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TITLE

INDICATIONS AND COVERAGE OF METABOLIC AND BARIATRIC SURGERY: A WORLDWIDE IFSO SURVEY COMPARING DIFFERENT NATIONAL GUIDELINES.

Shortened title:

MBS indications worldwide.

Key words: Bariatric Surgery, Metabolic Surgery, Guidelines, Indications, Coverage, IFSO, ASMBS.

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ABSTRACT:

INTRODUCTION: Knowing how Metabolic and Bariatric Surgery (MBS) is indicated in the different countries, is an essential information for the International Federation For the Surgery of Obesity and Metabolic Disorders (IFSO).

AIM: To analyze the indications for MBS recommended by each of the national societies that comprise the IFSO and how MBS is financed in their countries.

METHODS: All IFSO societies were asked to fill a survey asking whether they have, and which are their national guidelines, and if MBS is covered by their public health service.

RESULTS: Sixty-three out of the 72 IFSO national societies answered the form (87.5%). Among them, 74.6% have some kind of guidelines regarding indications for MBS. Twenty-two per cent are still based on the U.S. National Institute of Health (NIH) 1991 recommendations, 43.5% possess guidelines midway the 1991's and ASMBS/IFSO 2022 ones, and 34% have already adopted the latest ASMBS/IFSO 2022 guidelines. MBS was financially covered in 65% of the countries.

CONCLUSIONS: Most of the IFSO member societies have MBS guidelines. While more than a third of them have already shift to the most updated ASMBS/IFSO 2022 ones, another significant number of countries is still following the NIH 1991 guidelines or even do not have any at all. Besides, there is a significant number of countries in which surgical treatment is not yet financially covered. More effort is needed to standardize indications worldwide and to influence insurers and health policy makers to increase the coverage of MBS.

Key points:

- Almost 75% of IFSO member societies have MBS guidelines.
- Thirty-four percent of IFSO member societies have already updated their guidelines adopting the ASMBS/IFSO 2022 ones.
- MBS is fully or partially covered in 65.0% of the IFSO countries.
- MBS public coverage is limited and insufficient in most countries.

INTRODUCTION:

By 2025, global obesity prevalence is predicted to reach 18% in men and 21% in women. Of these, an estimated 257 million adults worldwide (6% of men and 9% of women) are forecast to be living with severe obesity in 2025, showing a rapid increase from an estimated 173 million in 2014 [1].

Metabolic and Bariatric surgery (MBS) is currently the most effective treatment for the control of severe obesity and its associated metabolic disorders [2-5]. Current evidence suggests that the sooner the intervention is performed, the greater the probability of obtaining positive results [6]. However, as MBS is an invasive treatment, and not without risks, as with all operations, it is imperative to define indications based on strong evidence in order to address the risk-benefit ratio [7].

One of the most important aspects of the medical guidelines is that they favor standardizing indications, providing access to MBS based on current evidence of the impact of significant and sustained weight loss on associated diseases, quality of life and life expectancy.

In 1991, the National Institute of Health in the U.S. (NIH) gathered a group of experts in the field of obesity and introduced the first indications for surgical treatment based on the scientific evidence available at the time [8-10].

These indications, based on Body Mass Index (BMI) and the presence or absence of comorbidities, have been used worldwide by most policy makers, medical societies, insurance companies, and in clinical hospital guidelines. However, since the 1991 consensus conference, MBS has undergone a progressive evolution, with the introduction of new procedures, minimally invasive approaches and application of advanced technology, which has led to a significant improvement in the efficacy and safety of these procedures [11-14].

Over the past few years, several medical associations, such as International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), the European Association for Endoscopic Surgery (EAES) or the American Diabetes Association (ADA) have proposed expanding the 1991 indications based on updated evidence

[15-19]. Finally, in December 2022, the IFSO and the American Society for Metabolic and Bariatric Surgery (ASMBS), published simultaneously in the journals *Obesity Surgery* and *Surgery for Obesity and Related Diseases* the most recent indications for MBS to date [20-21].

However, due to the large number of 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 [22].

The knowledge of how MBS is indicated in the different countries is an essential information for IFSO to design strategies for the implementation and standardization of the new guidelines worldwide.

The present study aims to analyze which are the indications for MBS recommended by each of the different national societies that constitute IFSO.

In addition, we evaluate whether the costs of MBS procedures are covered by their national health services.

