Metabolic and Bariatric Surgery Accreditation and Quality Improvement: Adolescent Center Designation

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Faculty Disclosure Information

Financial relationships with commercial entities:

Intuitive Surgical (Sunnyvale, CA) – Educational Honorarium

I **do not** intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

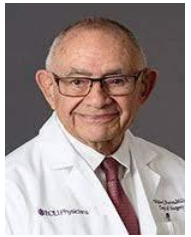
Learning Objectives

1. Development of national MBS standards and accreditation
2. Program elements and related resources
3. Current status of MBSAQIP (including pediatric designation)
4. Considerations for Pediatric MBS Programs
5. Where do we go from here

Centers of Excellence
ASMBS (2004 - 2005)

- Public and professional concerns related to patient safety led to the development of a COE framework.
- Provide the means to identify bariatric surgery programs that provide a comprehensive and standardized care and long-term follow-up."
- Routine reporting and compiling of patient outcomes will provide an opportunity to assess and verify risks and benefits of therapy"

Ken Champion



Walter Pories

https://asmbs.org/about/mbsaqip/ https://bariatrictimes.com/december-2011/

Champion JK, Pories WJ. COE for Bariatric Surgery. SOARD. 2005; (2): 148–151.

Parallel Program Development

- **Principles**: Surgeon Leadership, Multidisc Care, Registry.
- **Organizational Elements**: Case vol, institutional structure
- 2005-2012: Major payors endorse care at accredited ctrs.
- 2006: CMS Coverage in accredited ctrs. (ACS, ASMBS)
- 2012: ASMSB and ACS combine programs.

  ” …Including pediatric because it’s the right thing to do!” – R.B
- 2014: MBSAQIP released

Bruce Wolfe

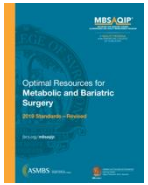
Dave Hoyte

Clifford Ko

Robin Blackstone

https://bariatrictimes.com/december-2011/

Why is Accreditation Important



- Multiple studies have examined patient safety in metabolic and bariatric surgery and support the value of accreditation. An article in *Surgical Endoscopy* (July 2013) found that in-hospital mortality rates at accredited centers were more than three times lower than the mortality rates at non-accredited centers (0.06% vs. 0.22%).

- Additionally, an October 2012 publication in the *Journal of the American College of Surgeons* showed nearly the same differences in mortality rates between accredited and non-accredited academic metabolic and bariatric surgery centers (0.06% vs. 0.21%, respectively).

Jafari et al. Surg Endosc 2013; 27:4538-4546.

Nguyen et al. J Am Coll Surg 2012; 215-467.

Outcomes of Bariatric Surgery Performed at Accredited vs. Nonaccredited Centers

Objective: Perioperative outcomes (accredited vs nonaccredited centers)

Methods: Retrospective of UHC Database (114 academic ctrs.) 2007-2009

Primary: In-hospital mortality,

Secondary: LOS, 30 readmission, overall complications

Results: 35,284 cases (89% AC vs. 11% non-AC)

In-hospital mortality (0.06% vs. 0.21%)

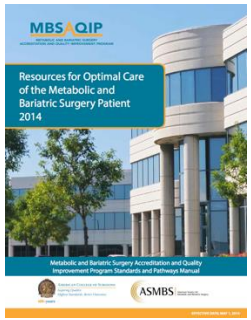
AC - Shorter LOS and Lower Cost, Lower rates of complication

Conclusion: Accreditation status is associated with small but significant improvement in in-hospital mortality and perioperative outcomes

Nguyen et al. J Am Coll Surg 2012; 215-467.

