American Foregut Society statement & definition of a Foregut Surgeon

Background: The American Foregut Society (AFS) is committed to positioning Foregut as a specialty of both surgery and gastroenterology. The foregut specialist is someone committed to a deep understanding of the pathophysiology, diagnosis and treatment of foregut disease and has expertise in a broad range of therapeutic options individualized to the specific needs of each patient. Expertise is assumed by patients, expected by medical colleagues, and integrated into guidelines. To date, no society or advocacy group has defined the specialty of foregut surgery and the scope of training required to establish either basic competency or expertise. This has led to communication, consensus, and quality gaps in the reporting of outcomes and the care of patients with diseases of the foregut. Elective procedures for benign and malignant foregut disorders have to be performed precisely and within a very narrow window of accepted outcomes in order to make a substantive impact on population health. In fact, variable levels of knowledge, experience, and expertise among practitioners has led to extreme deviations in preoperative evaluation, procedural technique, post-operative follow-up, and tracking of outcomes. It is therefore unsurprising that there has been a loss of trust and reduced collaboration between the referral community and those performing operative interventions as well as confusion over the expected outcomes following foregut surgery on the part of patients. The AFS believes that a practitioner identified as a Foregut Surgical Specialist should be held to a high standard of practice in order to provide reassurance to referring physicians and patients who are seeking the best outcomes for their foregut pathologies. This position paper addresses general requirements for the appropriate practice of anti-reflux surgery.

With regard to anti-reflux procedures, a foregut surgeon should possess the following qualities; 1) A comprehensive understanding of foregut physiology in health and disease; 2) The ability to coordinate a thorough preoperative evaluation and independent ability to interpret the esophageal physiology testing and endoscopic findings; 3) Specialized expertise or training in the major benign foregut procedures; 4) Equipoise in the recommendation of appropriate treatments according to the individual patient's physiology, psychology and desired outcomes, 5) A commitment to long-term follow up of patients in order to assess outcomes and quality of life; and 6) Expertise in, or collaborative ability with others regarding neoplastic conditions or other areas beyond his or her scope of practice is also expected.

In 1979, Lund and colleagues noted, *"There is wide acceptance of the hypothesis that, other things being equal, the quality of care improves with the experience of those providing it. If true, surgical mortality rates should be lower in hospitals performing higher volumes of a given procedure."* This remains true today, however even the most complicated operations do not have prescriptive volume and experience requirements of the surgeon performing them and/or the environment in which they take place. Foregut surgery and specifically anti-reflux/ hiatal hernia surgery has a recognized volume/quality relationship for both the surgeon and the hospital. In today's environment value (value= outcomes that matter to patients/ total cost of care episode) is an increasingly important factor in the delivery of healthcare. It is incumbent on our profession and specialty societies to ensure that those who deliver that care are best equipped to do so.

The learning curve for anti-reflux surgery was intensively researched in the first decade after the introduction of the laparoscopic technique. Some investigators looked at individual surgeons while others looked at the outcomes of a team or hospital. While criteria varied to assess overcoming the learning curve, they often focused on early complications requiring reoperation, need for dilation, operative times, and length of stay. Other investigators looked at late reoperation due to recurrent symptoms, recurrent herniation, or dysphagia. Acceptable training case volume varied from between 20 and 50 laparoscopic antireflux surgery (LARS) cases. Little distinction was made relative to ongoing year over year volume, though in all of the published reports the authors were known to be high-volume surgeons. In addition, surgeons must have the training volume while at the same time, be taught the proper techniques. The impact and importance of fellowship training or an established mentor-mentee training program in LARS has been under emphasized in relation to performing adequate volumes. This training should also encompass the skills to establish a program within a given hospital after training is complete.

It has been postulated that the significant drop-off of LARS after 1999 was partly due to the fact that many low-volume surgeons (caught up in the enthusiasm for laparoscopic revolution) were performing the majority of ARS. This led to both an increase in early complications as well as long-term failures. Today, LARS continues to be offered to less than 1% of patients who might benefit from an anti-reflux procedure.

More recently, investigators have looked at larger trends in ARS for gastroesophageal reflux disease (GERD) as well as for paraesophageal hernia (PEH). Colavita and colleagues examined regionalization of LARS and found that at high-volume centers (>38 procedures per year), complications were fewer, length of hospital stay was shorter, total charges were lower, and routine discharge was more common. This trend was found by Schlottmann and Patti as well (high-volume center >25 procedures per year). Concerningly, when they evaluated these same outcomes using the national inpatient sample (NIS) database [examining all benign esophageal procedures (ARS/PEH/esophageal myotomy)], they found that overall complications had increased for LARS.

Relative to PEH, multiple groups have looked at the relationship of volume and outcomes. Bowers et al, studied the surgeon volume and recurrence relationship, finding that low volume surgeons (<10 PEH/yr.) had a significantly higher recurrence rate. Schlottmann et al, utilized the NIS to evaluate hospital volume and outcomes. Similar to their work looking at LARS, they concluded that patients undergoing PEH repair at high-volume hospitals (>20 operations/yr.) were less likely to experience postoperative bleeding, cardiac failure, respiratory failure, and shock. Whealon et al, also compared low-volume vs high-volume centers, finding that mortality was double at low volume hospitals. Interestingly, while the threshold for a high volume hospital was set at 10, 75% of the patients in the entire study had their operation performed at a center that had a median case volume of 83/year. These findings suggest that the results likely apply to very high volume centers.

