



**AMERICAS HERNIA SOCIETY
QUALITY COLLABORATIVE FOUNDATION
ANNUAL REPORT
2018**

TABLE OF CONTENTS

| | |
|----|-----------------------------|
| 1 | PRESIDENT'S MESSAGE |
| 2 | 2018 LEADERSHIP |
| 3 | MISSION |
| 3 | NOTABLE ACHIEVEMENTS |
| 4 | MEMBERSHIP |
| 5 | QUALITY IMPROVEMENT SUMMIT |
| 7 | PUBLICATIONS |
| 8 | PROFESSIONAL DEVELOPMENT |
| 9 | STRATEGIC INITIATIVES |
| 10 | SPOTLIGHT: FEDERAL PROGRAMS |
| 11 | FOUNDATION PARTNERS |

PRESIDENT'S MESSAGE

Sometimes it feels like yesterday, but it was back in 2013 when I sat with a diverse group of hernia surgeons and we brainstormed a plan to improve our patient care and optimize cost in a real world setting. From this auspicious beginning, the Americas Hernia Society Quality Collaborative was born. This year marked the AHSQC's 5 year anniversary and as I reflect on the past half- decade, I'm filled with gratitude for all those who have supported this endeavor - the patients, surgeons, FDA leaders and Foundation Partners who are driven to help others through collaboration.



With the new year beginning, I took some time to recall the journey we've taken these past five years. As a surgeon, I instinctively assess situations objectively with my "go to" position as one that looks at the data – and what I see is something I feel so passionate about – Collaboration is the way to create real progress. The AHSQC as a whole is so much greater than the sum of our parts. This year's annual report highlights the tremendous achievements we have made together, letting the numbers speak for themselves.

Undoubtedly, the highlight of 2018 came in September when the AHSQC hosted our inaugural Quality Improvement Summit. Drawing upon in depth analysis of real world data from thousands of cases, the Quality Improvement Summit featured 1 ½ days of highly interactive engaging sessions where attendees shared practical approaches for optimizing surgical techniques and improving patient outcomes and long-term well-being. As a measure of the exceptional value of the QI Summit to practicing hernia surgeons, in a post-meeting survey, 82% of surgeon respondents indicated they would change their practice when they returned home following the Summit. Buoyed by such positive feedback, I'm pleased to share that preparation for the next QI Summit is already underway.

We remain focused on continued collaborative engagement with our stakeholders, expanding our reach both in the US and looking abroad for opportunities to share data. At the close of 2018, the AHSQC registry held data collected for quality improvement on over 42,000 ventral and inguinal hernia cases performed by over 320 surgeons in 40 states across the country. The AHSQC shares this wealth of high quality data widely, allowing others to assess and benefit from our collective experience. In addition to the QI Summit and the compendium of peer reviewed publications utilizing AHSQC data, I'm thrilled to share that since its launch, the AHSQC's free, online ORACLE risk assessment tool has garnered close to 1,000 hits. Utilizing the growing AHSQC database, ORACLE offers a real-world prediction of identified risks associated with ventral hernia repair using mesh and can be completed by patients directly or in consultation with health care providers.

At the national level, in 2018, the AHSQC was designated a strategic Coordinated Registry Network (CRN) by the FDA's Medical Device Epidemiology Network Public Private Partnership and the National Evaluation System for health Technology (NESTcc). As a CRN focusing on Abdominal Core Health, AHSQC is taking an active role in addressing key clinical questions and surveillance of techniques and devices essential to hernia patient outcomes.

As added value to surgeons, the AHSQC Foundation continues to offer participation in the AHSQC Registry free of charge to all hernia surgeons in the United States. The AHSQC was again recognized by CMS as a Qualified Clinical Data Registry and participation in the AHSQC continued to fulfill the Maintenance of Certification (MOC) Part 4 requirement for 2018. Supporting surgeons focusing their training on hernia care, in 2018 the Foundation was pleased to award 2 Resident/ Fellow Research Grants for work to improve hernia care.

