project
- Data protection
- Access
- Data ownership
- Publication and other use of the data
- Principles of operation: roles and responsibilities
- Data validation
- Supervising authorities

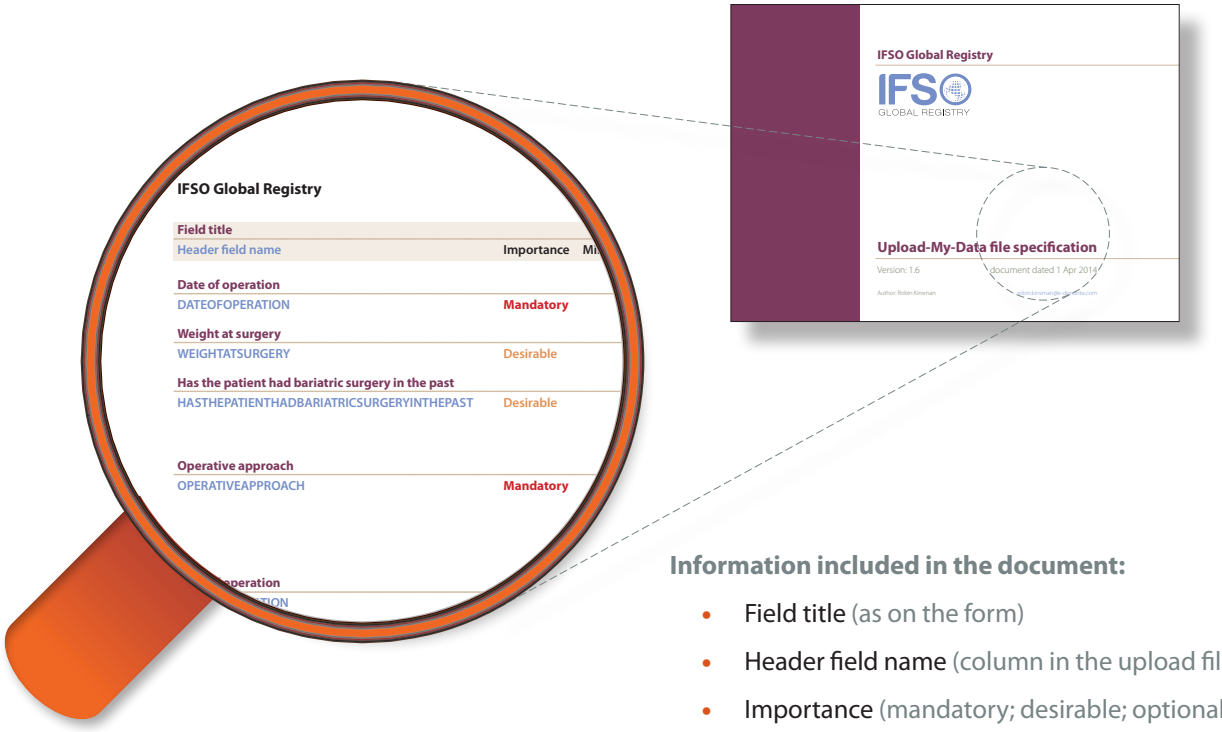
Once each invitee had returned their signed Charter document they were then sent a unique contributor / identifier code, a username and password to access the dedicated *Upload-My Data* portal, and four key documents:

Data collection methodology

1. The Database Form: to provide a quick overview of the central database design



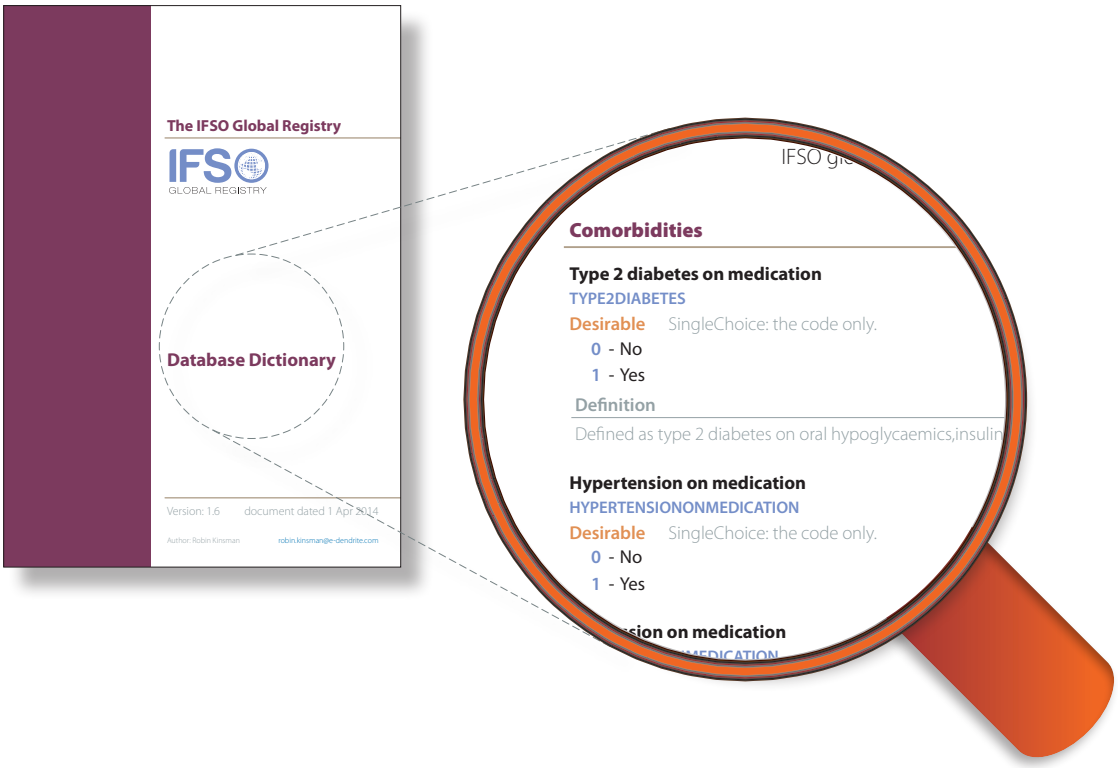
2. The File Specification Document: that provides a detailed specification of the file format output required for submitting / uploading electronic data files



Information included in the document:

- Field title (as on the form)
- Header field name (column in the upload file)
- Importance (mandatory; desirable; optional)
- Minimum permitted values
- Maximum permitted values
- Values allowed (options within the question)

3. The Data Dictionary: detailing the data definitions of the database answer options



4. The User Manual: to explain how the Upload-My-Data software can be used

Seven of the original 48 invitees refused or were unwilling to join the project and there were 3 non-responders. Ten of the initial 38 positive responders were subsequently unable to either secure the necessary permissions locally or from their National Society Executive Committees to submit data within the required timeframe to join the project. Of the remaining 28 positive responders, 25 were able to submit data successfully:

Three National Registries uploaded data successfully via the Upload-My-Data portal

Sweden
Scandinavian Obesity Surgery Registry (established 2007)

SOREG

United Kingdom
The UK National Bariatric Surgery Registry (established 2009)

The NBSR NATIONAL BARIATRIC SURGERY REGISTRY of The British Obesity & Metabolic Surgery Society

Russia
Russian National Bariatric Surgery Registry (established 2013)

BAREOREG.RU

Five contributors in five different countries successfully used the Direct Data Entry system

France
Centre Médico-Chirurgical du Mans, Pôle Santé Sud, Service de Chirurgie Viscérale, Le Mans

India
Department of Surgical Gastroenterology, Endocare Hospital, Vijayawada

Kingdom of Saudi Arabia
Kingdom Hospital and Consulting Clinic, Riyadh

Peru
Clinica de dia Avendaño, Lima

Spain
Hospital de Torrevieja, Alicante

Seventeen individual centres in thirteen countries submitted data via the Upload-My-Data portal

These centres were able to successfully use the Upload-My-Data portal, either independently or with e-mail / telephone guidance from Dendrite's Technical Support Team in London

Brazil

Fabio Viegas Instituto de Cirurgia do Aparelho Digestivo e Obesidade, Rio de Janeiro

Canada

Hôpital du Sacré-Coeur de Montreal

Chile

Centro Clínico de la Obesidad, Santiago

Center for the Treatment of Obesity and Metabolic Diseases, Pontificia Universidad Católica de Chile, Santiago

China

The First Affiliated Hospital of Jinan University, Guangzhou

France

Polyclinique, Lyon Nord-Rillieux

Germany

Marienkrankenhaus Kassel Chirurgische Klinik, Kassel

Adipositaszentrum Nordhessen, Kassel

India

Centre for Obesity and Digestive Surgery, Institute of Minimal Invasive Surgical Sciences, Saifee Hospital, Mumbai

Italy

Hospital San Giovanni Bosco, Naples

Mexico

Instituto Nacional de la Nutrición Salvador Zubirán, Mexico City

Centro Médico ABC, Mexico City

Spain

Hospital Clínico San Carlos, Complutense University Medical School, Universidad Complutense de Madrid

Taiwan

Min Sheng General Hospital, Taoyuan

Bariatric & Metabolic International Surgery Center E-Da Hospital, Kaohsiung City

Netherlands

Sint Lucas Andreas Ziekenhuis, Obesity Centre, Amsterdam

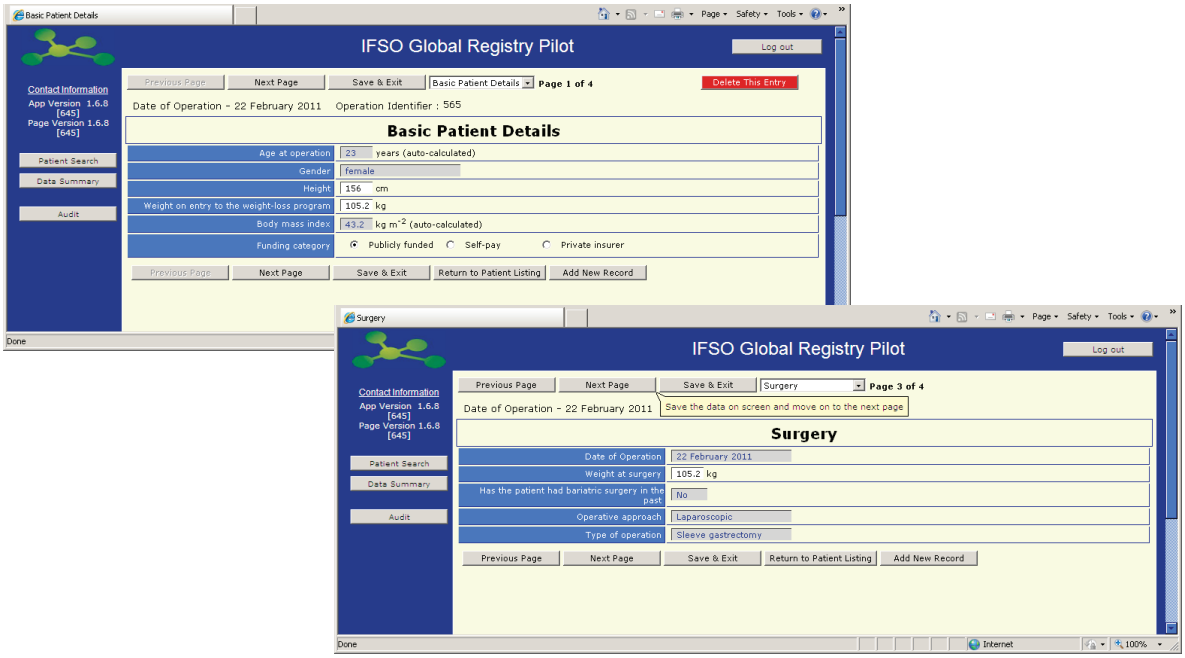
United Arab Emirates

Bariatric & Metabolic Institute Abu Dhabi, Sheikh Khalifa Medical City, Abu Dhabi

On-line data entry

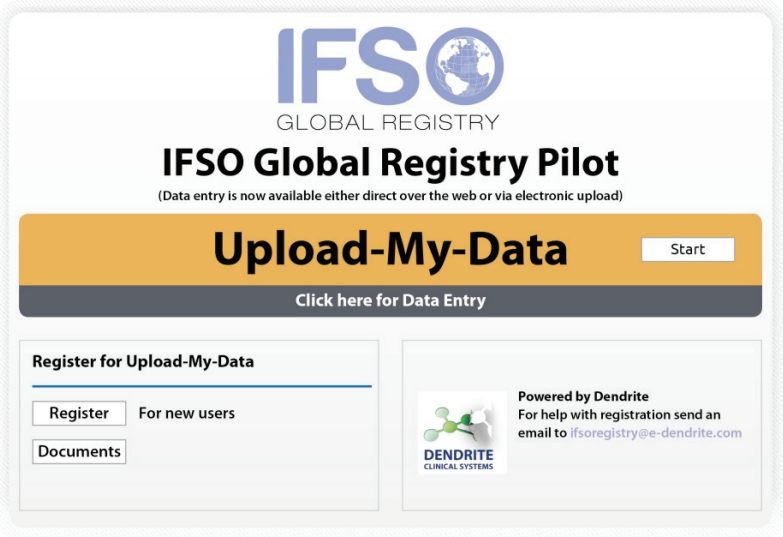
Dendrite constructed an on-line database system accessible over the Internet (accessible *via:* https://rs3.e-dendrite.com/csp/ifso/frontpages/index.html):

This portal enables surgeons / data managers to enter cases (with anonymised patient identifiers) using a simple on-line data form with just 4 pages of questions that typically takes just 3-4 minutes to complete *per* patient record.



Upload-My-Data

The Dendrite team also designed and created a dedicated IFSO *Upload-My-Data* web portal (accessible *via:* https://rs3.e-dendrite.com/csp/ifsoumd/frontpages/index.html).



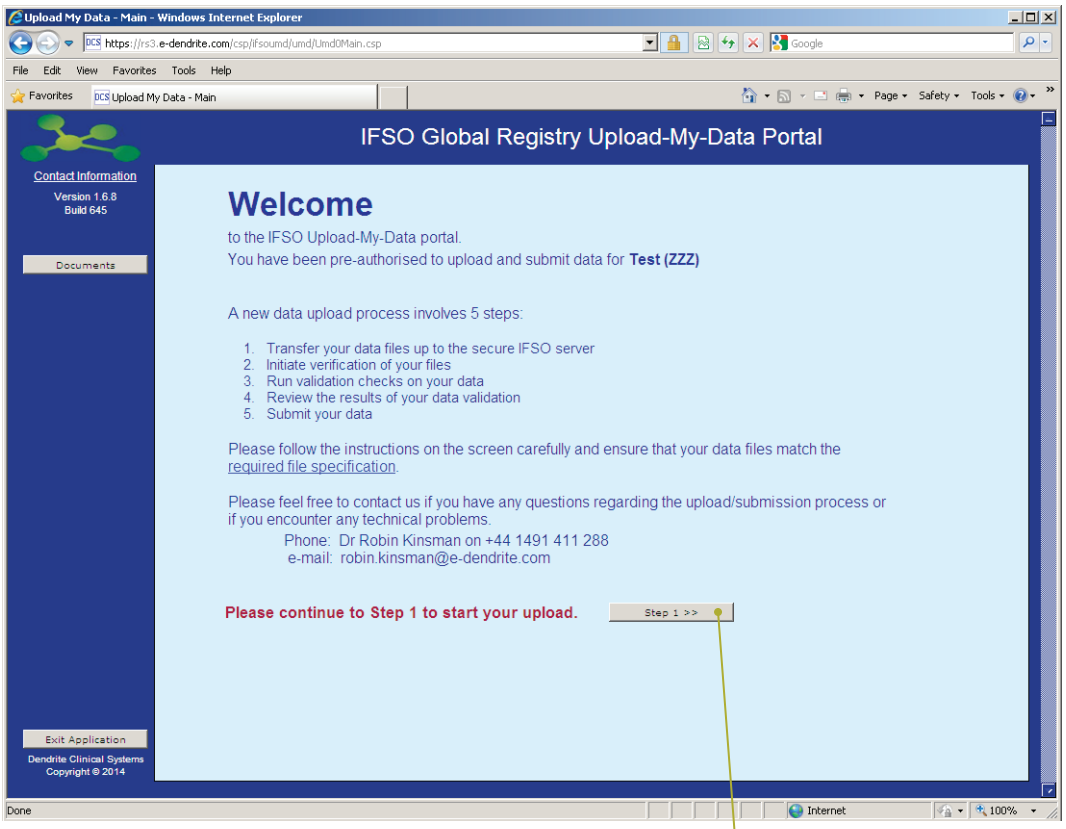
The Dendrite *Upload-My-Data* software platform is a proven interface designed to enable a community of surgeons or physicians to create a national or international database; even if there are different database systems at the local level, the data from each can be integrated into the central, merged registry. This platform has been successfully utilised in a number of other national and international registries (for cardiac surgery, thoracic surgery) and has been specifically tailored for the IFSO project to enable both individual centres and national registries to submit data in batches on-line.

The software has been designed to walk the user through a series of simple steps using a menu structure and on-screen instructions:

Welcome page

To enter the registry, users are required to use a nominated login user ID, and a strong-authentication password (comprising a minimum of 8 characters, including uppercase and lowercase alpha characters, and at least one numeric).

After an initial *Consent* screen, the welcome screen displays the name of the name contributor (in this case **Test**) and their associated **Submitter code** (**ZZZ** in the example below). It also describes the steps involved in successfully uploading data. There is a link on this page directly to the file specification document that describes how to name the data files and gives details on the data fields required for the upload.

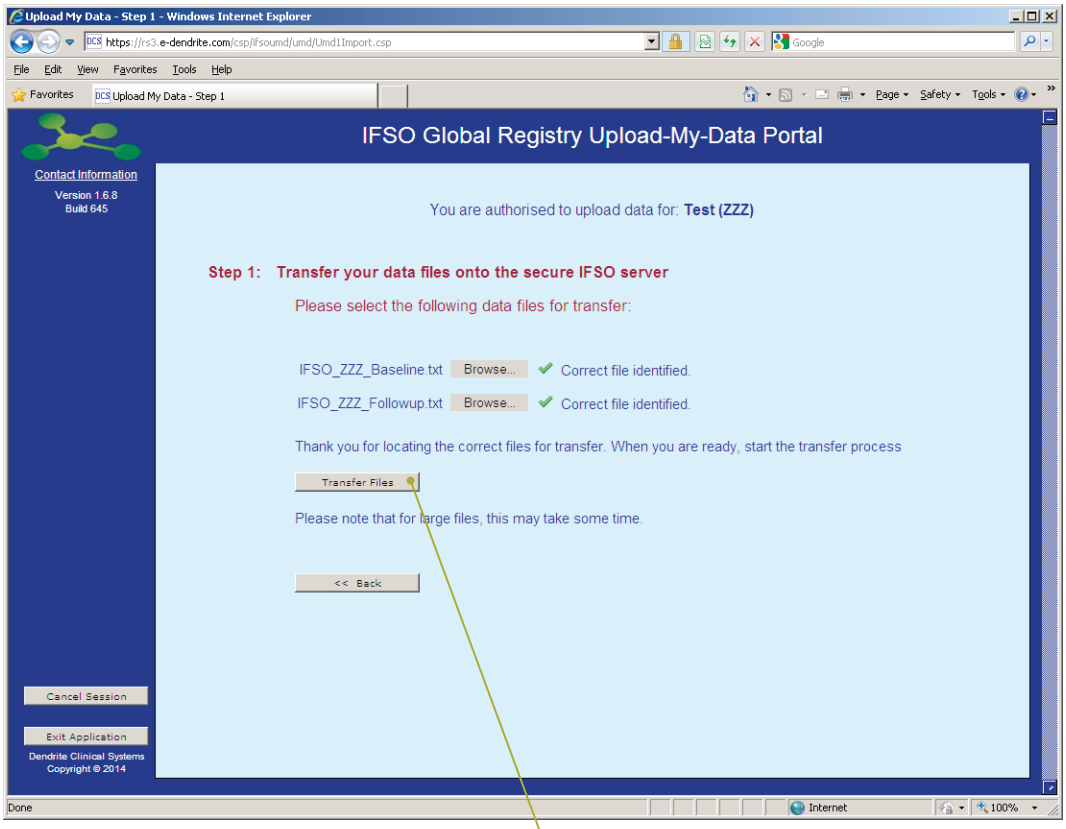


Start the process

To start the Upload-My-Data process click on the **Step 1** button.

Transferring the files

Once the required upload files have been correctly identified and presented to the portal, the screen changes to reveal a new button labelled **Transfer files**.



Begin the transfer

Clicking on the **Transfer files** button moves the files onto the IFSO secure server.

Starting the validation tests

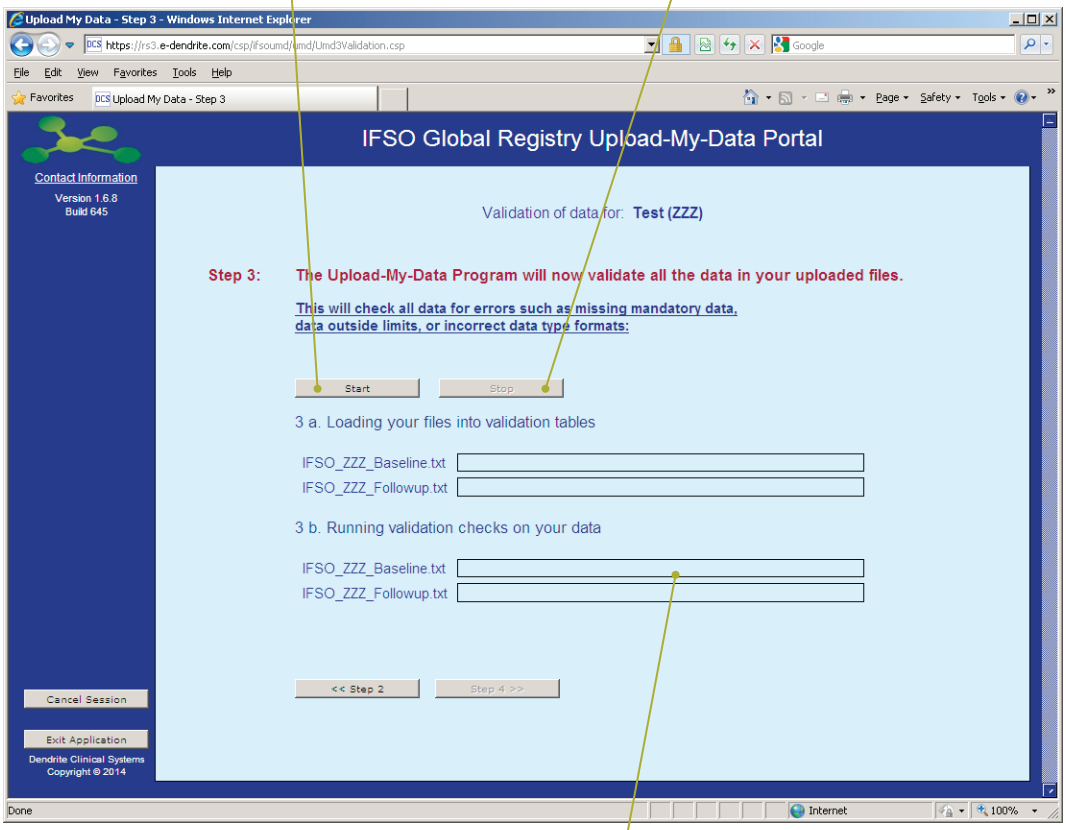
After an initial verification step that checks for complete and accurate header information, the next stage is a more in-depth validation of the uploaded files.

Start the process

The **Start** button is clicked to begin the validation process.

Stop the process

If users need to halt the process at any time they press the **Stop** button. This button becomes active after the **Start** button has been depressed.



Progress bars

Progresss bars indicate the passage through the validation processes.

Reviewing data validation results

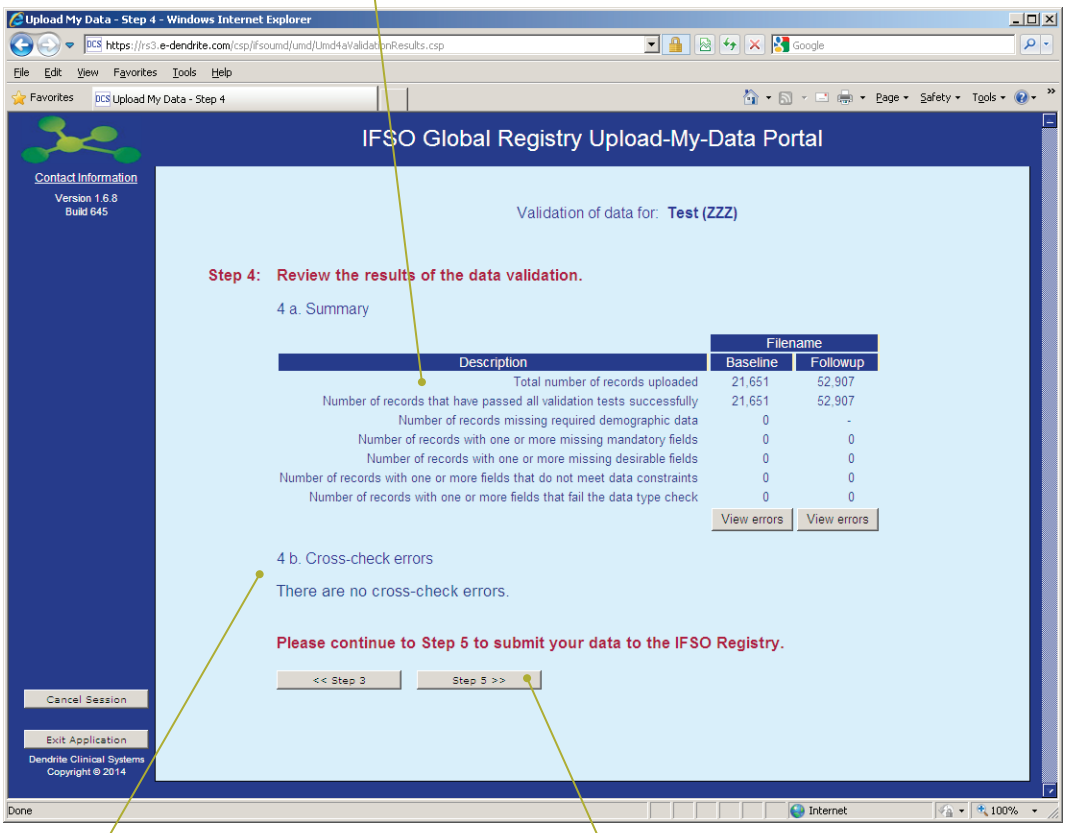
The Upload-My-Data portal reports back on the gross contents of uploaded files and various potential errors commonly found in upload files:

- total number of records uploaded
- number of records that have passed all validation tests
- number of records missing required demographic data
- number of records with one or more missing mandatory fields
- number of records with one or more missing desirable fields
- number of records with one or more fields that do not meet data constraints
- number of records with one or more fields that fail the data type checks

There are also, potentially, *cross-check errors*, which are essentially errors in data-linkage between the baseline and follow up data files.

Validation summary

The main body of the screen shows a summary of the validation tests.



Cross-check errors

Any issues with linkage of follow up data to data in the baseline file would be reported here. In this example there are no cross-check errors.

Proceed to commit the data

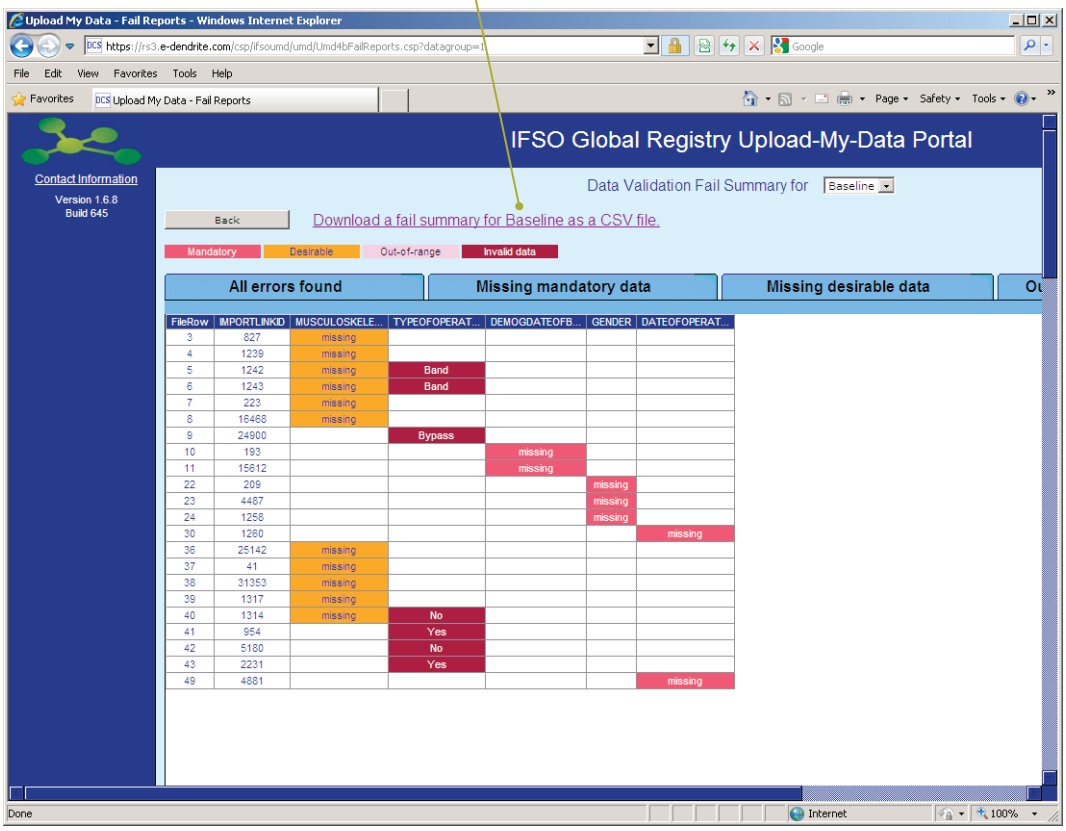
If happy with the results of the validation, users may move on to commit the data to the IFSO Global Registry.

File validation error details

If the review summary identifies missing or problematic data, a **View errors** button provides a spreadsheet detailing the errors that have been detected. This information can be downloaded as a comma-separated values file using the link next to the **Back** button.

Download a copy of the error report

Users may download a copy of the error report using the highlighted link.



