Development of ASMBS Research Agenda for Bariatric Surgery Using the Delphi Methodology

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Abstract

Background: While the number of research publications related to bariatric surgery have

increased remarkably in the past decade, research efforts remain uncoordinated, have limited

focus, and numerous important questions remain unanswered.

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Objective: To generate a research agenda in bariatric surgery.

Setting: National survey

Methods: The membership of the American Society of Metabolic and Bariatric Surgery (ASMBS)

was asked to submit research questions needed to advance the field of bariatric surgery. An

expert panel grouped and collated submitted questions and redistributed them back to the

membership to rate their importance on a 5 point Likert scale using a 3 round modified Delphi

methodology. The top research questions were determined based on provided rankings.

Results: 292 research questions were initially submitted that were collapsed to 59 unique

questions. The ratings for the top 40 questions ranged from 2.67 – 4.33 (overall mean 3.46).

The highest-ranked questions centered on the mechanisms of effectiveness of bariatric surgery

for weight loss and diabetes resolution, the underlying etiology of weight recidivism and

predictors of success.

Conclusions: A research agenda for bariatric surgery was developed using the Delphi

methodology. This research agenda may enhance the ability of investigators and funding

organizations, including the ASMBS, to focus attention to areas most likely to advance the

field, and by editors and reviewers to assess the merit and relevance of scientific contributions.

Keywords: Delphi process; bariatric surgery; research agenda; research priorities

Introduction

40 Bariatric surgery has seen tremendous growth over the past 2 decades due to the multiple benefits for patients with morbid obesity. (1-4) The number of bariatric procedures performed annually in the United States increased from 13,365 in 1998 (5) to 228,000 in 2017. (6) During the same timeframe research in bariatric surgery also increased remarkably and proportionally; a Pubmed search using the terms "bariatric surgery" revealed 264 related articles published in 1998 versus 2813 published in 2017. Despite this dramatic increase in research activity related 45 to bariatric surgery, however, most research efforts remain uncoordinated and with limited focus. Improved coordination and focus of research efforts could further advance the field of bariatric surgery. Importantly, while bariatric surgery has proved to be extremely effective for the treatment of morbid obesity and comorbidity resolution, (1-4) our understanding of the mechanisms behind the effectiveness of these procedures continue to evolve. (7-8) Some authors 50 have even argued that bariatric research priorities are misplaced and promote unwarranted innovation instead of a better understanding of mechanisms of action. (9) A consensus-based research agenda could advance the field by guiding investigator efforts, as well as funding agency decisions, with regards to allocation of resources to the highest impact areas, to help 55 answer the most pressing research questions. Indeed, several investigators and organizations have created and introduced research agendas to guide their field, including a publication by the National Institute of Health to guide obesity research efforts. (10) Unfortunately, no such agenda exists currently for bariatric surgery. The aim of this study, therefore, was to generate a research agenda in bariatric surgery to guide investigators and funding agencies through a

systematic survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS).

Methods

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After institutional review board approval from Indiana University, a modified Delphi methodology was employed in 2016 and 2017 to create the ASMBS research agenda. In brief, the Delphi methodology⁽¹¹⁾ systematically collects, evaluates, and analyzes expert opinion on a specific topic without requiring an in-person meeting. It consists of a formal anonymous group process in which participants answer questions in rounds. Participants achieve consensus by revising their opinions after review of replies provided by the rest of the group. Originally developed by the RAND Corporation to assess long-term trends in science and technology and their anticipated effects on society,⁽¹¹⁾ this methodology has also been applied extensively in the medical field to establish research agendas, facilitate directions in technological innovation, or determine appropriate treatments.^(12–17) Key features of the Delphi process include anonymity, iteration (ie, multiple stages), controlled provision of feedback, and aggregation of responses. A major advantage of this approach is that it weighs the opinion of every participant equally without allowing overly influential individual's opinions to dominate, which is typical of in-person consensus methodologies.⁽¹¹⁻¹⁴⁾