It is not insignificant that we as a Collaborative have made tremendous accomplishments that few in 2013 imagined could ever come to fruition. I'm humbled and inspired by these achievements and offer sincere appreciation to the patients, surgeons, FDA colleagues and Foundation partners who have all joined together on this journey. Your continued support and dedication to the pursuit of enhanced patient care is unsurpassed.

Thank You! The AHSQC's first five years were remarkable... and I truly believe, the best is yet to come.

A handwritten signature in black ink, appearing to read 'mf', written in a cursive style.

Michael Rosen, MD
Medical Director
Americas Hernia Society Quality Collaborative
rosenm@ccf.org

2018 LEADERSHIP

GOVERNING BOARD



Michael Rosen, MD
President
AHSQC Medical Director



Benjamin Poulouse, MD, MPH
Vice President
AHSQC Director for
Quality & Outcomes



Alfredo Carbonell, DO
Treasurer



Randy Janczyk, MD
Secretary

MEMBERS AT LARGE



Ajita Prabhu, MD



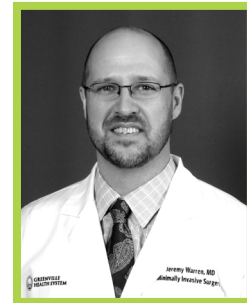
Jake Greenberg, MD, EdM



William Hope, MD



David Webb, MD



Jeremy Warren, MD

EXECUTIVE DIRECTOR

Carol Goddard

PRIVACY OFFICER

Shelby Dunstan

VARIABLES & DEFINITIONS COMMITTEE CO-CHAIRS

Ajita Prabhu, MD
Eric Pauli, MD

DATA USE & PUBLICATIONS COMMITTEE CHAIR

Corey Deeken, PhD

RESIDENT/FELLOW RESEARCH GRANT COMMITTEE

Jake Greenberg, MD, EdM
David Webb, MD

OPIOID REDUCTION TASK FORCE CHAIR

Michael Reinhorn, MD

INGUINAL HERNIA TASK FORCE

David Chen, MD
Jeffrey Blatnik, MD
Richard Pierce, MD

MISSION

To maximize quality and value of hernia patient care through collaboration.



“Surgeons are always striving to provide the right operation for the right patient at the right time. We realized we needed to capture and critically review information from everyday experiences of all surgeons and share collective feedback to ultimately enhance hernia treatment.”

-Ajita Prabhu, MD
AHSQC Founding Board Member

NOTABLE ACHIEVEMENTS

- Over 42,000 Patients
- 320 Participating Surgeons
- 40 States Represented
- 26 Peer Reviewed journal publications
- 6 AHSQC Resident/fellow Research Grants Awarded
- 3 years in a row - Designated by CMS as a Qualified Clinical Data Registry
- 4 years - MOC part 4 recognition by American Board of Surgery
- 50 attendees at the Inaugural AHSQC Quality Improvement Summit
- Close to 1,000 hits on the ORACLE free online patient risk assessment tool

5 Years of Collaboration

**42,000
Patients**

320 Surgeons

40 States

**6
Resident/Fellow
Research Grants**

**26
Peer Reviewed
Publications**

**50
Attendees
Inaugural
QI Summit**

**1000
Hits on ORACLE**
AHSQC data-driven
patient risk assessment tool

4 yrs - MOC Part 4 American Board of Surgery
3 yrs - CMS Qualified Clinical Data Registry

MEMBERSHIP

Over the past 5 years, the AHSQC has grown to include real world data collected for quality improvement on over 42,000 patients by over 320 surgeons in 40 states across the United States.