MATERIAL AND METHODS:

This is a descriptive study based on a specifically designed questionnaire that was sent to the representatives of the different societies affiliated to IFSO.

Questionnaire

The questionnaire consisting of 7 questions was designed using an online platform for questionnaires and surveys (Survey Monkey Inc.®, San Mateo, California, United States). These questions aimed at obtaining information on national bariatric / metabolic surgical indications and type of financial coverage. Three of the questions were closed: two dichotomous and one multiple-choice. Four questions were to be answered with free text, one of them numeric. Conditional branching was used to create a customized path based on the respondents' answers (Fig. 1).

This questionnaire was emailed by the IFSO secretariat to all the national bariatric / metabolic surgical societies members between December 2022 and July 2023. A maximum of three reminders were emailed in case of lacking response and, in case of imprecise or unclear answers, one of the co-authors of the study contacted the respondents to complete the specific answer or clarify any doubts.

Responses received up to the end of July 2023 were eligible for the final analysis.

The results of the study were analyzed globally and also grouped according to the 5 different geographical chapters of IFSO.

Analysis

All the answered questions were used for final analysis. The analysis was performed in a descriptive manner. Categorical data are presented as number of events and percentages. Statistical analysis was done using chi-squared test and the association between variables was analyzed with the Fisher's exact test. Differences were considered significant when $p < 0.05$.

RESULTS:

Response rate

Sixty-three out of the 72 IFSO national societies answered the form (87.5%). Brazil, Chile, Indonesia, Japan, the Netherlands, Pakistan, Slovenia and Taiwan answered the questionnaire partially, it is indicated in the text when data were not available. Finally, Honduras, Hungary, Lithuania, Panama, Peru, Serbia, Singapore, Thailand and United Arab Emirates did not respond and were excluded from data analysis. For each chapter the participation was 75.0% or higher. Figure 2 shows the responded countries by chapters.

Guidelines availability

The first item of the survey asked about the existence of national indications for MBS. Globally, 74.6% of IFSO members (47 out of 63 respondents) have some type of recommendations and/or guidelines regarding indications for MBS. Eight out of the 14 responding Latin American Chapter (LAC) national societies (57.1%) have their own guidelines. Twenty-one out of 28 European Chapter (EC) countries (75.0%) reported having guidelines. Higher percentages were found in the Asian-Pacific Chapter (APC) 83.3% (10 out of 12) and Middle East and North Africa Chapter (MENAC) 85.7% (6 out of 7). Finally, the two members that make up the North American Chapter (NAC), the Canadian and USA national societies, both have guidelines (100%).

Regarding which international guides have been the basis for the creation of their own, among the 47 societies with guidelines, 46 answered the question (Pakistan did not complete the survey). Twenty-one point seven percent of National Societies (10 out of 46) are still following the NIH 1991, 16 members (34.8%) have already adopted the ASMBS/IFSO 2022 guidelines, however, the majority (20, representing the 43.5%) possess guidelines distinct from NIH 1991 and ASMBS/IFSO 2022.

Interestingly, when comparing among the 5 different chapters that make up the IFSO, differences are found among them. APC is the chapter where fewer of its countries members (only 20% of them) follow the most widespread international guidelines (the NIH 1991 or the ASMBS/IFSO 2022 ones) (Figure 3).

The detailed information about the different national guidelines are summarized in Table 1. Brazil, Indonesia, The Netherlands, Slovenia and Taiwan did not provide additional information about their guidelines. As can be seen, in general, the indications for MBS are based on the patient's BMI and the presence or absence of comorbidity factors.

National/Public health system coverage and MBS

The last topic was focused on the national/public health coverage that the MBS receives among IFSO countries. Chile, Japan and Pakistan did not provide this

information (n = 60). In 39 of the consulted countries (65.0%) the MBS was totally or partially reimbursed (Table 2), and the coverage is independent of having or not national guidelines (p value = 0.546). Nevertheless, there were statistical differences in the coverage between chapters (p value = 0.035). Those chapters with a higher coverage of MBS were NAC with both countries covering it (100%), APC (81.8%) and EC (75.0%). In LAC the MBS was covered in only 38.5% of the countries and the lowest MBS coverage was found in MENAC (33.3%).

Interestingly, only 6 out of 39 (15.4%) of the countries fund the surgical procedure based on the BMI recommended by the latest ASMBS/IFSO guidelines, while the remaining 84.6% fund the procedure starting from a BMI that is still above the latest ASMBS/IFSO update.