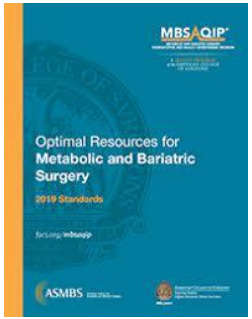
Broad Adoption:
Regulatory Framework
Policy Development

2014

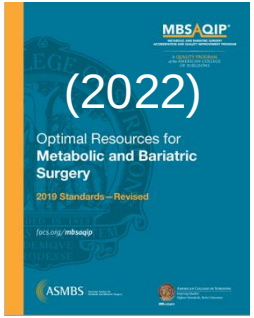


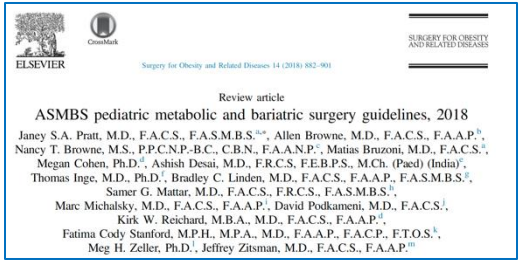
2016

2019



2019v.2





ELSEVIER

Surgery for Obesity and Related Diseases 14 (2018) 882–901

SURGERY FOR OBESITY AND RELATED DISEASES

Review article

ASMBS pediatric metabolic and bariatric surgery guidelines, 2018

Janey S.A. Pratt, M.D., F.A.C.S., F.A.S.M.B.S.[a,*], Allen Browne, M.D., F.A.C.S., F.A.A.P.[b], Nancy T. Browne, M.S., P.P.C.N.P.-B.C., C.B.N., F.A.A.N.P.[c], Matias Bruzoni, M.D., F.A.C.S.[a], Megan Cohen, Ph.D.[d], Ashish Desai, M.D., F.R.C.S, F.E.B.P.S., M.Ch. (Paed) (India)[e], Thomas Inge, M.D., Ph.D.[f], Bradley C. Linden, M.D., F.A.C.S., F.A.A.P., F.A.S.M.B.S.[g], Samer G. Mattar, M.D., F.A.C.S., F.R.C.S., F.A.S.M.B.S.[h], Marc Michalsky, M.D., F.A.C.S., F.A.A.P.[i], David Podkameni, M.D., F.A.C.S.[j], Kirk W. Reichard, M.B.A., M.D., F.A.C.S., F.A.A.P.[k], Fatima Cody Stanford, M.P.H., M.P.A., M.D., F.A.A.P., F.A.C.P., F.T.O.S.[k], Meg H. Zeller, Ph.D.[l], Jeffrey Zitsman, M.D., F.A.C.S., F.A.A.P.[m]

POLICY STATEMENT

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

PEDIATRICS

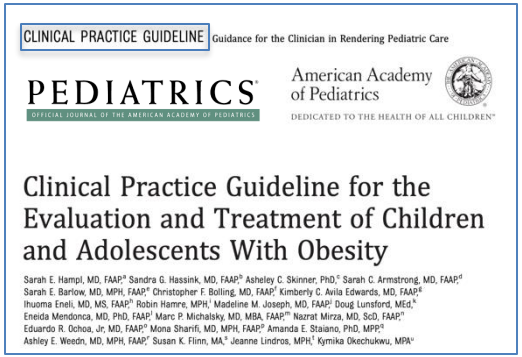
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practices

Sarah C. Armstrong, MD, FAAP,[a] Christopher F. Bolling, MD, FAAP,[b] Marc P. Michalsky, MD, FACS, FAAP, FASMBS,[c] Kirk W. Reichard, MD, MBA, FAAP, FACS,[d] SECTION ON OBESITY, SECTION ON SURGERY



CLINICAL PRACTICE GUIDELINE

Guidance for the Clinician in Rendering Pediatric Care

PEDIATRICS

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Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity

Sarah E. Hampl, MD, FAAP,[a] Sandra G. Hassink, MD, FAAP,[b] Asheley C. Skinner, PhD,[c] Sarah C. Armstrong, MD, FAAP,[d] Sarah E. Barlow, MD, MPH, FAAP,[e] Christopher F. Bolling, MD, FAAP,[f] Kimberly C. Avila Edwards, MD, FAAP,[g] Ihuoma Eneli, MD, MS, FAAP,[h] Robin Hamre, MPH,[i] Madeline M. Joseph, MD, FAAP,[j] Doug Lunsford, MEd,[k] Eneida Mendonca, MD, PhD, FAAP,[l] Marc P. Michalsky, MD, MBA, FAAP,[m] Nazrat Mirza, MD, ScD, FAAP,[n] Eduardo R. Ochoa, Jr, MD, FAAP,[o] Mona Sharifi, MD, MPH, FAAP,[p] Amanda E. Staiano, PhD, MPP,[q] Ashley E. Weedn, MD, MPH, FAAP,[r] Susan K. Flinn, MA,[s] Jeanne Lindros, MPH,[t] Kymika Okechukwu, MPA[u]

Pratt, Browne, Browne et. al SOARD 2018

Armstrong, Bolling, Michalsky and Reichard. Pediatrics 2019

Hampl, Hassink, Skinner, *et al*. Pediatrics 2023

Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practices

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

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Practice Level Pediatricians

- Pediatricians should recognize class 2 obesity (BMI≥35 or ≥120% of 95th percentile
- Seek out multidisciplinary/multimodality pediatric focused centers
- Support medical decision regarding risks, benefits, long term health implications of MBS.
- Identify eligible patients and provide timely referral to qualified centers.

System Level - Pediatricians

- Pediatricians should acknowledge disparities (race, ethnicity and socioeconomic status) in obesity-focused care and advocate for improved access to multidisciplinary pediatric-focused centers that provide bariatric surgical care.

System Level - Govt, Health, and Academic MC

- Use best practice guidelines to promote safe and effective multidisciplinary care.
- Avoid reliance on unsubstantiated lower age limits to inform clinical eligibility criteria
- Increase access to and number of multidisciplinary clinics focused on the continuum of obesity-related care

System Level - Public and Private Payors

- Provide payment for multidisciplinary preoperative and postoperative care
- Provide payment for MBS from evaluation through appropriate follow-up
- Reduce barriers to pediatric MBS (i.e., limited access, bureaucratic delays, inadequate payment, prolonged appeals process).

Armstrong, Bolling, Michalsky and Reichard. Pediatrics 2019

Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

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Key Action Statements

- There is no evidence to support either watchful waiting or unnecessary delay of appropriate treatment of children with obesity.
- Comprehensive obesity treatment may include include nutrition support, physical activity treatment, behavioral therapy, pharmacotherapy, and **metabolic and bariatric surgery.**
- **Intensive health behavior and lifestyle treatment** (IHBLT), while challenging to deliver and not universally available, is the most effective known behavioral treatment for child obesity. The most effective treatments include **26 or more hours** of face-to-face, family-based, multicomponent treatment over a **3- to 12-month** period.

Key Action Statements

- Physicians should offer adolescents ages 12 years and older with obesity weight loss **pharmacotherapy**, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.
- **Teens Age 13 and older with severe obesity (BMI ≥120% of the 95th percentile for age and sex) should be evaluated for metabolic and bariatric surgery.**

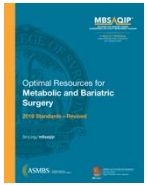
"Although no lower age limit exists to define the safety or effectiveness of surgery among children, there are currently limited data among children younger than age 13 years."

Nationwide Children's — When your child needs a hospital, everything matters.