In this study we initially surveyed (round 1) all ASMBS members to formulate and submit up to 5 research questions most urgently needed to advance the field of bariatric surgery. To ensure quality, participants were instructed to use the PICO methodology when constructing their

research questions. That is, questions were to be based on four areas of knowledge or action:

Patient or problem; Intervention, cause or prognosis; Comparison or control; and Outcome. (18)

ASMBS members received an email encouraging them to participate in the survey, which was web-based and anonymous. Submitted member questions were then analyzed, collated, and collapsed by an expert review panel comprised of six members of the ASMBS research committee, to eliminate duplicate submissions and ensure question clarity for the second Delphi round. Expert review panel members had expertise in bariatric surgery, basic science, epidemiology and the Delphi methodology.

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- The panel first grouped the submitted questions into categories using consensus. Each category was then assigned to a panel member who collated, combined and clarified the questions as necessary. The revised questions were reviewed by all panel members, and edited as necessary before inclusion in the next survey; this process ensured the accuracy and quality of generated questions.
- To minimize survey burden to the ASMBS membership, the devised questions were distributed in round 2 only to the membership of the ASMBS research committee (n=30). Committee members were asked to rate the importance of each research question using a 5-point Likert scale from 1 (not important) to 5 (extremely important).
 - The expert panel calculated average ratings submitted during round 2 and used them to rank all questions in priority order. The top-40 research questions, along with their mean priority rating from round 2, were then sent back to the ASMBS membership for review and rating (round 3).

 Responders were asked to rate the questions using the same 5-point Likert scale employed during round 2 [1 (not important) to 5 (extremely important)]. The expert panel again

calculated average ratings and standard deviations submitted during this final round and used them to determine the final rank of the 40 questions in order of priority to create the ASMBS research agenda.

The relationship of round 2 and round 3 rankings was assessed using Spearman's correlation to establish rating agreement between rounds.

110 Results

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Participation in each round of the study is shown in the outline of **figure 1**. Responder characteristics, by study round, are shown in **table 1**. There were no significant differences in participant characteristics between Rounds 1 and 3 that involved the ASMBS general membership. Round 2 participants had more research experience and publications than participants of the other rounds as expected.

A total of 292 research questions were submitted by 95 ASMBS members during the first study round (response rate 3%). The thematic breakdown of these questions is shown in **table 2**; the most common themes were "predictors of success/failure," "comparative effectiveness/outcomes," "underlying mechanisms," and "preop/postop care."

The expert panel distilled and collapsed submitted questions to 59 unique questions which were then rated by 19 out of 38 ASMBS research committee members (response rate 50%). The mean rating of questions from round 2 ranged from 2.00 - 4.17 (overall mean, 2.97) on the 5-point Likert scale of importance. The top 40 highest rated questions (all with rating >2.67) from round 2 were then rated by 239 ASMBS general members in round 3 (response rate 6%). The mean rating of questions from round 3 ranged from 2.67 – 4.33 (overall mean 3.46). The final

rankings of the top 40 questions are presenting in **table 3**. The highest-ranked questions centered on the mechanisms of effectiveness of bariatric surgery for weight loss and diabetes resolution, the underlying etiology of weight recidivism and predictors of success. Ratings of the top 40 questions were highly correlated (r=0.96; p<0.001) between Rounds 2 and 3 indicating high concordance between research committee member ratings and general ASMBS member ratings.

Discussion

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- In this study, we surveyed the ASMBS membership using a systematic methodology to identify and rank the most important research questions in bariatric surgery. The top research priorities identified in this study highlight the numerous gaps that exist in our knowledge around bariatric surgery including basic questions around the mechanism of bariatric surgery's effectiveness, as highlighted by other authors as well. (9-10) The top question "In morbidly obese patients undergoing bariatric surgery, what are the mechanisms of weight recidivism after surgery; which baseline patient characteristics/ risk factors can predict this recidivism?" highlights one of the biggest challenges of bariatric surgeons today. The mechanism of disease has also been highlighted in the research priorities defined for obesity by the NIH in 2011. (10)
- A similar methodology for the development of research agendas has been used in other fields.

