The art and science of bariatric surgery has progressed rapidly in recent years. From a variety of operations, we have now developed a number of surgical approaches that, by the agreement of experts in the field, achieve significant durable weight loss and remission of co-morbidities, with minimal mortality or complications. The use of laparoscopy has shortened the length of stay and greatly eased the recovery phase for the patient. We also know to a greater degree what complications can occur and what early signs herald their onset.

A significant problem remains. No strategy has been clearly defined for the development of new approaches to the surgical procedures or care paths. In gastric bypass surgery, for example, the ideal size of the gastric pouch, the length of the limbs, and the routing of the gut were not developed in clinical trials but were usually the result of an idea on the part of an individual surgeon or small group.
Often, versions of a procedure were tried on a small group of patients, and then abandoned when a different idea appeared in published reports or at a national conference.

The result of this undisciplined development was twofold. First, the success rates of the surgery performed by various surgeons were vastly different as one procedure was abandoned and another adopted. Many centers achieved durable weight loss and reversal of co-morbidities with low complication rates. Others had high mortality and morbidity rates, in some cases exceeding acceptable standards. This resulted in numerous lawsuits and a rise in malpractice premiums. Public perception began to grow that bariatric surgery was an unsafe weight loss option, and health plans began to deny coverage.

The second resulting phenomenon was the lack of data. The performance of multiple techniques, even for a single, accepted operation, meant that no aggregate data collection was possible. Data could be collected from an individual hospital or group of surgeons, but, because of the variance in technique, it was not possible to compare these data with those from another group or institution.

In contrast to surgeons, internists are able to apply therapies with greater confidence as a result of standardization. The introduction of new medications or medical devices must follow strict protocols through a phased and controlled trial process. As a result, patients diagnosed with pneumonia, for example, are protected by a defined choice of antibiotics and the added assurance of a precise formulation and optimal dosages.

To deal with this problem, some insurance carriers have developed their own “centers of excellence” programs. The idea was to recognize centers of bariatric surgery that had excellent outcomes and to establish a network of safe bariatric care for their members. The insurance carrier would then pay for the care of its members only if that care was performed in a “center of excellence.”

This was not an approach unique to bariatric programs; the certification of centers for complex care has a long history. Cancer centers have been recognized by the federal government through the National Cancer Institute; trauma centers have been certified by each state; and transplant centers are named by the United Network for Organ Sharing.

Laudable as it was in intent, the practice of insurance carriers establishing centers of excellence for bariatric surgery had several drawbacks. The standards by which a center of excellence was recognized were often based on opinion, rather than evidence. Also, the standards differed among payors, and the result was that major centers had to meet a variety of requirements established by the multiple payors represented in their patient mix.

Furthermore, the payors did not share the outcome data of the institutions in their programs with one another, the centers themselves, or the surgical community. This did not lend itself to meaningful comparison or the development of validated standards.

Thus, it became apparent that in an effort to bring genuine quality control to bariatric surgery, a nationwide program was needed. Integral to this program would be a uniform set of guidelines and the creation of a large outcomes database from which research could be conducted and the results published. The process would need to be independent and not-for-profit to ensure fairness.

The American Society for Bariatric Surgery (ASBS) established such a program in November 2003. Surgical Review Corporation (SRC) was formed as an independent nonprofit entity with the charge of developing and administering a national ASBS Bariatric Surgery Centers of Excellence program.

Although the SRC is independent of the ASBS, representation of the ASBS on SRC’s Board of Directors is broad. In addition, the Board members include representatives from third-party payors, malpractice insurance companies, and consumers.

**Development of a uniform set of guidelines**

To develop a program recognizing centers for “excellence,” standards that would constitute the basis of such a designation first needed to be determined. The first step in this development was a meta-analysis of the English language published reports dealing with bariatric surgery. In a meta-analysis, all relevant scientific studies are gathered and form the units of data for an overall analysis.

The next step was the organization of a consensus conference. World leaders of bariatric surgery assembled at Georgetown University in 2005. These two activities, plus numerous meetings with bariatric surgeons throughout the United States, formed the basis for the development of the standards.