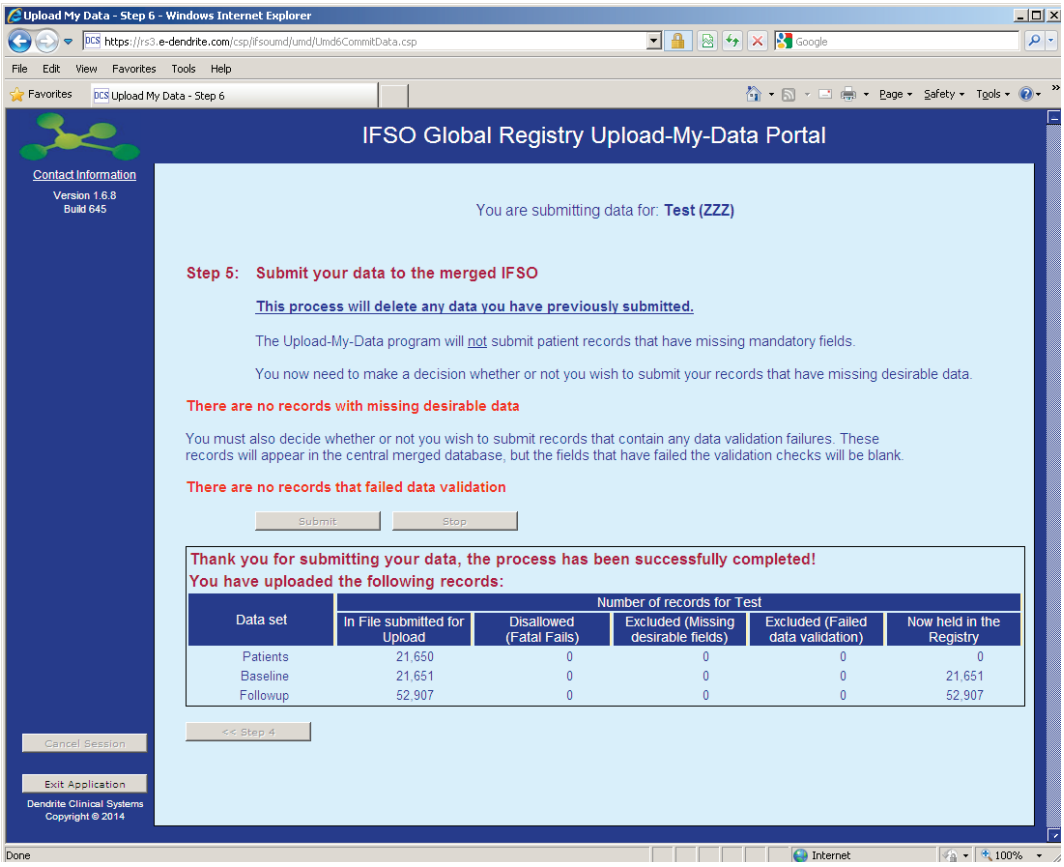
FileRow	IMPORTLINKID	MUSCULOSKELE...	TYPEOFOPERAT...	DEMOGDATEOFB...	GENDER	DATEOFOPERAT...
3	827	missing				
4	1239	missing				
5	1242	missing	Band			
6	1243	missing	Band			
7	223	missing				
8	16468	missing				
9	24900		Bypass			
10	193			missing		
11	15612			missing		
22	209				missing	
23	4487				missing	
24	1258				missing	
30	1260					missing
36	25142	missing				
37	41	missing				
38	31353	missing				
39	1317	missing				
40	1314	missing	No			
41	954		Yes			
42	5180		No			
43	2231		Yes			
49	4881					missing

In this example, the reported errors are largely missing desirable or mandatory data. However, there are also some invalid / inappropriate data in the **TYPEOFOPERATION** field; for example, in row 5, the file contains the text *Band* instead of the code 1, as requested in the Upload-My-Data file specification document.

Only rows with one or more errors are listed in the reports.

Reviewing the results of upload

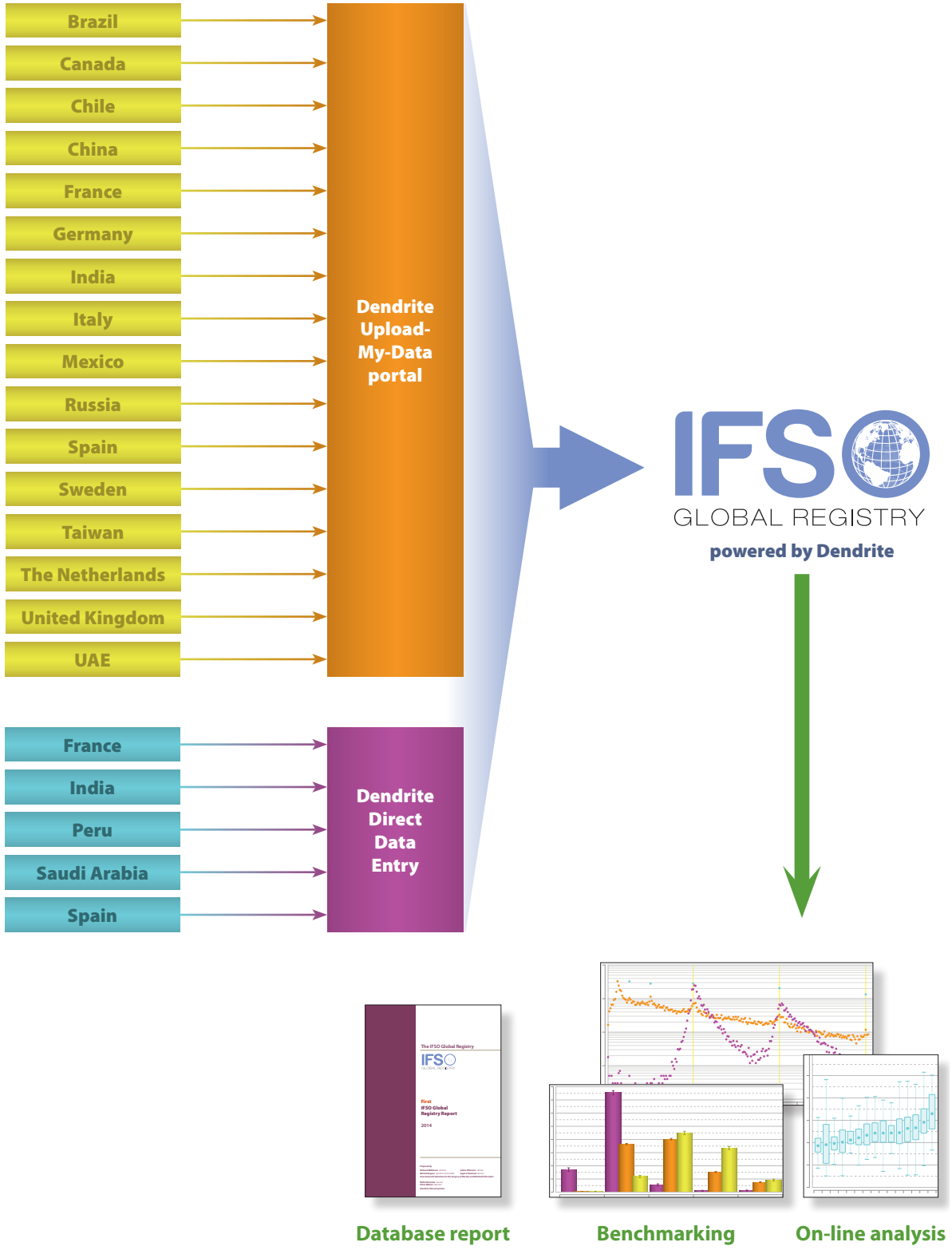
The final screen provides a brief *précis* of the data now held in the central IFSO Global Registry for each upload.



Data collection methodology

The flow of data from various sources

Dendrite Clinical Systems provide the central registry software for the IFSO Pilot Global Bariatric Surgery Registry. The schematic illustrates the data flow from different countries to the central registry.



The process of data submission is represented by three main scenarios:

1. Where the national registry uses Dendrite's Intellect Web national database software platform (*e.g.,* the United Kingdom National Bariatric Surgery Registry), the data were seamlessly exported and uploaded into the central Dendrite / IFSO Registry.
2. The same principle applies to those hospitals that submitted data on line on a case-by-case basis; the data were seamlessly exported and uploaded from the Dendrite on-line software into the central Dendrite / IFSO Registry.
3. Where the national registry or individual centre is using a third party generic or proprietary system, the data were exported locally and submitted *via* Dendrite's Upload-My-Data portal.

Data manipulation and data analysis were carried out using a suite of integrated software systems at Dendrite headquarters, and the final report was assembled using Adobe InDesign™ and Adobe Illustrator™.

For further information about Dendrite's *Intellect Web* National / International Registry Software Systems, the on-line database and the *Upload-My-Data* software and / or Dendrite's data analysis and report production methodologies, please contact:

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website www.e-dendrite.com

A note on the conventions used throughout this report

There are several conventions used in the report in an attempt to ensure that the data are presented in a simple and consistent way. These conventions relate largely to the tables and the graphs, and some of these conventions are outlined below.

The specifics of the data used in any particular analysis are made clear in the accompanying text, table or chart. For example, many analyses sub-divide the data on the basis of type of operation, and the titles for both tables and charts will reflect this fact.

Conventions used in tables

On the whole, unless otherwise stated, the tables and charts in this report record the number of procedures (see the example below).

IFSO Global Registry: funding of surgery

		Funding			
		Publicly funded	Privately funded	Unspecified	**All**
Region	North America [1]	502	788	2,144	**3,434**
	South America [2]	932	3,250	5,536	**9,718**
	Europe [3]	29,871	9,813	37,972	**77,656**
	Asia [4]	5	4,149	4,539	**8,693**
	The Middle East [5]	195	394	2	**591**
	All	**31,505**	**18,394**	**50,193**	**100,092**

Each table has a short title that is intended to provide information on the subset from which the data have been drawn, such as the patient's gender or particular operation sub-grouping under examination.

The numbers in each table are colour-coded so that entries with complete data for all of the components under consideration (in this example both region and source of funding) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as unspecified in purple text. The totals for both rows and columns are highlighted as emboldened text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value.

Rows and columns within tables have been ordered so that they are either in ascending order (age at procedure: <20, 20-24, 25-29,30-34, 35-39 years, *etc.*; post-procedure stay 0, 1, 2, 3, >3 days; *etc.*) or with negative response options first (No; None) followed by positive response options (Yes; One, Two, *etc.*).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

- insufficient space on the page to accommodate both the table and graph.
- there would be more rows and / or columns of data than could reasonably be accommodated on the page (for example, Kaplan-Meier curves).
- the tabular data had already been presented elsewhere in the report.

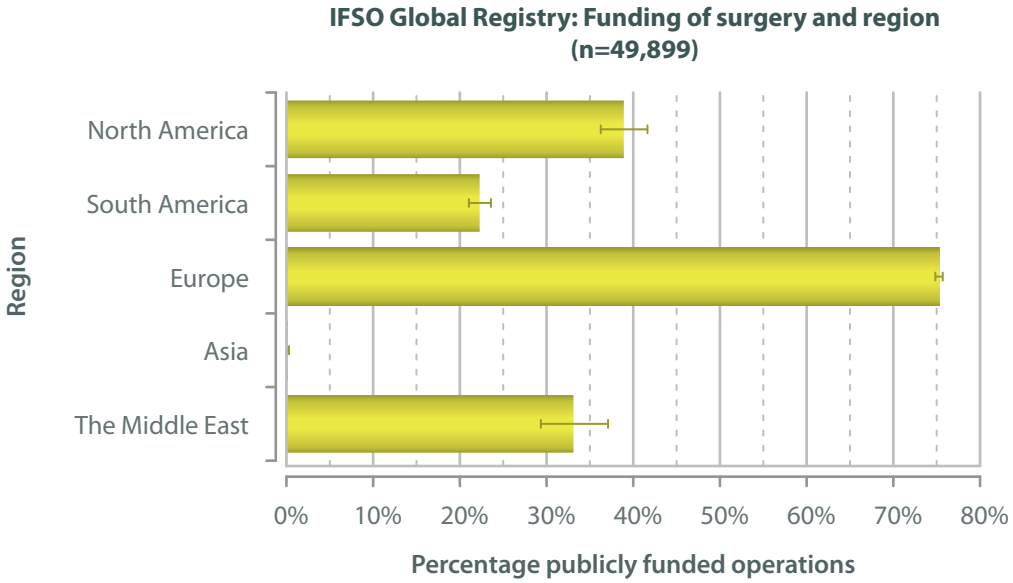
Conventions used in graphs

The basic principles applied when preparing graphs for this First IFSO Global Registry Report were based, as far as possible, upon William S Cleveland's book *The elements of graphing data* [1]. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: the counts (shown in parentheses at the end of each graph's title as n=) associated with each graph can be affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in this report are graphic representations of results for a particular group (or subset) extracted from the database, such as primary surgery. This clearly restricts the total number of database-entries available for any such analysis.

In addition to this, some entries within the group under consideration have data missing in one or more of the database questions under examination (reported as unspecified in the tables); all entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph below, only the database entries where the data on the source of funding for the operation is known are included in the analysis; this comes to 49,899 patient-entries (502 + 932 + 29,871 + 5 + 195 + 788 + 3,250 + 9,813 + 4,149 + 394; the 50,193 entries with unspecified data are excluded from the chart).



Confidence interval: in the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals [2]. The width of the confidence interval provides some idea of how certain we can be about the calculated rate of an event or occurrence. If the intervals around two rates do not overlap, then we can say, with the specified level of confidence, that these rates are different; however, if the bars do overlap, we cannot make such an assertion.

Bars around averaged values (such as patients' age, post-operative length-of-stay, *etc.*) are classical standard error bars or 95% confidence intervals; they give some idea of the spread of the data around the calculated average. In some analyses that employ these error bars there may be insufficient data to legitimately calculate the standard error around the average for each sub-group under analysis; rather than entirely exclude these low-volume sub-groups from the chart their arithmetic average would be plotted without error bars. Such averages without error bars are valid in the sense that they truly represent the data submitted; however, they should not to be taken as definitive and therefore it is recommended that such values are viewed with extra caution.

1. Cleveland WS. *The elements of graphing data*. 1985, 1994. Hobart Press, Summit, New Jersey, USA.
2. Wilson EB. Probable inference, the law of succession, and statistical inference. *Journal of American Statistical Association*. 1927; **22**: 209-212.

GLOBAL REGISTRY

Analyses

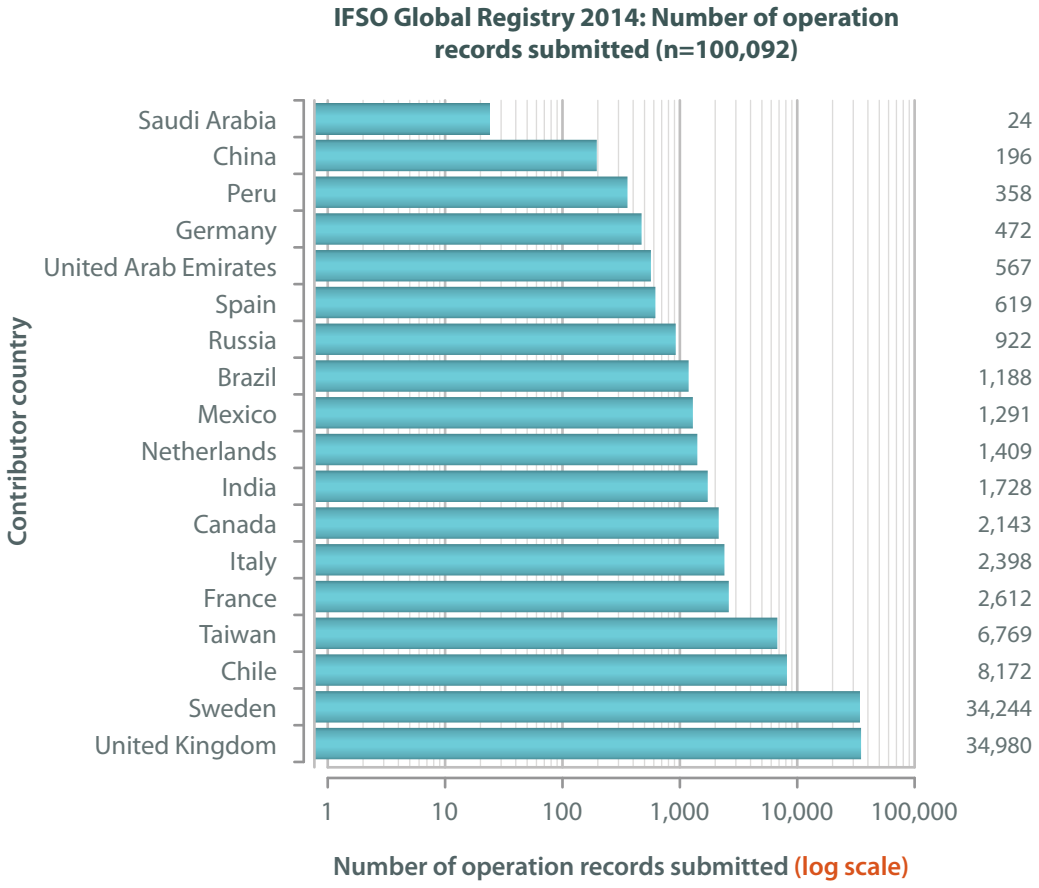
Database overview

Submissions

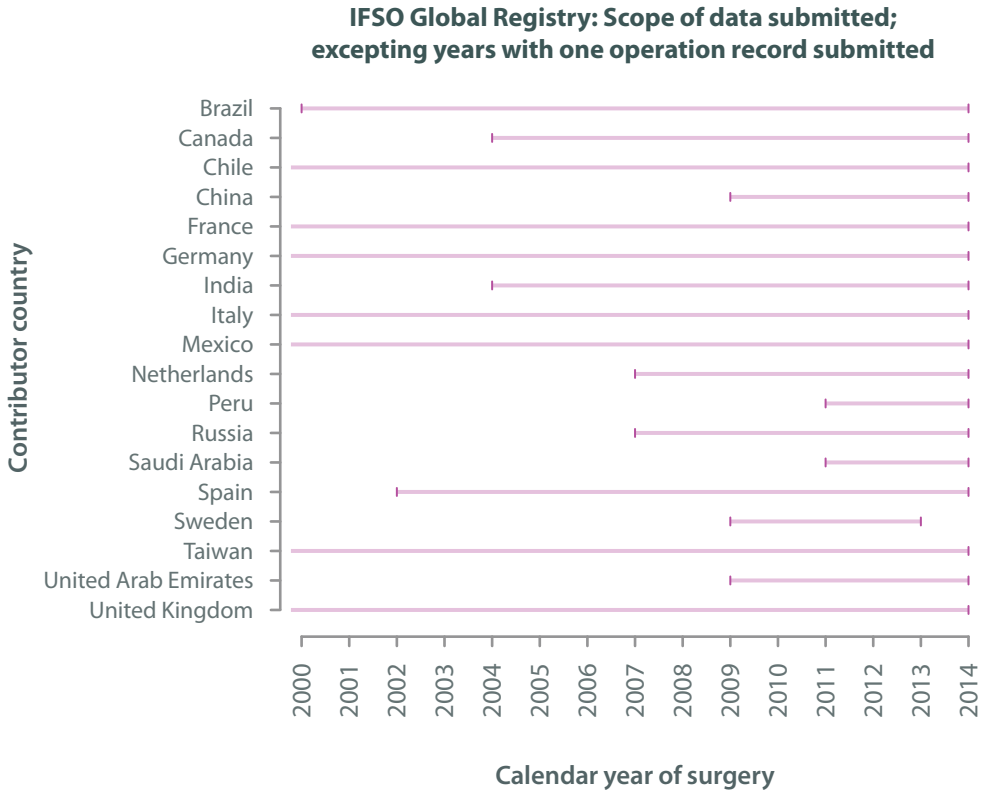
In this First IFSO Global Registry Report 2014 data from over 100,000 patient records were submitted from 18 countries. The numbers submitted range from exports of data from existing national registries (*e.g.,* Sweden and the United Kingdom) to individual units in other countries that might not be fully representative of overall existing practice in those countries.

However, this is the first time that data have been combined from so many countries. Thus, this is the start of an *iterative process* as data potentially accumulate over time. In future we hope to add data from more countries and describe accurately the demographics and prevalence of baseline obesity-related disease between different populations having bariatric surgery.

Clearly the data presented are also a snap-shot of surgery in each country and are not the total volume of surgery performed.



This graph shows the timeframe of data submission. We are grateful to so many individual units and countries that have been willing to submit data going back over more than a decade. Given the fact that many different databases and software products will have been used over time, it is pleasing that it has been technically possible to amalgamate the records.

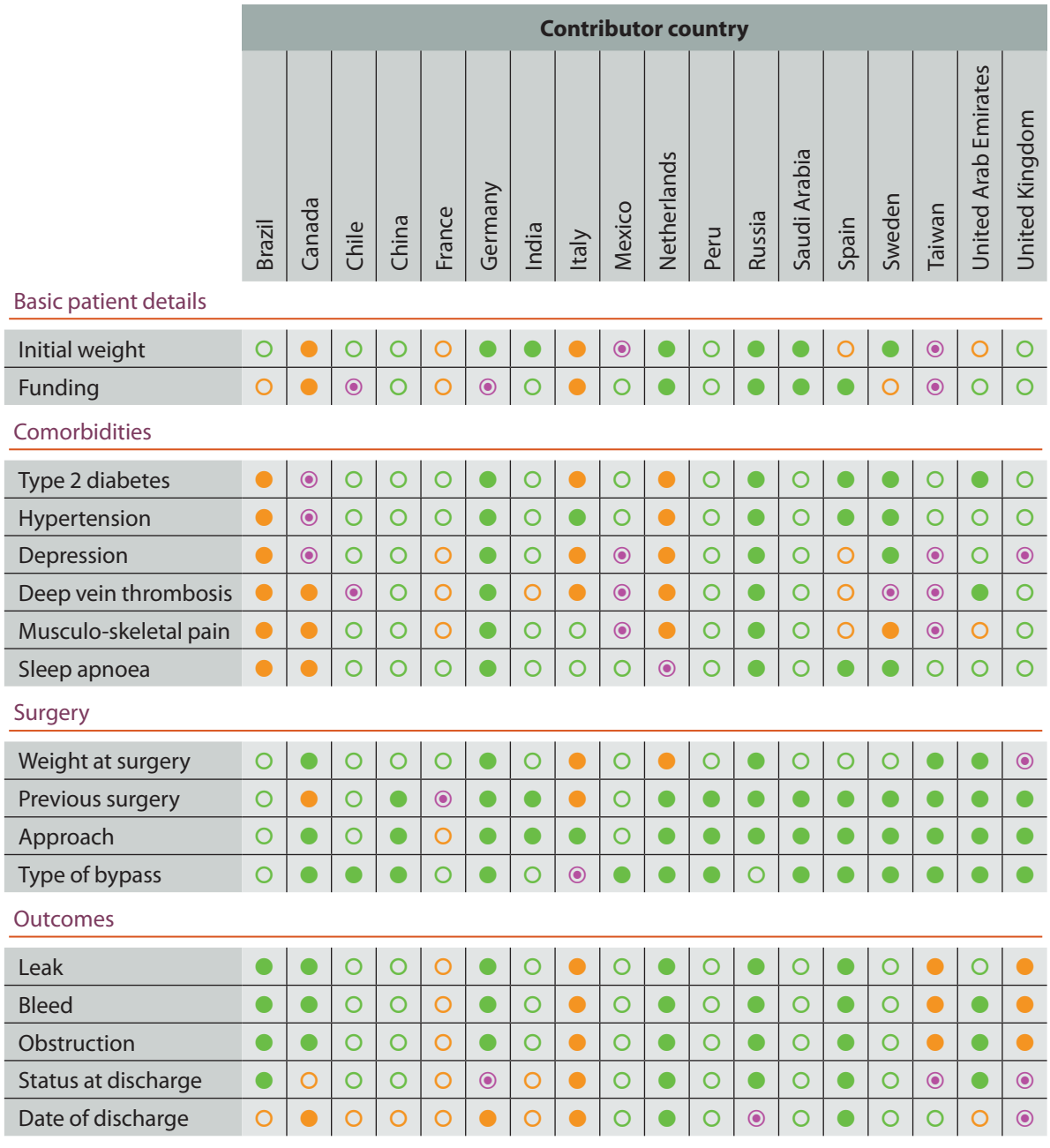


Missing data

Mandatory questions (required to create an entry on the database) were:

- the patient's date-of-birth or age in years
- the patient's gender
- the patient's height
- date-of-operation
- operative approach
- type of operation

Non-mandatory data in the IFSO Global Registry



This table shows the completeness of data submitted in the required electronic format for inclusion in the report. There was wide variation; this could either be due to the specific data-point not being included in the patient record that was uploaded to the Global Registry, or the data were left out of initial entry into the local database. For example, several countries (Brazil, the Netherlands, Russia, Spain and the United Arab Emirates) were able to demonstrate that every patient was documented as either alive or dead at discharge, thus the reported operative mortality for these contributors is more likely to be accurate.

Some apparently missing data reported here may represent a simple incompatibility between the local database and the central IFSO registry, rather than representing a complete absence of information at the local level. For example, the National Bariatric Surgery Registry in the United Kingdom does record operative complications, but not in a suitable format to map into the IFSO Global Registry.

In some countries data were missing or unavailable for the purposes of this report in over 90% patients.

Missing patient records, incomplete data entry and erroneous entries are major concerns, and act as impediments to meaningful and accurate reporting of outcomes. Some countries may have dedicated administrative staff who are able to check every record; however, it is unlikely that this is the case in perhaps the majority of countries submitting data here.

The quality of data might be expected to improve in future, but it is important to state that the purpose of this first report is **not** to provide benchmarks nor quality control; rather, it is intended to demonstrate that data can be submitted successfully to a central registry and useful basic analyses can be performed. It is remarkable that so many of the data fields are shared between different registries and are over 90% complete (the green circles in the table opposite).

The term musculo-skeletal pain was chosen as a generic term for all related conditions, so as to be inclusive, and garner as much data as possible on this comorbidity. Confirmed sleep apnoea includes only patients on therapy.

The full question titles and corresponding response-options are documented in the Appendix at the end of this report.

Funding

Funding and country

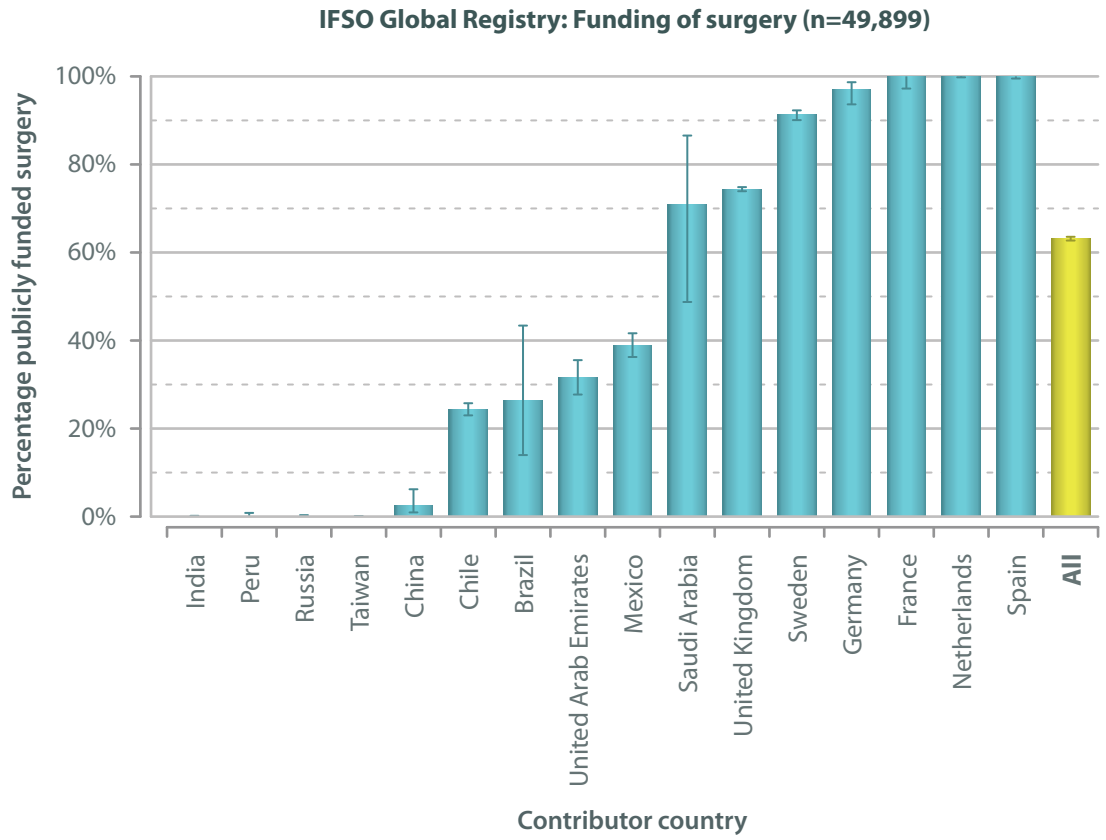
This is the first international report to compare the means by which surgery is funded in different countries. Clearly some of these differences may result from country-by-country variations in both BMI and number of obesity-related diseases in patients having bariatric surgery. We have not specified here the distinction between surgery funded through third party insurers and surgery paid for by individual patients. This is an area that is ripe for research with regard to access to bariatric surgery and healthcare inequalities.

IFSO Global Registry: funding of surgery

Contributor country	Funding			
	Publicly funded	Privately funded	Unspecified	**All**
Brazil	10	28	1,150	**1,188**
Canada	0	0	2,143	**2,143**
Chile	922	2,865	4,385	**8,172**
China	5	190	1	**196**
France	107	0	2,505	**2,612**
Germany	226	7	239	**472**
India	0	1,723	5	**1,728**
Italy	0	0	2,398	**2,398**
Mexico	502	788	1	**1,291**
Netherlands	1,409	0	0	**1,409**
Peru	0	357	1	**358**
Russia	0	922	0	**922**
Saudi Arabia	17	7	0	**24**
Spain	619	0	0	**619**
Sweden	2,374	228	31,642	**34,244**
Taiwan	0	2,236	4,533	**6,769**
United Arab Emirates	178	387	2	**567**
United Kingdom	25,136	8,656	1,188	**34,980**
All	**31,505**	**18,394**	**50,193**	**100,092**

The very high levels of public funding in Europe strongly suggests that it is in Europe that the key interest and work should be done on identifying those patients that should be considered eligible for surgery and those that should be prioritized. This required a major cooperation between experts in many fields and not simply a few sitting down and coming up their ideas!

It also suggests that countries seeking to improve public health should increase the rate of provision of bariatric surgery, especially when the majority of surgery is not publicly funded.



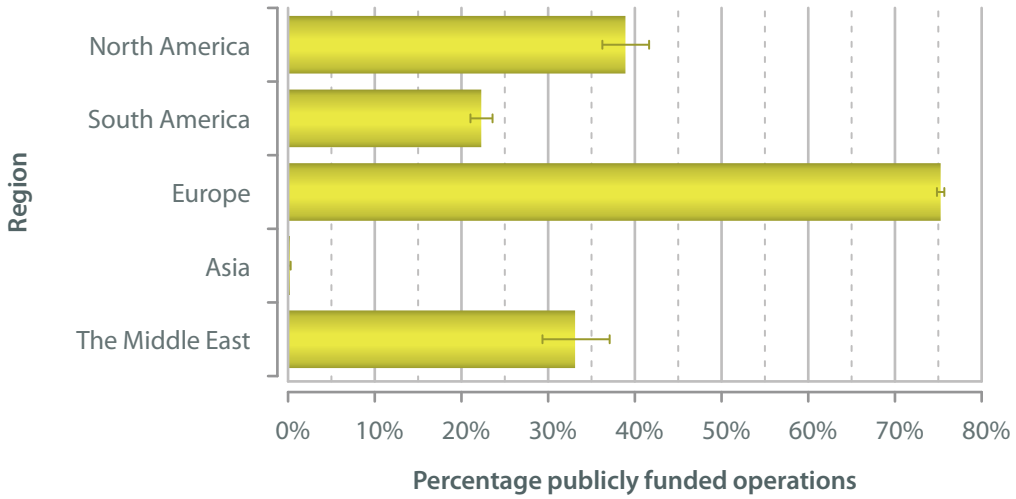
Funding and region

These are the first data to be shown in a graphical form of the funding process for bariatric surgery in different continents. There are large contrasts, and by implication the pathway to surgery will be different depending on the make up of each multi-disciplinary team. Little is known about how patients are prepared for surgery or followed up afterwards between different countries or whether this may have an effect on weight loss outcomes. Therefore collecting this information may be a step towards researching these issues.

IFSO Global Registry: funding of surgery

		Funding			
		Publicly funded	Privately funded	Unspecified	**All**
Region	North America [1]	502	788	2,144	**3,434**
	South America [2]	932	3,250	5,536	**9,718**
	Europe [3]	29,871	9,813	37,972	**77,656**
	Asia [4]	5	4,149	4,539	**8,693**
	The Middle East [5]	195	394	2	**591**
	All	**31,505**	**18,394**	**50,193**	**100,092**

IFSO Global Registry: Funding of surgery and region (n=49,899)



1. Canada and Mexico
2. Brazil, Chile and Peru.
3. France, Germany, Italy, the Netherlands, Russia, Spain, Sweden and the United Kingdom.
4. China, India and Taiwan.
5. Saudi Arabia and the United Arab Emirates.

Previous bariatric surgery

Obesity is a lifelong chronic disease [1,2]. It is not surprising, therefore, that there is no operation that lasts for a patient's lifetime. As more and more patients are operated, rates of revisional surgery are likely to increase, and these patients are likely to have higher rates of complications. For some countries it was not possible to distinguish primary *versus* revisional surgery for the purposes of this report.