The Ohio State University College of Medicine

Hample, Hassink, Skinner, *et al*. Pediatrics 2023

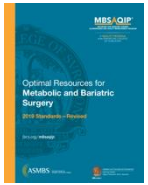
MBSAQIP Framework



- Standard 1: Institutional Administrative Commitment
- Standard 2: Program Scope and Governance
- Standard 3: Facilities and Equipment Resources
- Standard 4: Personnel and Services Resources
- Standard 5: Patient Care: Expectations and Protocols
- Standard 6: Data Surveillance and Systems
- Standard 7: Quality Improvement
- Standard 8: Education: Professional and Community Outreach

https://asmbs.org/about/mbsaqip/

Surgeon Verification - Standard 4.2



- Lifetime Volume Documentation – 100 stapled cases (may include 75 from accredited fellowship experience).
- Compliance with all MBSAQIP standards
- Maintenance of ABS board certification
- CME: 24 hrs. MBS Category 1 CME
- Annual case volume ≥ 15 stapled cases per year
- Co-surgeon requirement if < 15 cases per year

https://asmbs.org/about/mbsaqip/

Standard 3 – Facilities and Equipment Resources
Designated Bariatric Unit

Furniture

Shower & Gowns

Support & Toilets

Compression/VTE

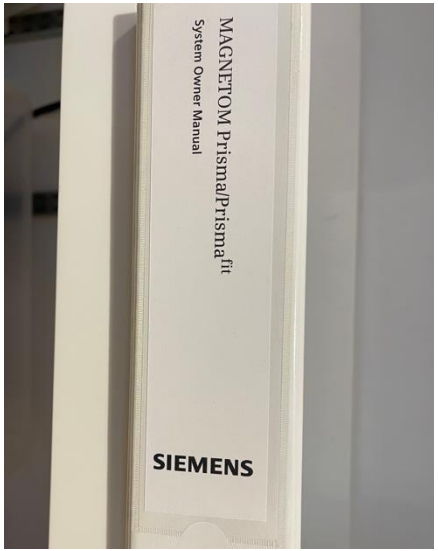
Operating Rooms

- DaVinci System
  - Extra long instrument arms
- Trumpf Bed 7000dV
  - 1,000 lbs Wt. Capacity
- Wide Entry Doors