Even if we take their local clinical guidelines as a reference, in 52.0% of the countries (13/25) the starting BMI at which MBS is covered by their public health system and the minimum BMI at which MBS is recommended in their clinical guidelines coincide. However, in 40.0% (10/25) of the countries the public health system finances surgery but starting at a BMI higher than that recommended by their clinical guidelines. Unfortunately, the BMI of the guidelines from Brazil, Indonesia, The Netherlands, Slovenia and Taiwan were not provided so had not been considered in this analysis.

DISCUSSION

The current study provides an overview of the MBS situation in IFSO's constituent countries during the first third of 2023 (shortly after the publication of the most recent IFSO/ASMBS guidelines). The research analyzes the impact of these recommendations on IFSO members' local guidelines and payment coverage.

The survey results show the maturity level of IFSO member societies, revealing that a substantial majority (74.6%) already have clinical guidelines.

The differences between the guidelines availability by chapters were analyzed descriptively finding that whilst >75% of the EC, MENAC, NAC and APC national

societies already have clinical guidelines, only 57.1% of the LAC members have theirs. Although the present survey does not provide information in this regard, it is very likely that surgeons in countries lacking their own national guidelines may indicate surgery following international criteria. However, the fact that their national society does not have its own recommendations can leave the local surgeon in a situation of helplessness. On the contrary, having recommendations at a national level gives strong support, confidence and even legal protection to the local surgeon. The data from the present study may be useful for IFSO to initiate campaigns to encourage and assist these national societies to develop their own clinical guidelines. A few societies that reported having national guidelines (21.7%) are still following the old 1991 NIH recommendations. Most of the respondent societies have already switched to more up-to-date ones (43%) having recommendations midway between those of 1991 and the most recent ASMBS/IFSO 2022 guidelines, basically including people with type two diabetes and lower BMI. This is probably a consequence of the large number of studies that have been published over the last few years clearly demonstrating the efficacy of MBS for the management of patients with type two diabetes [2-4, 23-25] . This solid scientific evidence has served as a basis for supranational societies, both medical and surgical, to update their recommendations including patients with type-two diabetes with lower BMIs [15-19] and these recommendations have finally been adopted at a national level. Lastly, 34% of the national societies have already included the newest ASMBS/IFSO recommendations in their local guidelines only a few months after their publication, reflecting the important work being done by IFSO to disseminate them. The process of adopting new guidelines may be different across countries, involving other medical societies and institutions, involved in the treatment of obesity or in the regulation of medical practices. On the other hand, the fact that a considerable percentage of countries have already adopted the so recently published guidelines, should serve as important reference for changing practices in countries where the

process is slower and more bureaucratic. The comprehension of these different processes will be useful to understand the differences in practices and help finding solutions for adopting the new guidelines easier.

Bariatric and metabolic surgery today is safer, but the correct performance of the surgical procedure requires sophisticated material and a complex structure. Despite the fact that the latest clinical guidelines extend the surgical indication to a greater number of people in need, lack of financial resources can be a barrier to its access for many patients. The implementation of some type of economic coverage by the public health system or by the health insurance companies of each country must be as important as the broadening of the surgical recommendations.

However, although obesity is widely recognized as a disease [26-28] and surgical treatment has proven to be the best alternative for its control in most of the cases [2-5], the economic cost of MBS is fully or partially covered in just 65.0% of the countries that are part of the federation. Moreover, only 15.4% of them finance the BMI recommended by the latest ASMBS/IFSO guidelines while the remaining 84.6% finance a BMI that is still above. Finally, there is a significant number of countries (35.0%), especially in Latin America and the Middle East, where surgical treatment is still not covered at all by their national health systems. Extending MBS coverage to a larger number of patients may not be possible to implement in many countries due to the economic impact this would entail, especially in those with fewer economic resources. In fact, the lack of public health infrastructure in many countries. Instead of being a specific problem regarding obesity treatment, it becomes a social and economic issue for the country.

There are also other variables that could influence economic coverage though, such as the patient's age. In contrast with the new ASMBS/IFSO recommendations, age seems to be a limiting factor when considering surgery in many countries. In Korea or the Netherlands for example, MBS coverage is limited to age 18 or older or when

bone growth is completed [29]. Similarly, Inge et al collected administrative and clinical data from five clinical centers dedicated to the bariatric treatment of adolescents in the U.S. and found that those who wish to undergo weight loss surgery often encounter obstacles in obtaining treatment authorization from insurers. They demonstrate that less than half of pediatric cases approval was granted upon initial request for coverage while in contrast, payers initially approved 80% to 85% of adults who met similar criteria. The age under 18 years was the most frequent reason for denial of financial coverage [30].