 The Society of American Gastrointestinal and Endoscopic Surgeons, through its research committee, used the same methodology to create a research agenda for minimally invasive

Surgery.⁽¹²⁾ This agenda is currently being used by its grant-reviewing committee to assess the importance and priority of grants submitted to the organization for funding. Similarly the Association for Surgical Education has defined research priorities to guide multi-institutional education research in an effort to improve the quality of research in the field.⁽¹³⁾ Furthermore, identifying research agendas has led to important changes in clinical practice,⁽¹⁶⁾ as well as the development of new clinical guidelines⁽¹⁷⁾ and funding schemes.⁽¹⁹⁾

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The definition of priority research questions can be very valuable for researchers, industry, funding agencies, and the surgical community in general. Obesity researchers may be able to focus their efforts on answering the most important questions first and to pursue collaborations and funding in common and relevant research areas. In addition, editors and peer-reviewers may benefit by better judging the importance and impact of original research reports. Industry and funding organizations may benefit by identifying the most pertinent, relevant, and innovative proposals that are the most likely to advance the field. Finally, and perhaps most importantly, bariatric surgery patients may benefit by having some fundamental questions in the field related to improved patient care answered. Additionally, patients will likely benefit by faster achievement of specific goals and objectives through the concentrated efforts of researchers and funding sources.

There are several limitations of this study that should be noted. First, our response rates during rounds 1 and 3 were low (3-6% of the membership). Electronic surveys to a large participant pool, however, are known to have low response rates in the literature. (12-14) Further, the response rate of the ASMBS research committee members was much higher (50%) which allowed us to obtain adequate feedback on the survey. Second, data were gathered from a

170 diverse group of self-selected experts in bariatric surgery and research. The demographic information provided by survey participants indicated, however, that 30-36% had no prior research publications. On the other hand, our diverse participants were highly experienced clinically with more than half of responders having >10 years in practice and over 70% of the surgeon responders having performed over 500 bariatric procedures, suggesting that the 175 research priorities we determined originate from individuals with good knowledge of the field and extensive experience with patient care. In addition, by targeting members of the ASMBS research committee with our round 2 survey we ensured that we obtained feedback from experienced obesity researchers. Our analysis demonstrated that ratings of round 2 and round 3 were highly concordant suggesting that both more experienced researchers and experienced 180 clinicians identified similar research priorities. Further, while our research agenda is not specific to basic science or any other research domain, several of the identified questions lend themselves to basic science research (examples include questions 1, 2, 10, 12, 15, 20, 29, 32). It is also worth noting that the definition of research priorities is not a one-off process but rather a dynamic process dependent on a variety of factors including the timing of its conduct and should therefore be repeated at regular intervals. 185

In conclusion, a research agenda for bariatric surgery was developed using the Delphi methodology. This research agenda may enhance the ability of investigators and funding organizations, including the ASMBS, to focus attention to areas most likely to advance the field, and by editors and reviewers to assess the merit and relevance of scientific contributions.

Disclosures

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250 Legends

Figure 1. Study Outline

Table 1. Study participant characteristics

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- Table 2. Breakdown of submitted questions in round 1 by thematic category
- **Table 3**. Top 40 research questions by Round 3 ratings (highest to lowest)