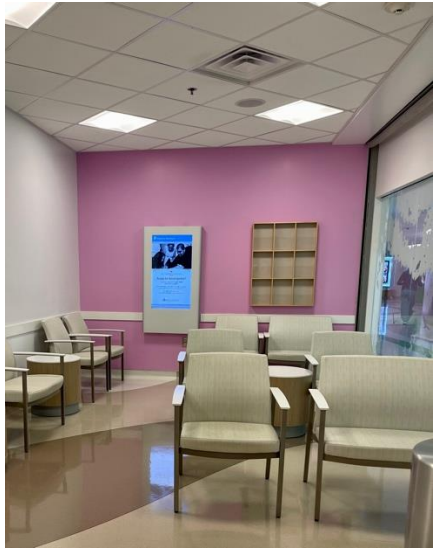
RADIOLOGY

CT: 500-600lbs
MRI: 350-550lbs

Fluro: 400-660lbs



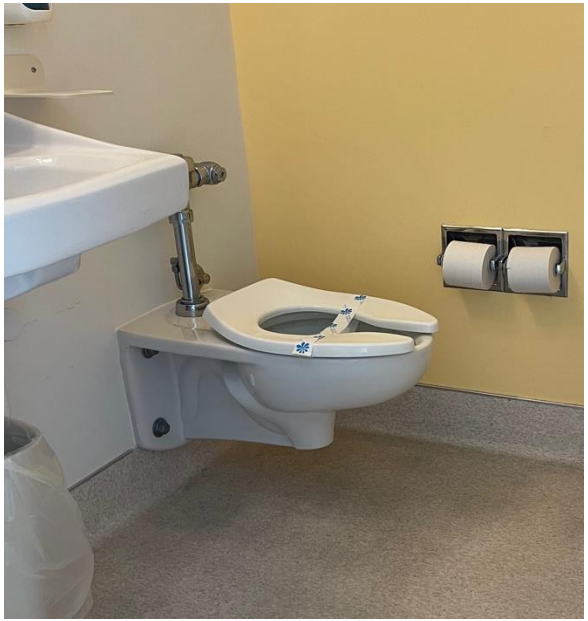
Resource Manual



High Wt Capacity Seating

PICU

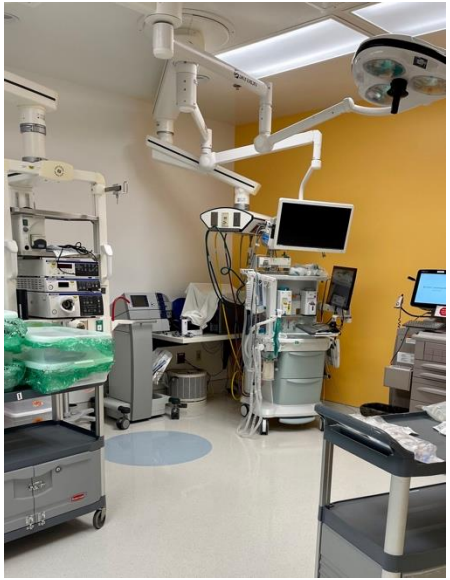
Hillrom Progressa - 500 lbs



Regard Bench – 500lbs/seat

Endoscopy

Stryker Prime - 700 lbs



Equipment

Difficult Airway

High Wt Capacity Seating

Emergency Room

Stryker Prime – 700 lbs

AFWALL® MILLENIUM™ FloWise® 1.28 GPF FLUSHOMETER TOILET SYSTEM

with EVERCLEAN® SELECTRONIC® FLUSH VALVE

BARRIER FREE

AFWALL® MILLENIUM™ FloWise® 1.28 GPF FLUSHOMETER TOILET SYSTEM with EVERCLEAN®

❑ **3351.528** 1.28 gpf Exposed Top Spud Bowl and Selectronic® Flush Valve

BOWL:
- Wall-mounted elongated flushometer valve toilet
- Vitreous china
- High Efficiency. Operates in the range of 1.1 gpf to 1.6 gpf (4.2 Lpf to 6.0 Lpf)
- Permanent EverClean® surface inhibits the growth of stain and odor-causing bacteria, mold, and mildew on the surface
- Condensation channel
- Powerful direct-fed siphon jet action
- 1-1/2" inlet spud
- Fully-glazed 2-1/8" trapway
- 10" x 12" water surface area
- 100% factory flush tested
- Bolt caps and seat not included
- Model 3351.101

SELECTRONIC® FLUSH VALVE:
- Factory-Installed CR-P2 Lithium Battery
- Self-Cleaning Piston with integral wiper spring significantly reduces clogging and maintenance
- Selectronic® Proximity System with universal sensor provides hygienic, "hands free" operation
- State-of-the-Art Electronics prevent ghost flushing
- Dezincification Resistant semi-red brass alloy
- Fully Mechanical Manual Override Button can flush the valve without power
- Fail-Safe: Valve automatically closes upon loss of power or water pressure and does not need to be reset
- Adjustable Sanitary Flush cleans the fixture & maintains the trap seal.
- Chemical Resistant EPDM Seals for extended life
- Adjustable Tailpiece for rough-in flexibility
- Can be installed left or right handed
- Model 6065.121

Includes:
- 047007-0070A Inlet Spud (furnished with bowl)
- 1" I.P.S. angle stop with back-flow protection and vandal resistant cap
- 1" Sweat solder kit including cover tube and wall flange
- 1-1/2" High back pressure vacuum breaker, spud coupling and flange

SEE REVERSE FOR ROUGHING-IN DIMENSIONS

High-Efficiency Toilet Systems:
- 20% water savings when compared to a 1.6 gpf toilet system

System MaP* Score:
- 1,000 grams of miso @ 1.28 gpf

* Maximum Performance (MaP) testing performed by IAPMO R&T Lab. MaP Report conducted by Veritec Consulting, Inc. and Koeller and Company.

BATTERY LIFE:
- 4 years @ 4,000 flushes per month

Operating Pressure:
25 psi (flowing) - 80 psi (static)

Flow Requirement:
25gpm (94.6 L/min.)

