

# Indications and Coverage of Metabolic and Bariatric Surgery:

A Worldwide IFSO Survey Comparing Different National Guidelines.

J. Pujol-Rafols, J. Carmona-Maurici, D. M. Felsenreich, S. A. Shikora, G. Prager, N. Di Lorenzo, M. De Luca, O. Uyanik, M. Mazzarella, S. D'Arco, L. Angrisani, E. Pardina, J. M. Balibrea.

Obesity Surgery (2024) 34:1395–1404

XXVII IFSO World Congress



Melbourne 2024

# **I have no pot**ential conflict of interest to report

XXVII IFSO World Congress



Melbourne 2024

In 1991, the US National Institute of Health gathered a group of experts in the field of obesity and introduced the first indications for surgical treatment for obesity based on the scientific evidence available at the time.

- NIH Conference: Gastrointestinal surgery for severe obesity. Consensus development conference panel. Ann Intern Med 1991;115:956–961.
- Gastrointestinal Surgery for Severe Obesity. Obes Surg. 1991 Sep;1(3):257-265.
- Gastrointestinal surgery for severe obesity: National Institutes of Health Consensus Development Conference Statement. Am J Clin Nutr. 1992 Feb;55(2 Suppl):6155-6195.

#### The American Journal of CLINICAL NUTRITION

Official Journal of The American Society for Clinical Nutrition, Inc.



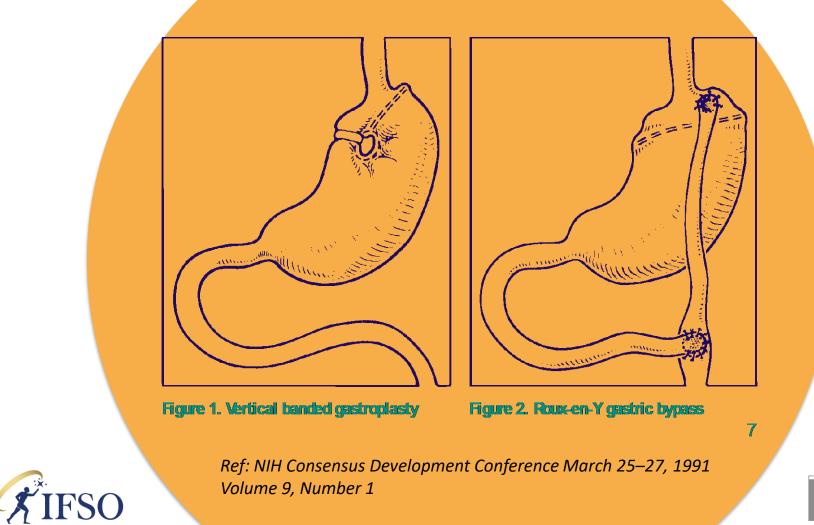
ISSN 0002-9165

VOLUME 55 NUMBER 2 FEBRUARY 1992











- Since the NIH consensus conference,
  - New procedures have been introduced.
  - Better approach routes and greater technological evolution (laparoscopy, robotic surgery, etc.).
  - We have a better understanding of the health hazards of obesity.
  - We have improved the efficacy and safety of MBS...



- Huppler L, et al.: How safe bariatric surgery is-An update on perioperative mortality for clinicians and patients. Clin Obes 2022 Jun;12(3):e12515.
- Aminian A, et al.: How safe is metabolic/diabetes surgery? Diabetes Obes Metab 2015 Feb;17(2):198-201.
- Blaine TP, et al: The history of metabolic and bariatric surgery: Development of standards for patient safety and efficacy. Metabolism 2018 Feb:79:97-107.
- Nguyen NT, et al. Proposal for a Bariatric mortality risk classification system for patients undergoing bariatric surgery. Surg Obes Relat Dis 2013 Mar-Apr;9(2):239-46.





Surgery for Obesity and Related Diseases 9 (2013) 239-246

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

### Proposal for a bariatric mortality risk classification system for patients undergoing bariatric surgery

Ninh T. Nguyen, M.D.<sup>a</sup>, \*, Brian Nguyen, B.S.<sup>a</sup>, Brian Smith, M.D.<sup>a</sup>, Kevin M. Reavis, M.D.<sup>a</sup>, Christian Elliott, B.S.<sup>a</sup>, Samuel Hohmann, Ph.D.<sup>b</sup>

<sup>a</sup>Department of Surgery, University of California, Irvine, Medical Center, Orange, California <sup>b</sup>University HealthSystem Consortium, Oak Brook, Illinois Received May 27, 2011; accepted December 13, 2011

• It analyses the records of 105,287 patients undergoing bariatric surgery between 2002 and 2009.