Table 1. Study participant characteristics

| Participant characteristics | Round 1 | Round 2 | Round 3 |
|--|------------|------------|-------------|
| Total number of responders | N=95 | N=19 | N=239 |
| Professional group | | A | |
| Bariatric surgeon | 57 (60%) | 15 (78.9%) | 163 (68%) |
| Dietician | 11 (11.6%) | 1 (5.2%) | 24 (10%) |
| Bariatrician | 9 (9.5%) | 1 (5.2%) | 22 (9.2%) |
| Bariatric nurse | 12 (12.6%) | 1 (5.2%) | 25 (10.4%) |
| Other | 6 (6.3%) | 1 (5.2%) | 5 (2%) |
| Researchers | 17 (17.9%) | 19 (100%) | 50 (21%) |
| Clinicians | 86 (90.5%) | 18 (94.7%) | 208 (87%) |
| ASMBS leadership | 25 (26.3%) | 19 (100%) | 55 (23%) |
| General ASMBS members | 70 (73.7%) | NA | 184 (77%) |
| Years in practice | | | |
| 1-3 | 6 (6.3%) | 1 (5.2%) | 14 (5.8%) |
| 3-5 | 8 (8.4%) | 3 (15.8%) | 38 (15.8%) |
| 5-10 | 26 (27.4%) | 5 (26.3%) | 75 (31.3%) |
| >10 | 55 (57.8%) | 10 (52.6%) | 112 (46.8%) |
| Number of bariatric procedures performed | N=57 | N=15 | N=163 |
| among surgeon responders | | | |

| <100 | 1 (1.7%) | | 3 (1.8%) |
|---------------------------------|------------|------------|------------|
| 101-300 | 4 (7%) | 2 (13.3%) | 16 (9.8%) |
| 301-500 | 5 (8.8%) | 3 (22%) | 24 (14.7%) |
| 501-1000 | 15 (26.3%) | 5 (33.3%) | 52 (31.9%) |
| >1001 | 32 (56.1%) | 5 (33.3%) | 68 (41.7%) |
| Number of research publications | | | |
| 0 | 34 (35.8%) | | 71 (29.7%) |
| 1-5 | 27 (28.4%) | 1 (5.2%) | 64 (26.7%) |
| 6-10 | 13 (13.7%) | 3 (15.8%) | 36 (15%) |
| 11-20 | 8 (8.4%) | 3 (15.8%) | 31 (12.9%) |
| >20 | 13 (13.7%) | 12 (63.2%) | 37 (15.4%) |

Table 2. Breakdown of submitted questions in round 1 by thematic category

| Thematic Category | Number (%) of |
|-------------------------------------|---------------|
| | Questions |
| Predictors of success/ failure | 34 (11.6%) |
| Comparative effectiveness/ outcomes | 30 (10.3%) |
| Underlying mechanism | 30 (10.3%) |
| Perioperative care | 30 (10.3%) |
| Patient subpopulations/ behavior | 23 (7.9%) |
| Revisional surgery | 22 (7.5%) |
| Medications | 22 (7.5%) |
| Nutrition/ vitamins | 21 (7.2%) |
| Surgical technique | 19 (6.5%) |
| Complications | 19 (6.5%) |
| Procedure choice | 13 (4.5%) |
| Other | 29 (9.9%) |
| Total | 292 (100%) |

 Table 3. Top 40 research questions by Round 3 ratings (highest to lowest)

| Rank | Question | Round 3 Rating |
|------|---|----------------|
| | In morbidly obese patients undergoing bariatric surgery, what are the | <u> </u> |
| 1 | mechanisms of weight recidivism after surgery; which baseline patient | 4.33 ± 0.7 |
| | characteristics/ risk factors can predict this recidivism? (4.00) | |
| 2 | What are the mechanisms that lead to weight loss and improvement or | 4 20 ± 0.8 |
| 2 | resolution of DM and other comorbidities after bariatric surgery? (4.17) | 4.30 ± 0.8 |
| 3 | What is the best treatment algorithm for patients who have regained | 4.07 ± 0.8 |
| | weight after bariatric surgery? (3.29) | 4.07 ± 0.0 |
| 4 | What are the best methods to educate primary care physicians about the | 3.92 ± 1.0 |
| | benefits/ risks of bariatric surgery? (3.47) | 3.92 ± 1.0 |
| | What baseline patient characteristics affect postoperative outcomes and | |
| | should guide the choice of a bariatric operation (sleeve gastrectomy, | 2 00 1 0 0 |
| 5 | gastric bypass, gastric band, or duodenal switch) or exclude patients | 3.89 ± 0.9 |
| | from all or specific bariatric operations? (3.11) | |
| 6 | What is the most effective and safe approach to resolving leaks after | 3.84 ± 1.1 |
| | sleeve gastrectomy? (3.87) | J.04 ± 1.1 |
| 7 | How do the currently available weight loss options compare in regards to | 3.82 ± 0.9 |
| | weight loss effectiveness, complications, comorbidity resolution, quality | 3.02 ± 0.9 |