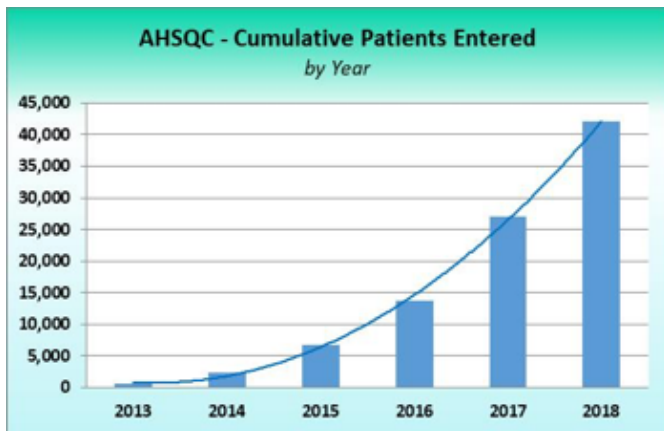
AHSQC member affiliation reflects the range of real-world practices including a representative mix of hernia surgeons in academic based and private practice settings.

The number of cases entered in the AHSQC continues to grow at a significant pace thanks to the dedication of actively engaged surgeons and their teams.

42,000
Patients

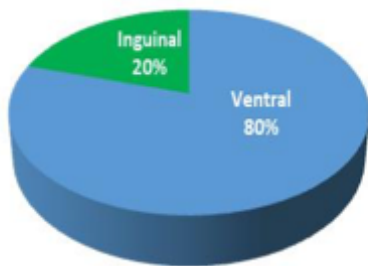
320
Surgeons

40
States



The number of cases entered in the AHSQC continues to grow at an significant pace thanks to the dedication of actively engaged surgeons and their teams.

Cumulative Patients Entered
by Hernia Type



The AHSQC began collecting data on inguinal hernia cases in 2017. At the close of 2018, inguinal cases now comprise 20% of all patients in the AHSQC registry.



"The data obtained from this Collaborative will engage surgeons... this is our way of learning how to best take care of our patients...and not somebody else telling us how to do it or why."

"The ability to track your own outcomes with risk adjustment in phenomenal"

SPOTLIGHT – OUR FIRST QUALITY IMPROVEMENT SUMMIT

The Americas Hernia Society Quality Collaborative convened its inaugural Quality Improvement Summit in the fall of 2018, setting the stage for a unique, highly interactive, clinically focused event. Featuring presentations by high performing AHSQC surgeons, the QI Summit gathered together a diverse group of over 50 participants who share a common goal – improvement of hernia patient care.

Designed to foster active collaborative engagement, surgeons were encouraged to assess their personal approaches alongside peers and were able to engage in individualized coaching sessions. Participants shared lessons, tips and tricks and left with actionable take-aways that could be implemented to impact the hernia patient experience.

As a testament to the exceptional value of the QI Summit to practicing hernia surgeons, in a post-meeting survey, **82% of surgeon respondents indicated they would change their practice when they returned home following the Summit.**

Through interactive discussions, QI Summit Consensus suggestions were developed which further explore methods to improve the patient experience. As part of the AHSQC mission, highlights and presentations from the QI Summit are available for all to view on the AHSQC website at <https://www.ahsqc.org/news/quality-summit>.

“Surgeons set a high bar before changing practice. By analyzing real world data from thousands of patients and hundreds of surgeons, the QI Summit offered an evidence-driven reason for quality improvement.”

- Ben Poulouse, MD, MPH
AHSQC Director for Quality & Outcomes

“It was gratifying to see anecdotal observations were validated through rigorous statistical assessment of our outcomes versus outcomes of the Collaborative as a whole. The opportunity to share approaches we’ve found to be beneficial with colleagues who face similar situations in their practices - and vice versa- was tremendously helpful.”

- Guy Voeller, MD, FACS



The AHSQC Quality Improvement Summit Consensus Statements

September 2018

PRE-OPERATIVE

- **Use of Prehospital Chlorhexidine Gluconate (CHG):** The use of prehospital CHG should be optional for ventral hernia repair as the results are equivocal at best for any benefit, with additional cost incurred with CHG use.