American Standard Brands
865 Centennial Avenue
Piscataway, NJ 08854
732.980.3000

1,000lb load test

10 Dec 14

Subject: Weight Loadings on Floor and Wall Mounted Vitreous China Toilets

To Whom It May Concern:

Please be advised that all American Standard, Crane, and Eljer floor mounted vitreous china toilets will withstand very high weight loadings in use. Vitreous china is extremely strong in compression and will handle static loadings of well over 1000 pounds without failure to the fixture. Additionally, our Right Width FloWise water closet is specifically rated at 2,000 lbs.

Please also be advised that all American Standard, Crane, and Eljer wall mounted vitreous china toilets have been tested to, and comply with, the static weight load test requirements of ASME A112.19.2 / CSA B45.1, that being a 500 pound load test. Our Millennium series of wall bowls have been internally validated to withstand 1,000lbs of static load.

The above is true for undamaged toilets. Any damage or cracking that occurs after the unit after it has been shipped by American Standard (i.e.: damaged during installation or while in service) will obviously result in reduced weight bearing capacity. Such fixtures must be put out of service and replaced immediately.

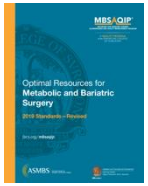
Please contact me at (732) 369 4045 if you have any questions regarding the above information.

Kind Regards,

(signed)

C.J. Lagan
Sr. Manager, Compliance Engineering
865 Centennial Ave.
Piscataway, NJ 08854
732 369 4045
laganc@americanstandard.com

Standard 3: Facilities and Equipment Resources



- Examination tables
- Operating room tables
- Radiology equipment
- Fluoroscopy equipment
- Medical imaging equipment
- Crash carts
- Blood pressure cuffs
- Sequential compression devices
- Scales
- Intensive care unit (ICU) equipment
- Surgical instruments (staplers, retractors, long instruments, etc.)
- Chairs
- Beds
- Doorways
- Showers
- Toilets Weight-rated or supported toilets.
- Weight-rated floor mounted
    - Weight-rated wall mounted
    - Supported floor mounted
    - Supported wall mounted
- Gowns
- Wheelchairs
- Walkers

https://asmbs.org/about/mbsaqip/

Why Should Pediatric Centers Join?

- Organizational Accountability
- Centralized QI Data Repository (Peds)
- Risk Adjusted Performance Analysis
- Quality Assurance Framework

Journal of Pediatric Surgery 58 (2023) 695–701

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.sciencedirect.com/journal/journal-of-pediatric-surgery

Utilization of an Enhanced Recovery After Surgery (ERAS) protocol for pediatric metabolic and bariatric surgery