| | of life, patient satisfaction, and cost effectiveness, in short and long | |
|----|---|----------------|
| | term? (3.79) | |
| | Do patients with BMI<35 benefit from bariatric surgery and if so should | |
| 8 | the current bariatric surgery eligibility criteria be adjusted to include | 3.80 ± 1.0 |
| | patients in whom the benefits outweigh the risks? (3.33) | > |
| | Which type of revisional bariatric procedure is best for which primary | |
| 9 | bariatric procedure in regards to perioperative risk, patient outcomes | 3.78 ± 1.1 |
| | and cost effectiveness? (3.44) | |
| 10 | What effect does sleeve gastrectomy have on reflux after surgery and | 3.71 ± 0.9 |
| 10 | what are the proposed mechanisms of this effect? (3.35) | 3.71 ± 0.9 |
| | What patient factors predict postoperative compliance with follow-up, | |
| 11 | diet and supplement intake and how can this compliance be improved? | 3.69 ± 1.1 |
| | (3.11) | |
| 12 | What hormonal and epigenetic changes occur after bariatric surgery? | 3.65 ± 1.0 |
| 12 | (3.89) | 3.03 ± 1.0 |
| | What are the expected long-term vitamin and mineral deficiencies after | |
| 13 | each type of bariatric surgery and what is the optimal supplementation | 3.64 ± 0.9 |
| | schedule with the highest patient compliance? (3.17) | |
| 14 | How should reflux be evaluated preop to guide optimal bariatric | 3.59 ± 0.8 |
| | procedure selection? (3.44) | |
| 15 | How does bariatric surgery affect the individual's microbiome and does | 3.57 ± 0.9 |
| | • | |

| | this impact weight-loss outcome after surgery? (4.00) | |
|----|--|------------|
| 16 | Which diet after bariatric surgery yields the best weight loss and preservation of lean body mass? (2.78) | 3.56 ± 1.0 |
| 17 | What are the most effective options for the treatment of GERD after bariatric surgery (endoluminal vs. pharmacologic)? (3.47) | 3.48 ± 1.1 |
| 18 | For patients undergoing bariatric surgery, which thromboembolism prophylaxis method and schedule (mechanical vs. chemical vs. combo; dose; duration) minimize perioperative bleeding complications, VTEs, and 30 day mortality? (3.11) | 3.48 ± 1.2 |
| 19 | Does the combination of bariatric surgery with weight loss medications yield better weight loss and comorbidity outcomes in the long term compared with bariatric surgery alone? (3.12) | 3.47 ± 1.0 |
| 20 | How does each bariatric procedure affect the absorption of medications and supplements and what dose adjustments are necessary to optimize patient outcomes? (2.94) | 3.46 ± 0.9 |
| 21 | Does behavioral modification therapy have any effect on outcomes before or after primary or revisional bariatric surgery? (2.67) | 3.42 ± 0.9 |
| 22 | What patient and/or surgical technique factors predict marginal ulcer formation after gastric bypass and how can marginal ulcers be prevented? (3.00) | 3.40 ± 1.1 |
| 23 | What is the ideal limb length after gastric bypass and duodenal switch to | 3.39 ± 1.0 |