OPERATIVE

- **Fascial Closure Technique:** Any method of fascial closure can be used during ventral hernia repair paying close attention to technique. This technique involves approximation of fascial layers only while avoiding inclusion of subcutaneous fat or muscle in the closure.
- **Reducing Enterotomy Rates During Ventral Repair:** Multiple technical points can be used to minimize the risk of enterotomy. Bowel resection and anastomosis are favored compared to primary repair in more complex cases.
- **Open Retromuscular Ventral Repair:** Greater attention should be paid to prehabilitation and soft tissue handling techniques. Consideration should be given to the “no touch” mesh technique and antibiotic irrigation.
- **Open Onlay Ventral Repair:** The open onlay ventral hernia repair using a modified Chevrel (The Voeller) technique is a useful extraperitoneal repair with minimal need for enterolysis.
- **Robotic IPOM Ventral Repair:** Robotic IPOM offers another minimally invasive approach to routine ventral hernia repair with suture fixation perhaps avoiding some of the early post op discomfort of transfascial suture fixation in standard laparoscopic IPOMs. Ongoing randomized controlled trials within the AHSQC will provide further information on the actual reduction in pain with each approach.
- **Robotic Inguinal Hernia Repair:** The robot continues to show promise in allowing surgeons to perform a minimally invasive inguinal hernia. Further data is needed to understand the advantages over a standard laparoscopic inguinal hernia repair.
- **Laparoscopic Inguinal Hernia Repair:** Standardization of technique and adequately sized piece of mesh is necessary to reduce recurrence rates and improve outcomes.

POST-OPERATIVE

- **Reduction of Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE):** The use of the AHSQC protocol may reduce DVT/PE rates after ventral hernia repair. Complete use of all components of the protocol will be tracked in the AHSQC.
- **Opioid Reduction After Ventral Repair:** Optional, comprehensive data collection will be instituted to evaluate opioid use after ventral hernia repair.

CONTINUOUS QUALITY IMPROVEMENT

- **AHSQC Registry Based Randomized Controlled Trials:** Each year, suggestions will be made for topics amenable to the performance of a registry based randomized controlled trial.
- **Surgical Coaching:** AHSQC will partner with the University of Wisconsin to implement a surgical coaching program and to evaluate clinical outcomes as a result of the program.



PUBLICATIONS

The AHSQC is recognized worldwide as a source of high caliber clinically relevant information. In 2018, the collection of peer-reviewed publications utilizing analyses of the rich AHSQC data continued to grow and now includes 26 articles in high-impact journals.

Peer reviewed publications utilizing AHSQC data in 2018 include:

- **Hybrid robotic-assisted transversus abdominis release versus open transversus abdominis release: a comparison of short-term outcomes.** Halka JT, Vasylyuk A, Demare A, Iacco A, Janczyk R. *Hernia*. 2018 Nov 19. doi: 10.1007/s10029-018-1858-1. [Epub ahead of print]
- **Does active smoking really matter before ventral hernia repair? An AHSQC analysis.** Petro CC, Haskins IN, Tastaldi L, Tu C, Krpata DM, Rosen MJ, Prabhu AS. *Surgery*. 2018 Sep 13. pii: S0039-6060(18)30499-9. doi: 10.1016/j.surg.2018.07.039. [Epub ahead of print]
- **Patients Undergoing Parastomal Hernia Repair Using the Americas Hernia Society Quality Collaborative: A Prospective Cohort Study.** Gavigan T, Stewart T, Matthews B, Reinke C. *J Am Coll Surg*. 2018 Oct;227(4):393-403.e1. doi: 10.1016/j.jamcollsurg.2018.07.658. Epub 2018 Aug 4.
- **Immunosuppression is not a risk factor for 30-day wound events or additional 30-day morbidity or mortality after open ventral hernia repair: An analysis of the Americas Hernia Society Quality Collaborative.** Haskins IN, Krpata DM, Prabhu AS, Tastaldi L, Perez AJ, Tu C, Rosenblatt S, Poulouse BK, Rosen MJ. *Surgery*. 2018 Sep;164(3):594-600. doi: 10.1016/j.surg.2018.05.023. Epub 2018 Jul 18.
- **Impact of inadvertent enterotomy on short-term outcomes after ventral hernia repair: An AHSQC analysis.** Krpata DM, Prabhu AS, Tastaldi L, Huang LC, Rosen MJ, Poulouse BK. *Surgery*. 2018 Aug;164(2):327-332. doi: 10.1016/j.surg.2018.04.003. Epub 2018 May 27.
- **Reducing Early Readmissions after Ventral Hernia Repair with the Americas Hernia Society Quality Collaborative.** Poulouse BK, Harris DA, Phillips S, Janczyk RJ, Yunis J, Voeller GR, Carbonell A, Warren J, Stoikes N, Webb D, Hope WW, Rosen MJ; Americas Hernia Society Quality Collaborative. *J Am Coll Surg*. 2018 May;226(5):814-824. doi: 10.1016/j.jamcollsurg.2018.01.048. Epub 2018 Feb 8.
- **Quality Measures in Hernia Surgery.** Rosen MJ. *Surg Clin North Am*. 2018 Jun;98(3):441-455. doi: 10.1016/j.suc.2018.01.007. Review.
- **Comparison of hernia registries: the CORE project.** Kyle-Leinhase I, Köckerling F, Jørgensen LN, Montgomery A, Gillion JF, Rodriguez JAP, Hope W, Muysoms F. *Hernia*. 2018 Aug;22(4):561-575. doi: 10.1007/s10029-017-1724-6. Epub 2018 Jan 6. Review.

26
Peer Reviewed
Publications

PROFESSIONAL DEVELOPMENT

The AHSQC stands committed to ongoing professional development and offers participation in the AHSQC free of charge to all US based surgeons who care for hernia patients.

Over the past 5 years, the AHSQC has paved many pathways to deliver a wide range of opportunities to research, measure, and review quality metrics to enhance patient centered hernia care.

These include continued collaboration with academic, government and professional partners at the national level. For the third consecutive year, the AHSQC registry was recognized at the federal level as a Qualified Clinical Data Registry (QCDR) by the Centers for Medicare and Medicaid Services (CMS).

Beginning in 2018, AHSQC surgeons who participate in the national Merit-Based Incentive Payment System (MIPS) had the opportunity to use the AHSQC registry to report their clinically relevant quality metrics related to hernia outcomes. The AHSQC is also a quality improvement effort that fulfills the American Board of Surgery (ABS) Maintenance of Certification (MOC) Part 4 "Evaluation of Performance in Practice" requirement.

The AHSQC disseminates information widely to all stakeholders in the continuum of patient care. In addition to publications and presentations at the annual Quality Improvement Summit, in 2018, AHSQC participants shared findings at the Americas Hernia Society annual meeting and the American College of Surgeons Clinical Congress.



RESEARCH GRANTS

In 2018, the AHSQC Foundation continued our tradition of awarding two annual Resident/Fellow Research Grants. The AHSQC Resident/Fellow Research Grant is open to all resident and fellow members of the AHS, with a mentor who is an AHSQC member in good standing. The Grant is conferred on a competitive basis by submission of a Grant application that is reviewed and evaluated by the AHSQC Resident/Fellow Research Grant Review Committee.

2018 RESIDENT/FELLOW RESEARCH GRANT RECIPIENTS:

- Aldo Fafaj, MD (Cleveland, OH): "Registry-Based, Randomized Controlled Trial Comparing Intra-operative Foley Catheter Versus no Catheter for Minimally invasive Inguinal Hernia Repair"
- Ibnalwalid Saad, MD (Greenville, SC): "Perioperative Analgesia with Transversus Abdominis Plane (TAP) Block Versus Epidural Analgesia: Analysis from the Americas Hernia Society Quality Collaborative"



Dr. Benjamin Poulouse, AHSQC Director for Quality and Outcomes joins the AHSQC's 2017 Resident/Fellow Research Grant recipients following their research presentations at the 2018 International Hernia Congress.

