The IFSO Global Registry

4th IFSO Global Registry Report

2018

Prepared by

Jacques Himpens MD PhD
Almino Ramos MD PhD
Richard Welbourn MD FRCS
John Dixon PhD FRACGP FRCP Edin
Robin Kinsman BSc PhD
Peter Walton MBA FRCP

IFSO & Dendrite Clinical Systems

The International Federation for the Surgery of Obesity and Metabolic Disorders

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The International Federation for the Surgery of Obesity and Metabolic Disorders operates the IFSO Global Registry in partnership with Dendrite Clinical Systems Limited. The Federation gratefully acknowledges the assistance of Dendrite Clinical Systems for:

- building, maintaining & hosting the web registry
- data analysis and
- publishing this report

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Preface

The year 2018 will be remembered as a landmark year for privacy protection. The Facebook™ scandal and the European GDPR legislation are just two examples of highly-publicized issues pertaining to the right of individuals to shield their private data. Unfortunately, data protection has evolved into becoming a significant obstacle in implementing what I have considered to be one of the primary tasks of the IFSO Federation, *i.e.,* the collection, interpretation and divulging of patients' data, provided they remain anonymous and untraceable to individuals.

Some, however, consider the gathering of even anonymized patient data incompatible with the privacy principle in the absence of individual *ad hoc* patient consent. Others think that national data collected in one country cannot be exported into an international Registry. I think we should avoid lapsing into a witch-hunt and look to the GDPR law, considered the most astringent in the world. It states that indeed, in principle, personal medical data may not be processed except when these medical data are completely anonymous. Only if the personal data / information can be traced back to an individual it is not considered anonymous under the GDPR. Clearly the Dendrite Registry does not breach this condition, hence the hesitation of some to participate to this beautiful piece of work, while understandable, can only be regretted.

I am of course aware that some fear that data may be *sold* to industry. Our Registry Committee as well as our Data Protection Committee were created precisely to address these concerns, and to detect, evaluate and possibly correct flaws, be they scientific or potentially commercial, of the current and future registries.

I know that some aspects of the Fourth IFSO Global Obesity Data Registry can still be improved, not least the fact that some key-countries did not include the majority of their data. I realize as well that some imperfections remain in the Registry, especially in terms of possible bias in data collection as well as absence of a universally accepted dictionary for complications and definitions such as remission of disease. Nevertheless, the truth is that this is by far the best international data registry in metabolic / bariatric surgery available so far. It gives a clear insight into the geographic and cultural differences in metabolic surgery across the globe. By doing so, and despite the aforementioned limitations, it provides an excellent working document for surgeons and other health care professionals, as well as politicians and stakeholders, and should allow for better insights into health policies, private and public alike. Hence it will eventually be of benefit to patients suffering from obesity and its related diseases. And this happens to be congruent with IFSO's mission.

Jacques Himpens,

IFSO President 2017-2018

Foreword

Resembling what happened in the 4-stages of the industrial revolution, we are now approaching a new, fourth stage in the evolution of surgery. In surgery v1.0, or open surgery, the objective was to understand anatomy and physiology, establish the fundamentals of surgical approaches, study different treatment options, and repair and remove internal organs; surgery v2.0 started with the era of minimally invasive surgery, basically the laparoscopic approach, which allowed the reduction of tissue damage, blood loss, infection and recovery time; robotic assistance inaugurated surgery v3.0, allowing surgeons a very natural and intuitive movement in a very ergonomic way, with reduction of tremor, provision of greater dexterity and 3D visualisation; the next stage, surgery v4.0, is starting now, based on infomatics, with cloud data storage, machine learning and a lot of big-data analytics. The accumulation and connection of data represent the heart of this new period.

Data technology is revolutionizing our understanding and treatment of diseases. With the proper analysis of these data it should be possible to create algorithms to help assess how patients respond to treatment and so help us make more appropriate treatment choices for each patient. This tailored approach should help to optimize outcomes, significantly decrease post-operative complications and reduce the need for revisional surgery. These new tools will be a great advance in the treatment of very complex diseases such as obesity / adiposity-based chronic disease (ABCD).

ABCD is the major non-infectious epidemic disease of this century. The excessive accumulation of adipose tissue accompanied by chronic, systemic inflammation can be associated with the development of more than one hundred associated conditions (hypertension, type 2 diabetes, cardiovascular disease, dyslipidemia, sleep apnea, orthopedic conditions, some types of cancer, *etc.*). According to the last reports of the World Health Organization (WHO), more than 2.1 billion adults were estimated to be overweight or obese, of whom 1.5 billion were overweight and 640 million were obese; on this basis about 25 million people have the classical NIH criteria for bariatric surgery. The most recent IFSO Worldwide Survey (Angrisani *et al.*, Obesity Surgery 2018) reported that 634,897 bariatric operations were performed worldwide in 2016; at this rate it would take 43 years to operate on the current pool of potential patients; and this does not account for all the extra people who will become eligible if current trends in the growth of obesity continue as expected.

One of the key bottle-necks preventing the expansion of bariatric surgery provision is the lack of faith that patients and clinical colleagues have in the efficacy of the surgery; this is partly down to our inability to communicate the benefits to them. A properly-designed and well-run registry could play an important role in helping to overcome this resistance by providing real-world evidence of the good outcomes we see for our patients.

National registries can be powerful tools to help us observe the course of a disease; to understand variations in treatments and outcomes; to examine factors that influence prognosis and quality of life; to monitor safety; and to measure the quality of the treatment. They are important at a national level to monitor and set standards of care, and also at an international level to provide a descriptive analysis of similarities and differences in patient populations. From a payer's perspective, registries can provide detailed information about the effectiveness of surgical options for different populations. IFSO and its federated bariatric societies, providers, health insurance companies, public health systems and hospitals can use the data to demonstrate quality of care, and improve the clinical outcomes for patients. Our big challenge is to convince more and more surgeons and national societies to join the Global Registry project.