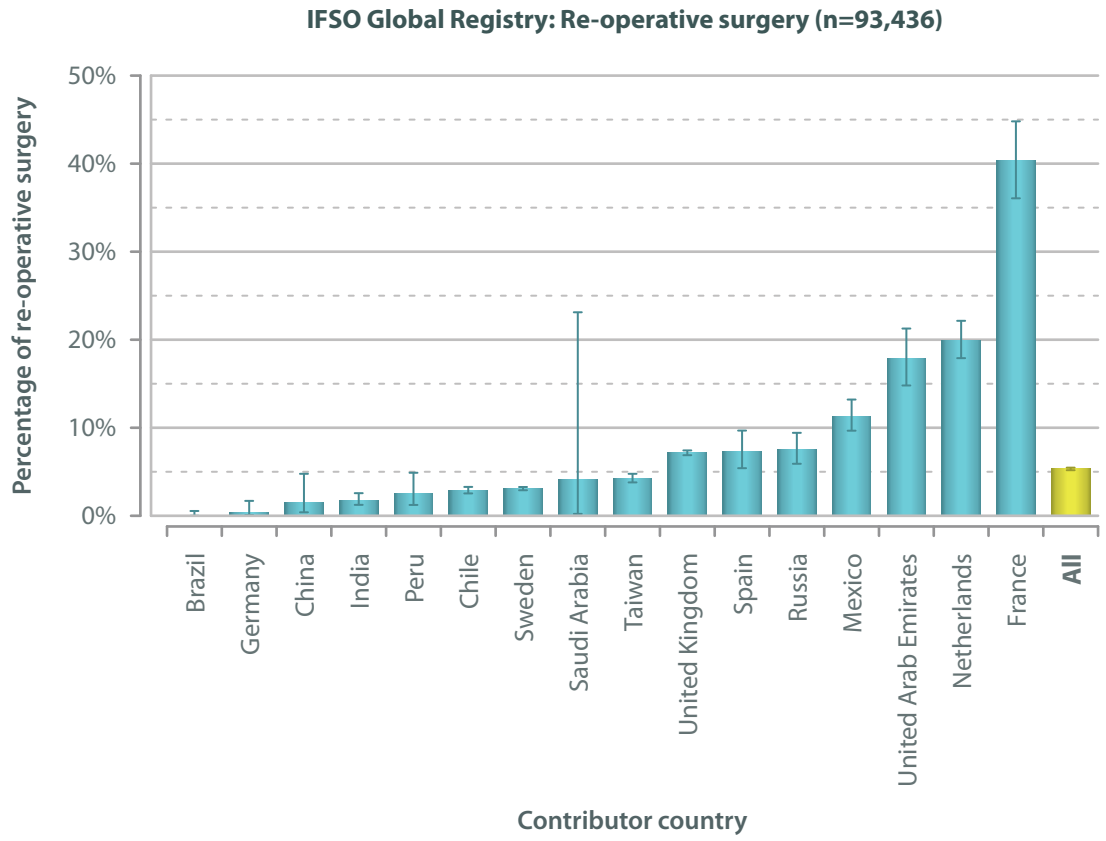
Provision of revision surgery may be highly dependent on the willingness of the payer to provide funds for this kind of surgery. The data presented are only a snap-shot of rates of revisional surgery.

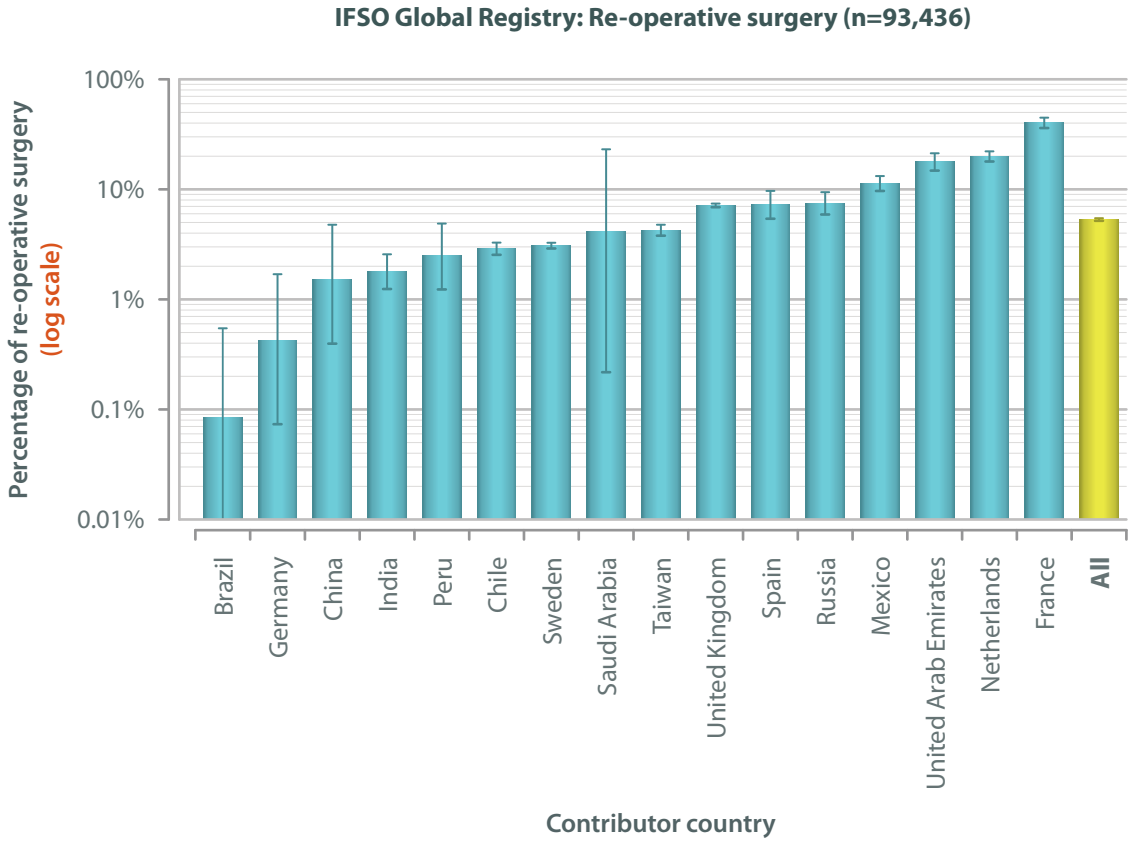
However, it is remarkable that so many patients in France (40%) are having re-operative surgery. The current dataset did not distinguish between patients having complications over time from one procedure, or whether these patients were being converted from one operation to another. The current dataset also did not allow us to distinguish between revision / re-operative surgery and planned second stage surgery, where this may occur.

IFSO Global Registry: previous bariatric surgery

		Previous bariatric surgery			
		No	Yes	Unspecified	**All**
Contributor country	Brazil	1,184	1	3	**1,188**
	Canada	0	0	2,143	**2,143**
	Chile	7,934	236	2	**8,172**
	China	193	3	0	**196**
	France	300	203	2,109	**2,612**
	Germany	470	2	0	**472**
	India	1,697	31	0	**1,728**
	Italy	0	0	2,398	**2,398**
	Mexico	1,144	146	1	**1,291**
	Netherlands	1,128	281	0	**1,409**
	Peru	349	9	0	**358**
	Russia	853	69	0	**922**
	Saudi Arabia	23	1	0	**24**
	Spain	574	45	0	**619**
	Sweden	33,189	1,055	0	**34,244**
	Taiwan	6,481	288	0	**6,769**
	United Arab Emirates	466	101	0	**567**
	United Kingdom	32,479	2,501	0	**34,980**
	All	**88,464**	**4,972**	**6,656**	**100,092**

1. Petroni LM. Chronic Care Models for Obesity Management. *Disabling Obesity*. 2013; 285-299.
2. Rippe JM, Crossley and Ringer R. Obesity as a Chronic Disease: Modern Medical and Lifestyle Management. *Journal of the American Dietetic Association*. 1998; **98(10)**: S9-S15.


IFSO Global Registry: Re-operative surgery (n=93,436)
Percentage of re-operative surgery
50%
40%
30%
20%
10%
0%
Brazil
Germany
China
India
Peru
Chile
Sweden
Saudi Arabia
Taiwan
United Kingdom
Spain
Russia
Mexico
United Arab Emirates
Netherlands
France
All
Contributor country


IFSO Global Registry: Re-operative surgery (n=93,436)
Percentage of re-operative surgery
(log scale)
100%
10%
1%
0.1%
0.01%
Brazil
Germany
China
India
Peru
Chile
Sweden
Saudi Arabia
Taiwan
United Kingdom
Spain
Russia
Mexico
United Arab Emirates
Netherlands
France
All
Contributor country

Gender

It is widely reported in the literature that female patients undergo bariatric surgery much more commonly than males. As far as we know this is the first report that demonstrates this in large numbers internationally.

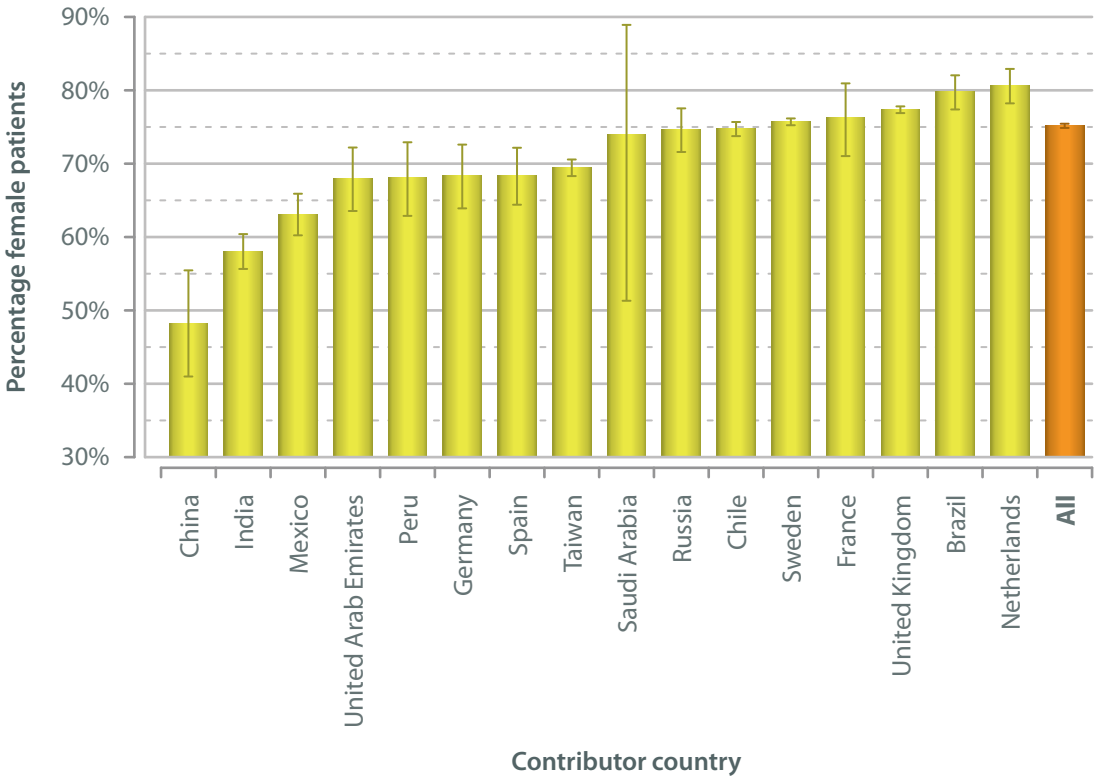
There are no very clear data on why there is such gender inequality for access to bariatric surgery. However, the marked difference in weight loss between males and females suggests that the proportion of male patients in any published series should be a standard feature of reporting, so as to allow for this.

Global inequality of access to bariatric surgery for gender and, perhaps, ethnicity, should be a priority for international obesity research.

Primary surgery: gender distributions

		Gender				
		Male	Female	Unspecified	**All**	Percentage female
Contributor country	Brazil	239	945	0	**1,184**	79.8%
	Chile	2,005	5,929	0	**7,934**	74.7%
	China	100	93	0	**193**	48.2%
	France	71	229	0	**300**	76.3%
	Germany	145	314	11	**470**	68.4%
	India	712	985	0	**1,697**	58.0%
	Mexico	422	722	0	**1,144**	63.1%
	Netherlands	218	910	0	**1,128**	80.7%
	Peru	111	237	1	**349**	68.1%
	Russia	216	637	0	**853**	74.7%
	Saudi Arabia	6	17	0	**23**	73.9%
	Spain	181	392	1	**574**	68.4%
	Sweden	8,063	25,126	0	**33,189**	75.7%
	Taiwan	1,975	4,490	16	**6,481**	69.5%
	United Arab Emirates	149	317	0	**466**	68.0%
	United Kingdom	7,355	25,124	0	**32,479**	77.4%
	All	**21,968**	**66,467**	**29**	**88,464**	**75.2%**

Primary surgery: The proportion of female patients (n=88,435)



Body mass index

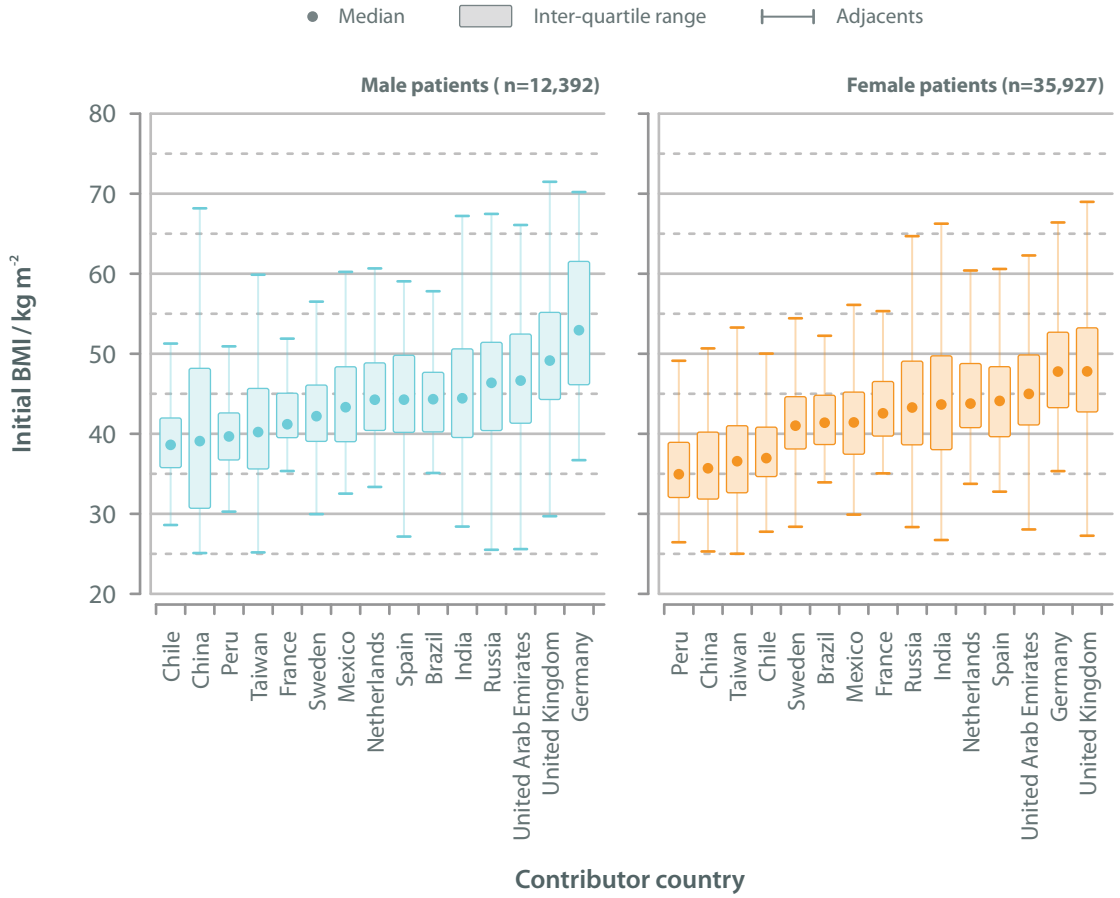
The graph below shows that there is a wide variation in the initial BMI of patients having bariatric surgery in different countries. Germany and the United Kingdom have the highest reported BMIs. For all the countries submitting data, the median BMI is higher for male patients compared to females.

As increasing BMI is generally associated with a greatest risk of operative complications and mortality, the graph clearly implies that there needs to be caution applied when comparing complication rates between series of patients from different countries.

Primary surgery: initial BMI, gender and contributor country; calendar years 2011-2013 [1]

Gender and contributor country			Statistics on initial BMI / kg m^{-2}		
			Count	Average (95% CI)	Median (IQR)
	Male	Brazil	82	44.3 (43.1-45.5)	44.3 (40.2-47.7)
		Chile	567	39.6 (39.1-40.1)	38.6 (35.8-42.0)
		China	76	41.1 (38.6-43.7)	39.1 (30.7-48.2)
		France	56	43.1 (41.5-44.6)	41.2 (39.5-45.1)
		Germany	53	53.4 (50.9-55.9)	52.9 (46.1-61.5)
		India	424	45.8 (45.0-46.7)	44.4 (39.5-50.6)
		Mexico	103	44.3 (43.0-45.7)	43.3 (39.0-48.4)
		Netherlands	147	45.6 (44.5-46.8)	44.3 (40.4-48.9)
		Peru	111	40.1 (39.1-41.0)	39.7 (36.7-42.6)
		Russia	149	47.4 (45.9-48.8)	46.4 (40.4-51.4)
		Spain	80	45.1 (43.3-47.0)	44.3 (40.2-49.8)
		Sweden	5,372	43.1 (43.0-43.3)	42.2 (39.1-46.1)
		Taiwan	756	41.3 (40.7-42.0)	40.2 (35.6-45.7)
		United Arab Emirates	121	48.3 (46.4-50.1)	46.6 (41.3-52.5)
		United Kingdom	4,292	50.2 (49.9-50.4)	49.2 (44.3-55.2)
	Female	Brazil	222	42.1 (41.4-42.7)	41.4 (38.7-44.8)
		Chile	1,770	38.1 (37.8-38.4)	37.0 (34.7-40.8)
		China	70	37.5 (35.5-39.6)	35.7 (31.8-40.2)
		France	164	44.0 (43.1-44.9)	42.6 (39.7-46.5)
		Germany	155	49.1 (47.9-50.3)	47.8 (43.3-52.7)
		India	532	44.6 (43.8-45.3)	43.7 (38.0-49.7)
		Mexico	165	42.4 (41.3-43.4)	41.4 (37.4-45.2)
		Netherlands	620	45.4 (44.9-45.9)	43.8 (40.8-48.8)
		Peru	235	36.1 (35.3-36.8)	34.9 (32.0-38.9)
		Russia	443	44.7 (43.9-45.5)	43.3 (38.6-49.1)
		Spain	152	44.5 (43.5-45.6)	44.1 (39.6-48.4)
		Sweden	16,655	41.8 (41.7-41.9)	41.0 (38.1-44.6)
		Taiwan	1,519	37.3 (36.9-37.6)	36.6 (32.6-41.0)
		United Arab Emirates	245	46.3 (45.4-47.1)	45.0 (41.1-49.9)
		United Kingdom	12,968	48.4 (48.3-48.6)	47.8 (42.7-53.2)

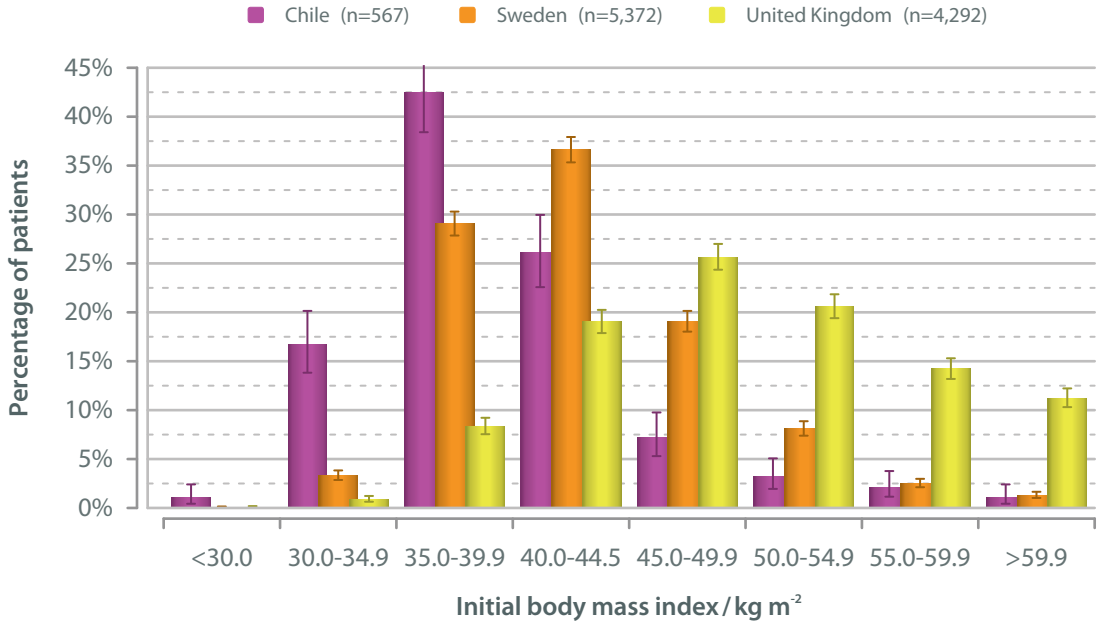
Primary surgery: Initial Body Mass Index and gender; calendar years 2011-2013



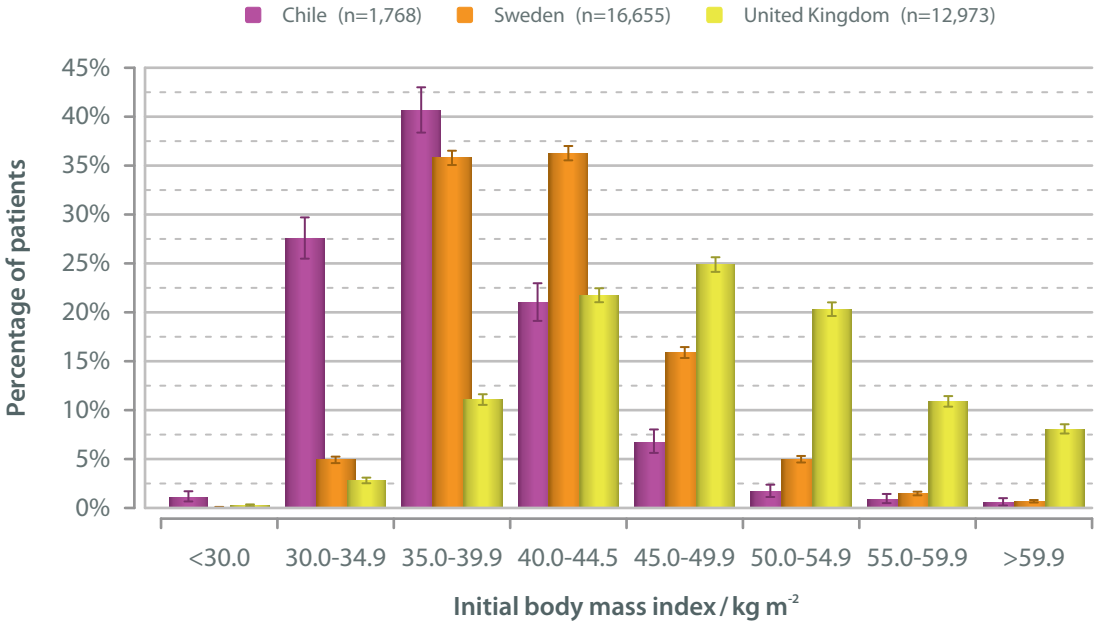
1. The patient's weight on entry into the weight loss program was used to determine initial BMI in preference to the weight at surgery, but for patients where only the weight at surgery was recorded, this weight was used to determine the patient's initial BMI.

The graphs below illustrate the differences in initial BMI in more detail. The median BMI for one South American country is markedly less than that of two European countries for both men and women. The reasons for this may relate to the local referral practices into bariatric surgery, with patients in a publicly funded system only having surgery at the higher BMIs. It is interesting to note that a proportion of patients in Chile (17.8% of men; 28.6% of women) are having surgery at a BMI threshold lower than the United States NIH and United Kingdom's NICE Guidance. The NIH Guidance was published in 1991, before laparoscopic techniques were widespread in bariatric surgery, and several of the operations commonly performed then are no longer done. As yet there is no direct, firm evidence in the literature as to the optimum timing for bariatric surgery; it may be that the greatest benefit, in terms of cost-effectiveness and comorbidity resolution, may be at the lower end of the spectrum of BMIs classified as *obese*.

Primary surgery for male patients: BMI distributions for selected contributors; calendar years 2011-2013



Primary surgery for female patients: BMI distributions for selected contributors; calendar years 2011-2013



Comorbidity

Type 2 diabetes

Type 2 diabetes mellitus is the obesity-related disease that has attracted most attention in bariatric surgery due to the demonstrable improvement in diabetes control with surgery, and data suggesting that surgery is cost effective. In publicly-funded healthcare systems, it may be that patients are being referred for surgery for these reasons, hence forming a substantial proportion of operated patients. To our knowledge this is the first demonstration of the prevalence of diabetes in the operated population across the world. This information constitutes basic demographic data as the bariatric community seeks to increase the provision of surgery for the increasing population with this comorbidity.

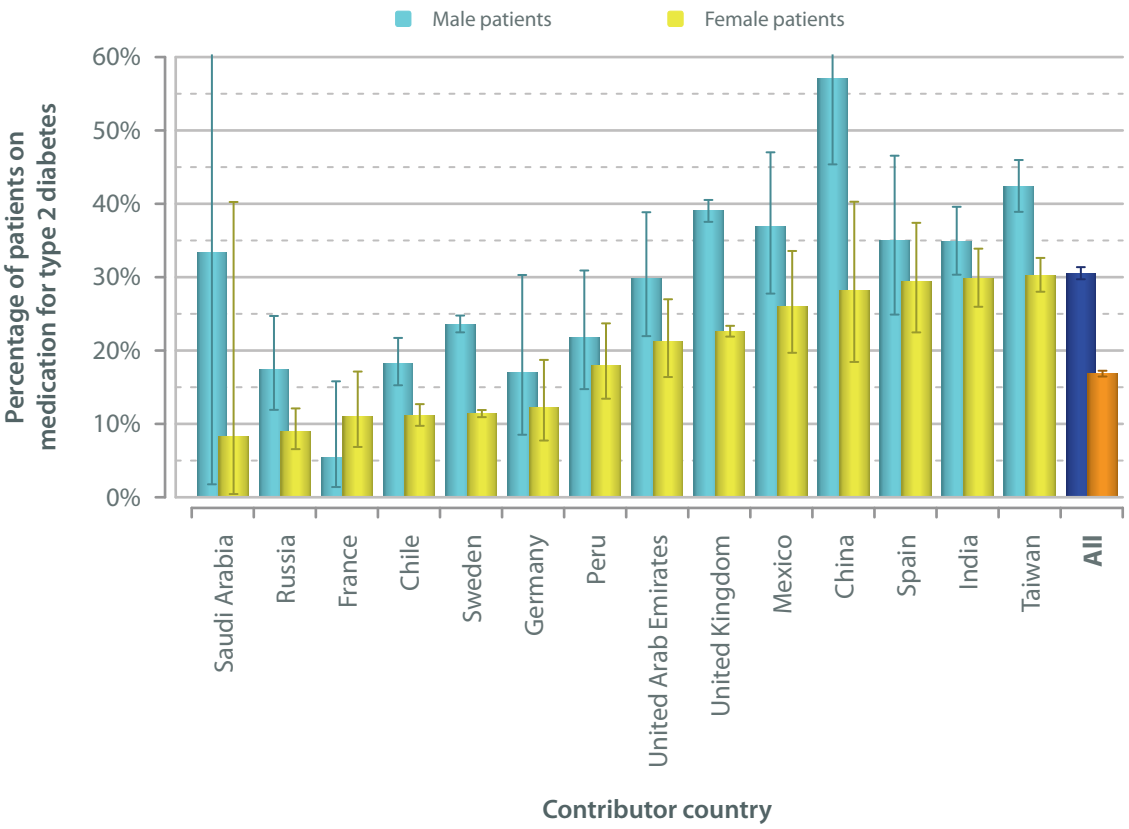
Interestingly China, India and Taiwan have some of the largest proportions of diabetic patients, possibly relating to the greater susceptibility of Asian people to developing diabetes at lower BMI levels.

The data need to be interpreted in the context of diabetes risk with ethnicity. It may also be that the *diabetes story* has been taken up as a driver for surgery in these countries, contrasting with some other countries where the proportion of patients with diabetes having surgery is much lower. This area of inequality of access to bariatric surgery is ripe for research.

Primary surgery: patients on medication for type 2 diabetes prior to surgery and gender; calendar years 2011-2013

Contributor country	Gender and type 2 diabetes on medication							
	Male				Female			
	No diabetes	Diabetes	Unspecified	Percentage with comorbidity	No diabetes	Diabetes	Unspecified	Percentage with comorbidity
Brazil	0	0	93	NA	0	0	262	NA
Chile	474	106	0	18.3%	1,605	201	0	11.1%
China	33	44	2	57.1%	51	20	0	28.2%
France	53	3	0	5.4%	145	18	1	11.0%
Germany	44	9	0	17.0%	136	19	0	12.3%
India	277	148	0	34.8%	375	159	0	29.8%
Mexico	65	38	0	36.9%	122	43	0	26.1%
Netherlands	0	0	147	NA	0	0	620	NA
Peru	86	24	1	21.8%	191	42	3	18.0%
Russia	123	26	0	17.4%	406	40	0	9.0%
Saudi Arabia	2	1	0	33.3%	11	1	0	8.3%
Spain	52	28	0	35.0%	108	45	0	29.4%
Sweden	4,104	1,268	0	23.6%	14,757	1,898	0	11.4%
Taiwan	447	329	0	42.4%	1,092	474	8	30.3%
United Arab Emirates	85	36	0	29.8%	193	52	0	21.2%
United Kingdom	2,541	1,626	130	39.0%	9,754	2,852	375	22.6%
All	**8,386**	**3,686**	**373**	**30.5%**	**28,946**	**5,864**	**1,269**	**16.8%**

Primary surgery: Patients on medication for type 2 diabetes prior to surgery; calendar years 2011-2013



Hypertension

Again, there is widespread variation in the prevalence of hypertension between the different countries, with Germany, Spain and Taiwan having the highest rates. In some countries hypertension is associated with diabetes as part of the metabolic syndrome. However, there is also strong ethnic propensity to one or the other condition.