 The number of hospital deaths per operations decreased from 4.0 to 0.6 0/00.

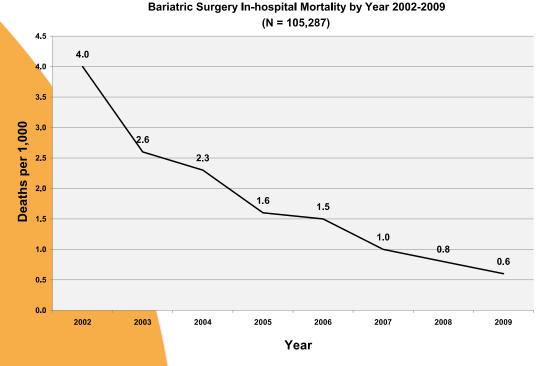


Fig. 2. In-hospital mortality according to year reported as number of deaths per 1000 bariatric operations, 2002–2009.

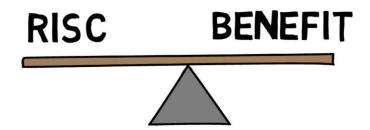


T. Nguyen et al, SOARD (9) 2013.

 Over the last 30 years, there has been an improvement in outcomes with a very significant reduction in morbidity and surgical mortality.



• "If the safety profile improves, the indication criteria could be expanded."



• Lerner H. et al Benefit-risk paradigm for clinical trial design of obesity devices: FDA proposal. Surg Endosc. 2013;27:702-7.



### **Annals of Internal Medicine**



### Treatment of Mild to Moderate Obesity with Laparoscopic Adjustable Gastric Banding or an Intensive Medical Program

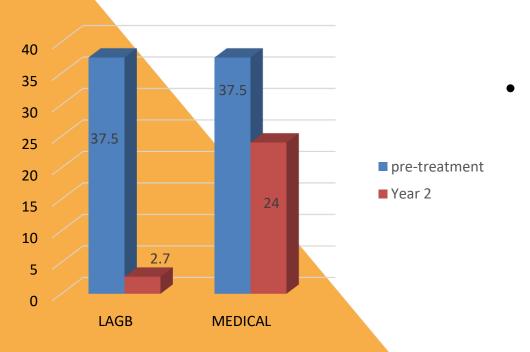
#### A Randomized Trial

Paul E. O'Brien, MD; John B. Dixon, MBBS, PhD; Cheryl Laurie, RN; Stewart Skinner, MBBS, PhD; Joe Proietto, MBBS, PhD; John McNeil, MBBS, MSc, PhD; Boyd Strauss, MBBS, PhD; Sharon Marks, MBBS, PhD; Linda Schachter, MBBS; Leon Chapman, MBBS; and Margaret Anderson, BHIM

- RCT study.
- LAGB + medical treatment vs. medical treatment for the control of Metabolic sd.
- BMI: 30-35.



• The surgery group...



- Obtained higher %EWL (87% vs. 22%; p < 0.001).</li>
- Achieved a significantly better improvement in comorbidities (93% vs. 36%; p<0.002).</li>

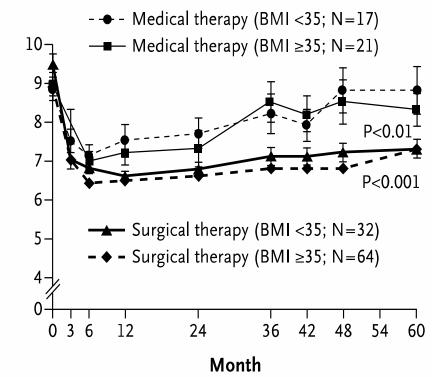
O' Brian et al. Ann Intern. Med. (144) 2006.



### **D** Glycated Hemoglobin According to Body-Mass Index

Glycated Hemoglobin Level (%)

 Courcoulas et al, Ikramuddin et al, Parikh et al and Schauer et al showed significantly better weight loss and diabetes improvement when medical treatment was combined with surgery in patients with BMI <35 kg/m2.</li>





Parikh et al, Annals of Surgery. 2014; 260 (4). Courcoulas AP, et al. JAMA Surg 2015;150(10). Ikramuddin S, et al. Diabetes Care 2016;39(9). Schauer PR, (2017) N Engl J Med 376(7).