In this Fourth Report we present information from the largest registry on bariatric surgery worldwide, comprising 394,431 operations from 18 single centres, 19 multi-centre submissions and 14 national registries coming from 51 countries. We would like to offer our sincere gratitude to all those societies, surgeons and centres who have submitted their data, and also to those directly involved in the project: our current president Jacques Himpens, Richard Welbourn the lead clinical author, and Peter Walton and Robin Kinsman from Dendrite.

We believe that this initiative is an important part of IFSO's response to the adiposity epidemic, and we would like to encourage all our members and national societies to actively participate in the next edition.

Almino Ramos

IFSO President 2018-2019

Introduction

It is a privilege to present data on baseline obesity-related disease, operation types, operative outcomes and disease status after 394,431 bariatric operations accumulated from local and national databases and registries from 51 countries across the world. This Global Registry 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 burden of obesity-related disease, 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.

This fourth iteration of the report again follows the comprehensive Founding Charter that was set up regarding the use and ownership of the accumulated and merged data. Contributors can continue to be reassured that we have steered well clear of attempting to make statistical comparisons between different units, and that their submitted data will not be misused. Similar to the previous 3 Reports, we are aware of the inherent problems of over interpretation of the data. Further aims could include agreeing and developing risk stratification models and the setting of international benchmarks for post-operative complications or mortality. The registry could help in these aims by standardizing data collection. We hope that a very large database could be useful in influencing policy internationally and increasing service provision in countries where there is currently little or no bariatric surgery. We 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. Thank you to all those surgeons who have committed their data for inclusion in this fourth report, your contribution is very much appreciated.

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. Scopinaro, Prof. Buchwald and more recently by Prof. Angrisani [1,2,3,4,5]. Although we know from their surveys which operations are being performed, we do not yet have basic demographic data on variables such as gender distribution, starting BMI, and prevalence of obesity-related disease such as type 2 diabetes, hypertension and sleep apnea. Nor do we have any data on surgical outcomes such as survival, length-of-stay or improvement in obesity-related disease between different populations. An initial step in this direction has been the peer-reviewed publication of data from the 2nd IFSO Global Registry report in Obesity Surgery [6]. Similar to the Third Report, the aims of this 4th iteration of the Global Registry project are to:

1. Establish baseline demographic characteristics for patients operated in different countries either from the respective national registries or individual units in these countries.
2. Report basic 1-year post-operative data within the limitations of the accumulated data.

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

Richard Welbourn

Richard Welbourn, Member of IFSO Global Registry Committee

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Fourth IFSO Global Registry Report

Executive summary

This is the fourth 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 collaboration with Dendrite Clinical Systems.

In overview

- 51 countries from 5 continents contributed a total of 394,431 operation records
- over 550 hospitals contributed data either directly or *via* their national registry submissions
- the number of records submitted ranged from 10 from a single centre to over 80,000 submitted by the national registry from Italy
- this précis reports on 165,138 Roux en Y gastric bypass operations (41.9% of all the records submitted), 128,417 sleeve gastrectomy procedures (32.6%),19,634 one anastomosis gastric bypass procedures (5.0%), and 47,858 gastric banding operations (12.1%)
- most of the database records fell in the period 2009-2018 (88.5% of the total); 220,348 operations were dated in the calendar years 2014-2018 (55.9%)

The dataset and completeness of data entry

- the simple dataset used for the previous IFSO report was extended slightly to include a total of 40 variables (28 baseline data-items; 12 in the follow-up section)
- overall, 46.2% of the baseline records were >80% complete for operations dated in the calendar years 2014-2018

Initial data on primary surgery from 2014-2018

Funding and gender inequality

- 68.0% of operations were funded by public health services; there was a great deal of variation in the rates of publicly-funded surgery across the contributor countries
- there was also a wide variation in the country-specific gender ratios, ranging from 50.9% female (in Georgia) to 100.0% female (in South Korea)

Primary operations and BMI range

- the patients' median BMI pre-surgery was 41.7 kg m^{-2} (inter-quartile range: 38.3-46.1 kg m^{-2}); there was a wide variation between different contributor countries, medians ranging from 34.2 kg m^{-2} in South Korea to 49.1 kg m^{-2} in Germany
- patients' median age was 42.0 years (inter-quartile range: 33.0-51.0 years)
- the overall proportion of female patients was 73.7% (95% CI: 73.5-73.9%)
- Mexico (81.0%), Colombia (79.2%) and Brazil (73.6%) reported the highest proportions of gastric bypass surgery; Australia (100.0%), Saudi Arabia (100.0%) and Guadeloupe (99.5%) reported the highest rates of sleeve gastrectomy operations
- 99.3% of all operations were performed laparoscopically
- 88.5% of patients who had a gastric band inserted were discharged within 1 day of their operation; after gastric bypass, 84.1% of patients were discharged within 2 days of surgery; and 84.5% of sleeve gastrectomy patients went home within 3 days of their operation

Obesity-related disease prior to surgery

- 19.8% of patients were on medication for type 2 diabetes (inter-country variation: 4.5-97.7%)
- 30.6% were treated for hypertension (inter-country variation: 10.9-92.6%)
- 12.4% of patients were on medication for depression (inter-country variation: 0.0-54.4%)
- 24.3% of patients required treatment for musculo-skeletal pain (inter-country variation: 0.0-65.1%)
- 18.6% of patients had sleep apnea (inter-country variation: 0.0-74.3%)
- 17.0% of patients had gastro-esophageal reflux disorder (inter-country variation: 0.0-54.8%)

Stratification for operative risk

- the Obesity Surgery Mortality Risk Score [1] (OSMRS) varied widely by country
- Georgia, Bulgaria and Hong Kong had the highest-risk patient populations (OSMRS groups B & C: 78.7%. 72.2% and 66.7% respectively)
- South Korea, Bolivia & Kuwait appeared to have the least risk (OSMRS groups B & C: 12.5%, 20.5% and 22.2% respectively)