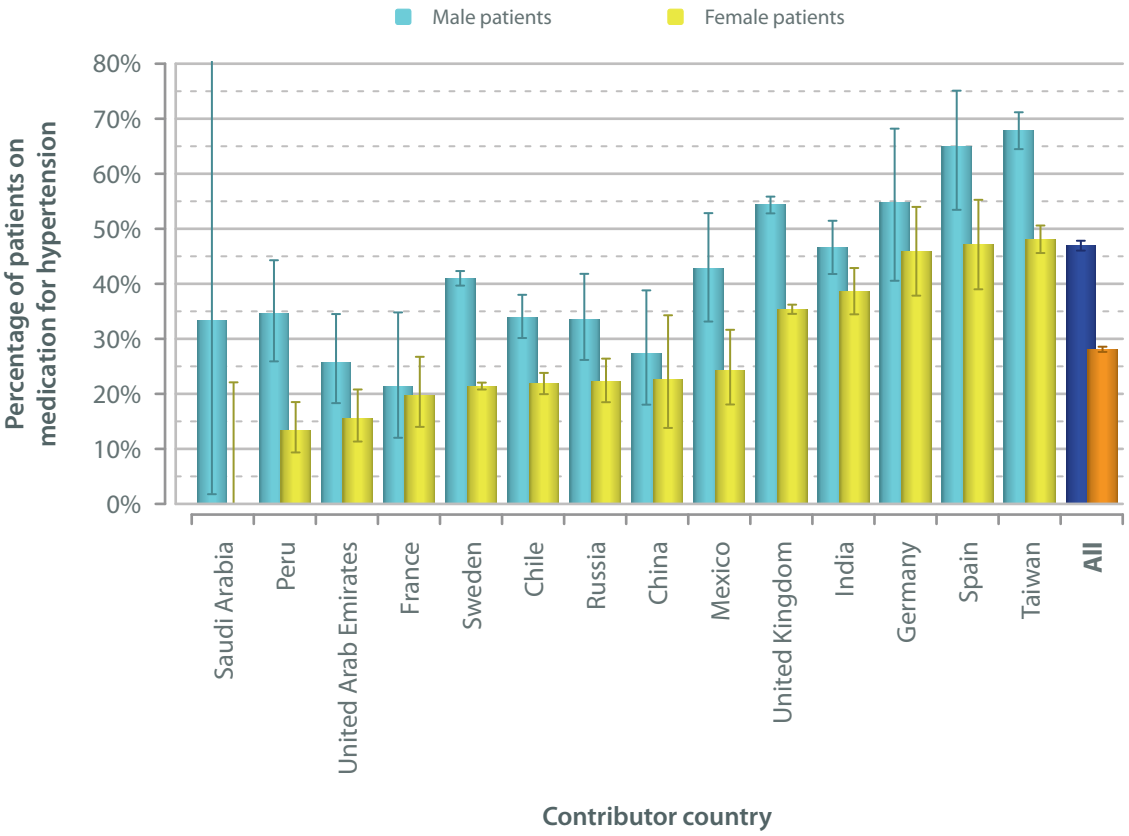
As hypertension is associated with central obesity, it would also be expected that this is a predictor of operative risk (more difficult laparoscopic surgery), and thus it is one of the factors included in the Obesity Surgery Mortality Risk Score (OSMRS) shown in the following section. Recording of the presence of hypertension is therefore needed as a prerequisite for comparing mortality between different series.

The wide variation in the reported rates of hypertension between countries might indicate a need for standardization in the recording of blood pressure between different countries and surgical centres. This would be the key towards achieving accurate reporting and must also be a priority for international research in bariatric surgery in this area.

Primary surgery: patients on medication for hypertension prior to surgery and gender; calendar years 2011-2013

		Gender and medication for hypertension							
		Male				Female			
		No hypertension	Hypertension	Unspecified	Percentage with comorbidity	No hypertension	Hypertension	Unspecified	Percentage with comorbidity
Contributor country	Brazil	0	0	93	NA	0	0	262	NA
	Chile	383	197	0	34.0%	1,412	394	0	21.8%
	China	56	21	2	27.3%	55	16	0	22.5%
	France	44	12	0	21.4%	131	32	1	19.6%
	Germany	24	29	0	54.7%	84	71	0	45.8%
	India	227	198	0	46.6%	328	206	0	38.6%
	Mexico	59	44	0	42.7%	125	40	0	24.2%
	Netherlands	0	0	147	NA	0	0	620	NA
	Peru	72	38	1	34.5%	202	31	3	13.3%
	Russia	99	50	0	33.6%	347	99	0	22.2%
	Saudi Arabia	2	1	0	33.3%	12	0	0	0.0%
	Spain	28	52	0	65.0%	81	72	0	47.1%
	Sweden	3,170	2,202	0	41.0%	13,089	3,566	0	21.4%
	Taiwan	248	525	3	67.9%	815	755	4	48.1%
	United Arab Emirates	90	31	0	25.6%	207	38	0	15.5%
	United Kingdom	1,905	2,266	126	54.3%	8,161	4,466	354	35.4%
	All	**6,407**	**5,666**	**372**	**46.9%**	**25,049**	**9,786**	**1,244**	**28.1%**

Primary surgery: Patients on medication for hypertension prior to surgery; calendar years 2011-2013



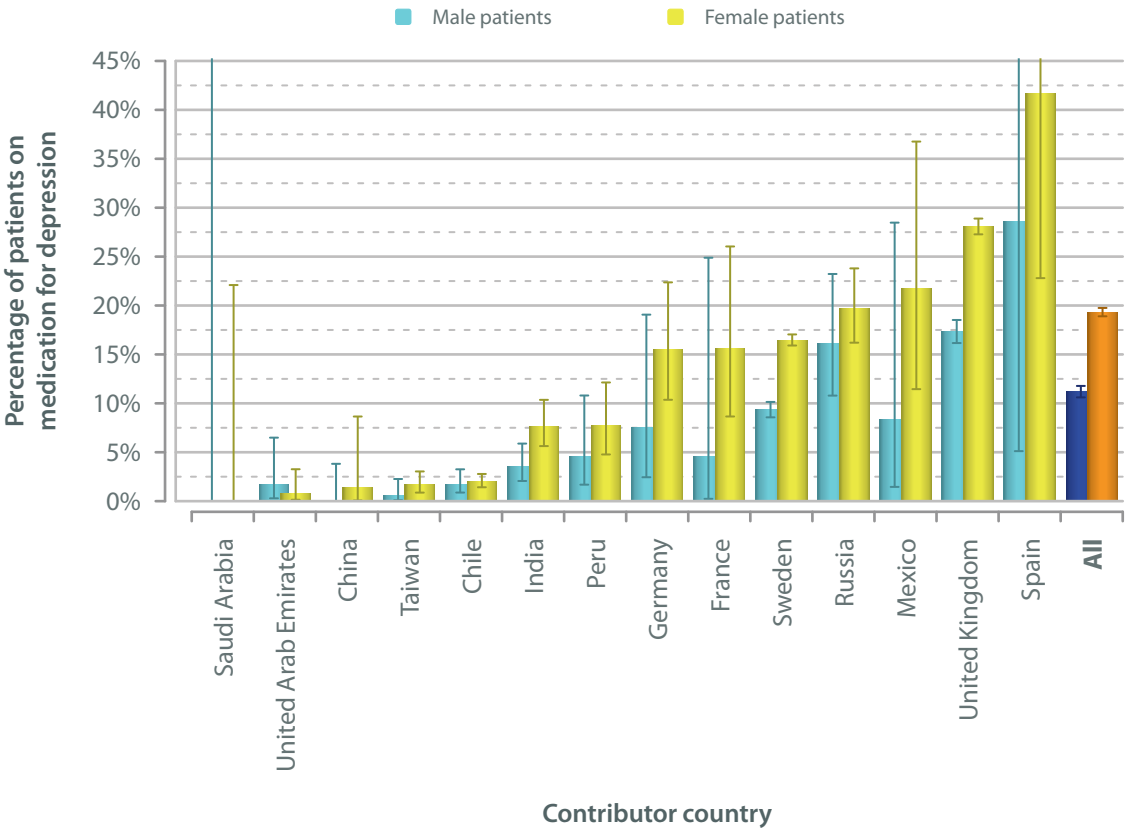
Depression

The table and graphs below show that there is widespread variation in the recorded rates of clinical depression in bariatric patients. The reasons for this are not known, and may relate to different methods of reporting or recording this comorbidity, or, perhaps, greater prevalence with increasing BMI. However, psychiatric comorbidity is known to be highly prevalent in severely obese patients. This information may be important in assessment of inequality of access to bariatric surgery between different healthcare systems.

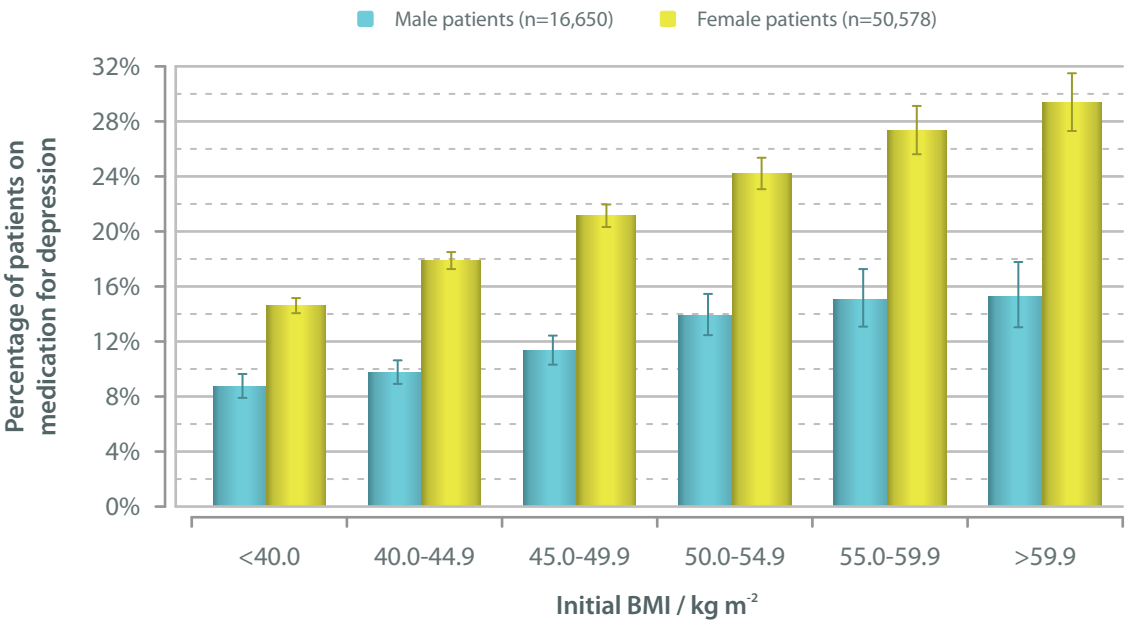
Primary surgery: patients on medication for depression prior to surgery and gender; calendar years 2011-2013

		Gender and recorded depression on medication							
		Male				Female			
		No depression	Depression	Unspecified	Percentage with comorbidity	No depression	Depression	Unspecified	Percentage with comorbidity
Contributor country	Brazil	0	0	93	NA	0	0	262	NA
	Chile	570	10	0	1.7%	1,770	36	0	2.0%
	China	77	0	2	0.0%	70	1	0	1.4%
	France	21	1	34	4.5%	65	12	87	15.6%
	Germany	49	4	0	7.5%	131	24	0	15.5%
	India	410	15	0	3.5%	493	41	0	7.7%
	Mexico	22	2	79	8.3%	36	10	119	21.7%
	Netherlands	0	0	147	NA	0	0	620	NA
	Peru	105	5	1	4.5%	215	18	3	7.7%
	Russia	125	24	0	16.1%	358	88	0	19.7%
	Saudi Arabia	3	0	0	0.0%	12	0	0	0.0%
	Spain	5	2	73	28.6%	14	10	129	41.7%
	Sweden	4,871	501	0	9.3%	13,912	2,743	0	16.5%
	Taiwan	350	2	424	0.6%	653	11	910	1.7%
	United Arab Emirates	118	2	1	1.7%	241	2	2	0.8%
	United Kingdom	3,339	699	259	17.3%	8,667	3,383	931	28.1%
	All	**10,065**	**1,267**	**1,113**	**11.2%**	**26,637**	**6,379**	**3,063**	**19.3%**

Primary surgery: Patients on medication for depression prior to surgery; calendar years 2011-2013



Primary surgery: Patients on medication for depression prior to surgery, gender and initial BMI; calendar years 2011-2013



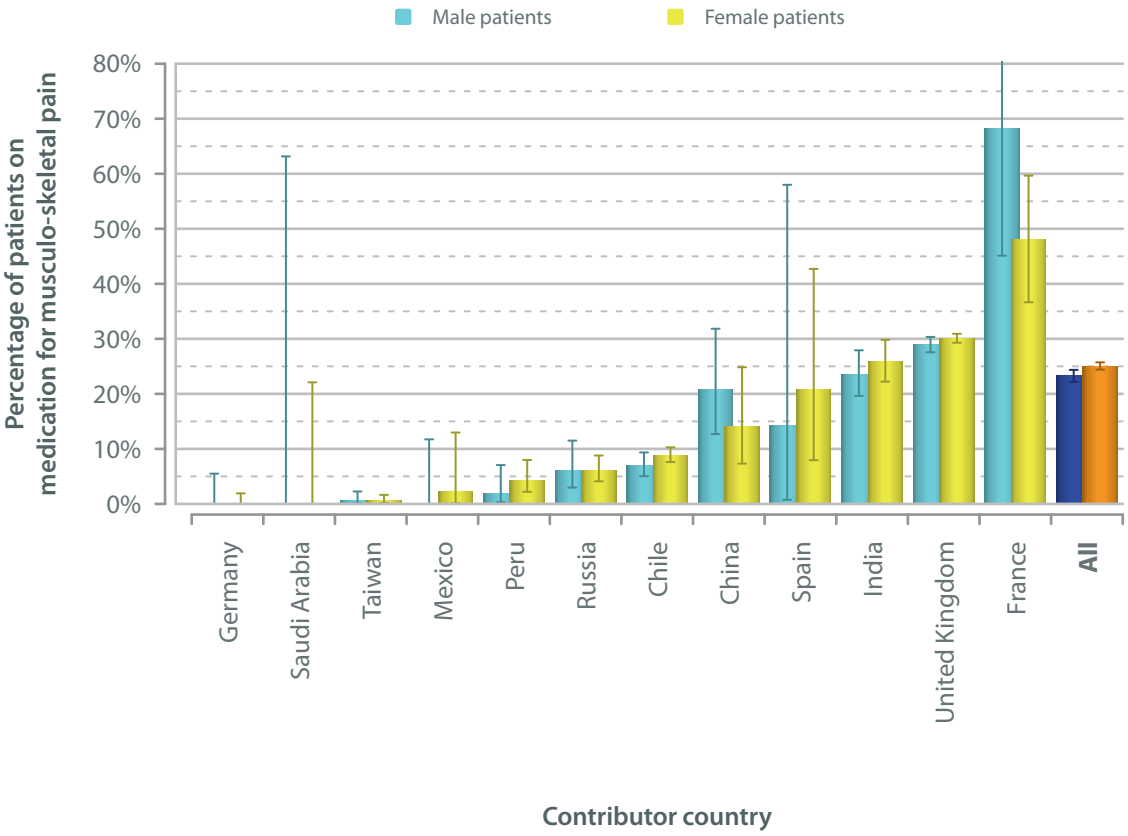
Musculo-skeletal pain

Many very obese people have problems with mobility and functional status due to musculo-skeletal pain, and therefore we included a question on this as part of the dataset. Interestingly, although there is variation between different countries in the recorded prevalence, fully 1 in 4 patients overall is on medication for musculo-skeletal pain. This comorbidity is generally not recognised by bariatric physicians or primary care physicians as a significant indication for bariatric surgery, but the data illustrate the high degree of disease in the operated population. It is also very interesting to observe that the highest prevalence is in France; however, the numbers are too small for meaningful statistical comparison.

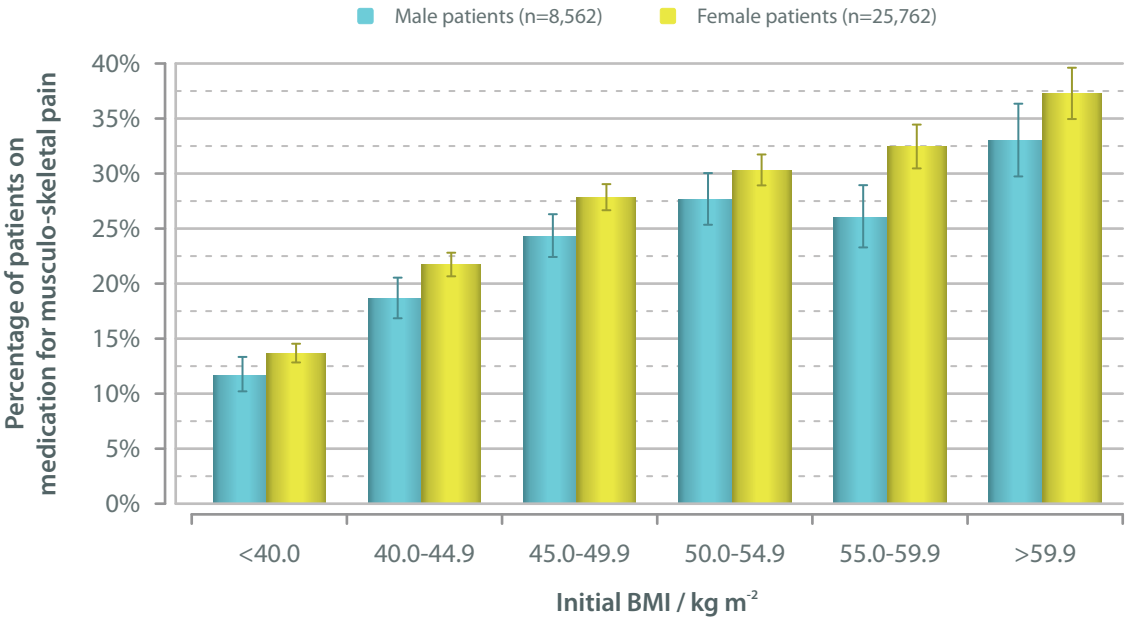
Primary surgery: patients on medication for musculo-skeletal pain prior to surgery and gender; calendar years 2011-2013

		Gender and medication for musculo-skeletal pain							
		Male				Female			
		No pain	Pain	Unspecified	Percentage with comorbidity	No pain	Pain	Unspecified	Percentage with comorbidity
Contributor country	Brazil	0	0	93	NA	0	0	262	NA
	Chile	540	40	0	6.9%	1,646	160	0	8.9%
	China	61	16	2	20.8%	61	10	0	14.1%
	France	7	15	34	68.2%	40	37	87	48.1%
	Germany	53	0	0	0.0%	155	0	0	0.0%
	India	325	100	0	23.5%	396	138	0	25.8%
	Mexico	24	0	79	0.0%	45	1	119	2.2%
	Netherlands	0	0	147	NA	0	0	620	NA
	Peru	108	2	1	1.8%	223	10	3	4.3%
	Russia	140	9	0	6.0%	419	27	0	6.1%
	Saudi Arabia	3	0	0	0.0%	12	0	0	0.0%
	Spain	6	1	73	14.3%	19	5	129	20.8%
	Sweden	0	0	5,372	NA	0	0	16,655	NA
	Taiwan	351	2	423	0.6%	661	4	909	0.6%
	United Arab Emirates	0	0	121	NA	0	0	245	NA
	United Kingdom	2,938	1,196	163	28.9%	8,716	3,753	512	30.1%
	All	**4,556**	**1,381**	**6,508**	**23.3%**	**12,393**	**4,145**	**19,541**	**25.1%**

Primary surgery: Patients on medication for musculo-skeletal pain prior to surgery; calendar years 2011-2013



Primary surgery: Patients on medication for musculo-skeletal pain prior to surgery, gender and initial BMI; calendar years 2011-2013



Sleep apnoea

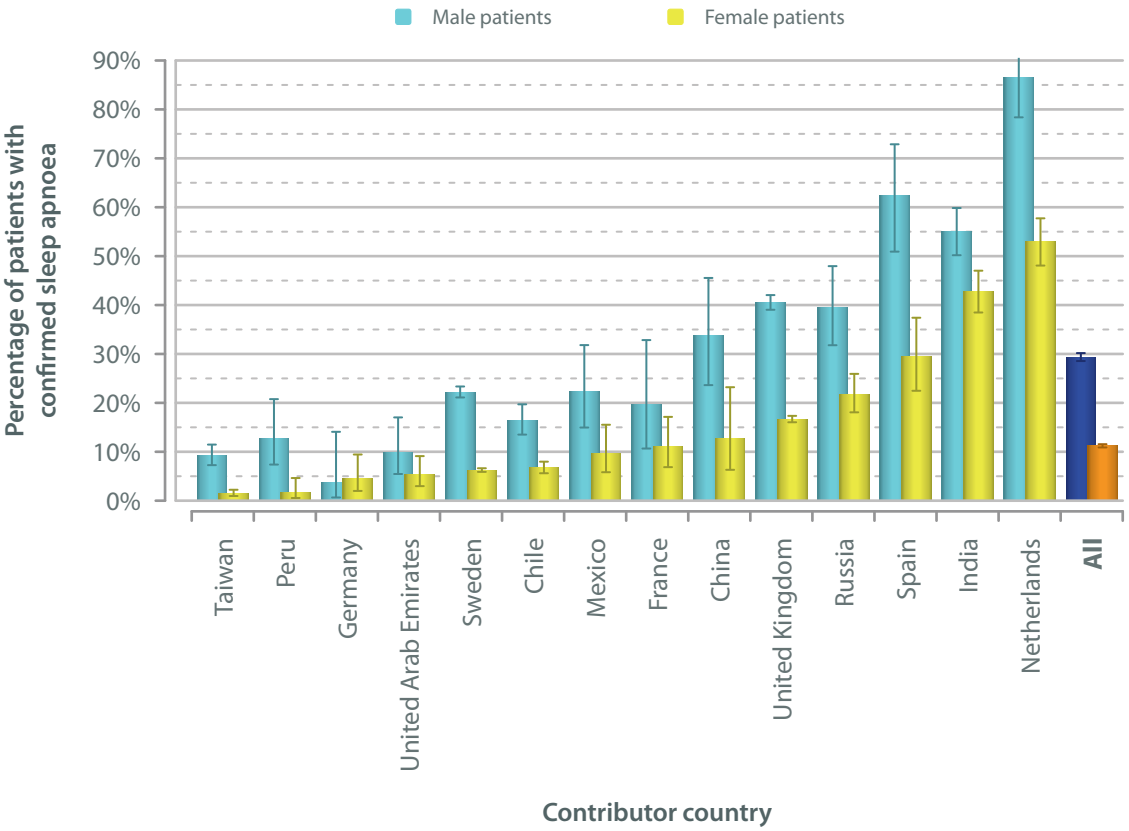
The data show clearly that in every country the rate of sleep apnoea is higher in male patients than in females. The reasons for this are not known, and again may reflect referral practice especially in the Netherlands, which has the highest recorded prevalence in patients having bariatric surgery.

Primary surgery: confirmed sleep apnoea prior to surgery and gender; calendar years 2011-2013

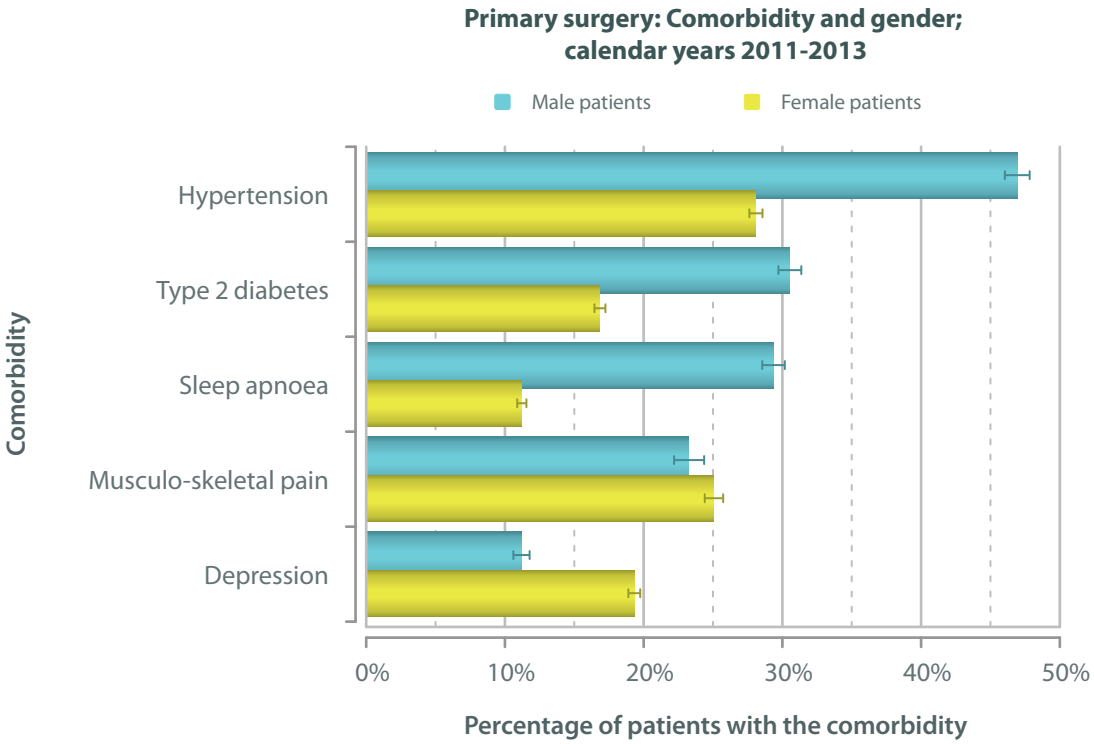
Contributor country	Gender and confirmed sleep apnoea [1]							
	Male				Female			
	No sleep apnoea	Sleep apnoea	Unspecified	Percentage with comorbidity	No sleep apnoea	Sleep apnoea	Unspecified	Percentage with comorbidity
Brazil	0	0	93	NA	0	0	262	NA
Chile	485	95	0	16.4%	1,685	121	0	6.7%
China	51	26	2	33.8%	62	9	0	12.7%
France	45	11	0	19.6%	145	18	1	11.0%
Germany	51	2	0	3.8%	148	7	0	4.5%
India	191	234	0	55.1%	306	228	0	42.7%
Mexico	80	23	0	22.3%	149	16	0	9.7%
Netherlands	15	96	36	86.5%	201	226	193	52.9%
Peru	96	14	1	12.7%	229	4	3	1.7%
Russia	90	59	0	39.6%	349	97	0	21.7%
Saudi Arabia	2	1	0	33.3%	12	0	0	0.0%
Spain	30	50	0	62.5%	108	45	0	29.4%
Sweden	4,179	1,193	0	22.2%	15,614	1,041	0	6.3%
Taiwan	704	71	1	9.2%	1,541	23	10	1.5%
United Arab Emirates	109	12	0	9.9%	232	13	0	5.3%
United Kingdom	2,480	1,690	127	40.5%	10,511	2,104	366	16.7%
All	**8,608**	**3,577**	**260**	**29.4%**	**31,292**	**3,952**	**835**	**11.2%**

1. Confirmed sleep apnoea: Confirmed sleep apnoea with the use of continuous positive airway pressure (CPAP) or bi-level positive air pressure (BiPAP).

Primary surgery: Patients with confirmed sleep apnoea prior to surgery; calendar years 2011-2013



The graph below shows basic demographic data on the prevalence of each of the five comorbidities in the dataset. A comparison may be made with the data that are collected at baseline for cancers, where many health systems have infra-structure already in place for accumulating information on tumour staging at presentation. As the IFSO Global Registry project progresses, further data comparisons could be made between different countries. To our knowledge this is the first time that these baseline data have been collated from across the globe, and the data may also be useful for comparing rates of access to surgery for patients with different comorbidities in each country. The data could also be relevant in cost-effectiveness calculations and benchmarking, where inequality of access for different populations is an issue.



Obesity Surgery Mortality Risk Score

The OSMRS (Obesity Surgery Mortality Risk Score) stratifies patients undergoing bariatric surgery into three categories depending on how many of the following risk factors they possess:

- Male gender
- Age ≥45 years at the time of surgery
- BMI >50 kg m^2
- Hypertension
- Risk factors for deep vein thrombosis / pulmonary embolism

The patient is ascribed one point for each of the above risk factors and a cumulative score determined, giving a total score in the range zero to five; this score is grouped into one of three categories [1,2]:

- Group A: score 0-1 (low risk)
- Group B: score 2-3 (moderate risk)
- Group C: score 4-5 (high risk)

Primary surgery: OSMRS; calendar years 2011-2013

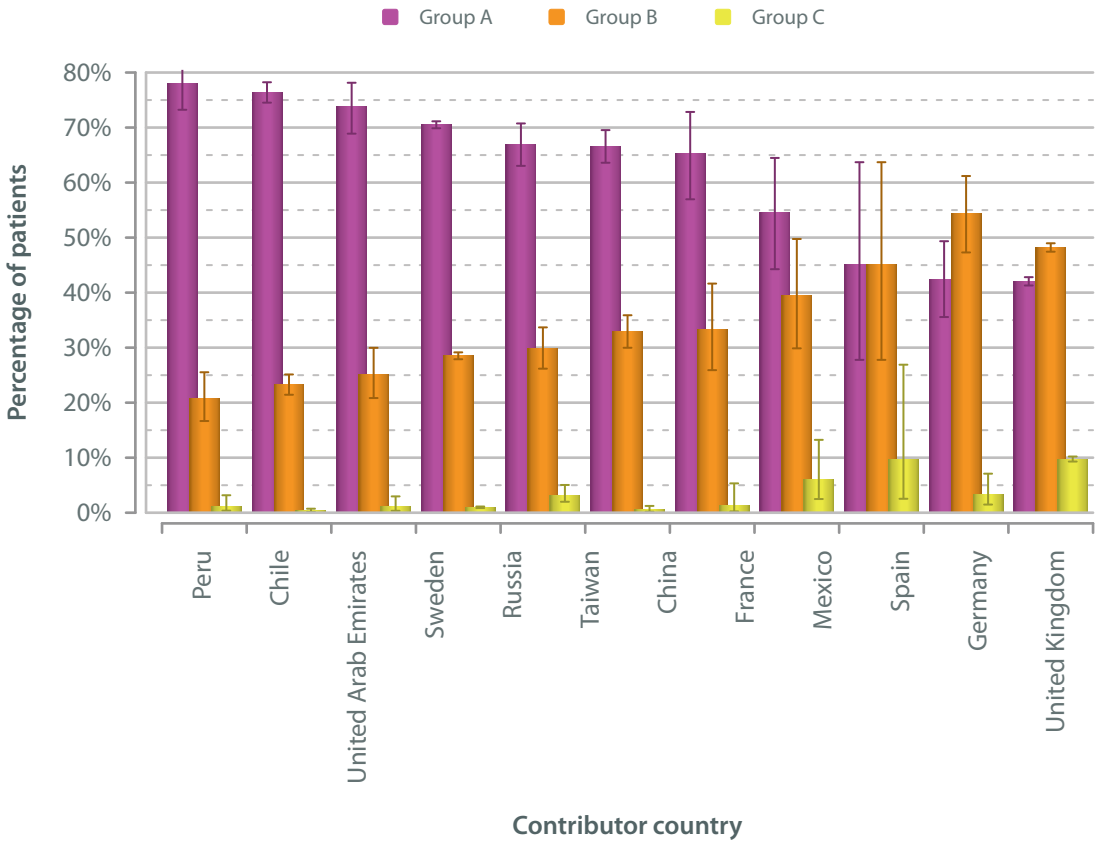
		OSMRS group				
		A (0-1)	B (2-3)	C (4-5)	Unspecified	**All**
Contributor country	Brazil	0	0	0	355	**355**
	Chile	1,579	480	7	320	**2,386**
	China	96	49	2	3	**150**
	France	54	39	6	121	**220**
	Germany	88	113	7	1	**209**
	India	6	2	0	951	**959**
	Mexico	34	32	4	198	**268**
	Netherlands	0	0	0	767	**767**
	Peru	267	71	4	6	**348**
	Russia	398	177	19	1	**595**
	Saudi Arabia	13	2	0	0	**15**
	Spain	14	14	3	203	**234**
	Sweden	14,206	5,745	197	1,879	**22,027**
	Taiwan	667	329	5	1,362	**2,363**
	United Arab Emirates	270	92	4	0	**366**
	United Kingdom	6,938	7,953	1,608	779	**17,278**
	All	**24,630**	**15,098**	**1,866**	**6,946**	**48,540**

1. DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: Proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. *Surgery for Obesity and Related Diseases*. 2007; **3**: 134-140.
2. DeMaria EJ, Murr M, Byrne TK, Blackstone R, Grant JP, Budak A, Wolfe L. Validation of the obesity surgery mortality risk score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. *Annals of Surgery*. 2007; **246**: 578-582.