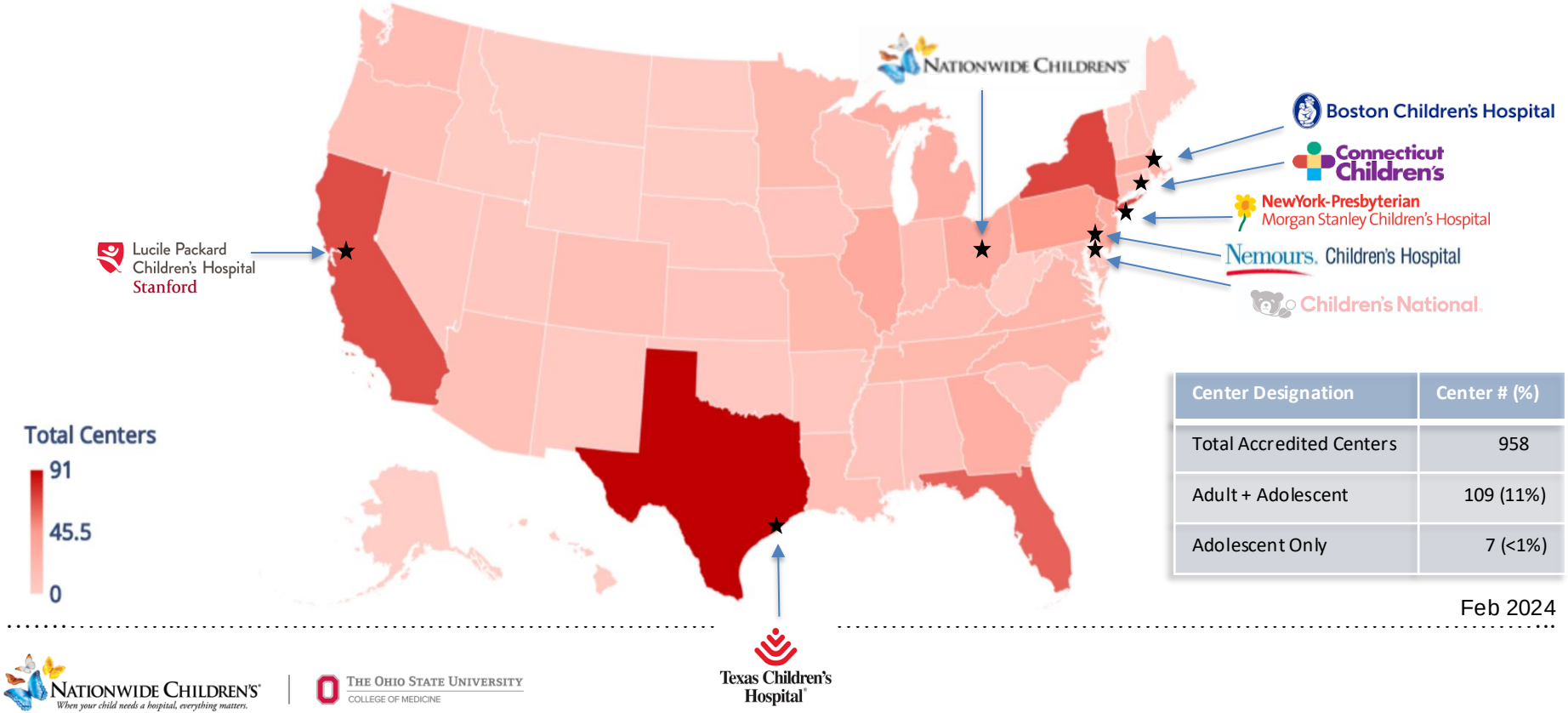
Wendy Jo Svetanoff [a], Karen Diefenbach [a], Brian Hall [b], Amber Craver [b], Sarah Rutledge [b], Cindy McManaway [a], Ihuoma Eneli [c], Joseph Tobias [c], Marc P. Michalsky [a,*]

Nationwide Children's Hospital

Laparoscopic Sleeve Gastrectomy

	Total Cases	Observed Events	Observed Rate	Pred Obs Rate**	Expected Rate	Odds Ratio	95% C.I. Lower	95% C.I. Upper	Outlier
LSG Morbidity	13	0	0.00%	1.03%	1.09%	0.94	0.26	3.38	No
LSG All Occurrences Morbidity	13	1	7.69%	3.62%	3.26%	1.11	0.48	2.60	No
LSG Serious Event	13	0	0.00%	1.00%	1.04%	0.96	0.34	2.75	No
LSG Leak	13	0	0.00%	0.18%	0.18%	0.99	0.22	4.41	No
LSG Bleeding	13	0	0.00%	0.32%	0.32%	0.99	0.32	3.04	No
LSG SSI	13	0	0.00%	0.30%	0.30%	0.98	0.23	4.09	No
LSG All Cause Reoperation	13	0	0.00%	0.60%	0.61%	0.98	0.36	2.66	No
LSG Related Reoperation	13	0	0.00%	0.37%	0.38%	0.98	0.26	3.62	No
LSG All Cause Intervention	13	0	0.00%	0.60%	0.62%	0.96	0.25	3.67	No
LSG Related Intervention	13	0	0.00%	0.46%	0.47%	0.97	0.22	4.27	No
LSG All Cause Readmission	13	1	7.69%	2.92%	2.59%	1.13	0.48	2.65	No
LSG Related Readmission	13	1	7.69%	2.36%	1.96%	1.21	0.45	3.24	No

MBSAQIP Program Participation



Center Designation	Center # (%)
Total Accredited Centers	958
Adult + Adolescent	109 (11%)
Adolescent Only	7 (<1%)

Feb 2024

Nationwide Children's — When your child needs a hospital, everything matters.