An initial set of standards was adopted. They were then circulated to all members of the ASBS for a 60-day period of comment. The responses were analyzed by SRC’s Board of Directors, changes were made, and a final set of standards was adopted.

**Becoming a Center of Excellence**

Becoming an ASBS Bariatric Surgery Center of Excellence is a two-step process. Programs are first granted Provisional Status when the surgeons and the hospitals document that they have the resources and experience required for the designation in place. Full Approval comes after a site inspection verifies the data in the provisional application and verifies that the outcomes are appropriately reported. The site inspection data are reviewed by the Bariatric Surgery Review Committee of SRC.

The requirements for Provisional Status and Full Approval and the process for application to become a Bariatric
Requirements for tertiary care facility Bariatric Surgery Centers of Excellence program

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<tr>
<th>Step</th>
<th>Requirement</th>
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### Provisional Approval Requirements

1. A. An institutional commitment at the highest levels of the applicant medical staff and the institution’s administration to excellence in the care of bariatric surgical patients as documented by an ongoing, regularly scheduled, in-service education program in bariatric surgery.

   B. An institutional commitment that is also demonstrated by using credentialing guidelines for bariatric surgery.

   This requirement refers to a culture in which the staff is prepared to treat morbidly obese patients, to treat these individuals with understanding and compassion, and to appreciate the burdens of the co-morbidities of the disease. The staff should be aware of the basic concepts of bariatric surgery through in-service programs. Those directly caring for these patients should be able to recognize the early signs of the common complications, including pulmonary embolus, anastomotic leak, infection, and bowel obstruction so that these can be managed promptly.

2. A. The reasonable expectation that the applicant institution will perform ≥125 bariatric surgical cases annually.

   B. The reasonable expectation that each applicant surgeon will have performed ≥125 total bariatric cases lifetime with ≥50 cases performed in the preceding 12-month period.

   “Bariatric surgical cases” are defined as primary operations and/or revisions. Endoscopies, placement of feeding jejunostomies, hernia repairs, and plastic surgical reconstructions are not included in this classification.

   “Performed” is defined as conducting a significant part of the operation as primary surgeon. Applicants may not include cases in which they served as the assisting surgeon.

   Applicants may include ≥75 operations performed during their fellowship in their total lifetime count.

3. The applicant maintains a designated physician medical director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution.

   The position of Bariatric Surgery Medical Director shall be filled by a qualified bariatric surgeon who is appointed through the administrative/medical staff process, with hospital minutes documenting his or her participation in the bariatric program decisions.

   Regularly scheduled meetings to address the bariatric program in the institution that involve medical staff, nursing, administration, central supply, operating room personnel, and the business office are required.

4. The applicant hospital maintains, within 30 minutes of request, a full complement on staff of the various consultative services required for the care of bariatric surgical patients, including the immediate availability of an Advanced Cardiac Life Support-qualified physician on site who can perform patient resuscitations.

   The facility must have a full-time staff with experience treating critically ill, morbidly obese patients with ventilators and invasive hemodynamic monitoring technologies that can support the management of a critically ill patient until the patient is sufficiently stable to leave the facility.

5. The applicant maintains a full line of equipment and instruments for the care of bariatric surgical patients, including furniture, wheelchairs, operating room tables, beds, radiologic capabilities, surgical instruments, and other facilities suitable for morbidly obese patients.

   Furniture, beds, scales, wheelchairs, operating room tables, and litters, strong enough and extra wide to accommodate the severely obese according to the weight limits established by the institution, must be available for those patients who need this specialized equipment.

   Patient movement/transfer systems for morbidly obese patients must be in place throughout the institution wherever the morbidly obese receive care. Ambulances serving the institution should also be equipped to handle these large patients with appropriate stretchers, straps, and transfer devices. Finally, and perhaps most important, the staff must be trained to use the equipment and be capable of moving these large individuals without injury either to the patients or the staff.