The comparison of operative risk and mortality between different series and different countries is problematic unless there is a way of stratifying for pre-operative risk. This may be relevant in the situation where systematic reviews and meta-analyses are undertaken when the baseline data are not comparable. The data in the graph show that there is, again, wide variation in OSMRS, an accepted risk-assessment tool, between different countries. Future reports could compare surgical mortality on a like-for-like basis in similar populations. Thus, there could be appropriate risk stratification in assessing outcomes.

This graphical representation of operative risk also provides important baseline information for prioritisation of which patients should receive treatment in different countries.

Primary surgery: OSMRS distributions; calendar years 2011-2013



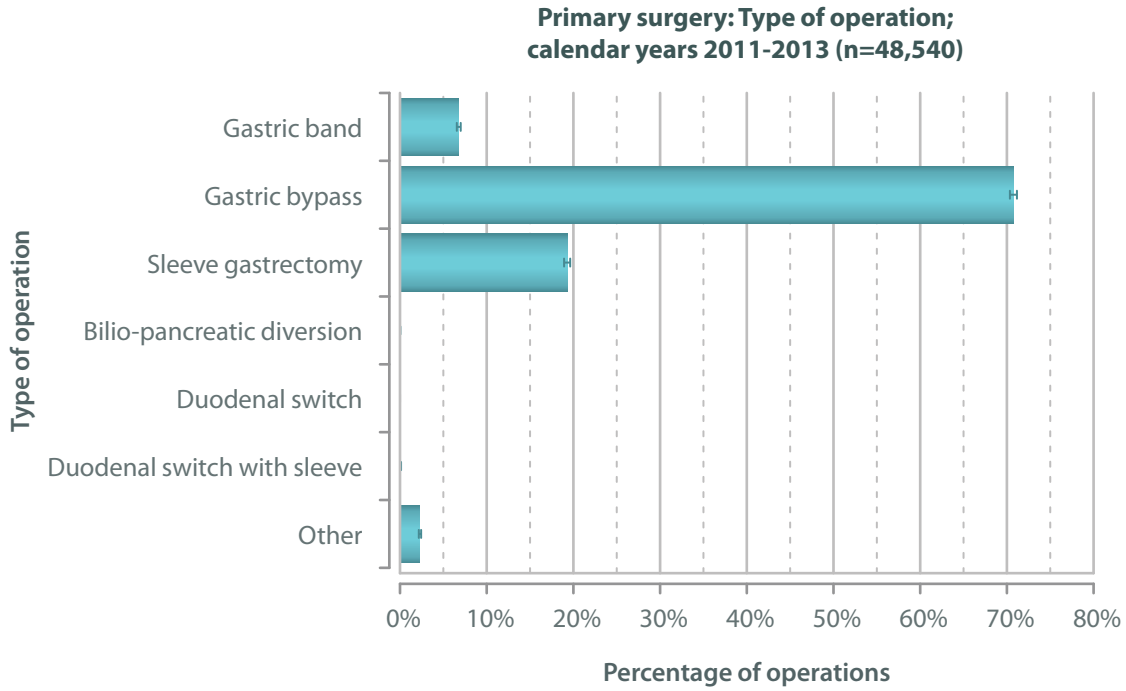
Surgery

Type of surgery

These data can be compared directly to those produced by Buchwald and Oien [1] where gastric bypass was the most prevalent operation in 2011, with sleeve gastrectomy and gastric banding the next most prevalent. Compared to cancer surgery, where the tiers of lymph node dissection, for instance, are carefully worked out and standardised, the types of bariatric surgery vary widely in practice between different countries, underlining, perhaps, the urgent need for randomised controlled trials to improve the knowledge base.

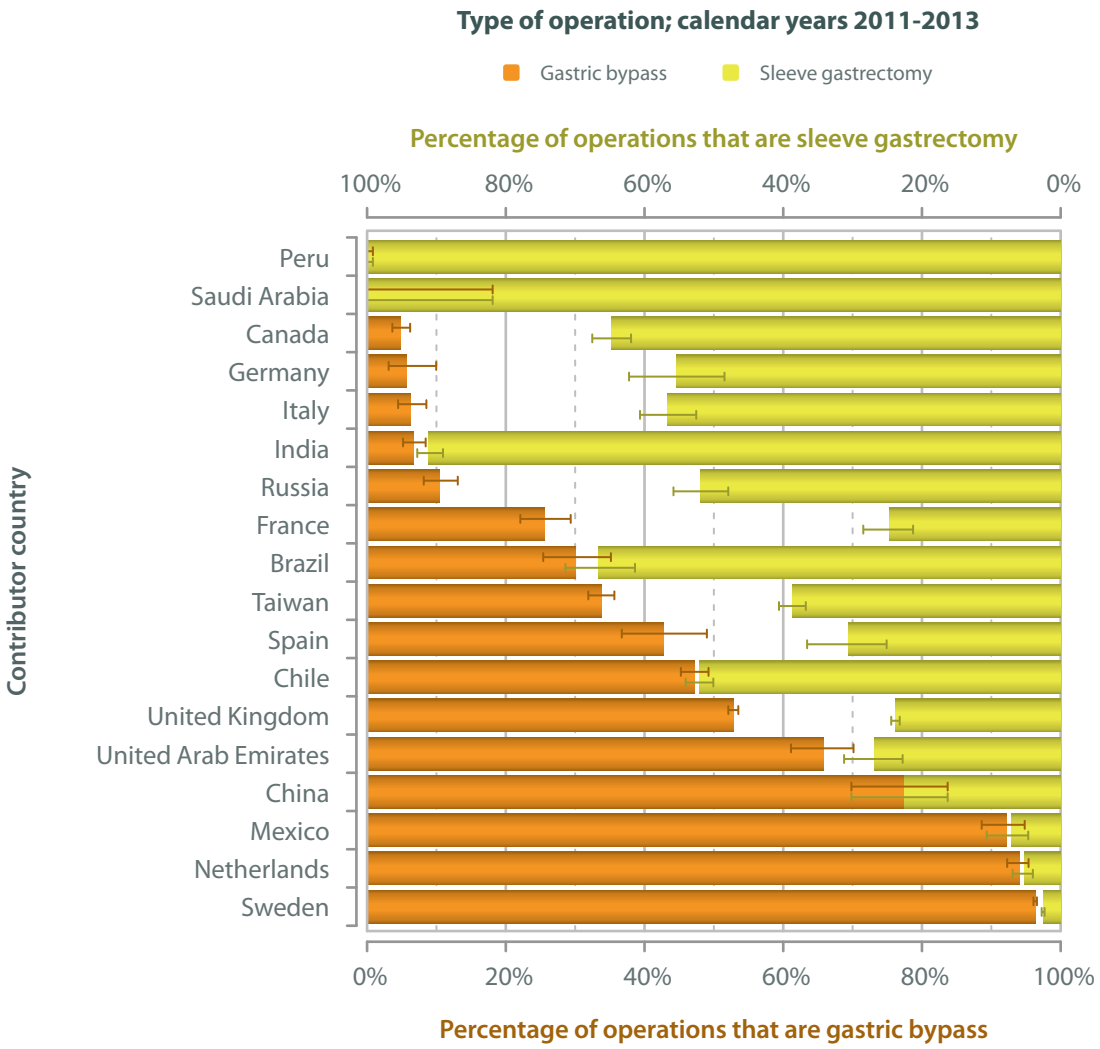
IFSO Global Registry: type of operation and previous bariatric surgery; calendar years 2011-2013

		Previous bariatric surgery			
		No	Yes	Unspecified	**All**
Type of operation	Gastric band	3,288	467	439	**4,194**
	Gastric bypass	34,344	1,404	92	**35,840**
	Sleeve gastrectomy	9,356	273	1,084	**10,713**
	Bilio-pancreatic diversion	10	6	1	**17**
	Duodenal switch	3	35	4	**42**
	Duodenal switch with sleeve	423	27	0	**450**
	Other	1,116	409	416	**1,941**
	All	**48,540**	**2,621**	**2,036**	**53,197**



1. Buchwald H & Oien DM. Metabolic / bariatric surgery worldwide 2011. *Obesity Surgery*. 2013; **23(4)**: 427-436.

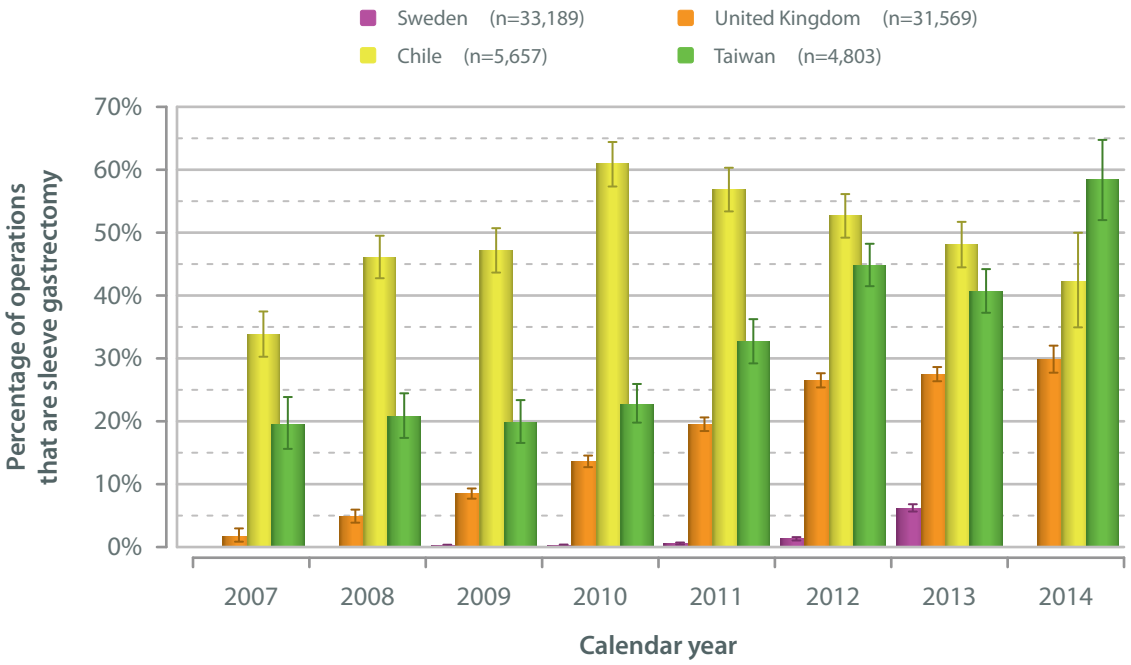
It is interesting to note that almost all the operations in Peru are sleeve gastrectomies, while in Sweden almost all are gastric bypasses. The reasons for these differences in practice are not known. It could be that countries newer to bariatric surgery have taken up sleeve gastrectomy, while countries with a longer history of this kind of surgery continue with the gastric bypass.



The importing of data from a large number of registries and databases worldwide could enable accurate trends to be observed. Here we see year-on-year changes in the proportion of bariatric surgery that was sleeve gastrectomy in four of the contributor countries.

It is interesting to observe that although the relative prevalence of this kind of surgery has increased and continues to increase in Taiwan, the United Kingdom and Sweden, the rate appears to be current trending downwards in Chile, having hit a peak in 2010. Further reports could analyse in more detail annual trends in operative procedures.

Primary operations: Changes in sleeve gastrectomy rates over time; selected contributor countries



Operative approach

The rapid expansion of bariatric surgery over the last 25 years has mirrored the development of laparoscopic techniques. The following table shows the prevalence of the laparoscopic approach for the different operations. Almost 98% of gastric bypasses and over 99% of sleeve gastrectomies were performed laparoscopically, an achievement that could not have been forecast even 20 years ago.

Primary operations: operative approach; calendar years 2011-2013

		Approach					
		Laparoscopic	Endoscopic	Laparoscopic converted to open	Open	Unspecified	Percentage open
Type of operation	Gastric band	3,283	2	2	1	0	0.09%
	Gastric bypass	33,610	0	149	560	25	2.07%
	Sleeve gastrectomy	9,205	1	6	49	95	0.59%
	Bilio-pancreatic diversion	1	0	0	9	0	90.00%
	Duodenal switch	3	0	0	0	0	0.00%
	Duodenal switch with sleeve	216	0	3	204	0	48.94%
	Other	810	300	0	6	0	0.54%
	All	**47,128**	**303**	**160**	**829**	**120**	2.04%

Post-operative outcomes

Immediate outcomes

The table below shows the recorded incidence of bleeding, leak, obstruction and in-hospital mortality after gastric banding, gastric bypass and sleeve gastrectomy. There are a large number of missing data points for each of the complications. This could reflect the software structure of the local or national registries where there was a lack of a simple *Yes / No* question to specify that a particular complication absolutely did not occur; it could also represent under-reporting of the complication or of mortality.

The mortality rates recorded are certainly lower than what is reported in the published literature from institutions where there is sufficient independent staffing infra-structure to validate outcomes before discharge. However, we recognise that most publicly- or privately-funded healthcare systems may not have such systems in place.

For instance an American College of Surgeons report in 2012 [1] demonstrated 30-day mortality rates of 0.05%, 0.14% and 0.11% for gastric banding, gastric bypass and sleeve gastrectomy in a total population of 28,616 patients.

Primary surgery: post-operative outcome rates; calendar years 2011-2013

			Type of operation				
			Gastric band	Gastric bypass	Sleeve gastrectomy	Others	**All**
30-day outcomes	**Bleed**	No	196	22,534	3,679	416	**26,825**
		Yes	0	432	35	1	**468**
		Unspecified	3,092	11,378	5,642	1,135	**21,247**
		Rate	0.00%	1.88%	0.94%	0.24%	**1.71%**
	Leak	No	196	22,748	3,691	411	27,046
		Yes	0	215	17	6	238
		Unspecified	3,092	11,381	5,648	1,135	**21,256**
		Rate	0.00%	0.94%	0.46%	1.44%	**0.87%**
	Obstruction	No	196	22,716	3,716	417	27,045
		Yes	0	250	2	1	253
		Unspecified	3,092	11,378	5,638	1,134	**21,242**
		Rate	0.00%	1.09%	0.05%	0.24%	**0.93%**
	In-hospital mortality	No	3,068	32,869	7,122	1,206	44,265
		Yes	0	8	6	0	14
		Unspecified	220	1,467	2,228	346	**4,261**
		Rate	0.00%	0.02%	0.08%	0.00%	**0.03%**

1. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3339264/Hutter.

Post-operative stay

Post-operative stay and country

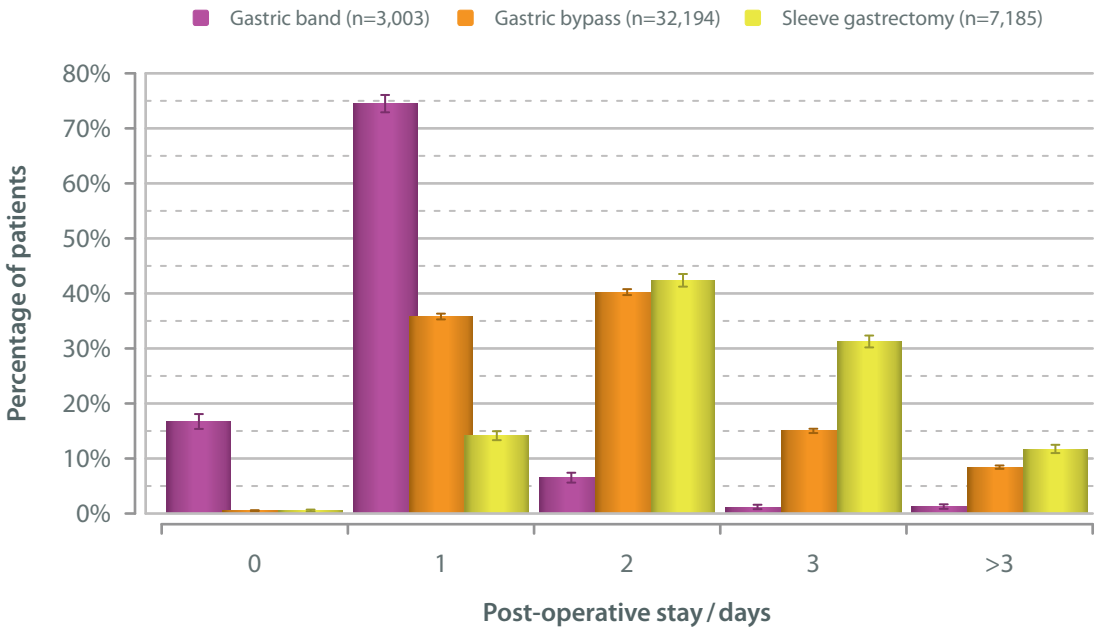
This is the first international comparison of post-operative length-of-stay between the 3 common kinds of operation: gastric banding, gastric bypass and sleeve gastrectomy. As expected, the shortest length-of-stay was for gastric banding, followed by gastric bypass and then sleeve gastrectomy. Over 85% of band patients were discharged within 24 hours of their operation, 75% of bypass patients were discharged by day 2 and nearly 90% of sleeves were discharged by day 3.

As is seen in the graphs on the facing page, the timing of discharge may very much depend on the local healthcare environment.

Primary operations: post-operative stay and type of operation; calendar years 2011-2013

		Type of operation				
		Gastric band	Gastric bypass	Sleeve gastrectomy	Others	**All**
Post-operative stay / days	0	501	168	37	181	**887**
	1	2,238	11,526	1,015	222	**15,001**
	2	194	12,955	3,045	475	**16,669**
	3	34	4,833	2,246	159	**7,272**
	>3	36	2,712	842	368	**3,958**
	Unspecified	285	2,150	2,171	147	**4,753**
	All	**3,288**	**34,344**	**9,356**	**1,552**	**48,540**

Primary surgery: Post-operative stay and operation; calendar years 2011-2013



Primary operations: Post-operative stay and procedure; selected contributor countries

Post-operative stay and region

The graphs below show the post-operative length-of-stay after gastric banding, gastric bypass and sleeve gastrectomy for 5 different continents. Length-of-stay tended to be shorter in Europe after gastric bypass and sleeve compared to South America. It is important not to over interpret this as many factors influence discharge stay, including the mechanism of funding; however, the data show the type of analysis that can easily be done through collecting a concise merged dataset.

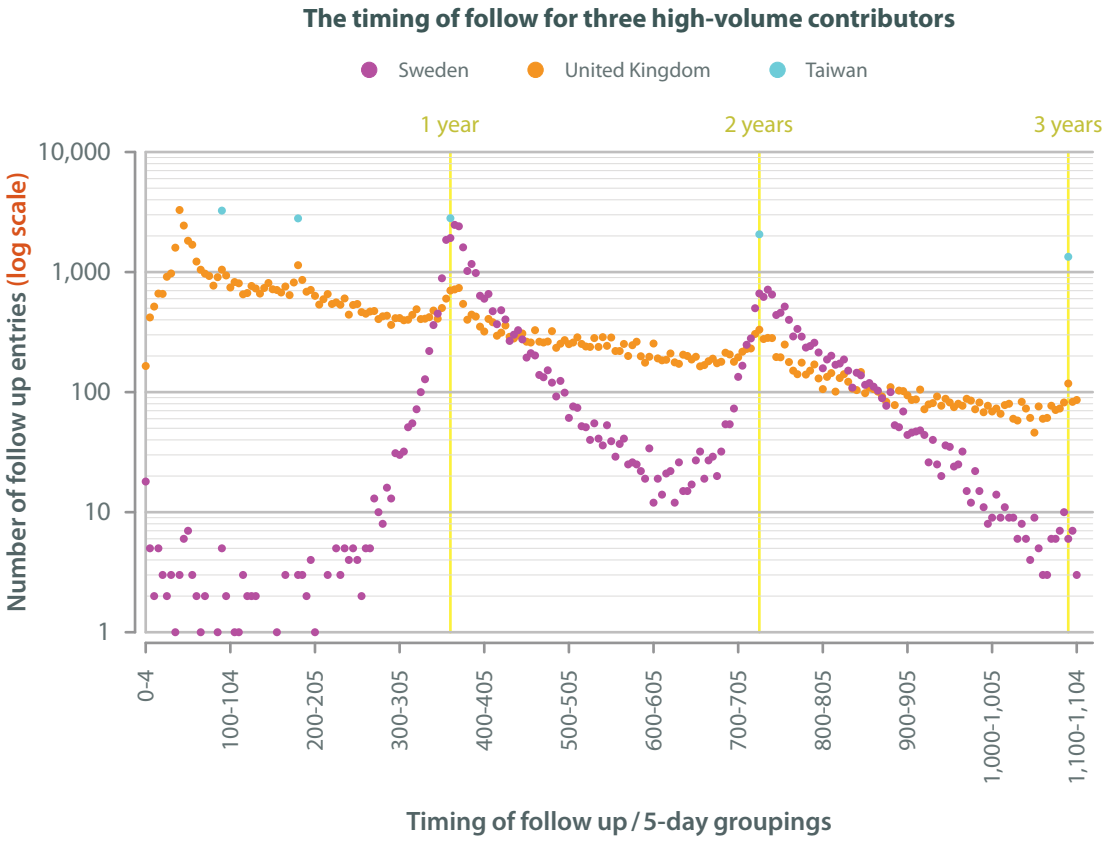
Primary surgery: post-operative stay, operation and region; calendar years 2011-2013

			Region				
			N America	S America	Europe	Asia	Middle East
Operation and post-operative stay / days	Gastric band	0	0	0	500	1	0
		1	0	0	2,230	8	0
		2	0	0	184	10	0
		3	0	1	30	3	0
		>3	0	0	34	2	0
		Unspecified	0	8	272	5	0
	Gastric bypass	0	0	0	158	10	0
		1	0	2	11,415	109	0
		2	169	109	12,355	322	0
		3	42	964	3,632	195	0
		>3	34	41	2,363	274	0
		Unspecified	1	110	1,725	68	0
	Sleeve gastrectomy	0	0	3	20	14	0
		1	0	242	619	154	0
		2	20	162	2,356	495	12
		3	2	1,150	934	158	2
		>3	0	40	647	154	1
		Unspecified	0	243	936	874	118

Primary operations: Post-operative stay, operation and region; calendar years 2011-2013

Follow up data

The data show the degree of detail that can be achieved in a registry: in this graph it is clear that in Sweden and Taiwan the timing of follow up is proscriptive, whereas in the United Kingdom there is much more variation in when patients are followed up.



Each patient can, of course, have multiple follow up entries in the database. Throughout this report, the follow up data are reported in such a way that each patient only contributes one observation at each predefined time-point.

For example, the analyses of weight loss at one year look at all the available weight data for all patients, and then reports on only one follow up record *per* patient. One-year follow up was defined as 365 days ± 61 days after the operation, so as to include as much information as possible, whilst maintaining a relatively tight focus around the precise one-year time-point. Only follow up entries that fell within this timeframe were eligible for analyses reporting on one-year weight loss, and for each patient the follow up record dated nearest to the one-year point (365 days) was used in analysis.

Long-term outcomes

Excess weight loss at one year

Percentage excess weight loss (%EWL) has been defined as:

$$\frac{\text{initial weight (kg) - current weight (kg)}}{\text{initial weight (kg) - [25 (kg m}^{-2}\text{)} \times \text{height}^2 \text{ (m}^2\text{)}} \times 100\%$$

It calculates the post-operative weight loss compared to the patient's initial weight and an arbitrary weight (equivalent to a BMI of 25 kg m^{-2}). Numerically, this is exactly the same as percentage excess BMI loss (%EBMIL) when the arbitrary *standard* is set at a BMI of 25 kg m^{-2}. Naturally, if the patient loses so much weight that their BMI drops below the arbitrary value of 25 kg m^{-2} then their percentage excess weight loss will be greater than 100%.

As far as we are aware, these are the first aggregated, international data that show weight loss after any bariatric procedure in such a large number of patients. The data are combined for all primary operations.

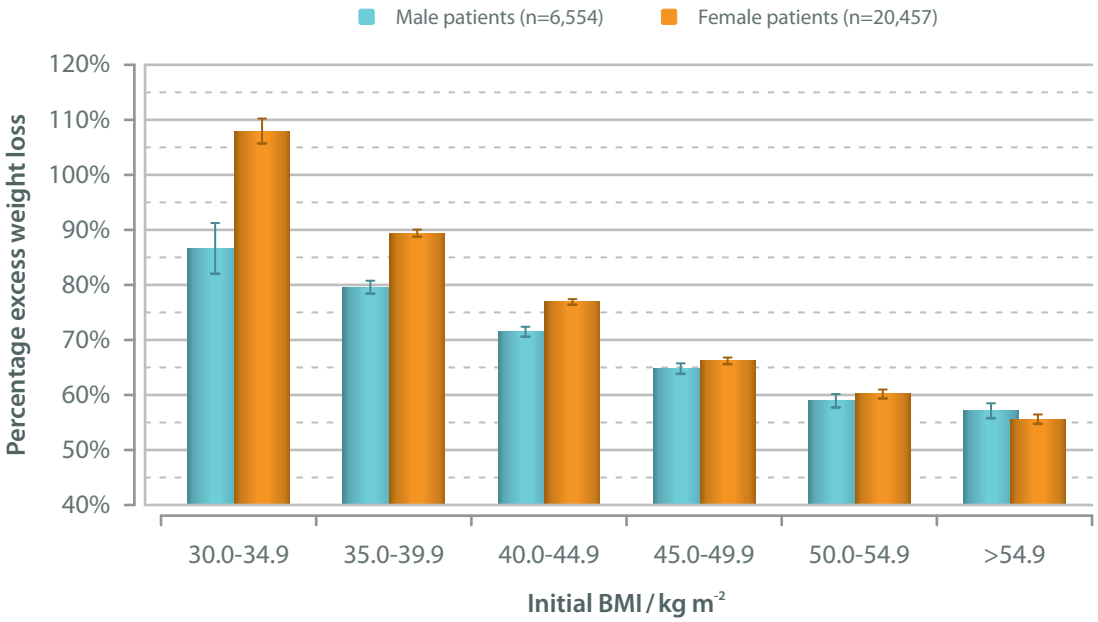
As expected, and well known by bariatric surgeons, weight loss after surgery far exceeds the amount that can be achieved by medical therapy and by repeated dieting. The data also show clear gender differences and illustrate the mathematical consequences of using percentage excess weight loss. A greater % excess weight loss (%EWL) is shown for a given amount of absolute weight lost if the patient's initial BMI is lower.

The data also illustrate the importance of including the gender distribution and the starting BMI when comparing weight loss results in follow up. Since the initial weight and height are included in the dataset, future reports of the IFSO Global Registry could use other measures of reporting weight loss.

Primary surgery: percentage excess weight loss one year after surgery; calendar years 2009-2013

Gender and initial BMI / kg m^{-2}			Statistics on percentage one-year excess weight loss		
			Count	Average (95% CI)	Median (IQR)
Male		30.0-34.9	181	86.6 (82.0-91.3)	90.1 (67.9-106.0)
		35.0-39.9	1,406	79.6 (78.4-80.8)	80.6 (65.6-95.2)
		40.0-44.9	1,991	71.5 (70.6-72.4)	72.2 (58.9-85.2)
		45.0-49.9	1,486	64.8 (63.8-65.7)	65.4 (53.4-77.1)
		50.0-54.9	819	58.9 (57.7-60.2)	59.9 (48.0-70.8)
		>55.0	671	57.1 (55.8-58.5)	57.7 (45.2-69.5)
Female		30.0-34.9	739	108.0 (105.7-110.2)	111.3 (90.7-129.7)
		35.0-39.9	5,412	89.4 (88.8-90.1)	91.6 (75.1-106.4)
		40.0-44.9	6,670	76.9 (76.4-77.4)	78.8 (64.4-91.3)
		45.0-49.9	4,068	66.2 (65.6-66.8)	67.3 (55.0-79.5)
		50.0-54.9	2,067	60.2 (59.4-61.0)	61.4 (49.4-72.7)
		>55.0	1,501	55.6 (54.8-56.5)	56.7 (45.0-66.8)

Primary surgery: Excess weight loss one year after surgery and gender; calendar years 2009-2013

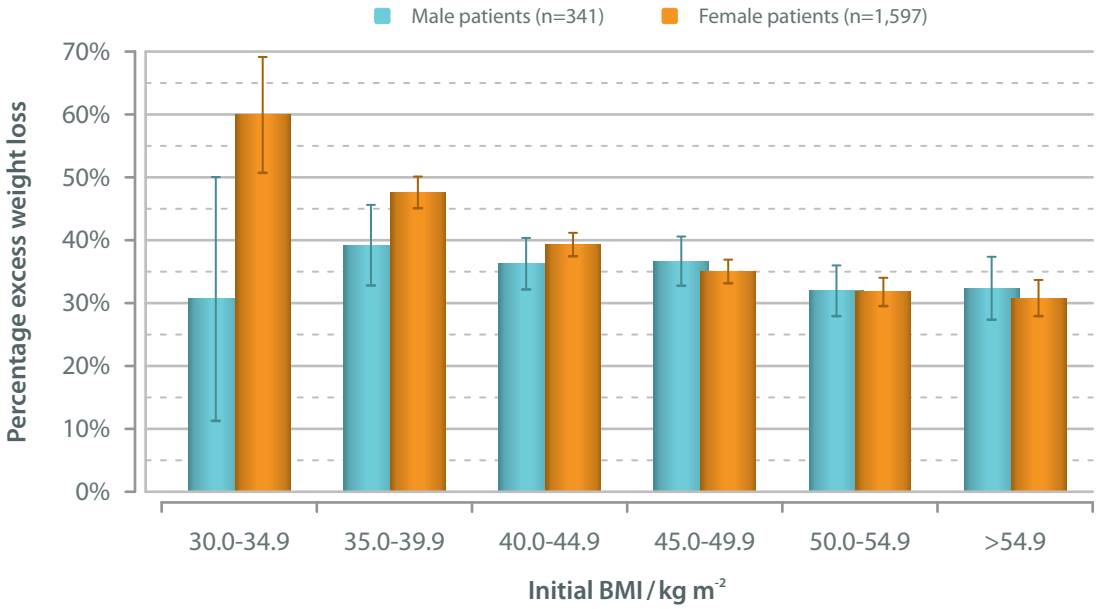


These 3 graphs show the %EWL one year after gastric banding, gastric bypass and sleeve gastrectomy operations. The data shown mirror the published literature of reported weight loss in follow up by procedure type.

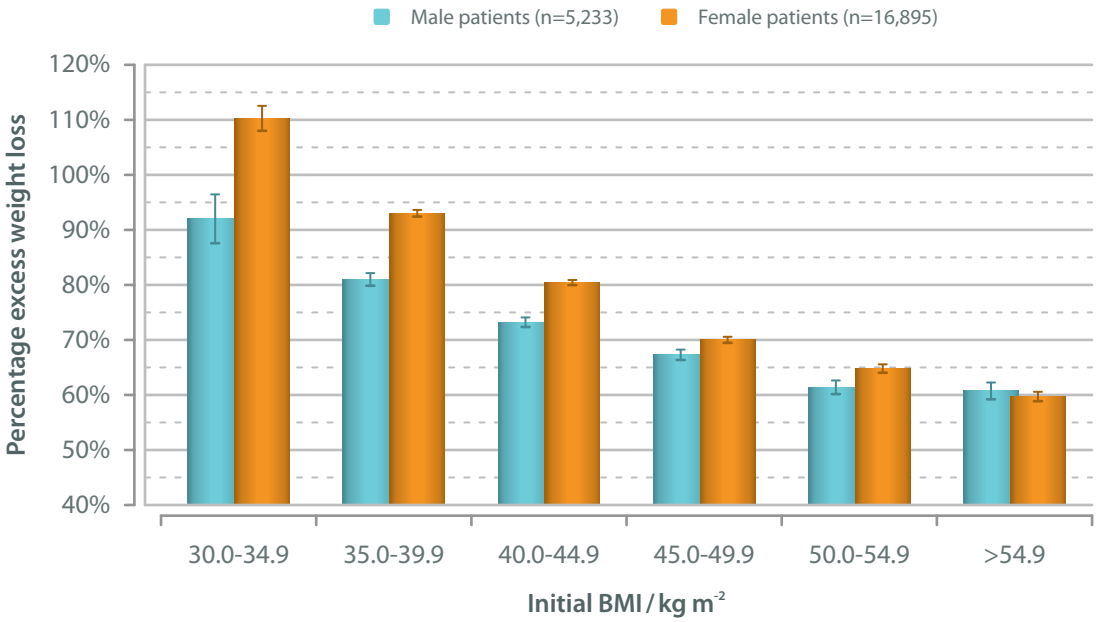
It is worth stating that, on average, all patients in each of the procedure groups, no matter what their starting BMI, lose a significant amount of weight. The data on bands are only a snap-shot of the evolution of weight loss after this operation; it is well established that weight continues to fall for at least 3 years, in contrast to gastric bypass and sleeve gastrectomy where the vast majority of the weight loss is within the first year after surgery.