In 2018 all IFSO Societies were also asked to fill in an IFSO survey form asking about the existence of national guidelines, and type of reimbursement for bariatric/metabolic surgery [22]. Throughout the 5 years that separate both publications more national societies have joined IFSO and some more have already published their own guidelines. At that time MBS was reimbursed in 35 countries, today it is 39 the number of countries where the cost of MBS is covered by their public service. Table 3 compiles the data from both studies.

The present study has some strengths and several limitations. The data were obtained through an international survey and, although the authors have attempted to validate all the responses, we cannot be sure that all the data are completely accurate. However, this would be compensated for by the high response rate (88%) which makes the results more robust. Besides there could be some internal variation per country on access and coverage, for example in the United States there is coverage by government policies and also by commercial private insurance companies, but not every patient has full access to the MBS coverage.

Finally, data was collected between December 2022 and July 2023 and offers a snapshot of the moment. Being MBS in constant evolution it is probable that some more countries have already updated their guidelines. However, it is less likely that the coverage policy of the analyzed countries has changed in such a short period of time. In any case, it could be interesting, and it is the intention of the authors, to

compare the present survey with future ones and investigate how IFSO guidelines are influencing national societies' activity and policymakers' decisions.

CONCLUSIONS

The present survey shows that most of the IFSO member societies have MBS guidelines. While more than a third of them have already shifted to the most updated ASMBS/IFSO 2022 ones, another significant number of countries are still following the NIH 1991 guidelines or even do not have any at all. Moreover, there is a significant number of countries (35%), especially but not only in Latin America and the Middle East, where surgical treatment is still not covered by their national health system.

Knowing how MBS is indicated and financed in the different countries is an essential step for IFSO to propose future strategies to standardize indications worldwide and to influence insurers and legislators on health policy with the aim of achieving greater economic coverage to a greater number of people in need.

COMPLIANCE WITH ETHICAL STANDARDS:

Conflict of Interest: The authors declare that they have no conflicts of interest.

Ethical Approval: This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent Statement: Informed Consent does not apply.

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Fig 1: Questionnaire

1.) Country:

open answer

2.) Name of the Society:

open answer

3.) Does your national society (Bariatric surgery society) have any Recommendations/Guidelines about indications/candidates for Bariatric and Metabolic Surgery?

- a) YES
- b) NO

4.) If you have answered “YES” in question number 1; Which are your national guidelines today?

- a) NIH 1991
- b) ASMBS-IFSO 2022
- c) OTHERS

5.) If you have answered “OTHERS” in the previous question, could you please specify which are them according to the patients’ BMI?

open answer

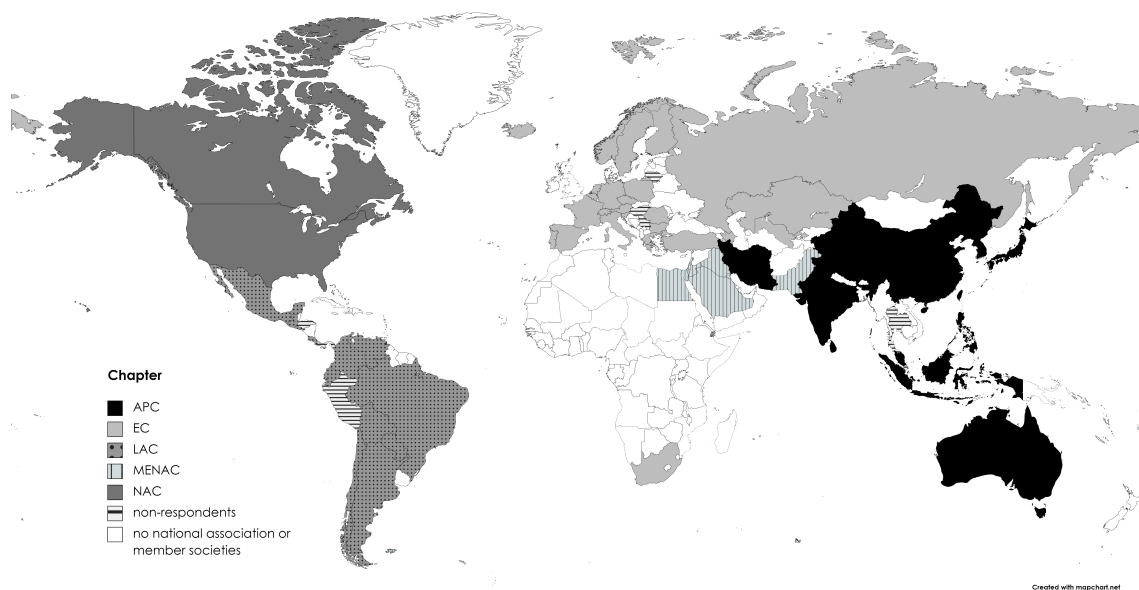
6.) Does your national/public health system financially cover MBS?