6. The applicant has a bariatric surgeon who spends a significant portion of his or her efforts in the field of bariatric surgery and who has qualified coverage and support for patient care.

   The surgeon must be or have been certified or be board eligible by the ABS, AOBS, and/or RCPSC. In addition, the surgeon must show evidence of bariatric surgical expertise in accordance with the guidelines of the ASBS.

   Qualified coverage is defined as the coverage required for the full care of a bariatric patient in the absence of the primary surgeon. The covering surgeon should be certified by the ABS, AOBS, and/or RCPSC, have significant experience in the care of bariatric surgical patients, and be capable of managing the full range of complications associated with surgery of the morbidly obese. For the on-call surgeons to demonstrate significant experience in treating bariatric patients and their complications, they must be board certified or currently board eligible, have ≥8 hours of continuing medical education in bariatric surgery and have assisted with at least five nonstapling gastric procedures and/or 10 gastric stapling and/or anastomotic procedures, depending on the covering arrangement. The covering surgeon must have completed these requirements by the time the applicant center reapplies for full approval status. However, a grace period exists under provisional status during which a center can be granted full approval without meeting the standard. Once full approval status is granted, the standard must be met before reapplying. This requirement only applies to general surgeons who cover bariatric cases and does not apply to coverage by bariatric surgeons.

7. The applicant uses clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure. In addition, all bariatric surgical procedures are standardized for each surgeon.

   It is the surgeon’s responsibility and duty to select which primary operations he or she will perform, and it is the expectation of SRC that the procedures, no matter what the choice, will be done in a standardized manner. Similarly, the surgeon should determine the details of the planned perioperative care. These details should be documented so that each member of the surgeon’s team is aware of the care plan and is prepared to follow the process as outlined by the surgeon. Unless such a process is followed, the outcomes cannot be evaluated.

   The clinical pathway protocols (i.e., a sequence of orders and therapies describing the routine care of the uncomplicated patient) must be available for review during the site inspection.

8. The applicant uses designated nurse or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients.
Surgery Center of Excellence are shown in Tables 1 and 2. A current version is also available for review on the SRC web site, www.surgicalreview.org [1].

Creation of an outcomes database

The second problem, that of creation of an outcomes database, was addressed by SRC through the development of the Bariatric Outcomes Longitudinal Database (BOLD™). BOLD™ is a web-based–data system compliant with the Health Insurance Portability and Accountability Act requirements. The BOLD™ software provides each user with a common format, co-morbidity scale, and data definition. The data are entered by those who care for the patient.

SRC anticipates accumulating >100,000 patient records each year in this database. The data will then be used to develop approaches for stratifying risks, as well as comparisons between operations, analysis of variations in these operations, and improvements to clinical pathways. From stratified risks, new criteria can be established for the Bariatric Surgery Centers of Excellence program.

BOLD™ will be available at two levels: BOLD™, CORE and BOLD™, Complete. BOLD™, CORE will be limited to the indicators of efficacy and safety required for quality control and continuous quality improvement. The BOLD™, Complete version will provide a full template for the evaluation and care of the bariatric surgical patient. The Clinical Research mode is a more detailed record that includes scales for the assessment of co-morbidities and other data sets for those centers that want to document the improvement of the diseases associated with obesity and that want to participate in the SRC Consortium for Bariatric Surgery Research, as described below.

BOLD™ will also have ability to probe adverse events, such as accidents and complications, in a nonjudgmental fashion. This is a similar approach to that used in the event of aircraft accidents. As these events occur, SRC will have the ability to investigate the causes in detail, make comparisons, and potentially prevent future deaths and complications.