Follow up data for primary surgery carried out in the calendar years 2011-2017

- there were 275,834 valid follow up records
- average recorded percentage weight loss was 28.9% one year after surgery
- one year after primary surgery 66.1% of those taking medication for type 2 diabetes beforehand were no longer on medication; the proportion of patients no longer treated for diabetes was highly dependent on weight loss achieved, with the rate of improvement increasing with higher percentage weight loss
- there were also significant reductions in the rates of treatment for depression, hypertension and musculo-skeletal pain
- rates of confirmed sleep apnea also fell one year after bariatric surgery

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 fourth report quantifies the gender inequality evident worldwide and also shows inequality of access to surgery in many countries
- 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 continues to 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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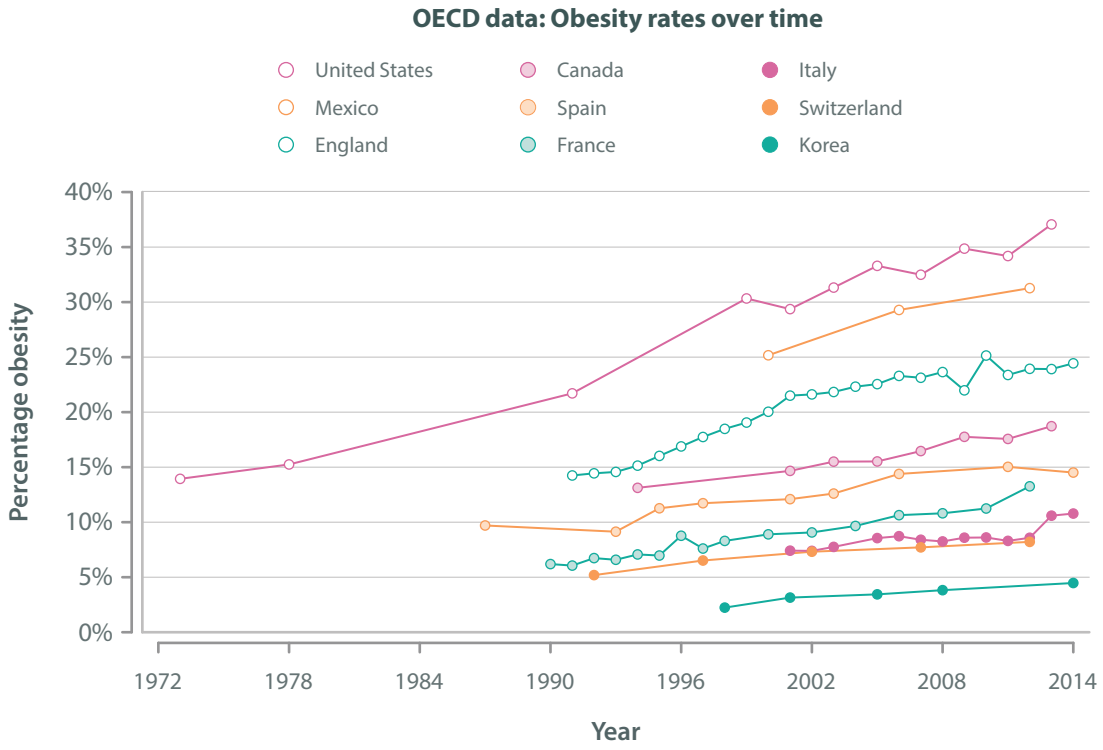
Contents

OECD & WHO data

The epidemiology of obesity – a call for collective action

The inexorable increase in obesity rates among the OECD countries can clearly be seen in the chart below. These data indicate that only one of the countries in this figure reported a lower obesity rate than in the previous survey. All others have increased and the reported rate in the United States for those over 15 years of age is now well over 35% [1]. The catastrophic trend continues. Where will this end?



The World Health Organization (WHO) report published in February 2018, indicated that obesity rates have tripled since 1975 [2]. Most of the world's population now live in countries where being overweight causes more deaths than being underweight. There are 340 million children and adolescents (age 5-19) who are overweight or obese. The WHO stresses that obesity is preventable!

A decade ago I considered that rates in the US, Mexico, the Middle East and Pacific Islands were so high that a ceiling would be reached by now and we would have an indication of a genetically driven limit, albeit at a very high level. Clearly this is not the case and the OECD has predicted that current trends will continue in a linear fashion out to 2030.

Of course obesity prevalence tells only part of the story as a doubling of the obesity rate in a country generates a 3-fold increase in the prevalence of a BMI >35, a 5 fold increase of a BMI >40, and a 9-10 fold increase in individuals with a BMI >50 [3]. Obesity rates are generally higher in women and the exponential rise in the more severe levels of obesity has been dominated by women globally [4]. Inequality in education and economic opportunity is also greater in women [1]. The relationship between obesity, poor education and lower socioeconomic status is self-sustaining. Obese people have poorer job prospects, are less likely to be employed and have more difficulty re-entering the labour market. Obese people have more sick days, are less productive at work and earn less. The OECD stresses that addressing obesity and the negative labour market outcomes would help address the vicious cycle of social and health inequality . The impact of obesity on our communities is far greater than just the burden of type 2 diabetes, cardiovascular disease, and the cancers that obesity generates. As individuals and teams engaged in the effective management of obesity, especially those people with the greatest impairment, we are being called to action. A nation's cost of obesity extends well beyond those of health care, and includes individual and societal costs of functional impairment leading to markedly reduced productivity [5].

A survey I conducted in 2015 prior to the Diabetes Surgery Summit Consensus Conference included 22 countries representing approximately 75% of all bariatric-metabolic procedures performed in 2014 and looked at the uptake of surgery as a treatment of type 2 diabetes [6].