The Ohio State University College of Medicine

Pediatric Volume (<18yr) Increasing

MBSAQIP Annual Cases	Case Volume Adult + Adolescent Adolescent-only
2020	266
2021	327
2022	358
2023 (Jan to Sept only)	361* (481 predicted?)

- Rate per 1 million (≥ class 2 obesity) - 227 (2009) to 331 (2017)
- Rate per 100,000 (<19 years) – 2.29 (2010) to 4.62 (2017)
- Approximately 1,300 to 1,900 cases per year

8 additional centers planning Pediatric MBS program

Bouchard ME, et al. Child Obes. 2022 Apr;18(3):188-196.
Steinberger, et al. Pediatrics. 2022; 150(6):e2022057316
Messiah, et al. Jama Peds. 2023; 177(8):856-857.

Volume: Non-Accredited Center

Non-Accredited Ctr Annual Cases	Pediatric Programs from Survey results
2020	137
2021	149
2022	162
2023	217
2024 predicted	(469)

Data from survey of bariatric/pediatric surgeons performing pediatric bariatric surgery collected via email survey of committee members and MBSAQIP accredited centers

Approx 8 additional centers planning Pediatric MBS program

Current estimates suggest that MBSAQIP is only capturing on fraction of annual case volume

Original Article
PEDIATRIC OBESITY

Obesity

Access to Care for Adolescents Seeking Weight Loss Surgery

Thomas H. Inge[1], Tawny W. Boyce[1], Margaret Lee[2], Linda Kollar[1], Todd M. Jenkins[1], Mary L. Brandt[2], Michael Helmrath[1], Stavra A. Xanthakos[1], Meg H. Zeller[1], Carroll M. Harmon[3], Anita Courcoulas[4] and Marc P. Michalsky[5]

Objective: Determine influencing factors related to insurance authorization

Methods: Retrospective review: consecutive cases at 5 centers (2009-2011)

Outcomes: number and timing of authorizations, denials, appeals.

Results: **47% insurance authorization at original request.**

Age <18 years cited as most common reason for denial

80% of initial denials were approved after appeal; as many as 5

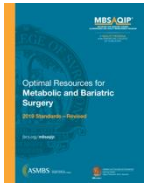
11% were unable to obtain authorization

Major Payors – require MBSAQIP accreditation for adult MBS programs

Implications for pediatric programs payor status - unclear

Inge et al, *Obesity*, 2014.

Strategy To Move Forward



- Add Pediatric-Specific Variables
  - Pediatric obesity is not the same as adult obesity
  - Proposed variables in development
  - All patients at peds only center and patients <18yrs at adult centers
- Long-Term Reporting and Risk Adjustment
  - To better inform timing of surgery, critical in childhood obesity
  - Develop pediatric risk adjusted model for Semi-Annual Reporting
- Develop Pediatric Center Cost Structure
  - Current administrative fees are proportionally very high for peds centers
  - Average Program volume in 2023 = 27 patients - Cost = $350 per patient
  - Pediatric patients on average 50-70% are publicly insured

QUESTIONS


Find A Doctor
Conditions We Treat
Specialties
Locations
Your Visit
Family Resources & Education
Search
Specialties
Bariatric Surgery
www.nationwidechildrens.org/bariatric-surgery
BARIATRIC SURGERY
Here for Every Step of the Journey to a Healthy Weight