Progress to date

Although it is too early to assess the long-term results, the process itself appears to be successful. Institutions throughout the United States are adopting the standards and seeking recognition for their high level of care. As of June 2006, 135 hospitals and 265 surgeons had achieved full approval as Bariatric Surgery Centers of Excellence. An additional 640 hospitals and 1090 surgeons were in the application process.
Table 2
Freestanding outpatient Bariatric Surgery Centers of Excellence program requirements

<table>
<thead>
<tr>
<th>Step</th>
<th>Requirement</th>
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<tr>
<td>1</td>
<td>The Applicant has an institutional commitment by the facility’s administration and medical staff to excellence in the care of outpatient bariatric surgical patients as documented with an ongoing regularly scheduled in-service education program in bariatric surgery and separate distinct credentialing guidelines for bariatric surgery. This requirement refers to a culture in which the staff is prepared to treat morbidly obese patients with understanding and compassion, and to appreciate the burdens of the co-morbidities of the disease. The staff should be aware of the basic concepts of bariatric surgery through in-service programs. Those directly caring for these patients should be able to recognize the early signs of the common complications, including pulmonary embolus, intestinal leak, infection, and bowel obstruction, as well as the complications of gastric banding procedures so that these can be managed promptly.</td>
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<td>2</td>
<td>The Applicant maintains that their facility will agree to limit bariatric surgery performed as an outpatient or a 23-hours, 59-minute stay to procedures in low-risk patients (defined as patients aged &lt; 60 years, a body mass index of &lt; 55 kg/m², weight ≤ 425 lb, an American Society of Anesthesiologist classification of &lt;Ⅳ, and no previous history of deep venous thrombosis or pulmonary embolism) that do not involve stapling or division of the gastrointestinal tract. This requirement is intended to limit the patient population to individuals who carry surgical risk levels appropriate to the outpatient setting. The definition noted above is a guideline; the SRC recognizes that patient exigency may require exceptions with the understanding that patient safety remains paramount.</td>
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<td>3</td>
<td>The applicant maintains that their facility must have in place a written transfer agreement with an inpatient facility capable of managing the full range of complications of bariatric surgery 24/7/365 and with equipment capable of transferring morbidly obese patients to that inpatient facility. This requirement is intended to ensure prompt and safe transfer to a full service tertiary care facility. It is difficult to design guidelines in terms of distance or time of transfer, but, in general, it should be possible to complete the full transfer from the time of decision to full care in the accepting facility in &lt; 1 hour. In addition, adequate staffing must be available to provide the emergency support, including the time during transfer, until the patient’s care is assumed by the other facility.</td>
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<td>4</td>
<td>The applicant maintains the expectation that the institution will perform a minimum of 100 bariatric surgical cases per year with each surgeon performing a minimum of 50 cases per year with a total lifetime experience of ≥ 125 cases as primary surgeon. “Bariatric surgical cases” are defined as primary operations and/or revisions. Endoscopies, placement of feeding jejunostomies, hernia repairs, and plastic surgical reconstructions are not included in this classification. “Performed” is defined as conducting a significant part of the operation as primary surgeon. Applicants may not include cases where they served only as the assisting surgeon. Applicants may include ≤ 75 operations performed as the primary surgeon during their residency or fellowship in their total lifetime count.</td>
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<td>5</td>
<td>The applicant has a dedicated medical director for bariatric surgery who participates in the relevant decision-making administrative meetings of the facility. The position of Bariatric Surgery Medical Director shall be filled by a qualified bariatric surgeon who is appointed through the administrative/medical staff process, with hospital minutes documenting his or her participation in the bariatric program decisions. Regularly scheduled meetings to address the bariatric program in the institution that involve medical staff, nursing, administration, central supply, operating room personnel, and the business office are required.</td>
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<tr>
<td>6</td>
<td>The applicant has a board-certified anesthesiologist supervising anesthesia delivery for all bariatric patients who is physically present in house when any bariatric patient is anesthetized, or, when anesthesia is not being given, an Advanced Cardiac Life Support-qualified physician is on site who can perform patient resuscitations. The facility must have a full-time staff with experience treating critically ill, morbidly obese patients with ventilators and invasive hemodynamic monitoring technologies that can support the treatment of a critically ill patient until he or she is sufficiently stable to be transferred to an inpatient facility.</td>
</tr>
<tr>
<td>7</td>
<td>The applicant has a full line of equipment and instruments for the care of bariatric patients, including surgical and radiologic facilities for evaluation of band placement, surgical instruments, and so forth for the morbidly obese, as well as the capability of performing band adjustments under fluoroscopic control. Furniture, beds, scales, toilets, wheelchairs, operating room tables, and litters, strong enough and extra wide to accommodate the severely obese according to the weight limits established by the institution, must be available for those patients who need this specialized equipment. Patient movement/transfer systems for morbidly obese patients must be in place throughout the institution wherever the morbidly obese receive care. Ambulances serving the institution should also be equipped to manage these large patients with appropriate stretchers, straps, and transfer devices. Finally, and perhaps most important, facility personnel must be trained to use the equipment and be capable of moving these large individuals without injury either to the patients or the staff.</td>
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<tr>
<td>8</td>
<td>The applicant center must have a bariatric surgeon co-applicant who is, or has been, board certified or is currently board eligible, by the ABS, AOBS, and/or RCPSC. The surgeon co-applicant must spend ≥50% of his or her efforts in the field of bariatric surgery. In addition, the surgeon must maintain surgical privileges at the inpatient transfer facility for managing the full range of complications from bariatric surgery and agree to manage and supervise complications that occur in their patients, including providing for band adjustments. The surgeon must have qualified coverage (i.e., by a colleague who is board certified or board eligible by the ABS, AOBS, or RCPSC); have ≥ 8 hours of continuing medical education in bariatric surgery; and have assisted on at least five nonstapling gastric procedures and/or 10 gastric stapling procedures involving anastomoses, depending on the coverage situation. Applicants who have received full approval must comply with these requirements before renewal of their certification.</td>
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The initial data from the operative results have suggested that the process may be achieving its goal of improving quality. On the basis of reports of 55,567 patients from the first 176 applicants for Full Approval and confirmed by SRC during the site inspections, the 90-day operative mortality rate was 0.35% (Table 3). These data are impressive compared with those from other common abdominal procedures such as resection of abdominal aortic aneurysms and pancreatectomies (Table 4).