- a) YES
- b) NO

7.) If you have answered “YES” in the previous question; What is the lower limit of BMI where the national/public health system in your country financially covers MBS? (just a number please)

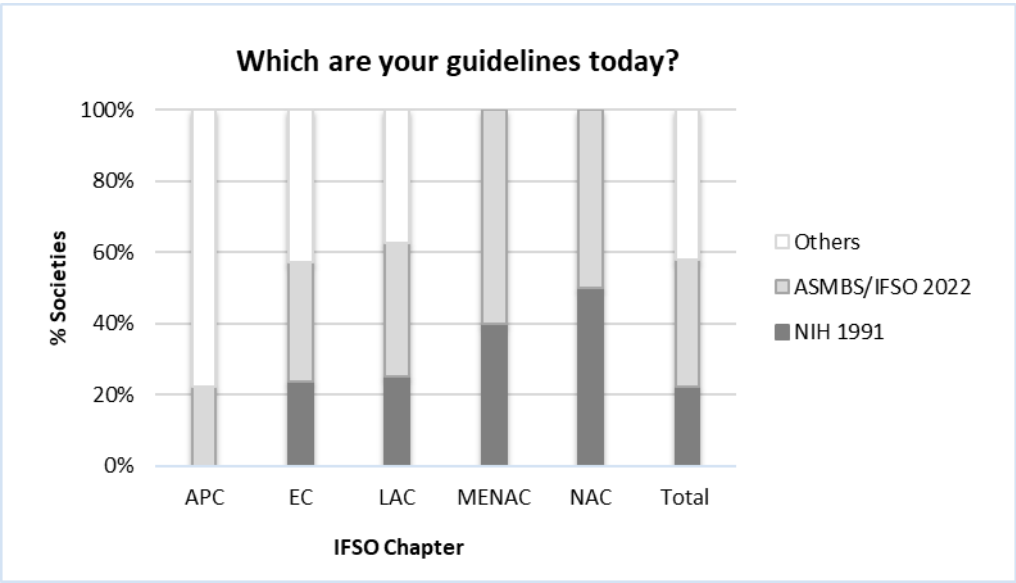
open answer (numeric)

Figure 2: Distribution of responding IFSO societies around the world by chapters.



Abbreviations: APC = Asian Pacific Chapter; EC = European Chapter; LAC = Latin American Chapter; MENAC = Middle East and North African Chapter; NAC = North American Chapter.

Figure 3: Reported frequency of recommended Guidelines by IFSO chapters.



Abbreviations: APC = Asian Pacific Chapter; MENAC = Middle East – North African Chapter; EC = European Chapter; LAC = Latin American Chapter; NAC = North American Chapter.

Table 1. Countries' criteria selection for MBS depending on the guidelines followed.

Guidelines	Country	BMI (kg/m ²)	BMI + comorbidities (kg/m ²)	BMI + T2DM (kg/m ²)
NIH 1991	Austria Canada Colombia Dominican Republic Finland Iraq Israel Russia Saudi Arabia United Kingdom	≥ 40	≥ 35	
ASMBS/IFSO 2022	Argentina Australia Azerbaijan Bulgaria Jordan Kuwait Lebanon Mexico Philippines Poland Romania South Africa Spain United States Uruguay Uzbekistan	≥ 35, Asian population ≥ 27.5	30-34.9	
Others	Chile France (a) Germany (a) Italy (a) Kazakhstan (b) Norway (c) Turkey Venezuela	≥ 40	≥ 35	≥ 30
	China (d)	≥ 37.5	37.5 - 32,5	≥ 32.5
	Hong Kong India Korea (f)	≥ 35 (e)	≥ 30	≥ 27.5
	Japan	-	≥ 35	≥ 32.5 & other comorbidities
	Malaysia	≥ 37	≥ 32	
	Switzerland	≥ 35	-	≥ 30

(a) ≥ 40 BMI: EASO, ADA, IFSO-EC 2013, EAES 2020.