Over the last few years, several medical societies have proposed expanding the 1991 indications based on the updated evidence...













ASMBS statements/guidelines

### Bariatric surgery in class I obesity (body mass index 30-35 kg/m<sup>2</sup>)

ASMBS Clinical Issues Committee\*

Received September 12, 2012; accepted September 13, 2012

# "For patients with BMI 30-35, who do not achieve improvement with non-surgical methods, bariatric surgery should be an available option".















#### Obes Facts 2013;6:449-468

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**Clinical Information** 

Interdisciplinary European Guidelines on Metabolic and Bariatric Surgery

## 1. With a BMI $\geq$ 40 kg/m2.

- 2. With BMI 35-40 kg/m2 with comorbidities.
- 3. BMI >30 and <35 kg/m2 with T2DM.



Ref: Fried, M et al. Obes Facts 2013; 6











#### OTHER

### **Bariatric Surgery in Class I Obesity**

A Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)

Luca Busetto • John Dixon • Maurizio De Luca • Scott Shikora • Walter Pories • Luigi Angrisani

 "Patients with grade I obesity, who are unable to achieve adequate weight loss with conservative treatment, should be considered for bariatric surgery".









 Rubino lead two Diabetes Surgery Summits bringing together 45 medical and scientific societies from around the world, including the International Diabetes Federation and the American Diabetes Association.



Rubino, F. et al. Diabetes Care (39) 2016.





Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations

Diabetes Care 2016;39:861-877 | DOI: 10.2337/dc16-0236

Francesco Rubino,<sup>1</sup> David M. Nathan,<sup>2</sup> Robert H. Eckel,<sup>3</sup> Philip R. Schauer,<sup>4</sup> K. George M.M. Alberti,<sup>5</sup> Paul Z. Zimmet,<sup>6</sup> Stefano Del Prato,<sup>7</sup> Linong Ji,<sup>8</sup> Shaukat M. Sadikot,<sup>9</sup> William H. Herman,<sup>10</sup> Stephanie A. Amiel,<sup>1</sup> Lee M. Kaplan,<sup>2</sup> Gaspar Taroncher-Oldenburg,<sup>11</sup> and David E. Cummings,<sup>12</sup> on behalf of the Delegates of the 2nd Diabetes Surgery Summit\*

 "Surgery should be considered as an option to treat type 2 diabetes in patients with grade I obesity who are inadequately controlled despite medical treatment".



Rubino, F. et al. Diabetes Care (39) 2016.



### 2020

Surgical Endoscopy (2020) 34:2332–2358 https://doi.org/10.1007/s00464-020-07555-y

#### GUIDELINES



Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP

Nicola Di Lorenzo<sup>1</sup> · Stavros A. Antoniou<sup>2,3</sup> · Rachel L. Batterham<sup>4,5</sup> · Luca Busetto<sup>6</sup> · Daniela Godoroja<sup>7</sup> · Angelo Iossa<sup>8</sup> · Francesco M. Carrano<sup>9</sup> · Ferdinando Agresta<sup>10</sup> · Isaias Alarçon<sup>11</sup> · Carmil Azran<sup>12</sup> · Nicole Bouvy<sup>13</sup> · Carmen Balaguè Ponz<sup>14</sup> · Maura Buza<sup>15</sup> · Catalin Copaescu<sup>15</sup> · Maurizio De Luca<sup>16</sup> · Dror Dicker<sup>17</sup> · Angelo Di Vincenzo<sup>6</sup> · Daniel M. Felsenreich<sup>18</sup> · Nader K. Francis<sup>19</sup> · Martin Fried<sup>20</sup> · Berta Gonzalo Prats<sup>14</sup> · David Goitein<sup>21,22</sup> · Jason C. G. Halford<sup>23</sup> · Jitka Herlesova<sup>20</sup> · Marina Kalogridaki<sup>24</sup> · Hans Ket<sup>25</sup> · Salvador Morales-Conde<sup>11</sup> · Giacomo Piatto<sup>16</sup> · Gerhard Prager<sup>18</sup> · Suzanne Pruijssers<sup>13</sup> · Andrea Pucci<sup>4,5</sup> · Shlomi Rayman<sup>21,22</sup> · Eugenia Romano<sup>23</sup> · Sergi Sanchez-Cordero<sup>26</sup> · Ramon Vilallonga<sup>27</sup> · Gianfranco Silecchia<sup>8</sup> R<sup>55</sup>ociation for **UD** un C 0 0 Interventi

The European Association for Endoscopic Surgery (EAES) coordinated a joint work with the European Chapter of IFSO (IFSO-EC), the European Association for the Study of Obesity (EASO) and the European Society for the Perioperative Care of the Obese Patient (ESPCOP).