**Table 2**
Continued.

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<tr>
<td>10</td>
<td>The applicant uses standardized operations and clinical pathways to enable objective evaluation and interinstitutional comparisons of outcomes. It is the surgeon’s responsibility and duty to select which primary operations he or she will perform and it is the expectation of the SRC that the procedures, no matter what the choice, will be done in a standardized manner. Similarly, the surgeon should determine the details of the planned perioperative care. These details will be documented so that each member of the surgeon’s team is aware of the care plan and is prepared to follow the process as outlined by the surgeon. Unless such a process is followed, outcomes cannot be evaluated. The clinical pathway protocols (i.e., a sequence of orders and therapies describing the routine care of the uncomplicated patient), must be available for review during the site inspection.</td>
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<tr>
<td>11</td>
<td>The applicant has nurses or physician extenders dedicated to serving bariatric surgical patients who are involved in continuing education in the care of bariatric patients at the facility and in the surgeon’s office. The facility should have a subset of nurses who routinely care for the bariatric patients and receive regular in-service education on their care, preferably assigned to a designated bariatric section of that facility. There should be a bariatric coordinator designated to supervise the bariatric program. The physician’s practice should also have nursing and physician extenders who provide continuing education and care to the bariatric patients in the practice. This should be outlined in the practice portfolio if it is a split practice that still performs significant general surgery.</td>
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<tr>
<td>12</td>
<td>The applicant maintains the availability of organized and supervised support groups for all patients who have undergone bariatric surgery at the facility. The activities of the support group should be documented, including group locations, meeting times, supervisor, curriculum, and attendance. For example, such activities as on-line chat rooms, web-based support groups, exercise, instruction, and clothing sales should be noted.</td>
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<tr>
<td>13</td>
<td>The applicant maintains documentation of a program dedicated to a goal of long-term patient follow-up of ≥75% at 5 years, with a monitoring and tracking system for outcomes. The applicant also maintains an agreement to provide a yearly outcome summary to the SRC in a manner consistent with HIPAA regulations. This requirement is based on the observation that a significant number of patients develop nutritional deficiencies, return of previous emotional disorders, as well as other late complications related to their procedure. There is no requirement that the surgeon provide the follow-up personally, only that he or she is aware of the long-term status of the patient as provided by a certified and licensed healthcare provider. Accordingly, the follow-up data can be gathered during group sessions, reunions, or through visits at other physicians’ offices. The applicant agrees to enter all patients who undergo surgery in the group or individual practice; no patients will be excluded.</td>
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</table>

Abbreviations as in Table 1.