Modelling based on numbers of individuals operated, population prevalence, and proportion of patients eligible for surgery indicated trivial uptake. The highest uptake was in The Netherlands with 1.9% of those eligible treated annually with the lowest in China and Japan (<0.01%). Most countries had national guidelines and several had diabetes specific criteria, but it was rare to have more than 1% of those eligible operated in a year. Bariatric-metabolic surgery as therapy for type 2 diabetes had not entered the established care pathways. The conference outcome was remarkable in that all major global diabetes organizations supported the recommendation that surgery become a recommended therapy for selected patients with type 2 diabetes [7].

Managing the health burden of the obesity-diabetes epidemic will require a chronic disease model of care that provides an appropriately trained trans-disciplinary team approach, sufficient clinical capacity, and well defined clinical pathways. The care provided will need to be evidence based, collaboratively provided, and regularly evaluated. Medical, surgical, specific dietary and behavioural therapies will need to be combined to provide optimal health outcomes for individual patients. Although we have had clear evidence that combining therapies provides better outcomes, we continue to work largely in silos. Comments such as *only surgery is effective*, *I don't believe in very low calorie diets or meal replacements*, *surgery is a last resort* and *weight loss drugs are dangerous, ineffective and for short term use only* are not evidence-based and represent myopic, personal views.

Currently managing clinically severe obesity and its complications is stigmatized and neglected. Effective surgical and medical therapies beyond those of behavioural-lifestyle interventions are used by less than 1% of those eligible [6]. Put simply *things that actually work are rarely used*. This provides the most blatant example of clinical inertia (to fail to scale up of effective therapies in a timely manner). It would be unconscionable to report beyond behavioural-lifestyle intervention uptake at trivial levels for the management of hypertension, diabetes, cardiovascular disease and cancer. Weight management is extraordinarily challenging [8]. Currently we are not treading water, but drowning in a tsunami of increasing need.

We manage obesity and its related risks and complications. We need to think carefully about the language we choose to promote the quality of care that we can provide. The messaging in our area of health care appears woefully inadequate or inappropriate [9].

We need global data, and a collective will, to address this global epidemic; both prevention and treatment. It is important to pool our resources and understand the delivery of bariatric-metabolic surgery on a global basis. The IFSO international registry provides a vital component in monitoring and evaluating our response to this epidemic. I applaud the progress made with the IFSO global registry during this last year.

John Dixon, Head Clinical Obesity Research, Baker Heart and Diabetes Institute

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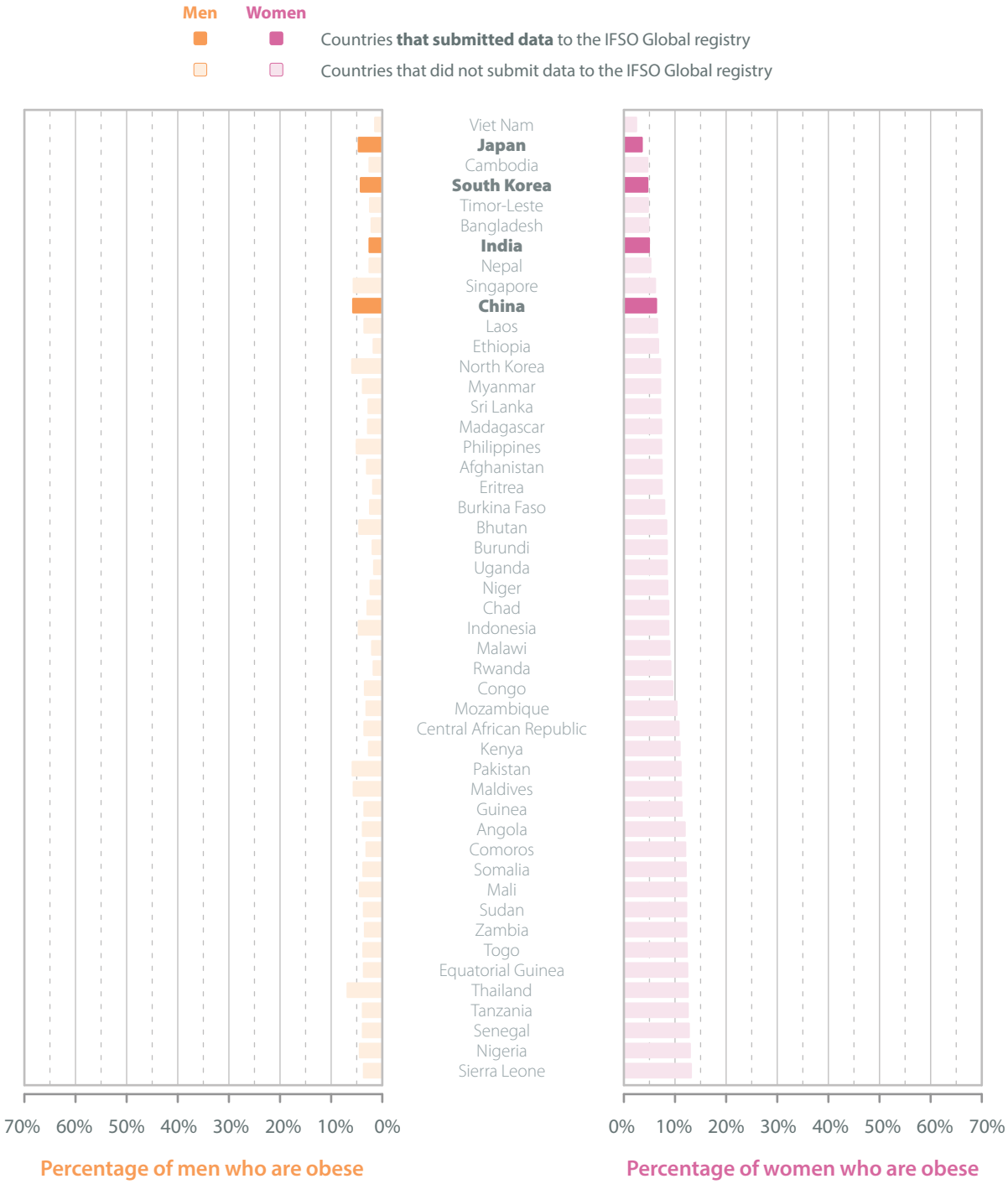
OECD & WHO data

Global prevalence of obesity

The next four graphs show the latest data available for the prevalence of obesity (defined as body mass index of ≥30 kg m^{-2}) by gender from the World Health Organisation (apps.who.int/gho/data/view.main.CTRY2450A?lang=en). Together with the graph on the previous page they illustrate the severity of the problem affecting all countries, especially the more developed. These charts are updated versions of those presented in the Third IFSO Report.