New technology is moving rapidly into the foregut space. While this technological flow has been of great benefit to patients, it sets up potential training and education dilemmas. An example of the need to define adequate experience in foregut surgery, the first precaution in the

LINX FDA Indications For Use states, "*Implantation of the device should only be performed by a surgeon who has experience in laparoscopic anti-reflux procedures and has received product specific training."* The statement is clear that experience matters when it comes to the outcomes of anti-reflux surgery (ARS) and LINX in particular. Unfortunately, exact numbers and circumstances surrounding what constitutes enough experience are difficult to ascertain and the literature is murky. Nonetheless, guidance must be given and defined so that patients, hospitals/credentialing committees, and the medical community may understand what it means to be an expert practitioner in ARS. Many of the more recently FDA approved anti-reflux procedures/technologies have specific limitations relative to esophageal function, hiatal hernia size, prior foregut surgery, and medical conditions. Thus, as new technology emerges, the need for specific foregut expertise increases. With the great influx of technology comes great responsibility on the part the surgeon.

Despite the impressive technological advances in foregut surgery, it is also important to keep in mind that the classic operations continue to serve as the foundation of a foregut surgeon's training. There are more than six commonly performed classic operations that all continue to have a role. Thoracic operations, esophageal lengthening procedures, and complex repairs of diaphragm all need to be within the expert foregut surgeon's armamentarium.

Doing no harm is a central tenant of medicine. The desire to improve the outcomes of certain high risk procedures through regionalization to high-volume centers is a concept that should be met with universal approval. Virtually every study evaluating outcomes relating to morbidity and mortality have shown that high-volume centers/surgeons have improved outcomes for complex surgery. Anti-reflux surgery by any definition falls into this category. Redo surgery of the esophagus carries even higher risk and should be performed at a high volume center by an experienced foregut surgeon. To quote Dr. John Birkmeyer, *"Low-volume hobbyists are bad for patients and we have to stop them."*

The AFS recognizes that experience goes well beyond strict numbers of procedures and encompasses the environment and circumstances of where, when, why, and on whom procedures are performed. This takes into account accessibility to appropriate pre-operative work-up facilities, commitment to long-term follow-up, tracking long-term longitudinal outcomes, hospital experience in these procedures, and ideally development of a GI/Surgeon dyad for the care of patients with benign disorders of the foregut. The expert foregut surgeon has a firm understanding of esophageal physiology, collaborates with GI colleagues, develops a sound surgical plan and procedure based on the latest literature, executes the surgical plan with minimal morbidity based on extensive experience and training, is able to identify and take care of complications, and follows the patient and outcomes.

Recommended standards for performance of ARS: With the above in mind, the AFS currently recommends that a surgeon performing any foregut surgery meet the following:

1. Demonstrate fellowship or general surgery training during which 50 anti-reflux operations were performed under the supervision of an experienced mentor.
2. Performs a minimum of 25 anti-reflux procedures per year.

3. Be facile in flexible upper endoscopy and the interpretation of endoscopic findings both in the pre- and postoperative settings.
4. Demonstrated expertise in performance or interpretation of the requisite diagnostics (e.g., endoscopy, pH monitoring, and high-resolution manometry)
5. Demonstrated expertise in, or access to, advanced therapeutic endoscopy to deal with complications of anti-reflux procedures.
6. Advanced procedures such as intrathoracic paraesophageal hernias, redo procedures, resectional therapies, or post-bariatric surgery should be restricted to surgeons with demonstrated expertise in these areas and have a minimum of 50 procedures per year in these applications. This would include application of novel technologies and endoluminal procedures in these settings.
7. Utilize a robust longitudinal patient tracking program for CQI purposes and ensure long-term follow up.

In summary, there is a clear relationship to quality outcomes and decreased morbidity and mortality based on specialization, hospital, and surgeon volumes. Currently, LARS is performed in less than 0.1% of patients who might benefit. The reasons for this are multifactorial, but seem to hinge on the fact that all of the procedures for GERD need to be performed with precision in the appropriate patients. When poorly performed or inappropriately applied, the consequences to patients can be devastating, which has led to prejudice against these procedures by the medical community at large and patients in particular. There needs to be a concerted effort to increase the value of these operations by decreasing morbidity and mortality as well as demonstration of lasting benefit to patients. In medicine, Value equals Outcomes that matter to patients divided by Cost (V=O/C). Relative to foregut surgery in general and ARS specifically, we must increase the overall value to patients, payors, and the medical community. The classic operations for foregut diseases remain foundational and relevant, while technological innovations have the potential to greatly improve the quality of life in patients and in certain situations are superior to the "gold standard". However, new technology must be introduced and performed responsibly in the hands of surgeons who are best equipped to safely and effectively apply the technology. Partnerships between medical professionals, its societies, and industry are paramount in this endeavor and will continue to benefit patients.