2020

"Surgery should be considered in patients with BMI between 30-35 kg/m2 and T2DM and/or hypertension with poor control despite medical treatment".





**ORIGINAL CONTRIBUTIONS** 





2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Indications for Metabolic and Bariatric Surgery

Dan Eisenberg<sup>1</sup> · Scott A. Shikora<sup>2</sup> · Edo Aarts<sup>3</sup> · Ali Aminian<sup>4</sup> · Luigi Angrisani<sup>5</sup> · Ricardo V. Cohen<sup>6</sup> · Maurizio de Luca<sup>7</sup> · Silvia L. Faria<sup>8</sup> · Kasey P.S. Goodpaster<sup>4</sup> · Ashraf Haddad<sup>9</sup> · Jacques M. Himpens<sup>10</sup> · Lilian Kow<sup>11</sup> · Marina Kurian<sup>12</sup> · Ken Loi<sup>13</sup> · Kamal Mahawar<sup>14</sup> · Abdelrahman Nimeri<sup>15</sup> · Mary O'Kane<sup>16</sup> · Pavlos K. Papasavas<sup>17</sup> · Jaime Ponce<sup>18</sup> · Janey S. A. Pratt<sup>1,19</sup> · Ann M. Rogers<sup>20</sup> · Kimberley E. Steele<sup>21</sup> · Michel Suter<sup>22,23</sup> · Shanu N. Kothari<sup>24</sup>

Published online: 7 November 2022





- MBS is recommended for individuals with BMI  $\geq$  35 kg/m<sup>2</sup>, regardless of the presence, absence or severity of comorbidities.
- •MBC should be considered for individuals with metabolic disease and BMI 30-34.9 kg/m2\*.

(\*adjusted in the Asian population).

Eisenberg, D et al. SOARD. (2022) 1-12. & Obes Surg 33, 3-14 (2023).





However, due to the large number of national societies that make up IFSO and their different socio-economic contexts, the indications for MBS at a national level may not follow these recommendations to 100% and could vary from one country to another.





Obesity Surgery (2024) 34:1395–1404 https://doi.org/10.1007/s11695-024-07142-3

**ORIGINAL CONTRIBUTIONS** 





### Indications and Coverage of Metabolic and Bariatric Surgery: A Worldwide IFSO Survey Comparing Different National Guidelines

J. Pujol-Rafols<sup>1</sup> · J. Carmona-Maurici<sup>2</sup> · D. M. Felsenreich<sup>3</sup> · S. A. Shikora<sup>4</sup> · G. Prager<sup>3</sup> · N. Di Lorenzo<sup>5</sup> · M. De Luca<sup>6</sup> · O. Uyanik<sup>7</sup> · M. Mazzarella<sup>8</sup> · S. D'Arco<sup>8</sup> · L. Angrisani<sup>9</sup> · E. Pardina<sup>2</sup> · J. M. Balibrea<sup>10,11</sup>







Indications and Coverage of Metabolic and Bariatric Surgery: A Worldwide IFSO Survey Comparing Different National Guidelines

J. Pujol-Rafols<sup>1</sup> · J. Carmona-Maurici<sup>2</sup> · D. M. Felsenreich<sup>3</sup> · S. A. Shikora<sup>4</sup> · G. Prager<sup>3</sup> · N. Di Lorenzo<sup>5</sup> · M. De Luca<sup>6</sup> · O. Uyanik<sup>7</sup> · M. Mazzarella<sup>8</sup> · S. D'Arco<sup>8</sup> · L. Angrisani<sup>9</sup> · E. Pardina<sup>2</sup> · J. M. Balibrea<sup>10,11</sup>

- <u>Objective</u>: IFSO aimed to analyze which are the indications for MBS recommended by each of the different national societies.
- The second objective was to assess whether the costs of MBS procedures were covered by their national health services.