- (b) ≥ 30 BMI with T2D or + reproductive disfunction.
- (c) ≥ 30 BMI For public hospitals the NIH 1991 guidelines with modification in 2014.
- (d) BMI decreased with increased waist circumference.
- (e) IFSO-APC 2011 guidelines.
- (f) Limited to age > 18 years or older, or when bone growth is completed.

MBS = Metabolic and bariatric surgery; BMI = Body mass index; EASO = European Association for the Study of Obesity; ADA = American Diabetes Association; IFSO-EC = International Federation for the Surgery of Obesity and Metabolic Disorders European Chapter; EAES = European Association for Endoscopic Surgery; T2D = Type-two diabetes; NIH = National Institute of Health; IFSO-APC = International Federation for the Surgery of Obesity and Metabolic Disorders Asian-Pacific Chapter.

Table 2. Financial coverage of the MBS and minimum BMI above which surgery is covered by each country public system.

National health system covering MBS	Country	Starting covered BMI (kg/m ²)
APC Chapter		
YES	Australia	35
	Hong Kong	30
	Indonesia	30
	Iran	40
	Korea	30
	Malaysia	32
	Philippines	30
	Sri Lanka	40
	Taiwan	35
NO	China	-
	India	-
EC Chapter		
YES	Austria	35
	Azerbaijan	35
	Belgium	35
	Czech Republic	35
	Finland	30
	France	30
	Germany	35
	Greece	35
	Iceland	35
	Israel	35
	Italy	30
	Netherlands	35
	Norway	30
	Poland	35
	Portugal	35
	Slovenia	30
	Spain	30
	Sweden	35
	Switzerland	35

	Turkey	35
	United Kingdom	35
NO	Bulgaria	-
	Kazakhstan	-
	Romania	-
	Russia	-
	South Africa	-
	Ukraine	-
	Uzbekistan	-
LAC Chapter		
YES	Argentina	35
	Brazil	35
	Colombia	35
	Costa Rica	35
	Mexico	35
NO	Bolivia	-
	Dominican Republic	-
	Ecuador	-
	El Salvador	-
	Guatemala	-
	Paraguay	-
	Uruguay	-
	Venezuela	-
MENAC Chapter		
YES	Kuwait	35
	Saudi arabia	35
NO	Egypt	-
	Iraq	-
	Jordan	-
	Lebanon	-
NAC Chapter		
YES	Canada	35
	United States	35

Table 3: Situation of MBS worldwide: Data extracted from the two surveys launched by IFSO in 2018 and 2023.

	Angrisani study (2018) (22)	Present study (2023)
Number of nations surveyed	65	72
Number of nations responded	57	63
% of responses	87.7	87.5
Number of countries with national guidelines	45	47
Number of countries where MBS has public reimbursement (Total or partial)	35	39
EC countries with national guidelines.	20/26 (77%)	21/28 (75%)
EC countries where MBS has public reimbursement (Total or partial)	20/26 (77%)	21/28 (75%)
LAC countries with national guidelines ¹ .	9/12 (75%)	8/14 (57.1%)
LAC countries where MBS has public reimbursement (Total or partial) ¹	6/13 (46.1%)	5/13 (38.4%)
NAC countries with national guidelines.	2/2 (100%)	2/2 (100%)
NAC countries where MBS has public reimbursement (Total or partial) ²	1/1 (100%)	2/2 (100%) ³
APC countries with national guidelines.	9/10 (90%)	10/12 (83.3%)
APC where MBS has public reimbursement (Total or partial)	6/10 (60%)	9/11 (81.8%)
MENAC countries with national guidelines.	5/6 (83.3%)	6/7 (85.7%)
MENAC countries where MBS has public reimbursement (Total or partial) ¹	4/6 (66.6)	2/6 (33.3%)

¹ Small difference can be explained in part by the fact that there are countries with very limited coverage and by the difference in non-responding/responding countries among both studies.

² USA did not respond.

³ Limited coverage.

MBS = Bariatric and Metabolic surgery, EC = European Chapter, LAC = Latin American Chapter, NAC = North American Chapter, APC = Asian Pacific Chapter, MENAC = Middle East and North African Chapter.