On this first page, we see the countries with the lowest prevalence of obesity. The difference in the prevalence between men and women is clear and consistent throughout these countries that currently exhibit the lowest levels of obesity, with the female populations in each country, in general, having a higher rate of obesity than the corresponding male populations; there are two exceptions: China and Japan, where this pattern is reversed.

WHO data: Gender & age standardised rates of obesity by country; countries ordered by increasing rates of obesity in the female population; people over the age of 17; data from the year 2016



Countries represented on this page are from a range of geographical regions. It is easy to recognise the European countries as it is in these countries that the prevalence of obesity in men is similar to or even exceeds that in the female population.

There are many developed countries contributing to the IFSO Global Registry in this group of countries. It is noticeable that the gender divide in obesity prevalence is greatest in the sub-Saharan African nations where obesity is much more prevalent in women. Notably, there are more contributors to the IFSO Global Registry in this group of countries, than in previous iterations of the database.

WHO data: Gender & age standardised rates of obesity by country; countries ordered by increasing rates of obesity in the female population; people over the age of 17; data from the year 2016

OECD & WHO data

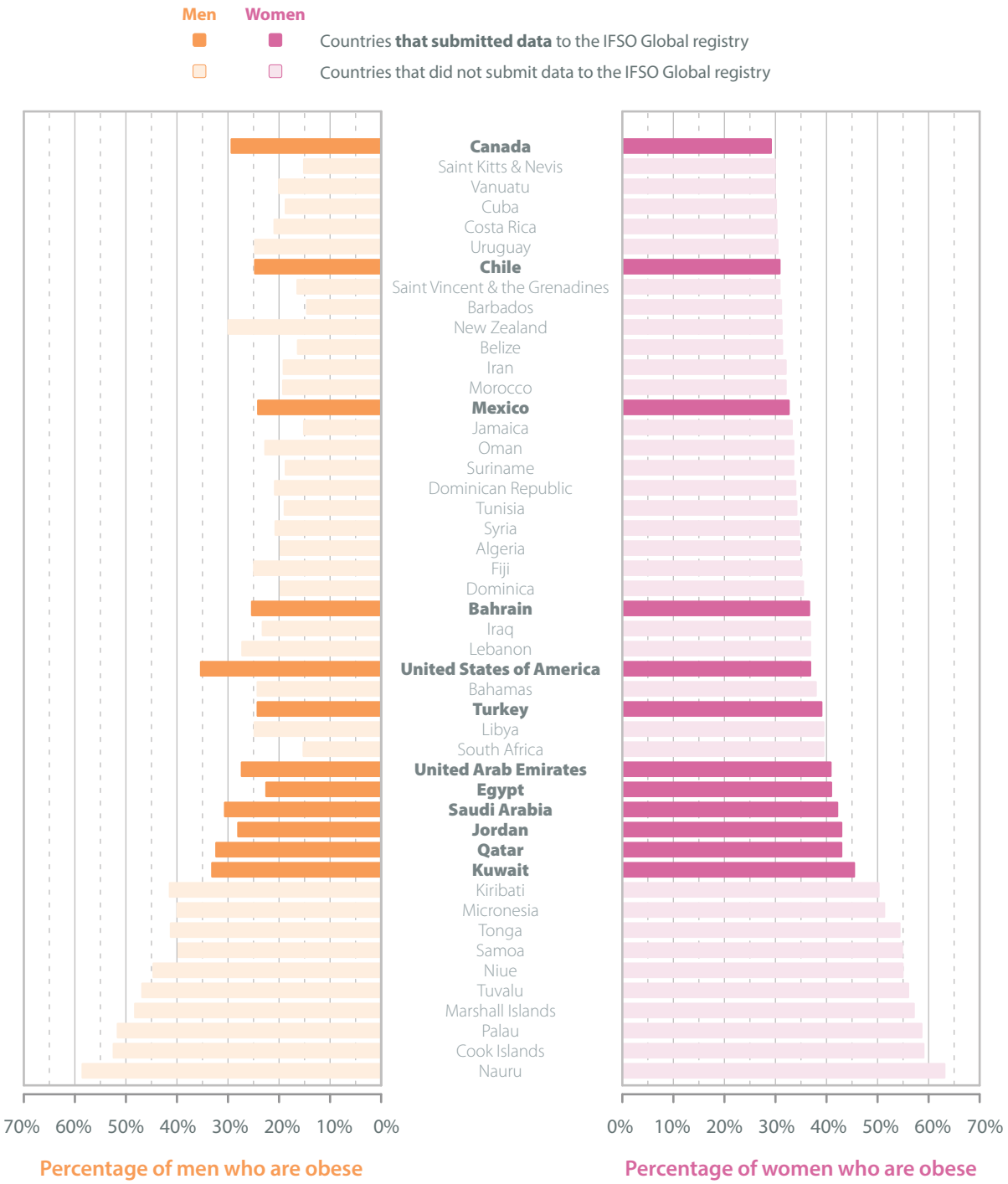
The information on these four pages might suggest to some readers that countries represented in the first chart (those with the lowest rates of female obesity), should have less to worry about than those on the last page (where in some of these countries more than half of the female population are obese). However, some simple calculations might suggest otherwise: if, as indicated by the first chart, around 3.9% of the Indian adult population and 6.2% of the Chinese adult population are obese then just these two countries, which together currently account for about 36% of the world's population, would represent a burden of disease totalling approximately **106 million** obese adults in 2016; and this number has increased by about **13 million** in just the last two years alone, which is a phenomenal increase in the burden of disease.