Regular and ongoing follow up for bariatric surgery patients is important. Again, it is worth making the comparison with after-care for patients following cancer surgery, where the infra-structure exists in every country to monitor cancer incidence, stage, recurrence and survival. No country yet has systems in place to monitor BMI in the long term on an operated-population basis.

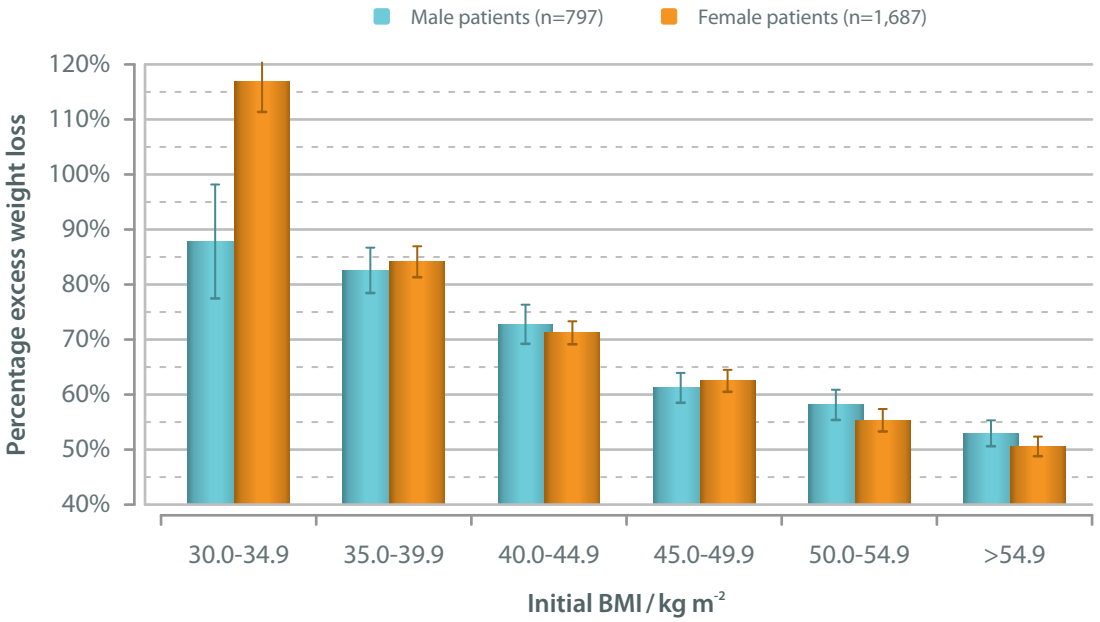
Primary gastric band: Excess weight loss one year after surgery & gender; calendar years 2009-2013



Primary gastric bypass: Excess weight loss one year after surgery & gender; calendar years 2009-2013



Primary sleeve gastrectomy: Excess weight loss one year after surgery & gender; calendar years 2009-2013



Weight loss at one year

This graph shows weight loss expressed as the percent of the patient's initial weight (%WL). The results seem completely different from the graphs on the preceding two pages; however, they are derived from the same data. The %WL for patients with BMI <35 kg m^{-2} is much less than the %EWL data from the graphs would suggest it to be.

The presentation of data in this way is preferred by many non-surgeons as it avoids the pitfalls of interpretation that are seen above. It also allows direct comparison between studies of non-surgical weight loss therapies (where %WL is typically used in medical journals) and bariatric surgery.

This is the first report as far as we know that demonstrates percentage weight loss in an internationally collected series of bariatric surgery patients.

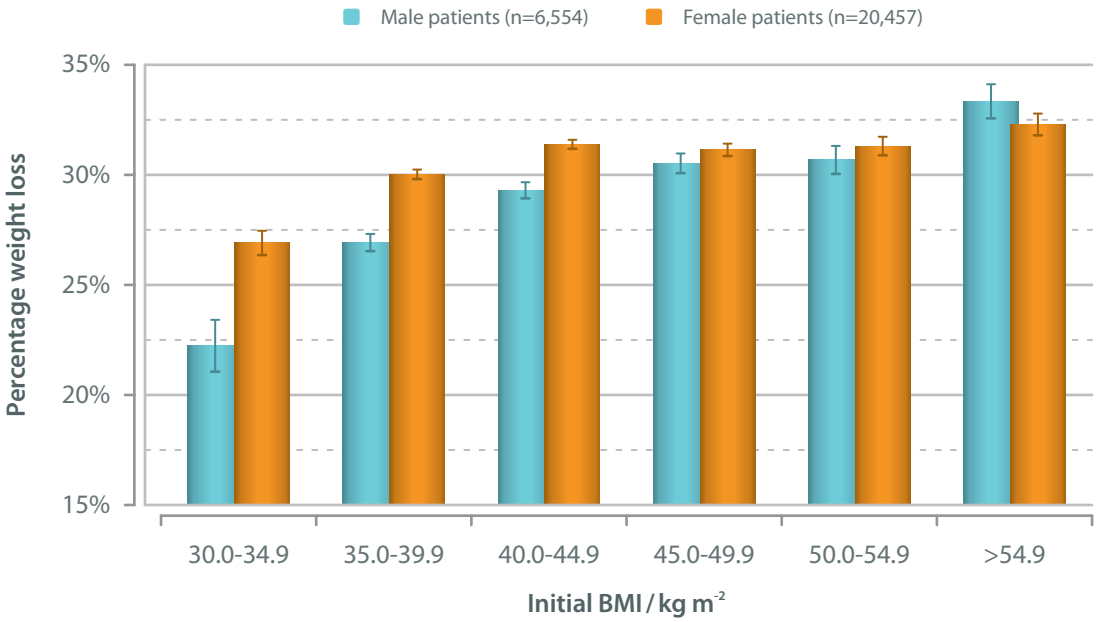
The illustration of data in this way again shows the type of analysis that can be done through collecting and merging a small dataset.

Primary surgery: percentage weight loss one year after surgery; calendar years 2009-2013

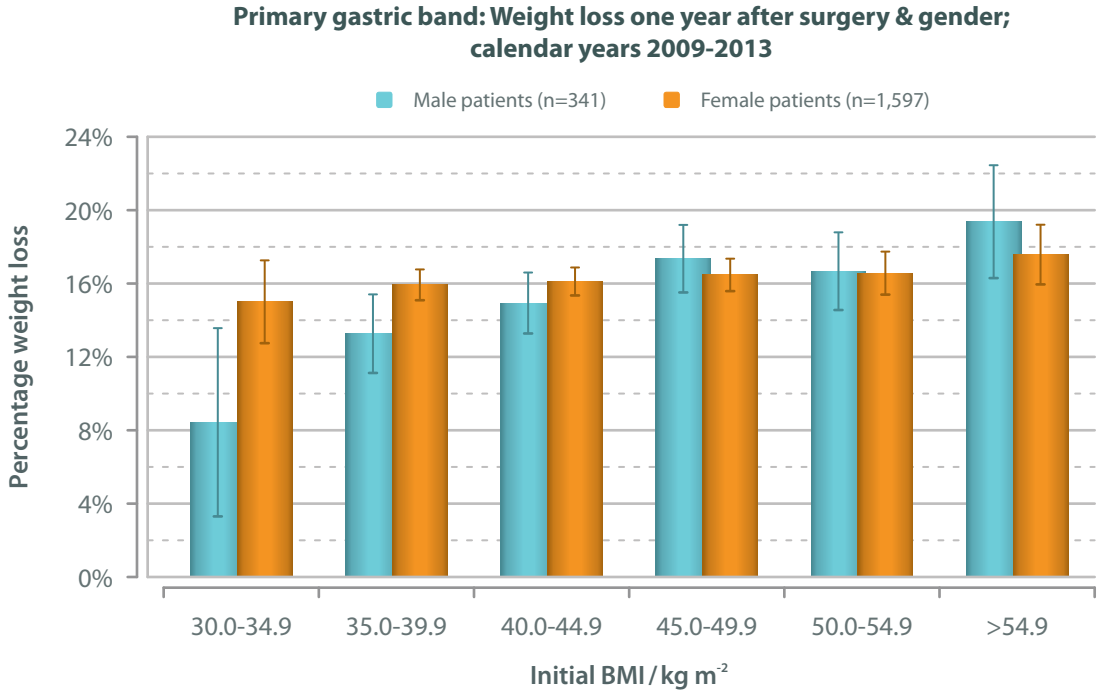
Gender and initial BMI / kg m^{-2}			Statistics on one-year percentage weight loss		
			Count	Average (95% CI)	Median (IQR)
Male		30.0-34.9	181	22.2 (21.1-23.4)	23.3 (17.8-27.5)
		35.0-39.9	1,406	26.9 (26.5-27.3)	27.4 (22.4-32.1)
		40.0-44.9	1,991	29.3 (28.9-29.7)	29.7 (24.2-35.1)
		45.0-49.9	1,486	30.5 (30.1-31.0)	30.9 (25.2-36.4)
		50.0-54.9	819	30.7 (30.0-31.3)	30.9 (25.1-37.0)
		>55.0	671	33.3 (32.6-34.1)	33.8 (26.4-40.5)
Female		30.0-34.9	739	26.9 (26.4-27.5)	28.1 (22.2-32.1)
		35.0-39.9	5,412	30.0 (29.8-30.2)	30.9 (25.3-35.6)
		40.0-44.9	6,670	31.4 (31.2-31.6)	32.2 (26.4-37.3)
		45.0-49.9	4,068	31.1 (30.9-31.4)	31.7 (25.8-37.5)
		50.0-54.9	2,067	31.3 (30.9-31.7)	32.0 (25.7-37.9)
		>55.0	1,501	32.3 (31.8-32.8)	32.9 (26.6-38.7)

1. Hatoum IJ, Kaplan LM. Advantages of percent weight loss as a method of reporting weight loss after Roux-en-Y Gastric Bypass. *Obesity*. 2013; **21**: 1519-1525.
2. Dixon JB, McPhail T, O'Brien PE. Minimal reporting requirements for weight loss: Current methods not ideal. *Obesity surgery*. 2005; **15**: 1034-1039.

Primary surgery: Weight loss one year after surgery and gender; calendar years 2009-2013

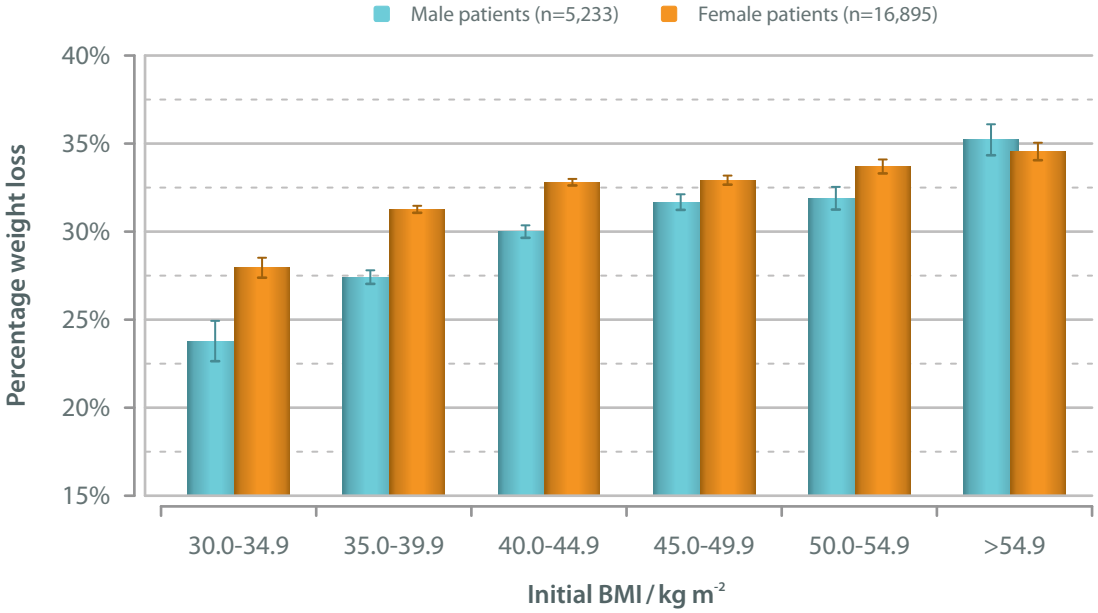


As commented above, the %WL data one year after gastric banding needs to be interpreted with caution, since weight continues to be lost for 3 years or more with this operation. As the dataset matures, future reports will be able to compare weight loss data with other bariatric surgery operations as well, as and when they become more widely adopted.

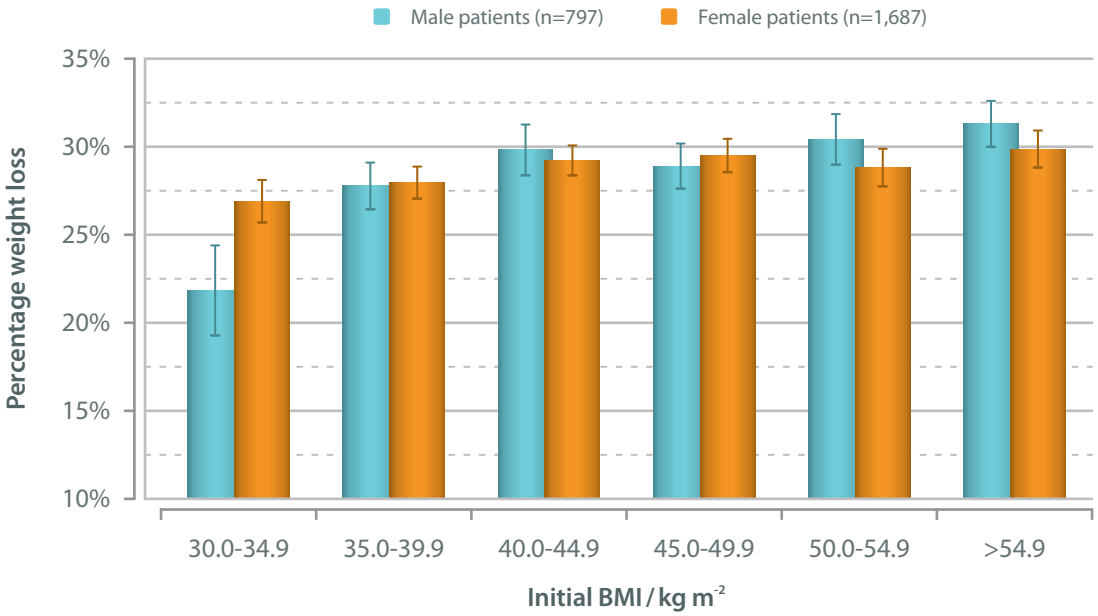


Caution should also be used when making direct comparisons between the %WL data for gastric bypass and sleeve gastrectomy since these are selective data contributed by enthusiasts, and may not be altogether representative.

Primary gastric bypass: Weight loss one year after surgery & gender; calendar years 2009-2013



Primary sleeve gastrectomy: Weight loss one year after surgery & gender; calendar years 2009-2013



Comorbidity resolution

The difficulty in collecting data on outcomes at one year is illustrated in the table below, where the majority of outcomes are not reported in most patients 12 months after surgery. Nevertheless, the data demonstrate that it is possible to aggregate data from a large number of submitted records from different countries as the start of a process of standardising data collection and outcomes-monitoring.

Another, alternative explanation for some of the missing data reported below is that not all the data-items are captured by all the units and countries submitting their data for this initial report of the IFSO Global Registry. Some of the missing data are, therefore, simply a reflection of mis-matches between the local datasets and the central IFSO Global Registry dataset.

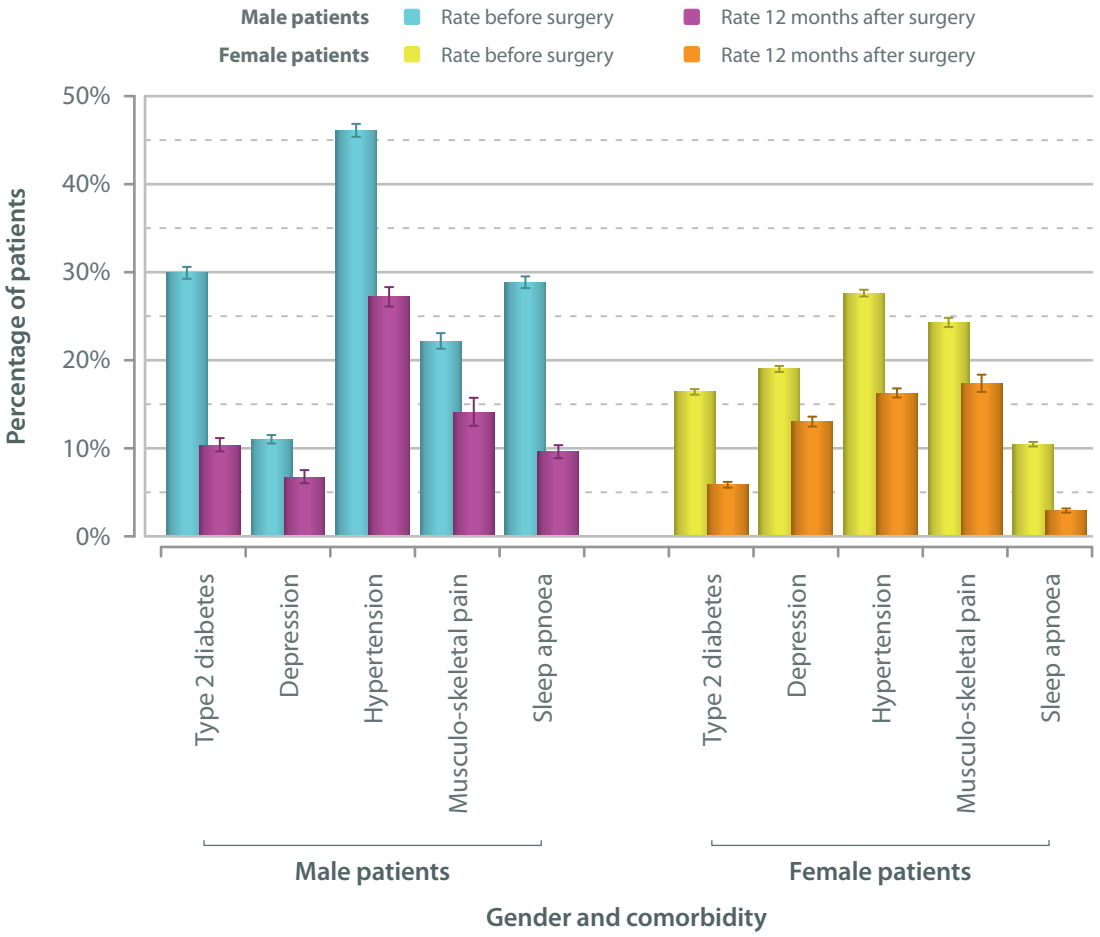
The data do, however, demonstrate that there is significant improvement in each of the obesity-related diseases included in the dataset one year after surgery. As reporting systems and the quality of submitted data improve, the IFSO Global Registry could examine these effects in more detail.

Primary surgery: comorbidity before and after surgery, and gender; calendar years 2009-2013

			Comorbid status							
			Prior to surgery				12 months after surgery			
			No	Yes	Unspecified	Comorbidity rate	No	Yes	Unspecified	Comorbidity rate
Gender and comorbidity	Male	Type 2 diabetes	12,447	5,315	643	29.9%	5,669	656	12,080	10.4%
		Depression	14,842	1,837	1,726	11.0%	4,195	303	13,907	6.7%
		Hypertension	9,578	8,197	630	46.1%	4,601	1,718	12,086	27.2%
		Musculo-skeletal pain	6,687	1,906	9,812	22.2%	1,631	267	16,507	14.1%
		Sleep apnoea	12,739	5,166	500	28.9%	5,685	603	12,117	9.6%
	Female	Type 2 diabetes	44,669	8,762	2,148	16.4%	18,653	1,158	35,768	5.8%
		Depression	41,031	9,631	4,917	19.0%	12,027	1,800	41,752	13.0%
		Hypertension	38,713	14,775	2,091	27.6%	16,588	3,225	35,766	16.3%
		Musculo-skeletal pain	19,567	6,279	29,733	24.3%	4,860	1,021	49,698	17.4%
		Sleep apnoea	48,276	5,637	1,666	10.5%	19,169	576	35,834	2.9%

The graph below illustrates that it is possible to do quite detailed analysis from the submitted data. The confidence intervals are tight around the calculated rates of comorbidity because the numbers under analysis are so great, and all of the differences between pre-surgery and one-year follow-up rates, for both men and for women, are statistically significant ($p<0.001$).

Primary surgery: Comorbidity status before and after surgery, and gender; calendar years 2009-2013



Focus on type 2 diabetes

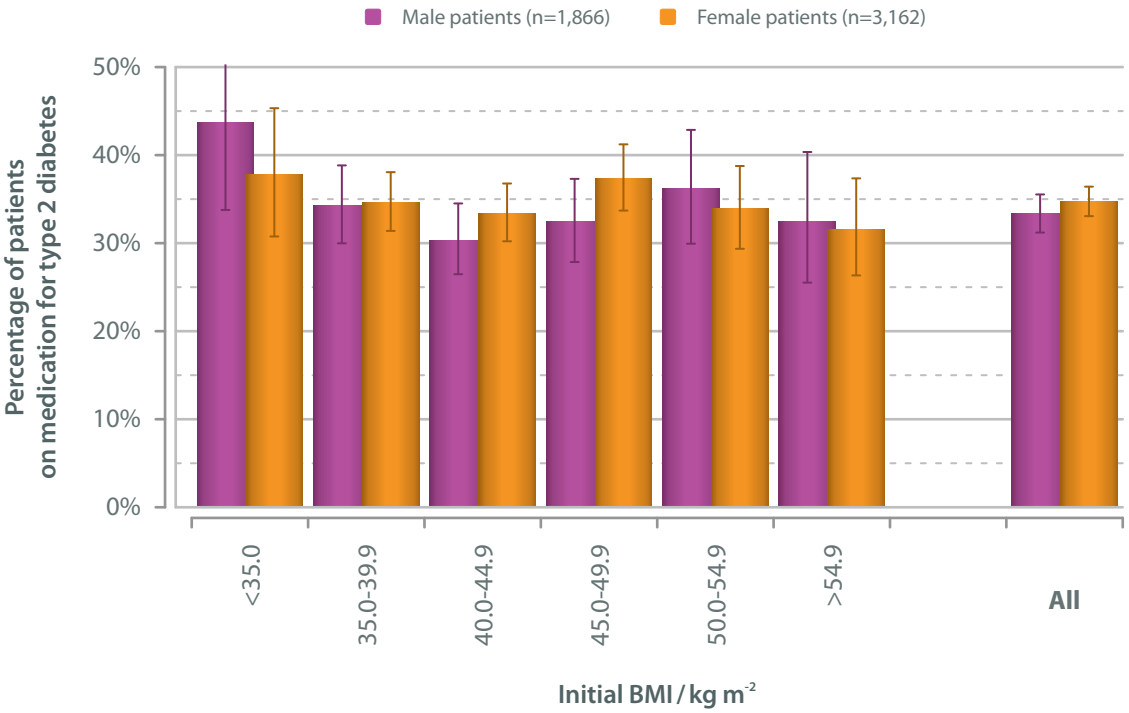
The graph below shows the proportion of diabetic patients who were still clinically diabetic 12 months after surgery. These are the first data worldwide that give an approximation of the overall effect of bariatric surgery on an operated-population basis. The data give a firm message that bariatric surgery improves this condition.

The data suggest that recovery from diabetes is likely for all the ranges of initial BMI, and illustrates, again, that it is relatively straightforward to make quite complex analyses from a small dataset. Future reports of the IFSO Global Registry project could expand the information produced, assuming an increase in the number of contributors and a slightly refined dataset. The effect on diabetes could be used internationally to call for increased acceptance of bariatric surgery for the treatment of diabetes.

Primary surgery for patients on medication for type 2 diabetes: medication for type 2 diabetes 12 months after surgery, gender and initial BMI; calendar years 2009-2013

		Gender and medication for type 2 diabetes							
		Male				Female			
		No diabetes	Diabetes	Unspecified	Rate of diabetes	No diabetes	Diabetes	Unspecified	Rate of diabetes
Initial BMI / kg m^{-2}	<35.0	54	42	316	43.8%	112	68	520	37.8%
	35.0-39.9	303	158	690	34.3%	528	280	1,158	34.7%
	40.0-44.9	365	159	859	30.3%	546	274	1,340	33.4%
	45.0-49.9	267	128	684	32.4%	412	246	1,115	37.4%
	50.0-54.9	143	81	436	36.2%	269	138	714	33.9%
	>54.9	110	53	453	32.5%	197	91	724	31.6%
	Unspecified	2	1	11	33.3%	0	1	29	100.0%
	All	**1,244**	**622**	**3,449**	**33.3%**	**2,064**	**1,098**	**5,600**	**34.7%**

Primary surgery for patients on medication for type 2 diabetes: Type 2 diabetes 12 months after surgery, initial BMI and gender; calendar years 2009-2013



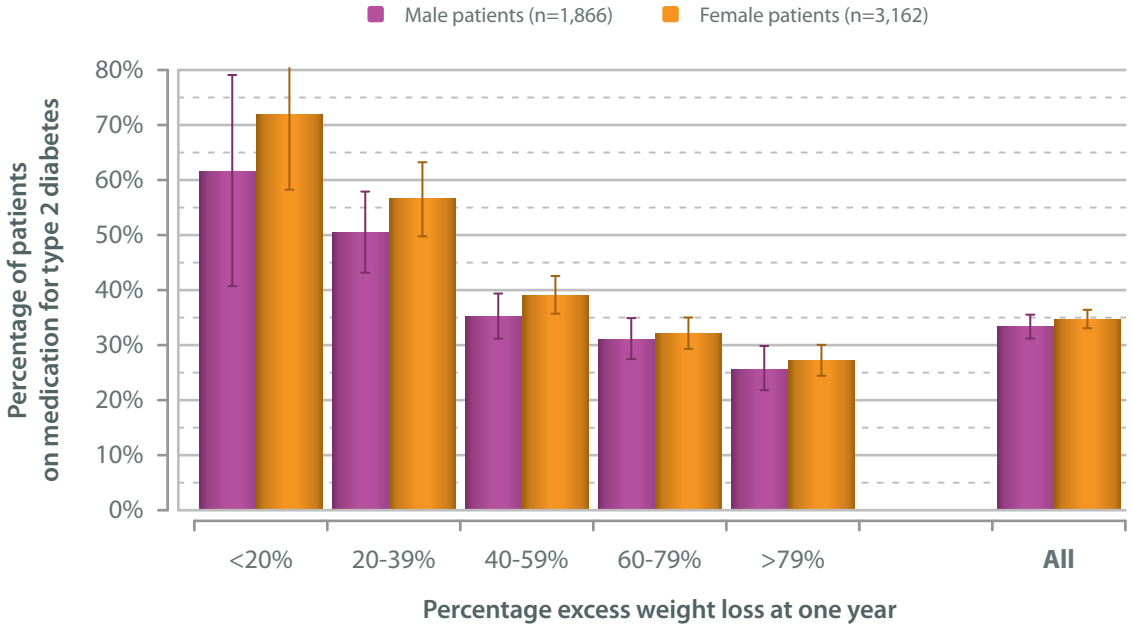
This graph of diabetes status at one year strongly suggests that weight loss *per se* is an important factor in recovery from diabetes. These are the first international data to show this finding, and more detailed analysis could assess recovery rates for each specific operation.

These are also potentially powerful data that surgeons can use in discussing the beneficial effects of bariatric surgery with those who commission and fund services.

Primary surgery for patients on medication for type 2 diabetes: medication for type 2 diabetes 12 months after surgery, gender and excess weight loss at one year; calendar years 2009-2013

		Gender and medication for type 2 diabetes							
		Male				Female			
		No diabetes	Diabetes	Unspecified	Rate of diabetes	No diabetes	Diabetes	Unspecified	Rate of diabetes
Percentage excess weight loss at one year	>20%	10	16	6	61.5%	16	41	3	71.9%
	20-39%	92	94	11	50.5%	95	124	17	56.6%
	40-59%	352	191	18	35.2%	491	315	30	39.1%
	60-79%	426	192	22	31.1%	721	341	43	32.1%
	>79%	354	122	23	25.6%	727	271	46	27.2%
	Unspecified	10	7	3,369	41.2%	14	6	5,461	30.0%
	All	**1,244**	**622**	**3,449**	**33.3%**	**2,064**	**1,098**	**5,600**	**34.7%**

Primary surgery for patients on medication for type 2 diabetes: Medication for type 2 diabetes 12 months after surgery, one-year excess weight loss & gender; calendar years 2009-2013

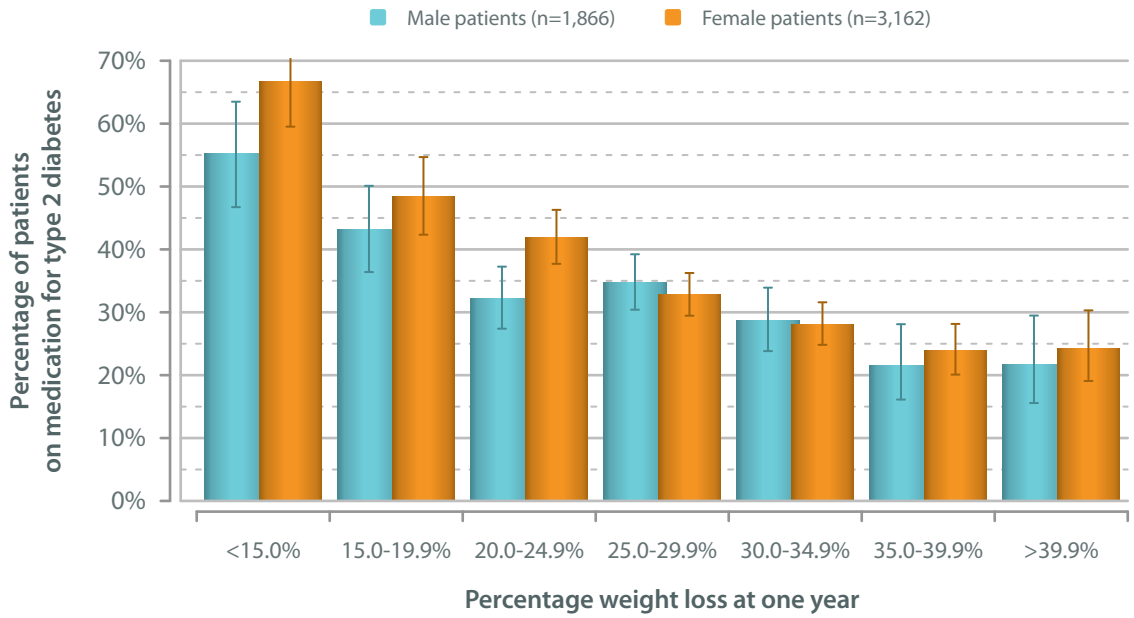


These analyses, showing the percentage of patients at one year on medication for diabetes according to the %WL, appear to show overwhelming support for the concept that it is the amount of weight loss that accounts for the improvement in diabetes after bariatric surgery. To our knowledge these are the first collaborative international data to show improvement in diabetes compared to %WL after surgery. The data should be interpreted with caution since the dataset did not record laboratory measures of diabetes such as HbA1c.