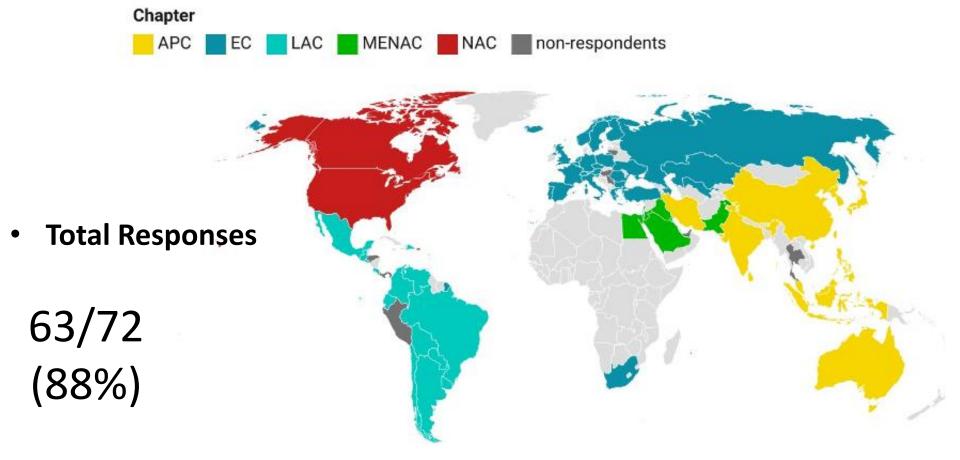




## **Materials and Methods**

A questionnaire was developed in order to obtain information on national guidelines and the type of financial coverage they have in each country.

- This survey was sent by email to the representatives of the different national societies.
- The results were analyzed as a whole and also grouped according to the different geographical chapters of the federation.



• For each chapter, the participation was  $\geq$  75.0%.

FIFSO



# • **RESULTS**:



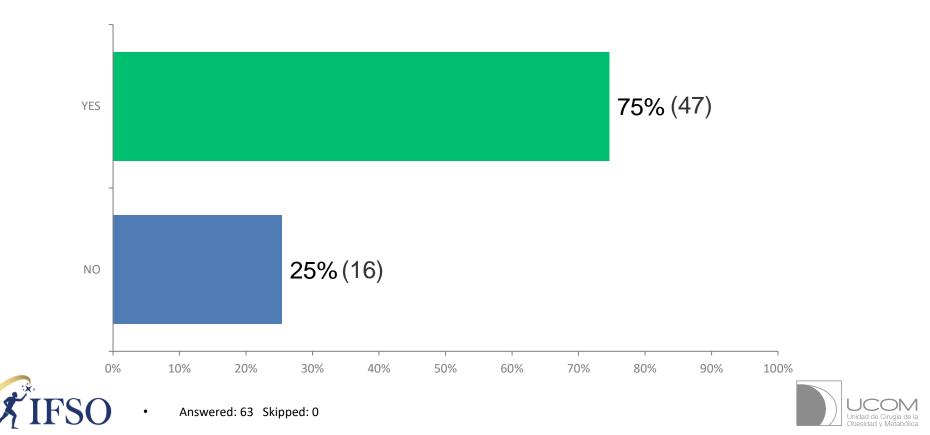


# Q1: Does your national MBS society have any recommendations about candidates for Bariatric and Metabolic Surgery?





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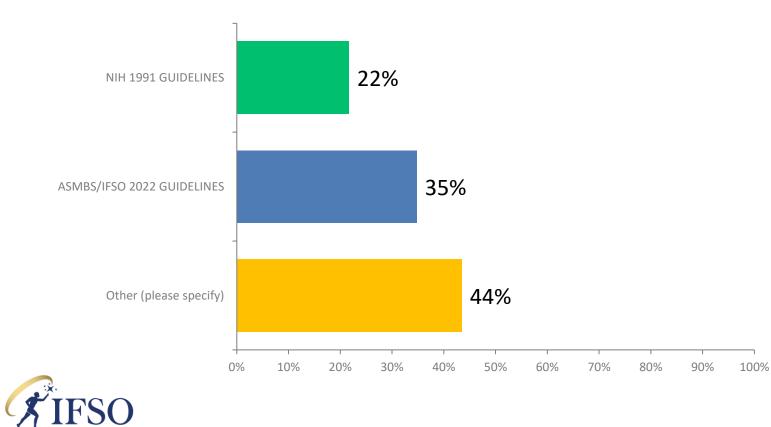


## Q2: Which are your guidelines?





### Q2: Which are your guidelines?





## Others:

Some countries have recommendations halfway between those of 1991 and those of 2022.