Recently, the Centers for Medicare and Medicaid Services gave formal recognition to the program, as well as to an alternate program developed by the American College of Surgeons. After February 2006, Medicare and Medicaid refused reimbursement for bariatric surgery unless it was done in a Center of Excellence recognized by one of these two programs.

**Future plans**

Two initiatives are currently underway within the SRC to enhance care: the development of a bariatric physician network and the development of a forum for research.

Bariatric surgery patients should be followed up for ≥5 years after the operative procedure because of the possibility of serious long-term complications. Owing to the prevalence of severe obesity and the number of individuals who would be candidates for surgery, the number of bariatric surgeons is not adequate to perform such follow-up. SRC is currently developing, in cooperation with other professional societies, a network of primary care physicians who receive special training in the care of bariatric surgery patients.
These physicians will then be cognizant of the elements of long-term follow-up and can be relied on to direct the patient back to the bariatric surgeon when necessary.

The next logical step in the process is the establishment of a forum for research. The large number of centers, coupled with the large volume of data collected with the BOLD software, provides an excellent research opportunity. The SRC Research Consortium will be established to facilitate the collaboration of centers of excellence in the research endeavor. Members of the consortium will be invited to participate in scientific protocols with reimbursement for involvement in these studies. In addition, the members will be invited to serve as a collective body of experts to help consumers, healthcare professionals, and industry stakeholders make informed decisions about bariatric surgery.

## Conclusion

Bariatric surgery is a significant medical advance, but it must be delivered with efficacy, efficiency, and safety. The ASBS Bariatric Surgery Centers of Excellence program offers the potential for improving care through the assurance of a combination of expertise, volume, and needed resources. The additional components of the program (i.e., a network of bariologists, BOLD™ database system, and the Research Consortium), hold promise of additional progress.

## Reference


## Editorial comment

Considering the longevity of the subspecialty, the need for benchmarks in bariatric surgery is past due. The rapid growth in our subspecialty has jettisoned our outcomes into the limelight highlighting the need for quality Improvement and setting benchmarks. The ASBS has promulgated the belief that bariatric surgery is not just a procedure but is only successful with adequate pre and postoperative care. Collection of data and assessment of outcomes has been a cornerstone of our subspecialty. It is fitting that the ASBS was the first society to concern itself with establishing standards of excellence with an eye to improving patient outcomes, because this is what the Society has been about for 23 years. The Centers of Excellence (COE) model allows us to approach outcomes in bariatric surgery from a positive position and a position of strength in pooled data. The COE initiative allows us to examine complications and plan changes in practice. The data presented gathered from the different SRC centers across the US reflects commitment to long-term patient care and demonstrates that knowing your data is the only way to impact your outcomes. The plan to use the BOLD database to answer pivotal research questions and further our understanding of obesity is an excellent way to harness the power of pooling patient data.

The collected data, to date, shows below average mortality amongst the Centers of Excellence. The statistical power of the data is great and all the centers should be congratulated. These data have been confirmed with site inspections by Registered Nurses who have examined the hospital data and patient records. There must a long-term mechanism to ensure that audits are performed and the data confirmed. The use of BOLD as the database will help in future data analysis and research endeavors but having an interface capability with existing databases used by the centers (such as Exemplor, Remedy and and Lapbase) is a key adjunct. A complete interface from the onset which allows access to existing data as well as ongoing data collection enhances the effectiveness of our research efforts as well as broadening the scope of our outcomes data.

Marina Kurian, M.D.
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