Primary surgery for patients on medication for type 2 diabetes: medication for type 2 diabetes 12 months after surgery, gender and weight loss at one year; calendar years 2009-2013

		Gender and medication for type 2 diabetes							
		Male				Female			
		No diabetes	Diabetes	Unspecified	Rate of diabetes	No diabetes	Diabetes	Unspecified	Rate of diabetes
One-year percentage weight loss	<15.0%	64	79	17	55.2%	65	130	16	66.7%
	15.0-19.9%	120	91	9	43.1%	136	128	13	48.5%
	20.0-24.9%	245	116	11	32.1%	306	221	20	41.9%
	25.0-29.9%	305	162	16	34.7%	511	249	34	32.8%
	30.0-34.9%	232	93	13	28.6%	507	198	27	28.1%
	35.0-39.9%	153	42	7	21.5%	344	108	16	23.9%
	>39.9%	115	32	7	21.8%	181	58	13	24.3%
	Unspecified	10	7	3,369	41.2%	14	6	5,461	30.0%
	All	**1,244**	**622**	**3,449**	**33.3%**	**2,064**	**1,098**	**5,600**	**34.7%**

Primary surgery for patients on medication for type 2 diabetes: Medication for type 2 diabetes 12 months after surgery, weight loss & gender; calendar years 2009-2013



Focus on hypertension

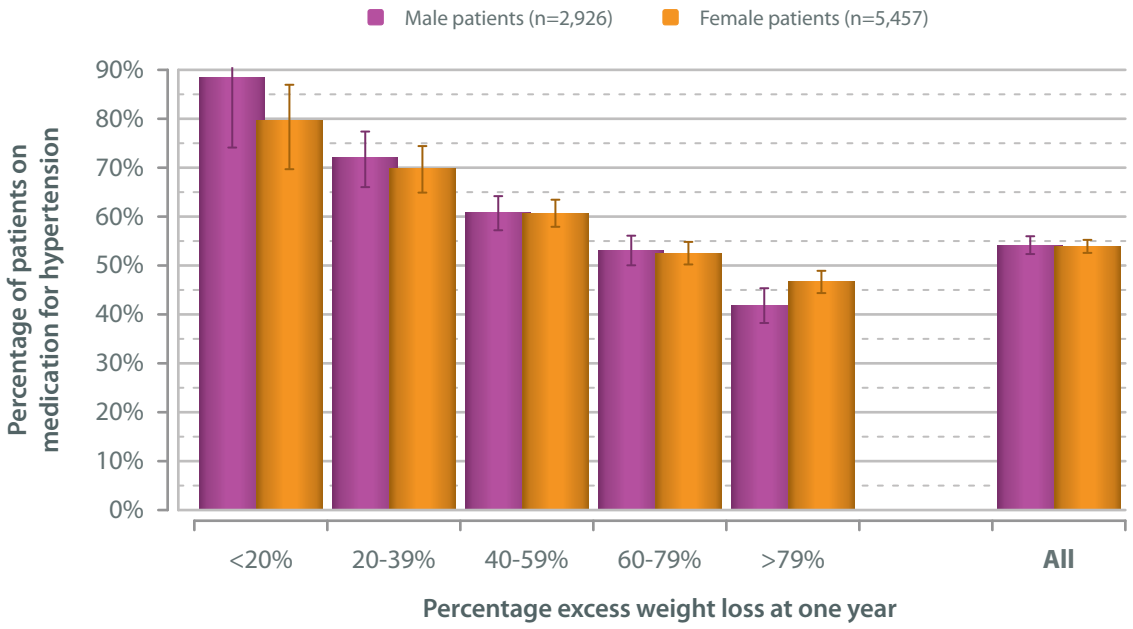
This graph again shows a novel way of assessing improvement in hypertension after bariatric surgery. The data suggest that improvement at one year is dependent on the weight loss achieved. However, we do not know from the dataset which criteria are being used to justify stopping medication. Future reports and refinement of the dataset (including internationally standardised ways of reporting comorbidities) could elucidate this further.

The data again demonstrate that quite complex analysis of pooled and merged data can be achieved from a small dataset.

Primary surgery for patients on medication for hypertension: patients requiring medication for hypertension 12 months after surgery, gender and excess weight loss at one year; calendar years 2009-2013

		Gender and medication for hypertension							
		Male				Female			
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate
Percentage excess weight loss at one year	>20%	5	38	9	88.4%	19	74	9	79.6%
	20-39%	71	183	13	72.0%	113	262	31	69.9%
	40-59%	305	472	39	60.7%	482	745	53	60.7%
	60-79%	503	569	29	53.1%	874	967	70	52.5%
	>79%	445	319	39	41.8%	1,006	879	81	46.6%
	Unspecified	13	5	5,140	27.8%	21	15	9,074	41.7%
	All	**1,342**	**1,586**	**5,269**	**54.2%**	**2,515**	**2,942**	**9,318**	**53.9%**

Primary surgery for patients on medication for hypertension: Medication for hypertension 12 months after surgery, one-year excess weight loss and gender; calendar years 2009-2013

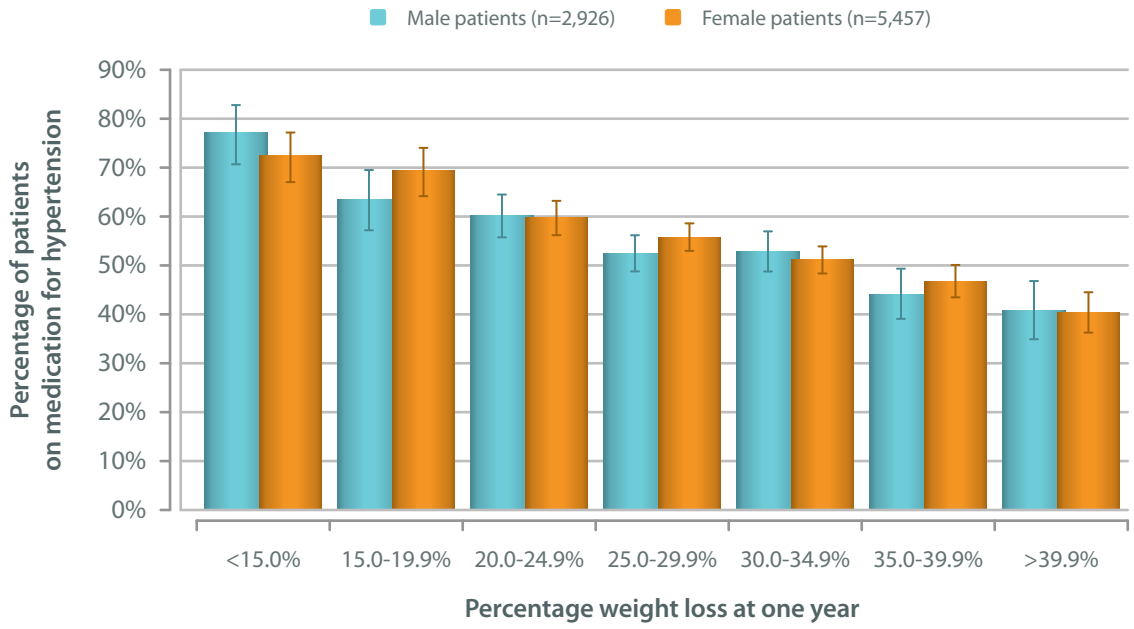


This graph shows the % of patients recorded as being on medication for hypertension at one year after surgery according to the %WL. The data suggest a near linear relationship with the degree of weight loss; however, as noted above, the data need to be interpreted with caution.

Primary surgery for patients on medication for hypertension: medication for hypertension 12 months after surgery, gender and weight loss at one year; calendar years 2009-2013

One-year percentage weight loss	Gender and medication for hypertension							
	Male				Female			
	No	Yes	Unspecified	Rate of hypertension	No	Yes	Unspecified	Rate of hypertension
<15.0%	45	153	20	77.3%	87	228	30	72.4%
15.0-19.9%	90	157	15	63.6%	108	244	26	69.3%
20.0-24.9%	199	301	21	60.2%	312	463	38	59.7%
25.0-29.9%	344	380	23	52.5%	544	687	41	55.8%
30.0-34.9%	278	312	19	52.9%	629	658	57	51.1%
35.0-39.9%	210	166	18	44.1%	478	420	33	46.8%
>39.9%	163	112	13	40.7%	336	227	19	40.3%
Unspecified	13	5	5,140	27.8%	21	15	9,074	41.7%
All	**1,342**	**1,586**	**5,269**	**54.2%**	**2,515**	**2,942**	**9,318**	**53.9%**

Primary surgery for patients on medication for hypertension: Medication for hypertension 12 months after surgery, weight loss & gender; calendar years 2009-2013



Analyses

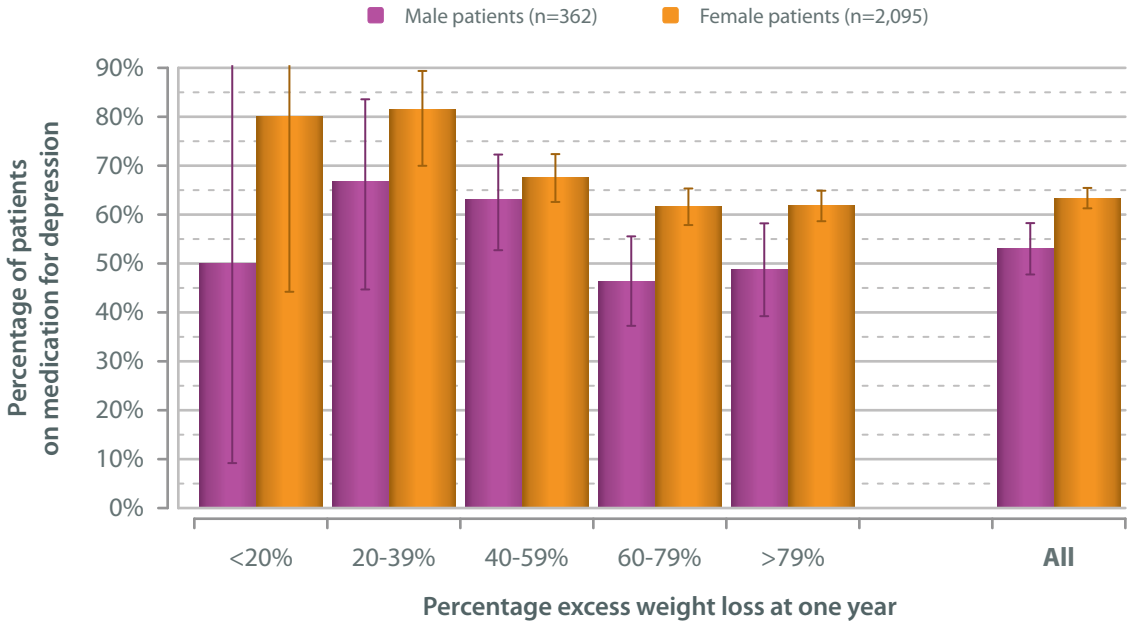
Focus on depression

Clinically significant depression is common in obese people, and improvement in psychological status and quality of life is one of the benefits of surgery. Even though improvement in depression is difficult to define, the data suggest that worldwide there is a difference between the prevalence at baseline and at one year after surgery.

Primary surgery for patients on medication for depression: patients on medication for depression 12 months after surgery, gender and excess weight loss at one year; calendar years 2009-2013

		Gender and depression							
		Male				Female			
		No depression	Depression	Unspecified	Rate of depression	No depression	Depression	Unspecified	Rate of depression
Percentage excess weight loss at one year	>20%	2	2	16	50.0%	2	8	76	80.0%
	20-39%	8	16	44	66.7%	13	57	219	81.4%
	40-59%	37	63	113	63.0%	119	249	434	67.7%
	60-79%	65	56	79	46.3%	258	415	506	61.7%
	>79%	58	55	46	48.7%	367	594	296	61.8%
	Unspecified	0	0	1,177	NA	8	5	6,005	38.5%
	All	**170**	**192**	**1,475**	**53.0%**	**767**	**1,328**	**7,536**	**63.4%**

Primary surgery for patients on medication for depression: Medication for depression 12 months after surgery, excess weight loss & gender; calendar years 2009-2013



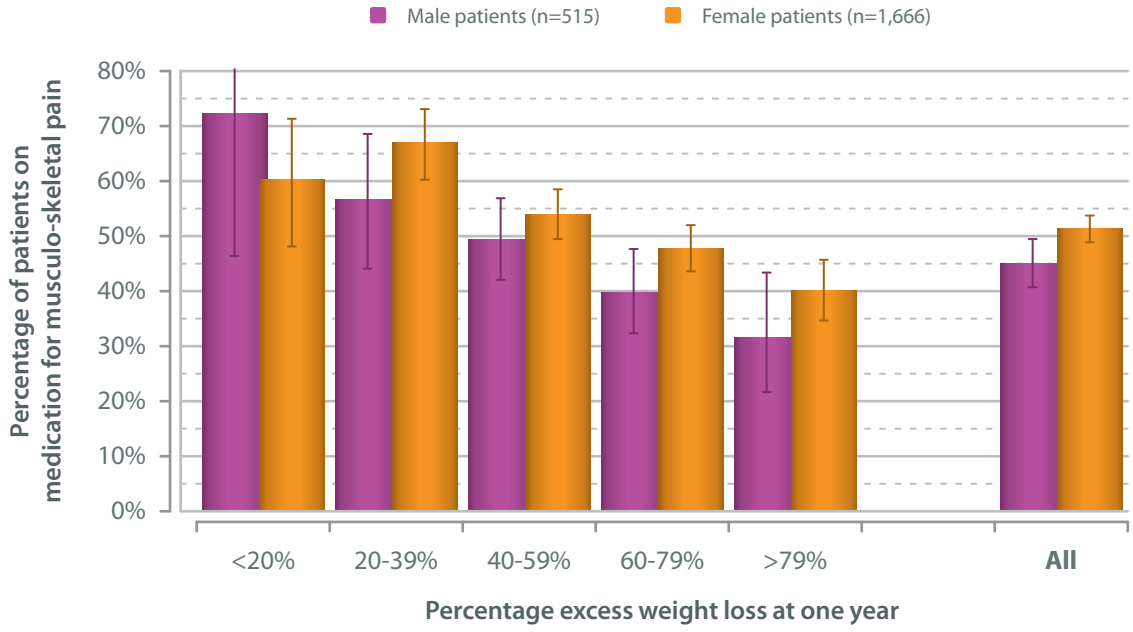
Focus on musculo-skeletal pain

Although there are missing fields in the submitted data that generated the graph below, it can still be seen that improvement in musculo-skeletal pain appears to be dependent on weight loss. This is the first time that an analysis like this has been done on such a large scale and shows the clinical improvement that can be seen when a large number of patient records are analysed. These data can contribute to the international data on the positive effects of bariatric surgery.

Primary surgery for patients on medication for musculo-skeletal pain: patients requiring medication for musculo-skeletal pain 12 months after surgery, gender and excess weight loss at one year; calendar years 2009-2013

		Gender and medication for musculo-skeletal pain							
		Male				Female			
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate
Percentage excess weight loss at one year	>20%	5	13	0	72.2%	29	44	4	60.3%
	20-39%	29	38	6	56.7%	72	146	14	67.0%
	40-59%	93	91	4	49.5%	223	262	15	54.0%
	60-79%	100	66	4	39.8%	295	270	19	47.8%
	>79%	52	24	0	31.6%	190	127	17	40.1%
	Unspecified	4	0	1,377	0.0%	2	6	4,544	75.0%
	All	**283**	**232**	**1,391**	**45.0%**	**811**	**855**	**4,613**	**51.3%**

Primary surgery for patients on medication for musculo-skeletal pain: Medication for musculo-skeletal pain 12 months after surgery, excess weight loss and gender; calendar years 2009-2013



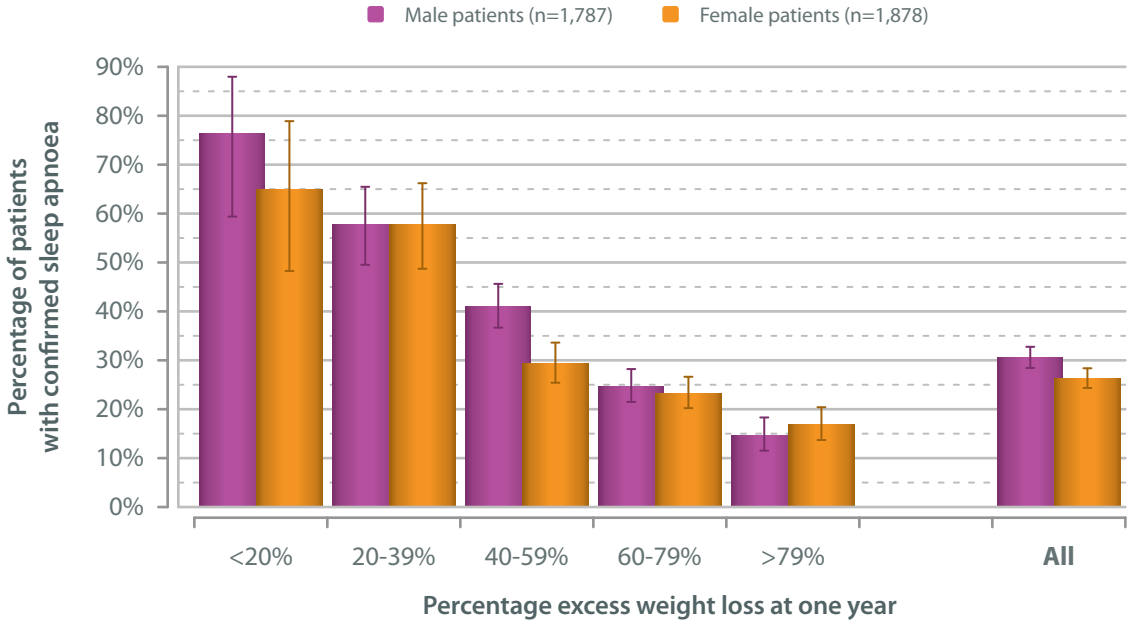
Focus on sleep apnoea

This graph shows the status of patients with sleep apnoea at one year after surgery, and again suggests that improvement is dependent on the weight loss achieved. However, there is no agreement in the published literature that bariatric surgery improves sleep apnoea and thus this area of the dataset is *soft*.

Primary surgery for patients with confirmed sleep apnoea: confirmed sleep apnoea 12 months after surgery, gender and excess weight loss at one year; calendar years 2009-2013

		Gender and confirmed sleep apnoea							
		Male				Female			
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate
Percentage excess weight loss at one year	>20%	9	29	4	76.3%	14	26	0	65.0%
	20-39%	66	90	8	57.7%	55	75	8	57.7%
	40-59%	284	198	20	41.1%	349	145	23	29.4%
	60-79%	497	163	16	24.7%	534	162	16	23.3%
	>79%	380	65	14	14.6%	421	85	19	16.8%
	Unspecified	5	1	3,317	16.7%	11	1	3,693	8.3%
	All	**1,241**	**546**	**3,379**	**30.6%**	**1,384**	**494**	**3,759**	**26.3%**

Primary surgery for patients with confirmed sleep apnoea: Sleep apnoea 12 months after surgery, excess weight loss and gender; calendar years 2009-2013

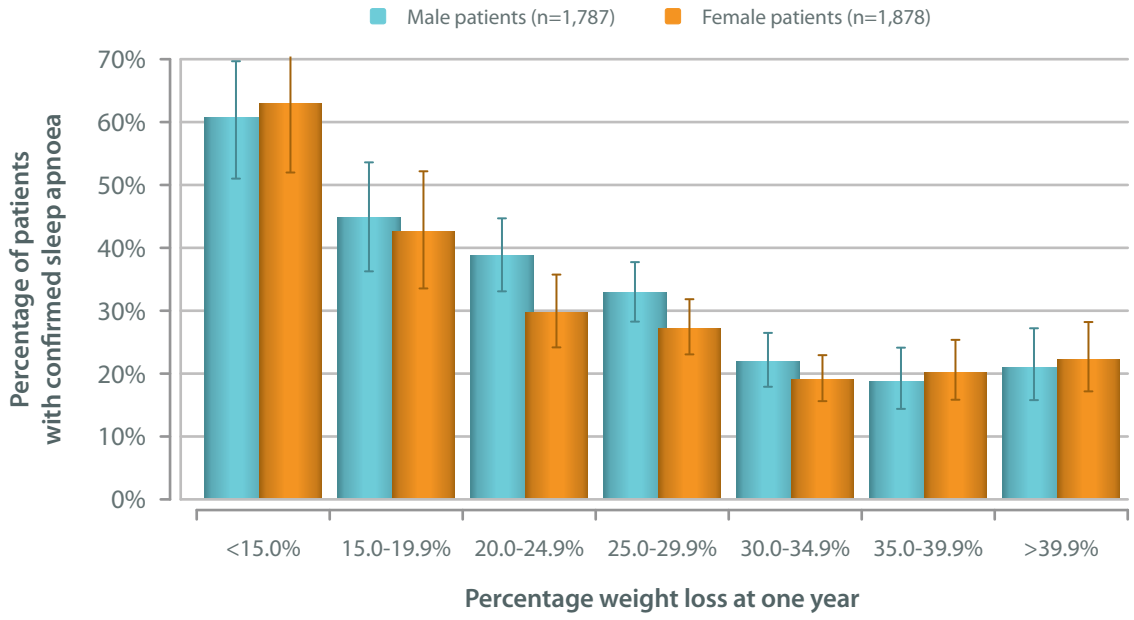


As above, the same data are here presented as %WL, demonstrating again the complexity of analysis that can be done with pooled, merged datasets. The same caution, as noted above, should be used in the interpretation.

Primary surgery for patients with sleep apnoea: confirmed sleep apnoea 12 months after surgery, gender and weight loss at one year; calendar years 2009-2013

		Gender and confirmed sleep apnoea							
		Male				Female			
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate
One-year percentage weight loss	<15.0%	44	68	12	60.7%	33	56	4	62.9%
	15.0-19.9%	74	60	3	44.8%	66	49	4	42.6%
	20.0-24.9%	174	110	9	38.7%	178	75	10	29.6%
	25.0-29.9%	266	130	10	32.8%	302	113	13	27.2%
	30.0-34.9%	296	83	11	21.9%	379	89	11	19.0%
	35.0-39.9%	216	50	9	18.8%	233	59	11	20.2%
	>39.9%	166	44	8	21.0%	182	52	13	22.2%
	Unspecified	5	1	3,317	16.7%	11	1	3,693	8.3%
	All	**1,241**	**546**	**3,379**	**30.6%**	**1,384**	**494**	**3,759**	**26.3%**

Primary surgery for patients with confirmed sleep apnoea: Sleep apnoea 12 months after surgery, weight loss and gender; calendar years 2009-2013



Comparing outcomes for two contributors

Percentage excess weight loss

The graph below demonstrates again how analysis of thousands of records submitted from international centres can show weight loss data in different ways. In this example the data are shown stratified for initial BMI, and thus the importance of reporting this as well as simply excess weight loss is seen. The data also show a potential difficulty with using %EWL as the measure of weight progression. In patients across the whole BMI range the upper quartiles include some with more than 100% %EWL. This type of analysis could potentially be used to identify those who need more nutritional support.

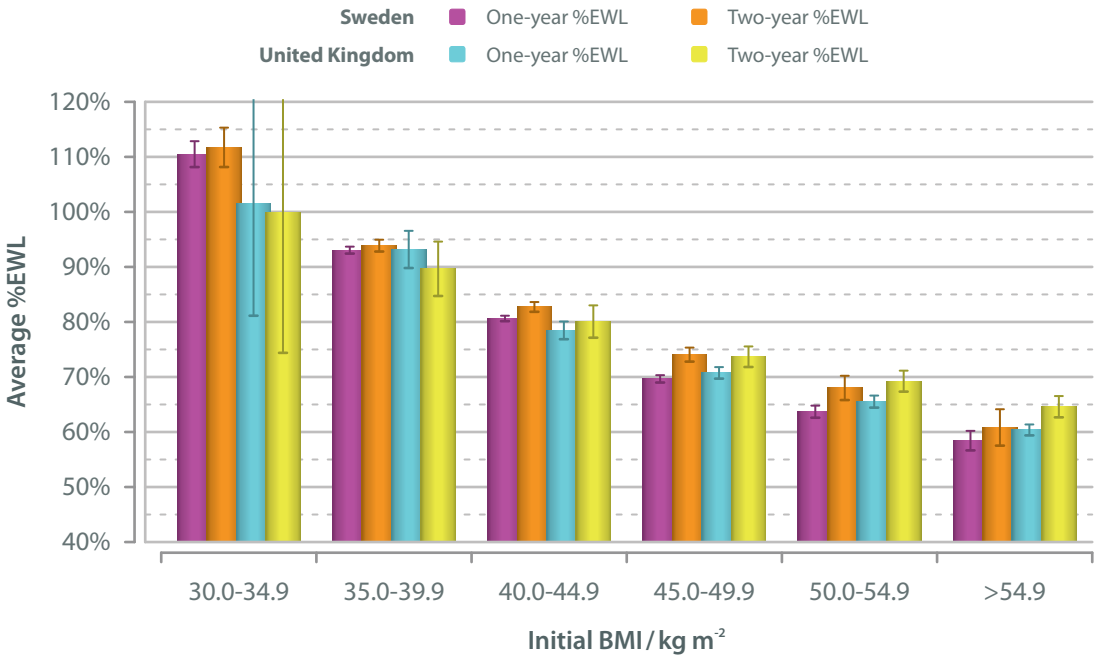
Primary gastric bypass for female patients: excess weight loss at one year after surgery for two high-volume contributor countries; calendar years 2009-2013

Contributor country & initial BMI / kg m^{-2}			One-year percentage excess weight loss		
			Count	Average (95% CI)	Median (IQR)
Sweden		30.0-34.9	481	110.5 (108.1-112.8)	111.7 (94.4-127.5)
		35.0-39.9	4,291	93.1 (92.4-93.7)	94.2 (79.5-107.9)
		40.0-44.9	4,980	80.6 (80.1-81.1)	81.0 (68.3-93.1)
		45.0-49.9	2,263	69.7 (69.0-70.3)	69.4 (58.7-80.8)
		50.0-54.9	726	63.7 (62.6-64.8)	64.0 (53.6-73.5)
		>54.9	285	58.4 (56.7-60.2)	57.7 (48.2-68.0)
United Kingdom		30.0-34.9	9	101.5 (81.1-121.8)	110.2 (69.3-132.2)
		35.0-39.9	175	93.2 (89.8-96.6)	93.9 (77.6-107.9)
		40.0-44.9	579	78.5 (76.9-80.1)	80.9 (66.7-90.4)
		45.0-49.9	973	70.7 (69.7-71.8)	70.8 (60.4-81.5)
		50.0-54.9	761	65.5 (64.4-66.6)	66.1 (55.3-75.5)
		>54.9	683	60.4 (59.4-61.4)	60.7 (51.7-69.5)

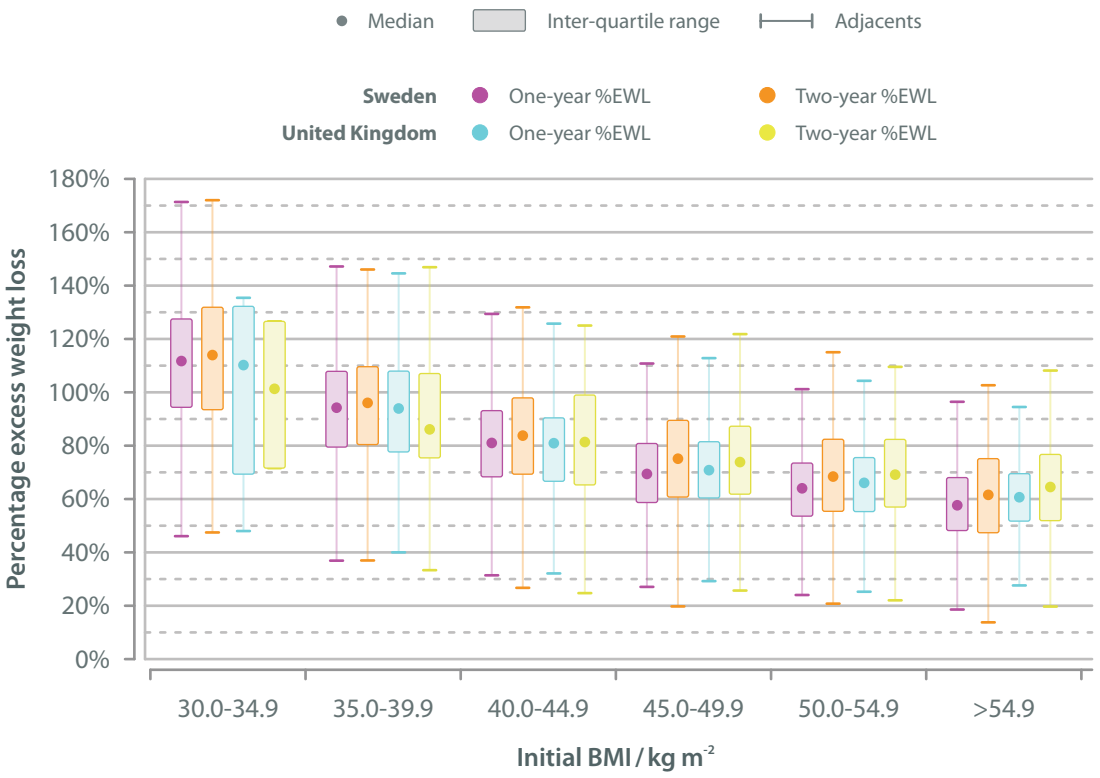
Primary gastric bypass for female patients: excess weight loss at two years after surgery for two high-volume contributor countries; calendar years 2009-2013

Contributor country & initial BMI / kg m^{-2}			Two-year percentage excess weight loss		
			Count	Average (95% CI)	Median (IQR)
Sweden		30.0-34.9	209	111.7 (108.2-115.3)	114.0 (93.5-131.9)
		35.0-39.9	1,757	93.9 (92.8-94.9)	96.0 (80.4-109.6)
		40.0-44.9	2,155	82.7 (81.8-83.6)	83.8 (69.3-97.9)
		45.0-49.9	932	74.1 (72.8-75.3)	75.1 (60.7-89.5)
		50.0-54.9	306	68.0 (65.8-70.2)	68.4 (55.4-82.4)
		>54.9	126	60.8 (57.5-64.1)	61.6 (47.4-75.1)
United Kingdom		30.0-34.9	3	99.8 (74.4-125.3)	101.3 (71.6-126.6)
		35.0-39.9	81	89.7 (84.7-94.6)	86.1 (75.4-107.0)
		40.0-44.9	226	80.1 (77.1-83.0)	81.4 (65.3-99.0)
		45.0-49.9	442	73.7 (71.8-75.5)	73.9 (61.8-87.3)
		50.0-54.9	359	69.2 (67.3-71.1)	69.1 (57.0-82.4)
		>54.9	303	64.6 (62.7-66.5)	64.5 (51.9-76.7)

Primary gastric bypass for female patients: Percentage excess weight loss and initial BMI for two high-volume contributors; calendar years 2009-2013



Primary gastric bypass for female patients: Percentage excess weight loss and initial BMI for two high-volume contributors; calendar years 2009-2013



These graphs show the same data analysed in the format of %WL. Again, complex analyses can be made from merged, pooled data from many different countries using a simple dataset.