(\*) EASO, ADA, IFSO-EC 2013, EAES 2020.

(\*\*) IFSO APC 2011 guidelines.

(\*\*\*) Age, 18 years of age or older, or when bone growth is completed

30 kg/m2 + T2D 35 kg/m2 + comorbidities. >40Kg/m2 (*)	France Germany Italy
>27.5 + T2D >30 + comorbidities BMI >35 (**)	Hong Kong India Korea (***)
>32 + DM or 2 other comorbidities. >37	Malaysia
>30 kg/m2 + T2D > 35 kg/m2	Switzerland
>35 + comorb. >32,5 + T2D & 1 other comorb.	Japan
>30 + T2D or reproductive disfunction. >35 + comorb. >40	Kazakhstan
>30 + comorbidities. >40	Venezuela

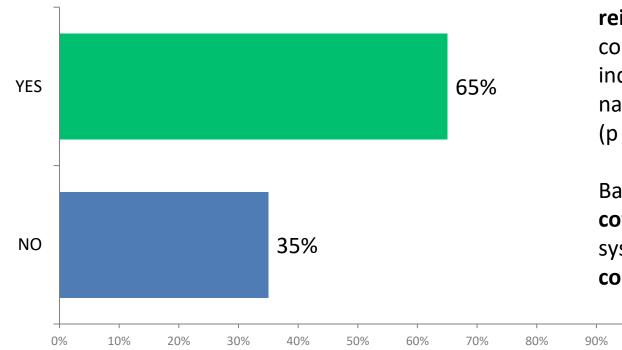


# Q3: Does your national/public health system financially cover MBS?





# Q3: Does your national/public health system financially cover MBS?



MBS was totally or partially reimbursed in 65% of the countries, and the coverage is independent of having or not national guidelines (p = 0.546).

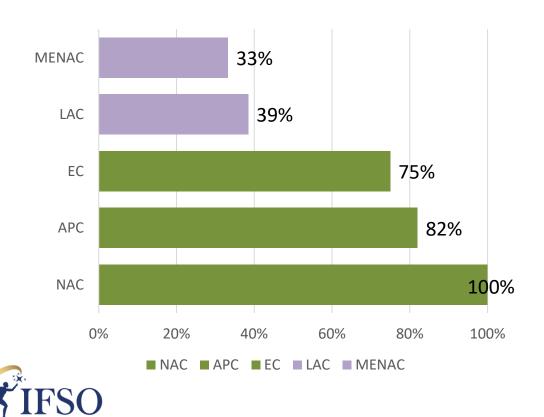
Bariatric surgery is **not covered** by the public health system **in 35% of the countries** that make up IFSO.

100%



• Answered: 60 Skipped: 3

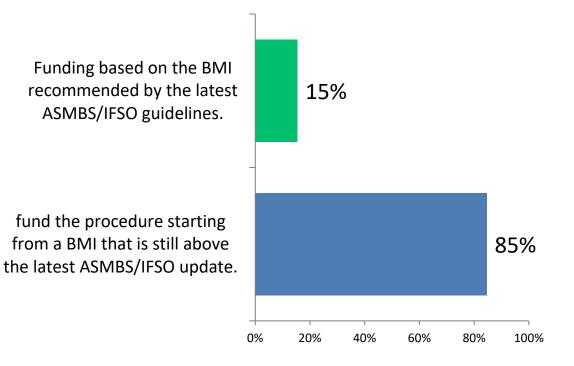
Percentage of countries with MBD financially covered by the public health system in different IFSO chapters.



- There were statistical differences in the coverage between chapters (p = 0.035).
- In the Middle East and Latin America there are fewer countries where bariatric surgery is covered by the public health system.



# Q3: Does your national/public health system financially cover BMS?



Only 15% of the countries fund the surgical procedure based on the BMI recommended by the latest ASMBS/IFSO guidelines.

85% fund the procedure from a BMI that is still above the latest ASMBS/IFSO recommendations.