| | maximize weight loss and minimize nutritional complications? (3.07) | |
|-----|---|----------------|
| 24 | What patient factors determine cross addictions (i.e. alcohol, drugs) after | 3.39 ± 1.1 |
| 2-1 | bariatric surgery and can counseling prevent them?(3.00) | 5.55 ± 1.1 |
| | In morbidly obese patients being considered for bariatric surgery, how | |
| 25 | should psychopathology be evaluated and addressed to optimize | 3.38 ± 0.9 |
| | postoperative outcomes? (2.82) | |
| 26 | What is the incidence of reactive hypoglycemia after bariatric surgery | 2 20 ± 1 1 |
| 26 | and how is it optimally managed? (3.00) | 3.30 ± 1.1 |
| | Do gastric pouch size and gastrojejunal anastomosis size correlate with | |
| 27 | weight loss after gastric bypass surgery and what sizes lead to optimal | 3.27 ± 0.9 |
| | long term weight loss and minimize complications? (3.06) | |
| 28 | What is the effectiveness and safety profile for bariatric surgery in | 3.26 ± 1.0 |
| 28 | specific sub-populations (e.g.: pediatrics, diabetics, elderly, etc.)? (2.78) | 3.20 ± 1.0 |
| 29 | What is the pathophysiology, risk and prevention of portal vein | 3.22 ± 1.0 |
| 23 | thrombosis after bariatric surgery? (3.2) | 3.22 ± 1.0 |
| 30 | How do patient outcomes compare between accredited centers in | 3.16 ± 1.1 |
| 30 | bariatric surgery and non-accredited programs? (2.8) | 3.10 ± 1.1 |
| 31 | Does mandatory preoperative physician supervised weight loss improve | 3.16 ±0.9 |
| 21 | postoperative weight loss outcomes after bariatric surgery? (3) | 3.10 ±0.3 |
| 32 | What is the incidence of idiopathic chronic abdominal pain after bariatric | 2 1E ± 1 1 |
| 32 | surgery and what are possible explanations or treatments for this? (3.13) | 3.15 ± 1.1 |

| 33 | What are the differences in outcomes for the super morbid obese | 3.14 ± 1.0 |
|----|---|------------|
| | patient between a one-stage or two-stage operation? (2.87) | |
| | What is the ideal bougie size and distance from pylorus to maximize | _ |
| 34 | weight loss and minimize postoperative complications after sleeve | 3.09 ± 1.1 |
| | gastrectomy? (2.87) | |
| | Which is the most effective and cost efficient patient evaluation | |
| 35 | structure (type and number of assessments/educational sessions) prior | 3.08 ± 1.2 |
| | to and after bariatric surgery for optimal outcomes? (2.89) | |
| 36 | Is outpatient surgery as safe as inpatient stay after bariatric surgery and | 3.05 ± 1.1 |
| | for which patients/procedures is this acceptable? (2.93) | |
| 37 | Does probiotic use after bariatric surgery improve weight loss and if so | 3.04 ± 0.9 |
| | what is its optimal timing/ duration? (3.13) | |
| 38 | What factors influence patient choices for bariatric surgery? (2.67) | 2.90 ± 0.8 |
| 39 | Which are the best patient reported outcomes to monitor and study | 2.85± 0.9 |
| 39 | after bariatric surgery? | 2.83± 0.9 |
| 40 | Does telementoring decrease complication rate and/or shorten learning | 2.69 ± 0.7 |
| .5 | curve for new bariatric surgeons? (2.73) | |

Ratings provided as mean \pm standard deviation

Numbers in parenthesis at the end of each question represent mean Round 2 ratings



The expert panel consolidated these questions into 59 newly formulated unique research questions

Round 2: 19 members of the ASMBS research committee rated the importance of these 59 questions. The expert panel chose the top 40 for the final round

Round 3: 239 ASMBS members rated the importance of the top 40 questions. Data analysis revealed the top 10

- A research agenda for bariatric surgery was generated using a modified Delphi technique
- The membership of the American Society of Metabolic and Bariatric Surgery (ASMBS)
 was surveyed to determine the top 40 research priorities in bariatric surgery
- The highest-ranked questions centered on the mechanisms of effectiveness of bariatric surgery for weight loss and diabetes resolution, the underlying etiology of weight recidivism and predictors of success after bariatric surgery