WHO data: Gender & age standardised rates of obesity by country; countries ordered by increasing rates of obesity in the female population; people over the age of 17; data from the year 2016

The countries represented here are those with the highest prevalence of obesity globally. Regions are very distinct and include the Pacific Islands, the Middle East, the United States & Canada, Mexico, Caribbean Islands, and parts of Central and South Americas.

Despite the major concerns of Western European countries about the continued increasing levels of obesity reaching so-called *crisis* levels, there are very few European countries found in this chart, which represents those with the highest levels of obesity in the female population across the globe.

WHO data: Gender & age standardised rates of obesity by country; countries ordered by increasing rates of obesity in the female population; people over the age of 17; data from the year 2016



Database mechanics

Dendrite Clinical Systems, as the information management provider for the IFSO Global Registry, have provided two parallel web-portals for submitting data,

- an Upload-My-Data portal for submission of electronic data files, and
- a Direct Data Entry portal for entering cases one-by-one over the Internet for those individual surgeons who do not have a local or national database system.

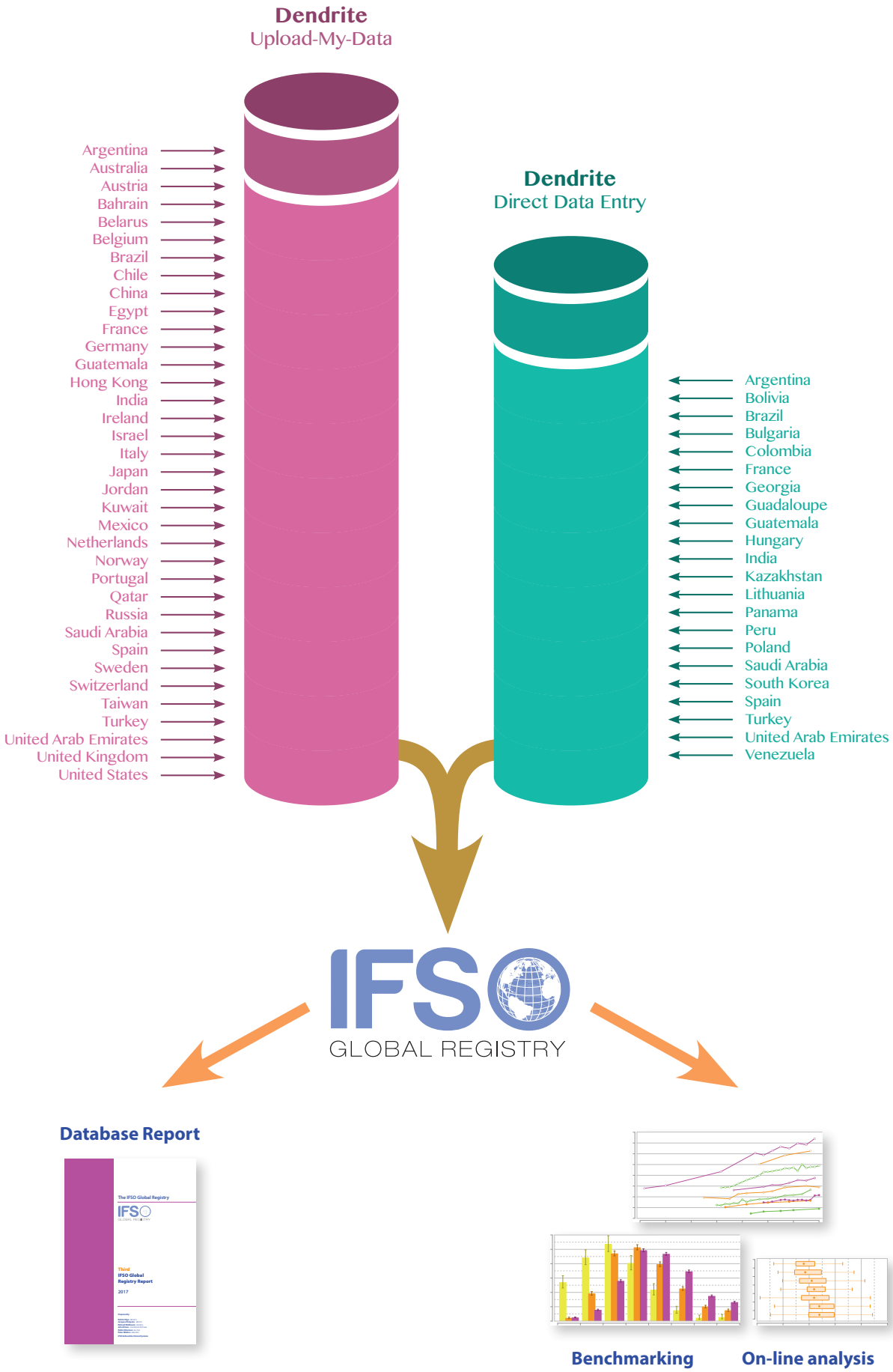
Access to these portals was arranged *via* the setup of secure ID and passwords to ensure that only authorized users could gain access to the registry. For those that had the capability to upload data electronically, each was then sent a unique contributor submit identifier code, and four key documents:

1. The Database Form: to provide a quick overview of the central database design. This is available in the Appendix in this report on pages 74-77.
2. The File Specification Document: that provides a detailed specification of the file format output required for submitting / uploading electronic data files.
3. The Data Dictionary: detailing the definitions of the database answer options.
4. The User Manual: to explain how the Upload-My-Data software works.