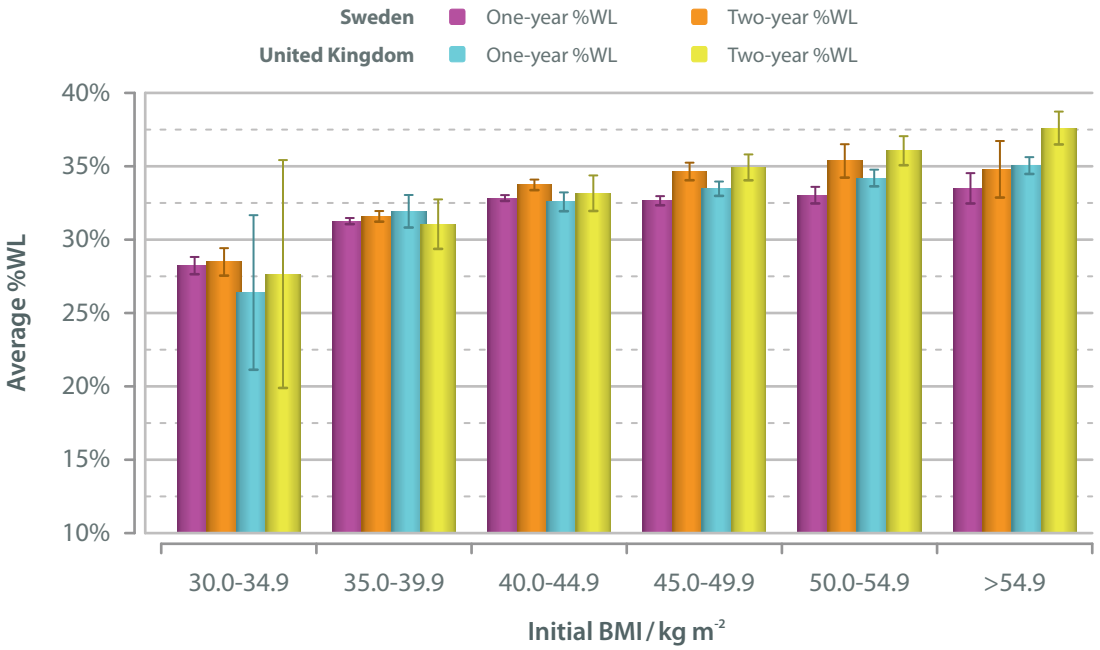
Primary gastric bypass for female patients: weight loss at one year after surgery for two high-volume contributor countries; calendar years 2009-2013

Contributor country & initial BMI / kg m^{-2}			One-year percentage weight loss		
			Count	Average (95% CI)	Median (IQR)
Sweden		30.0-34.9	481	28.2 (27.6-28.8)	28.9 (24.0-32.6)
		35.0-39.9	4,291	31.3 (31.1-31.5)	31.7 (26.9-36.1)
		40.0-44.9	4,980	32.8 (32.6-33.0)	33.0 (28.0-37.8)
		45.0-49.9	2,263	32.7 (32.3-33.0)	32.5 (27.5-38.0)
		50.0-54.9	726	33.0 (32.5-33.6)	33.0 (28.0-38.2)
		>54.9	285	33.5 (32.5-34.5)	32.9 (27.6-38.9)
United Kingdom		30.0-34.9	9	26.4 (21.1-31.7)	27.2 (18.9-33.5)
		35.0-39.9	175	31.9 (30.8-33.0)	32.0 (27.5-36.5)
		40.0-44.9	579	32.6 (31.9-33.2)	33.4 (27.9-37.9)
		45.0-49.9	973	33.5 (33.0-34.0)	33.5 (28.6-38.6)
		50.0-54.9	761	34.2 (33.6-34.8)	34.5 (28.9-39.3)
		>54.9	683	35.0 (34.5-35.6)	35.1 (29.8-40.1)

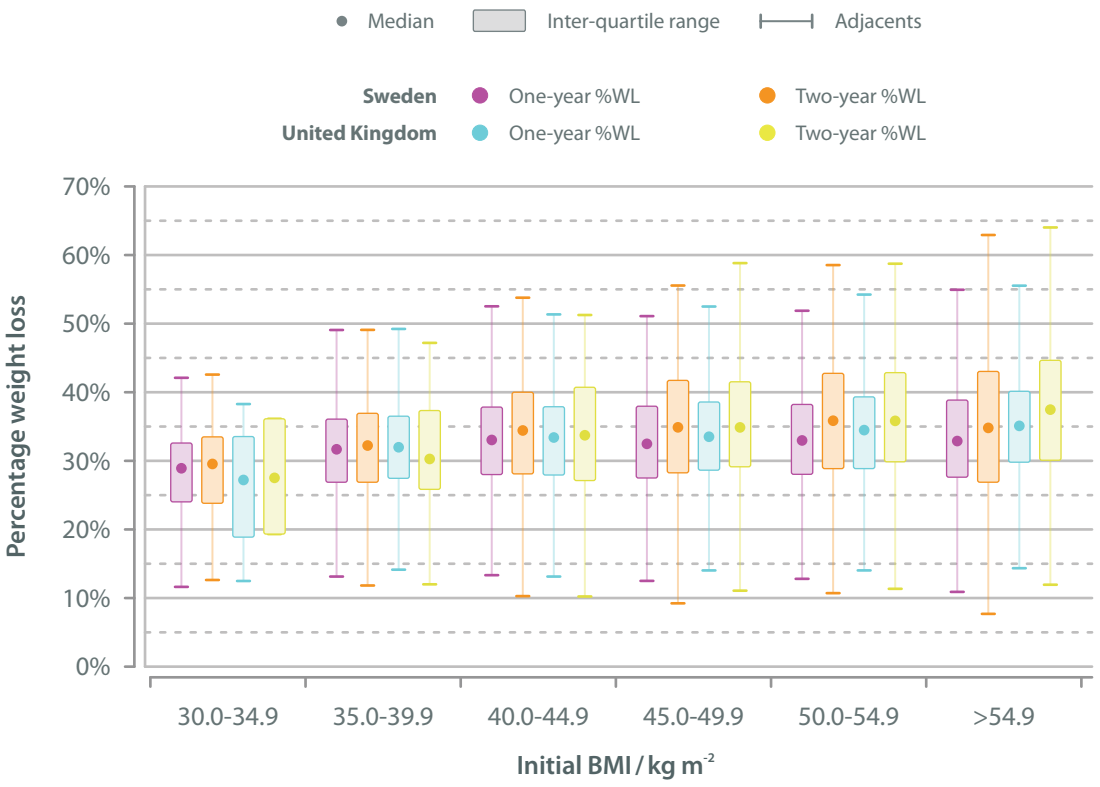
Primary gastric bypass for female patients: weight loss at two years after surgery for two high-volume contributor countries; calendar years 2009-2013

Contributor country & initial BMI / kg m^{-2}			Two-year percentage weight loss		
			Count	Average (95% CI)	Median (IQR)
Sweden		30.0-34.9	209	28.5 (27.5-29.4)	29.5 (23.8-33.5)
		35.0-39.9	1,758	31.6 (31.2-32.0)	32.2 (26.9-36.9)
		40.0-44.9	2,155	33.7 (33.4-34.1)	34.4 (28.1-40.0)
		45.0-49.9	933	34.6 (34.0-35.2)	34.9 (28.3-41.7)
		50.0-54.9	306	35.4 (34.2-36.5)	35.8 (28.9-42.8)
		>54.9	126	34.8 (32.9-36.7)	34.8 (26.9-43.0)
United Kingdom		30.0-34.9	3	27.7 (19.9-35.4)	27.5 (19.3-36.1)
		35.0-39.9	81	31.1 (29.4-32.7)	30.3 (25.8-37.3)
		40.0-44.9	226	33.2 (32.0-34.4)	33.7 (27.1-40.7)
		45.0-49.9	442	34.9 (34.0-35.8)	34.9 (29.1-41.5)
		50.0-54.9	359	36.1 (35.1-37.1)	35.8 (29.9-42.9)
		>54.9	303	37.6 (36.5-38.7)	37.5 (30.1-44.7)

Primary gastric bypass for female patients: Percentage weight loss and initial BMI for two high-volume contributors; calendar years 2009-2013

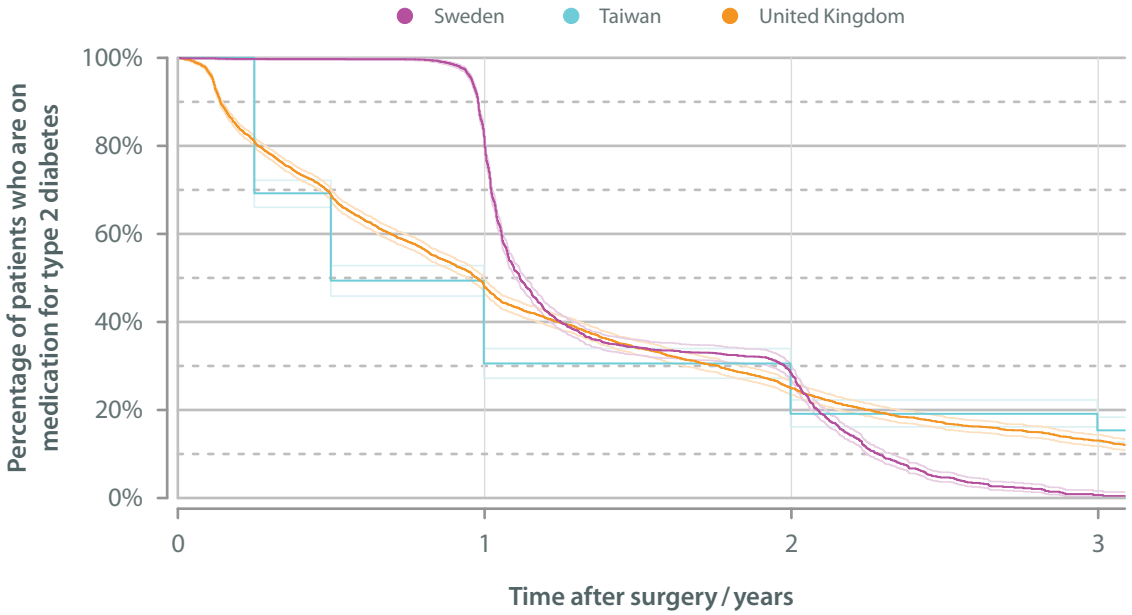


Primary gastric bypass for female patients: Percentage weight loss and initial BMI for two high-volume contributors; calendar years 2009-2013



It might be attractive to show changes in each comorbidity according to the date of the clinic visit when they are recorded, in the form of a Kaplan-Meier curve. For example the data from the United Kingdom suggest a gradual reduction in the percentage of patients on medication for type 2 diabetes. However, in Sweden and Taiwan, patients are having their data recorded at specific time-points, which makes the plotting of Kaplan-Meier curves more problematic. However, the overall message that on an international scale diabetes improves after bariatric surgery is overwhelming. Future reports with more sophisticated and evolved datasets could explore diabetes progression in more detail.

Primary surgery for patients on medication for type 2 diabetes pre-operatively: Changes in recorded rates of medication for type 2 diabetes; calendar years 2009-2013



GLOBAL REGISTRY

Appendix

Appendix

The database form

International Federation for the Surgery of Obesity and metabolic disorders

IFSO Global Registry

Baseline section; Page 1; Version 1.6 (1 Apr 2014)

Basic demographic data

All baseline data refer to the condition of the patient at the time of surgery, unless otherwise specified.

Unique patient identifier

Baseline data

Basic patient details

Date of birth dd / mm / yyyy

Gender ○ Male ○ Female ○ Unknown

Height cm

Weight on entry to the weight-loss program kg

Funding category ○ Publicly funded ○ Self-pay ○ Private insurer

Comorbidities

Type 2 diabetes on medication	○ No	○ Yes
Hypertension on medication	○ No	○ Yes
Depression on medication	○ No	○ Yes
Increased risk of DVT or PE	○ No	○ Yes
Musculo-skeletal pain on medication	○ No	○ Yes
Confirmed sleep apnoea	○ No	○ Yes

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IFSO GLOBAL REGISTRY

International Federation for the Surgery of Obesity and metabolic disorders

IFSO Global Registry

Baseline section; Page 2; Version 1.6 (1 Apr 2014)

Unique patient identifier	
Date of operation	dd / mm / yyyy

Surgery

Date of operation	dd / mm / yyyy
Weight at surgery	kg
Has the patient had bariatric surgery before	○ No ○ Yes
Operative approach	○ Laparoscopic ○ Endoscopic ○ Lap converted to open ○ Open
Type of operation	○ Gastric band ○ Gastric bypass ○ Duodenal switch with sleeve ○ Sleeve gastrectomy ○ Bilio-pancreatic diversion ○ Duodenal switch ○ Other
Type of bypass	○ Roux-en-Y ○ Mini gastric bypass
Details of other procedure	○ Gastric plication ○ Single anastomosis duodenal-ileal surgery ○ Vertical banded gastroplasty ○ Other

Outcomes

Leak within 30 days of surgery	○ No ○ Yes
Bleeding within 30 days of surgery	○ No ○ Yes
Obstruction within 30 days of surgery	○ No ○ Yes
Patient status at discharge	○ Alive ○ Deceased
Date of discharge or death	dd / mm / yyyy

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IFSO GLOBAL REGISTRY

Appendix

International Federation for the Surgery of Obesity and metabolic disorders

IFSO Global Registry

Follow up section; Page 3; Version 1.6 (1 Apr 2014)

Unique patient identifier		
Date of follow up		dd / mm / yyyy

Follow up

Weight at follow up		kg
Type 2 diabetes on medication	○ No	○ Yes
Hypertension on medication	○ No	○ Yes
Depression on medication	○ No	○ Yes
Musculo-skeletal pain on medication	○ No	○ Yes
Confirmed sleep apnoea	○ No	○ Yes
Patient status	○ Alive	○ Deceased

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Appendix

Appendix

Upload-My-Data file specification

IFSO Global Registry

IFSO GLOBAL REGISTRY

Upload-My-Data file specification

Version: 1.6 document dated 1 Apr 2014

Author: Robin Kinsman robin.kinsman@e-dendrite.com

Glossary of terms and definitions

Multi-choice separator

The Multi-choice separator (MCS) is a character that is used to separate values in a multi-choice field that contains two or more coded values. This separator is included in the first column of each row of every upload file. The separator may be a comma, a semicolon, a caret, *etc.*

Layout specification version

Layout Specification Version is the version of layout defined by this specification. For this specification the column should contain the value 1. This allows the Upload-My-Data utility to check that the data files being imported are interpreted using the correct definition.

Submitter code

The Submitter code is an alpha code that is used to identify the group to which the data belong. The code will be provided to each person who registers on the system by the IFSO Global Registry / Dendrite administration team. Each record in the upload files must be tagged with a valid Submitter code, otherwise they will be rejected out-of-hand.

DEMOGID

DEMOGID is a value that uniquely identifies each patient. Only one patient record is created for each DEMOGID. If there are multiple Baseline records for a given patient, they must all have the same DEMOGID. This will typically be an integer value, such as a RowID from the source database's demographic data table.

The IFSO Global Registry database is an anonymised database, so it is important that this DEMOGID should NOT be something that could be used to identify the patient in reality (such as a hospital number).

IMPORTLINKID

The IMPORTLINKID is an integer value that is used to identify each operation record in the **Baseline** upload file. It is also used to link the data in the **Baseline** upload file and the **Followup** upload file.

Database field type

Mandatory

Must be present in the record. Any record with missing mandatory data will NOT be imported into the merged IFSO Global Registry.

Desirable

Deemed to be important for data analysis, but not a requisite for an entry in the merged registry.

Optional

Part of the IFSO Global Registry minimum dataset, but neither mandatory nor desirable.

Date

All date data must be in ODBC format: yyyy-mm-dd *e.g.,* 2012-04-23

Time

All time data must be in ODBC format: hh:nn:ss *e.g.,* 12:43:22

SingleChoice

One code from the specified list.

TableSingleChoice

One code from the lookup table indicated.

MultiChoice

The code(s) only. Multiple codes should be separated by your defined delimiter of choice (see Multi-choice separator on page 2); *e.g.,* 1,2,3.

Integer

A whole number such as 1 or 25 or 55 or 105, providing the constraints are not breached.

Floating point

Numeric values like 0.54 or 243.21, providing the constraints are not breached.

String

Any combination of characters excepting control characters. Only a single line of text is permitted; carriage returns are not acceptable. Other conditions / limitations for specific string fields are detailed on a field-by-field basis.

Upload file requirements

File format

The data should be in a text file.

File headers

The data file should include all the appropriate headers (see Header field name in the main body of this document, highlighted in **blue**) as the first row of data.

Field separators

The file may use any field separator, as long as it is used consistently throughout the file. The type of delimiter used is self-documenting as it comprises the second character of first row of data containing the file's headers.

File nomenclature

There are two upload files required for this submission to the IFSO registry. The following example names are for a contributor whose Submit code is **DEN**:

- baseline data file name: **IFSO_DEN_Baseline**
- follow up data file: **IFSO_DEN_Followup**

Appendix

Upload file

Baseline

fields included:

Multichoice separator
Layout specification version
Submitter code
Import link ID
Patient identifier
Patient date of birth
Age at operation
Gender
Height
Weight on entry to the weight-loss program
Funding category
Type 2 diabetes on medication
Hypertension on medication
Depression on medication
Increased risk of DVT or PE
Musculo-skeletal pain on medication
Confirmed sleep apnoea
Date of operation
Weight at surgery
Has the patient had bariatric surgery in the past
Operative approach
Type of operation
Type of bypass
Details of other procedure
Leak within 30 days of surgery
Bleed within 30 days of surgery
Obstruction within 30 days of surgery
Patient status at discharge
Date of discharge or death

IFSO Global Registry | **Upload-My-Data file specification** | **file: Baseline**

Field title / Header field name	Importance	Min value	Max value	Values allowed
Multichoice separator				
S	**Mandatory**			**A character:** you may define the single character you wish to use to separate values in multi-value fields.
Layout specification version				
SPECVERSION	**Mandatory**			**Integer:** enter a whole number.
Submitter code				
SUBMITCODE	**Mandatory**			**TableSingleChoice:** a code used to identify the source of the data.
Import link ID				
IMPORTLINKID	**Mandatory**			**Integer:** enter a whole number.
Patient identifier				
DEMOGID	**Mandatory**			**String:** can contain any value.
Patient date of birth				
DEMOGDATEOFBIRTH	**Mandatory**			**Date:** ODBC date as yyyy-mm-dd.
Age at operation				
AGEATOPERATION	**Mandatory**			**Integer:** enter a whole number.
Gender				
GENDER	**Mandatory**			**TableSingleChoice:** see table SEX
Height				
HEIGHT	**Mandatory**			**Integer:** enter a whole number.
Weight on entry to the weight-loss program				
WEIGHTONENTRYTOTHEWEIGHTLOSSPROGRAM	Desirable			**Floating point:** enter a numeric value.
Funding category				
FUNDINGCATEGORY	Desirable			**SingleChoice:** the code only. 1 - Publicly funded 2 - Self-pay 3 - Private insurer

IFSO Global Registry | **Upload-My-Data file specification** | **file: Baseline**

Field title / Header field name	Importance	Min value	Max value	Values allowed
Type 2 diabetes on medication				
TYPE2DIABETES	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Hypertension on medication				
HYPERTENSIONONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Depression on medication				
DEPRESSIONONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Increased risk of DVT or PE				
INCREASEDRISKOFDVTORPE	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Musculo-skeletal pain on medication				
MUSCULOSKELETALPAINONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Confirmed sleep apnoea				
CONFIRMEDSLEEPAPNOEA	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes

IFSO Global Registry | **Upload-My-Data file specification** | **file: Baseline**

Field title / Header field name	Importance	Min value	Max value	Values allowed
Date of operation				
DATEOFOPERATION	Mandatory			**Date:** ODBC date as yyyy-mm-dd.
Weight at surgery				
WEIGHTATSURGERY	Desirable			**Floating point:** enter a numeric value.
Has the patient had bariatric surgery in the past				
HASTHEPATIENTHADBARIATRICSURGERYINTHEPAST	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Operative approach				
OPERATIVEAPPROACH	Mandatory			**SingleChoice:** the code only. 1 - Laparoscopic 2 - Lap converted to open 3 - Endoscopic 4 - Open
Type of operation				
TYPEOFOPERATION	Mandatory			**SingleChoice:** the code only. 1 - Gastric band 2 - Gastric bypass 3 - Sleeve gastrectomy 4 - Duodenal switch 5 - Duodenal switch with sleeve 6 - Bilio-pancreatic diversion 9 - Other
Type of bypass				
TYPEOFBYPASS	Desirable			**SingleChoice:** the code only. 1 - Roux-en-Y 2 - Mini gastric bypass

Appendix

IFSO Global Registry | **Upload-My-Data file specification** | **file: Baseline**

Field title / Header field name	Importance	Min value	Max value	Values allowed
Details of other procedure				
DETAILSOFOTHERPROCEDURE	Optional			**SingleChoice:** the code only. 1 - Gastric plication 2 - Single anastomosis duodeno-ileal surgery 3 - Vertical banded gastroplasty 9 - Other procedures
Leak within 30 days of surgery				
LEAKWITHIN30DAYSOFSURGERY	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Bleed within 30 days of surgery				
BLEEDWITHIN30DAYSOFSURGERY	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Obstruction within 30 days of surgery				
OBSTRUCTIONWITHIN30DAYSOFSURGERY	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Patient status at discharge				
PATIENTSTATUSATDISCHARGE	Desirable			**SingleChoice:** the code only. 0 - Alive 1 - Deceased
Date of discharge or death				
DATEOFDISCHARGEORDEATH	Desirable			**Date:** ODBC date as yyyy-mm-dd.

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Upload file

Follow up

fields included:

Multichoice separator
Layout specification version
Submitter code
Import link ID
Date of follow up
Weight
Type 2 diabetes on medication
Hypertension on medication
Depression on medication
Musculo-skeletal pain on medication
Confirmed sleep apnoea
Patient status

IFSO Global Registry | **Upload-My-Data file specification** | **file: Follow up**

Field title Header field name	Importance	Min value	Max value	Values allowed
Multichoice separator				
S	**Mandatory**			**A character:** you may define the single character you wish to use to separate values in multi-value fields.
Layout specification version				
SPECVERSION	**Mandatory**			**Integer:** enter a whole number.
Submitter code				
SUBMITCODE	**Mandatory**			**TableSingleChoice:** a code used to identify the source of the data.
Import link ID				
IMPORTLINKID	**Mandatory**			**Integer:** enter a whole number.
Date of follow up				
DATEOFFOLLOWUP	**Mandatory**			**Date:** ODBC date as yyyy-mm-dd.
Weight				
WEIGHT	Desirable			**Floating point:** enter a numeric value.
Type 2 diabetes on medication				
TYPE2DIABETESONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Hypertension on medication				
HYPERTENSIONONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Depression on medication				
DEPRESSIONONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes

IFSO Global Registry | **Upload-My-Data file specification** | **file: Follow up**

Field title Header field name	Importance	Min value	Max value	Values allowed
Musculo-skeletal pain on medication				
MUSCULOSKELETALPAINONMEDICATION	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Confirmed sleep apnoea				
CONFIRMEDSLEEPAPNOEA	Desirable			**SingleChoice:** the code only. 0 - No 1 - Yes
Patient status				
PATIENTSTATUS	Desirable			**SingleChoice:** the code only. 0 - Alive 1 - Deceased

Appendix

The database dictionary

The IFSO Global Registry

Database Dictionary

Version: 1.6 document dated 1 Apr 2014

Author: Robin Kinsman robin.kinsman@e-dendrite.com

International Federation for the Surgery of Obesity and metabolic disorders
IFSO global registry; Database Dictionary 2014

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Appendix

International Federation for the Surgery of Obesity and metabolic disorders
IFSO global registry; Database Dictionary 2014

Basic patient details

Basic patient details

Multichoice separator
S
Mandatory A character: you may define the single character you wish to use to separate values in multi-value fields.

Layout specification version
SPECVERSION
Mandatory Integer: enter a whole number.

Submitter code
SUBMITCODE
Mandatory Table Single Choice: A code used to identify where the data comes from. For national datasets, use Country Code (See Note 1, below)

Import link ID
IMPORTLINKID
Mandatory Integer: enter a whole number.

Patient identifier
DEMOGID
Mandatory String: Can contain any value. Site can use to tie back to their own records. Only use for Dendrite system is to link (possible) multiple records for a single patient.

Patient date of birth
DEMOGDATEOFBIRTH
Mandatory Date: ODBC date as yyyy-mm-dd.

Age at operation
AGEATOPERATION
Mandatory Integer: enter a whole number.

Gender
GENDER
Mandatory TableSingleChoice: see table SEX

Height
HEIGHT
Mandatory Integer: enter a whole number.

Weight on entry to the weight-loss program
WEIGHTONENTRYTOTHEWEIGHTLOSSPROGRAM
Desirable Floating point: enter a numeric value.

Definition

The initial weight in kg recorded in the bariatric surgery clinic patient record after referral from the General Practitioner or self-referral. If the referral comes from a secondary care bariatric physician the weight recorded is the initial weight on entry to the medical weight management programme.

Version: 1.6

International Federation for the Surgery of Obesity and metabolic disorders
IFSO global registry; Database Dictionary 2014

Basic patient details continued ...

Funding category
FUNDINGCATEGORY
Desirable SingleChoice: the code only.
1 - Publicly funded
2 - Self-pay
3 - Private insurer

Appendix

Comorbidities

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IFSO global registry; Database Dictionary 2014

Comorbidities

Type 2 diabetes on medication
TYPE2DIABETES
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Defined as type 2 diabetes on oral hypoglycaemics,insulin therapy or other treatments such as GLP-1 analogues.

Hypertension on medication
HYPERTENSIONONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Depression on medication
DEPRESSIONONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Clinical depression on medication as an indication for bariatric surgery.

Increased risk of DVT or PE
INCREASEDRISKOFDVTORPE
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Defined as any one or more of the following: history or known risk factor for deep vein thrombosis / pulmonary embolus, venous oedema with ulceration, vena cava filter, obesity hypoventilation syndrome.' Used as one component part of the OSMRS calculation.

Musculo-skeletal pain on medication
MUSCULOSKELETALPAINONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Defined as taking medication daily / regularly for obesity-related musculoskeletal symptoms.

Confirmed sleep apnoea
CONFIRMEDSLEEPAPNOEA
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Confirmed sleep apnoea with the use of continuous positive airway pressure (CPAP) or bi-level positive air pressure (BiPAP).

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IFSO global registry; Database Dictionary 2014 7

Surgery

Date of operation
DATEOFOPERATION
Mandatory Date: ODBC date as yyyy-mm-dd.

Weight at surgery
WEIGHTATSURGERY
Desirable Floating point: enter a numeric value.

Definition

Weight in kg at the time of surgery.

Has the patient had bariatric surgery in the past
HASTHEPATIENTHADBARIATRICSURGERYINTHEPAST
Desirable SingleChoice: the code only.

0 - No
1 - Yes

Operative approach
OPERATIVEAPPROACH
Mandatory SingleChoice: the code only.

1 - Laparoscopic
2 - Lap converted to open
3 - Endoscopic
4 - Open

Type of operation
TYPEOFOPERATION
Mandatory SingleChoice: the code only.

1 - Gastric band
2 - Gastric bypass
3 - Sleeve gastrectomy
4 - Duodenal switch
5 - Duodenal switch with sleeve
6 - Bilio-pancreatic diversion
9 - Other

Definition

Gastric band excludes vertical banded gastroplasty. Vertical banded gastroplasty should be recorded as Other.

Duodenal switch after prior sleeve gastrectomy or gastric bypass.

Bilio-pancreatic diversion according to Scopinaro.

Type of bypass
TYPEOFBYPASS
Desirable SingleChoice: the code only.

1 - Roux-en-Y
2 - Mini gastric bypass

Definition

These data should **only** be submitted if the **Type of operation** is recorded as **Gastric bypass**.

document dated 1 Apr 2014

Appendix

Outcomes

Surgery continued ...

Details of other procedure

DETAILSOFOTHERPROCEDURE

Optional SingleChoice: the code only.

1 - Gastric plication
2 - Single anastomosis duodeno-ileal surgery
3 - Vertical banded gastroplasty
9 - Other procedures

Definition

These data should only be submitted if the **Type of operation** is recorded as **Other**.

These data should be submitted **only** if all three of the options 1-3 can be positively identified in the source database; all operations that do not fall into one of the three options 1-3 should be classified as other.

It is acceptable to submit data files containing only 2 or 3 of the codes listed above (for example, 1 and 9, or 1, 3, and 9) as long as the codes not present in the upload file are operations that are never carried out in the country represented.

International Federation for the Surgery of Obesity and metabolic disorders
IFSO global registry; Database Dictionary 2014

Outcomes

Leak within 30 days of surgery
LEAKWITHIN30DAYSOFSURGERY
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Definition

Defined as a leak from the gastrointestinal tract, including an anastomotic leak or perforation of other viscus, that may settle without treatment or may need intervention or re-operation.

Bleed within 30 days of surgery
BLEEDWITHIN30DAYSOFSURGERY
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Definition

Defined as a clinically significant bleed from the gastrointestinal tract, intra-abdominal or elsewhere that may or may not require transfusion, intervention or re-operation.

Obstruction within 30 days of surgery
OBSTRUCTIONWITHIN30DAYSOFSURGERY
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Definition

Defined as a clinically significant obstruction from any cause, including internal hernias, anastomotic problems and adhesions, that may settle without treatment or may need intervention or re-operation.

Patient status at discharge
PATIENTSTATUSATDISCHARGE
Desirable SingleChoice: the code only.
0 - Alive
1 - Deceased

Date of discharge or death
DATEOFDISCHARGEORDEATH
Desirable Date: ODBC date as yyyy-mm-dd.

Appendix

Follow up

Follow up

Multichoice separator
S
Mandatory A character: you may define the single character you wish to use to separate values in multi-value fields.

Layout specification version
SPECVERSION
Mandatory Integer: enter a whole number.

Submitter code
SUBMITCODE
Mandatory Table Single Choice: A code used to identify where the data comes from. For national datasets, use Country Code (See Note 1, below)

Import link ID
IMPORTLINKID
Mandatory Integer: enter a whole number.

Date of follow up
DATEOFFOLLOWUP
Mandatory Date: ODBC date as yyyy-mm-dd.

Weight
WEIGHT
Desirable Floating point: enter a numeric value.

Definition

Weight in kg at the time of follow up.

Type 2 diabetes on medication
TYPE2DIABETESONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Definition

Defined as type 2 diabetes on oral hypoglycaemics,insulin therapy or other treatments such as GLP-1 analogues at the time of follow up.

Hypertension on medication
HYPERTENSIONONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Depression on medication
DEPRESSIONONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes

Definition

Clinical depression on medication at the time of follow up.

Version: 1.6

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IFSO global registry; Database Dictionary 2014

Follow up continued ...

Musculo-skeletal pain on medication
MUSCULOSKELETALPAINONMEDICATION
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Defined as taking medication daily / regularly for obesity-related musculoskeletal symptoms at the time of follow up.

Confirmed sleep apnoea
CONFIRMEDSLEEPAPNOEA
Desirable SingleChoice: the code only.
0 - No
1 - Yes
Definition
Confirmed sleep apnoea with the use of continuous positive airway pressure (CPAP) or bi-level positive air pressure (BiPAP) at the time of follow up.

Patient status
PATIENTSTATUS
Desirable SingleChoice: the code only.
0 - Alive
1 - Deceased

document dated 1 Apr 2014

The First IFSO Global Registry Report 2014

This is the first comprehensive, international analysis of outcomes from bariatric (obesity) and metabolic surgery, gathered under the auspices of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

> *I applaud this first report of the IFSO global bariatric surgery registry. It marks an historic first step in bringing together real world data from around the globe. It will provide essential support in understanding risk stratification, and refining those most likely to benefit from surgery.*
>
> **John Dixon**

> *The report provides fascinating county-to-country and region-to-region comparisons, as well as demonstrating the safety and effectiveness of bariatric and metabolic surgery on a global scale.*
>
> **Michel Gagner**

> *I encourage all key stakeholders in bariatric surgery, especially surgeons, providers and commissioners of care, to embrace this data collection and reporting process at individual clinics & hospitals, and onwards/upwards at both national and international levels. It will require widespread involvement and on-going commitment from all those involved in the care of the bariatric patient to ensure high quality data can be collected, properly analysed & shared so that we will be able to better understand shifts in disease patterns, practice and outcomes on a global scale.*
>
> **Richard Welbourn**

> *The present report is a bold and outstanding approach to processing this signal: diverse data from around the world have been painstakingly collated and filtered for their similarities. The differences uncovered are intriguing.*
>
> **Alberic Fiennes**

This report is a tribute to the professionalism and willingness of bariatric surgeons in 18 countries to share data on over 100,000 patients. It could be the beginning of an important journey in bariatric surgery, and demonstrates a professional commitment to hard-nosed analysis of results.

It is timely and impressive that so many bariatric surgeons have contributed so many patients to this first report of an international registry.

IFSO
GLOBAL REGISTRY

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