#### In many countries insurance coverage also limits those who can undergo surgery based on age.

- Coverage approval was granted in less than half of pediatric cases in US. In contrast, payers approved 80% to 85% of adults who met similar criteria.
- Age under 18 years was the most frequent reason for denial of financial coverage in adolescents (73%).

Inge et al. Obesity (2014) 22, 2593–2597.

• In other countries, such as Korea or the Netherlands, MBS coverage is limited to age 18 or older.

Sang Kuon L, Korean' guidelines.

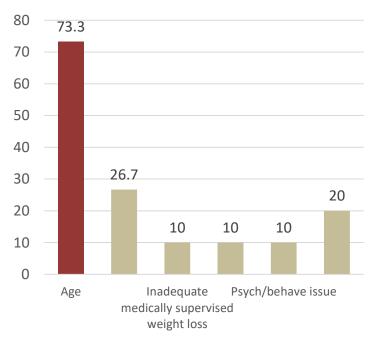


Fig: Inge et al. Obesity (2014) 22, 2593–2597.



Reasons for denial (%)

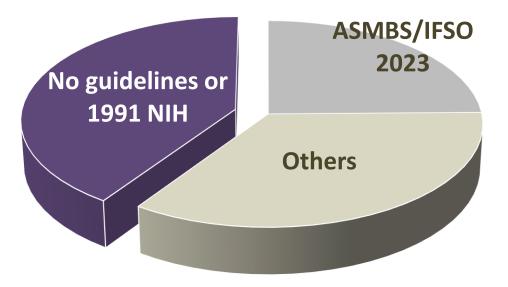
## **Conclusion:**





### **Conclusion:**

- Most of the IFSO member societies (75%) do have MBS guidelines (with no difference between chapters).
- 25% of them have already shift to the most updated ASMBS/IFSO 2022 guidelines.
- There is still 41% of countries with 1991 guidelines or without any guidelines.



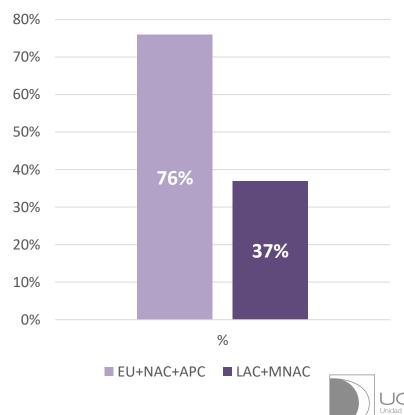




### **Conclusion:**

- There are still 35% of IFSO member national societies where MBS is not covered by the public health system.
- Most are in the **Middle East** and **Latin America**, where only 37% of their countries cover MBS.

% of countries per chapter where MBS is already covered by public health system





#### **Closing remarks:**

- IFSO is doing a lot of work to disseminate the new clinical guidelines.
- We must continue to encourage some of the national societies that make up IFSO to develop or update their clinical guidelines.
- We need to intensify our contacts with insurance companies, policy makers and health care payers to achieve global coverage.



#### 13<sup>th</sup>Congress of the International Federation for the Surgery of Obesity (IFSO) European Chapter

15-17 May 2025 | Venice, Italy



#### IFSO-EC2025.COM

#### XXVII IFSO World Congress



Melbourne 2024

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Harraca J.L, Chisholm J, Beckerhinn P, Omarov T, Dillemans B, Bakry H, Valezi A, Grozdev K, Garneau P, Muñoz R, Wang C, Lopez L, Murillo J, Haluzík M, Lazala E, Mendoza J, Moustafa A.A, Velarde T, Salminen P, Pattou F, Dietrich A, Skroubis G, Behrens E, Simon W, Sigurdsson A, Kular K.S, Rudiman R, Kermansaravi M, Mukhtar R, Sakran N, Zappa M, Matsubara H, Ahmad S, Ospanov O, Lee S.K, Al jarallah M, Mcheimeche H, Ritza Kosai N, Rodriguez J, Emous M, Kristinsson J, Maher M, Rodriguez A, Oliveros E, Tarnowski W, Santos J, Khatsiev B, Alqahtani A, Pintar T, Van der Merwe T, Sánchez-Pernaute A, Garcia ruiz de Gordejuela A, Wijeratne T, Olbers T, Bueter M, Wang W, Taskin E, Andriy L, Menon V, LaMasters T, Rodriguez Temesio G, Teshaev O, Level L.











J. Pujol Ràfols, et al.