The diagram opposite illustrates which submissions came through which route, and shows that most countries (and all national databases) were successfully able to upload data electronically through the Upload-My-Data web portal.

By combining / merging the data from the Upload-My-Data area with the data submitted on-line case-by-case, through the Direct Data Entry module, it was then possible to run the analyses in this report on data gathered from 51 countries from around the world.

For more information on how to participate in the Dendrite / IFSO Global Registry *via* either the Upload-My-Data or Direct Data Entry route, please contact Dr Peter K H Walton, Managing Director, Dendrite Clinical Systems *via* e-mail: peter.walton@e-dendrite.com


Dendrite
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A note on the conventions used throughout this report

There are several conventions used in this 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 the kind of operation performed, 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).

Primary surgery: age and gender; calendar years 2014-2018

		Gender			
		Male	**Female**	**Unknown**	**All**
Age at surgery / years	<21	1,800	3,993	94	**5,887**
	21-30	6,776	24,205	353	**31,334**
	31-40	11,536	35,023	242	**46,801**
	41-50	15,180	41,370	124	**56,674**
	51-60	10,826	27,622	43	**38,491**
	61-70	3,475	6,983	8	**10,466**
	>70	176	249	2	**427**
	Unspecified	27	64	6	**97**
	All	**49,796**	**139,509**	**872**	**190,177**

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 age and gender) 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 orange 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.

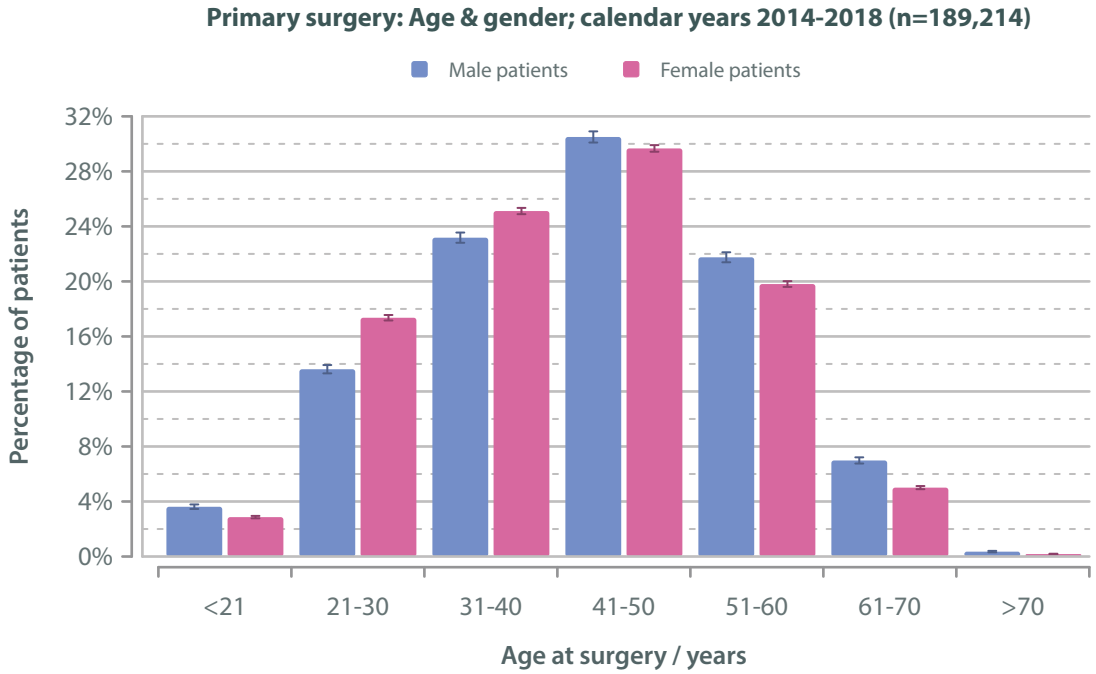
Conventions used in graphs

The basic principles applied when preparing graphs for this Fourth 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 operations. 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 patient is having primary surgery in the calendar years 2014-2018, and both the patient's age and gender are known are included in the analysis; this comes to 189,214 patient-entries (1,800 + 3,993 + 6,776 + 24,205 + 11,536 + 35,023 + 15,180 + 41,370 + 10,826 + 27,622 + 3,475 + 6,983 + 176 + 249 ; the 963 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.

Analysis

The growth of the IFSO Global Registry

The info-graphics opposite show the steady growth of the IFSO Global Registry over the last four years, from its initial inception in 2015. The goal set out last year for this year was:

> *to hit a target of contributions from 50 countries and hopefully see a doubling in the total number of records that have been submitted.*

Despite this being seen by some as an ambitious target, it was achieved and is testament to the commitment of so many surgeons and their specialist surgical societies around the world to join this project; so many thanks to those people who have made this happen, in particular to the Executive Boards of the 14 National Specialist Societies who have committed their national data.

As stated in the Third IFSO Global Registry Report 2017, there has been an evolution in the maturity of each successive IFSO Registry Report. What started out as a feasibility project in 2015 has since gathered great pace and now significant momentum. Indeed, the very existence of the Global Registry has sparked interest and activity in National Specialist Societies developing their own new national registries right around the world. This Fourth Report represents a further milestone in providing global data on the practice of bariatric and metabolic surgery and provides more in-depth analyses than in previous reports.

It is important to reflect for a moment on the purpose of individual national registries *versus* the Global Registry. The function and purpose of individual national registries varies from country to country, but in essence they are all about providing a rich resource of data to drive up the quality of care, provide a benchmark of activity and outcomes, and lend transparency to the outside world about the benefits and risks of bariatric and metabolic surgery. The *outside world* here is represented by local medical and surgical communities, general practitioners, commissioners of care, governments, Departments of Health, epidemiologists, health observatories, the Press (and the list goes on!), and of course importantly includes individuals who are exploring the surgical options for treating obesity and obesity-related conditions as potential patients.

The Global Registry has never been intended to replace the role of national registries; rather, it is there to provide a global perspective on what is happening in this speciality in different countries and in different regions around the world. Indeed, it is specifically **not** the role of a global registry to reach out to individual patients to track long-term outcomes. This is the domain of national registries, which cannot be supplanted by a global registry in particular because the data that are held by IFSO centrally are fully anonymised as far as patient-identification is concerned, which is, of course, a requirement for the newer General Data Protection Regulation (GDPR) laws. Nevertheless, the Global Registry can provide a very useful additional layer of information above and beyond the capabilities of individual national registries, as it allows surgeons to get a better understanding of the context of the patient populations they are treating in comparison to practice elsewhere. This maybe particularly true where access to bariatric surgery through government funding is very open and freely available, or at the other extreme where access is very restricted.

The greatest information challenge in bariatric surgery (as it is with many other specialities) is to gather comprehensive long-term data on patient outcomes. To date some countries have submitted data to the IFSO Global Registry from systematic follow ups, whilst some other countries have provided no post-discharge data at all. Certain countries, such as Sweden, now have the ability to cross check outcomes through linkage of records from one national registry to another (*e.g.,* bariatric registry to the diabetes registry) and this probably represents a gold standard that many countries might like to emulate, but few will manage to do at least in the near future. Even so, as information technology advances at a pace, for example, with the dramatic development of wearable monitoring devices, it is probably the case that we're currently only scratching the surface of what data it is possible to collect when looking forwards only a short way into the future.

The goal for next year is to hit a target of contributions of data from 55 countries and to have over half a million procedure records under analysis.

For more information on how to participate in the Dendrite / IFSO Global Registry and / or on how to set up your own local or national database so that it is compliant with the IFSO Global Registry minimum dataset, please contact:

Dr Peter K H Walton, Managing Director, Dendrite Clinical Systems *via* e-mail: peter.walton@e-dendrite.com

2015 data merge

100,092
operations

8 single centres
7 multi-centre submissions
3 national registries

2016 data merge

142,748
operations

19 single centres
5 multi-centre submissions
7 national registries

2017 data merge

196,188
operations

21 single centres
13 multi-centre submissions
8 national registries

2018 data merge

394,431
operations

18 single centres
19 multi-centre submissions
14 national registries

Contributors

The tables on these two facing pages show which countries, from which broad geographical areas, have contributed data to the Fourth IFSO Global Registry. They show the number of procedure records sent in from each country and whether the submissions were from a national registry, multiple centres or from a single centre. It is notable that the European countries are currently the largest contributors to the registry. This is not necessarily because more bariatric surgery is performed here; rather it reflects the fact that European countries have embraced the need to set up national registries earlier than in other regions and as a result they have accumulated more historical data. Kuwait and Brazil, for example, have only just started their national registries.

This year Italy, Sweden and the United Kingdom are the top three contributors in total, but it is likely that in future other countries that perform high numbers of cases *per* head of population on an annual basis (such as France, Brazil or Saudi Arabia) might predominate in future. Some countries with well-established registries such as the USA and Australia have not yet agreed to participate in the Global Registry project, it is hoped that this situation will change in future years.

Nevertheless it is very gratifying that so many countries have embraced the Global Registry, which has truly become a significant surgical *community effort*. The simple aim is to provide a useful information benchmark that can assist individual surgeons to better understand demographic patterns, and surgical practice and outcomes on a very grand scale. There is a *caveat*; like all registries, the Dendrite / IFSO Global Registry is on a *journey* and one that is never finished, but each year as it moves forward the Registry increases in value.

Europe

Western Europe	282,698 records	
Austria	1,713	**National registry**
Belgium	12,549	**National registry**
France	4,080	Multi-centre
Germany	472	Multi-centre
Ireland	572	Multi-centre
Italy	80,364	**National registry**
Netherlands	40,765	**National registry**
Norway	3,726	**National registry**
Portugal	418	Single centre
Spain	711	Multi-centre
Sweden	63,084	**National registry**
Switzerland	7,863	Multi-centre
Turkey	3,041	**National registry**
United Kingdom	63,340	**National registry**

Eastern Europe	6,682 records	
Belarus	115	Single centre
Bulgaria	19	Single centre
Czech Republic	1,319	Single centre
Georgia	110	Multi-centre
Hungary	73	Single centre
Lithuania	134	Single centre
Poland	647	Multi-centre
Russia	4,265	**National registry**

Americas

North America		10,309 records
Canada	2,143	Single centre
Guadeloupe	211	Single centre
Mexico	1,838	Multi-centre
United States of America	6,117	Single centre
Central America	**374 records**	
Guatemala	278	Single centre
Panama	96	Multi-centre
South America	**16,682 records**	
Argentina	3,264	Multi-centre
Bolivia	128	Single centre
Brazil	2,013	Pilot **National registry**
Chile	10,011	Multi-centre
Colombia	356	Single centre
Peru	762	Single centre
Venezuela	148	Single centre

Other countries

Middle East		48,308 records
Bahrain	500	Single centre
Egypt	481	Multi-centre
Israel	34,125	**National registry**
Jordan	466	Single centre
Kuwait	4,011	**National registry**
Qatar	2,832	Single centre
Saudi Arabia	4,231	Multi-centre
United Arab Emirates	1,662	Multi-centre
Asia	**29,057 records**	
China	4,126	Multi-centre
Hong Kong	842	Multi-centre
India	15,308	**National registry**
Japan	961	**National registry**
Kazakhstan	338	Single centre
South Korea	10	Multi-centre
Taiwan	7,472	Multi-centre
Australasia	**321 records**	
Australia	321	Multi-centre