STRATEGIC INITIATIVES

OPIOID REDUCTION

The opioid crisis in our country is widespread and cannot be ignored. According to the CDC, around 46 people die every day from overdoses involving prescription opioids.

A surgical patient's acute post-operative course can often include prescription of opioid medication. As a leader in hernia patient care, the AHSQC has the opportunity and responsibility to utilize our resource to help surgeons consider how to most appropriately manage their patients' post-operative pain.

"The AHSQC has an opportunity and responsibility to utilize our resources to help hernia surgeons address the current opioid epidemic in the US. The AHSQC should strive to minimize use of opioids through strategic data collection, analysis, and continuous quality improvement."

-Michael Reinhorn, MD Chair,
AHSQC Opioid Reduction Task Force



Chaired by Dr. Michael Reinhorn, in 2018 the AHSQC Opioid Reduction Task Force commenced work on expanding the AHSQC Registry to include an optional module designed to collect key data points including pre-operative risk factors, post-operative pain management techniques and 30-day patient reported utilization of opioid medication prescribed post-operatively. It is our hope that measurement and analyses of these data will allow the AHSQC to offer suggestions that may decrease the use of post-operative prescriptions while maintaining hernia patients' post-operative quality of life. Presentation of the initial results of a QI project using opioid reduction education efforts is anticipated in 2020.

FOCUS ON FOLLOW-UP

As the Collaborative continues to grow and develop, we are cognizant of the need to not lose sight of the fact that patient healthcare is a lifetime experience and our role in enhanced patient care continues long beyond the OR table.

Currently 30-day follow-up is captured on close to 90% of patients in the QC Registry, however our patients' journey doesn't end 30 days post-op. While some longer term follow-up is captured in the Registry, in order to assess longer term surgical outcomes and device performance, there is a great need for the collection of more clinically meaningful information years after surgery.

As part of the AHSQC's Focus on Follow Up, the AHSQC is performing several quality improvement efforts to collect more long-term patient reported outcomes measures including direct outreach using both internal and external clinical resources, and enhanced patient communications tools. Continued efforts to augment the collection of long-term patient follow-up in the AHSQC Registry are an ongoing priority and the results of our endeavors will be presented at upcoming Collaborative meetings.



PATIENT OUTREACH

Hernia patients are at the center everything we do at the AHSQC. Utilizing the wealth of data collected in our Registry, last year the AHSQC launched ORACLE - Outcomes Reporting App for CLinician and Patient Engagement tool. ORACLE offers a real-world prediction of identified risks associated with ventral hernia repair using mesh and can be completed by patients directly or in consultation with health care providers. Within the first year, the free, online tool had garnered close to 1,000 hits. The AHSQC encourages hernia patients to take an active role in understanding their individual risks regarding surgery and to discuss them with their surgeons. The use of ORACLE may assist in these conversations.

SPOTLIGHT – PARTNERSHIP AT THE FEDERAL LEVEL



The FDA has committed significant resources to create strategies and tools which would allow the use of real-world data to support and enhance pre-market and post-market decisions and surveillance efforts.

In a November 2018 statement on FDA's updates to the Medical Device Safety Action Plan, Commissioner Scott Gottlieb, MD and CDRH Director Jeff Shuren, MD detailed the agency's ongoing commitment to these initiatives designed to leverage real world data sources and actively generate information that portrays real world device performance. Included in this update, the FDA committed new resources to the National Evaluation System for health Technology.

The National Evaluation System for health Technology (NEST), is a diverse coordinated body with a mission to set real world data quality standards and offer value to stakeholders - patients, clinicians, payers, health systems, the FDA and the medical device industry.

Coordinated Registry Networks (CRNs)

A number of strategic coordinated registry networks (CRNs) have been developed with and in support of the NEST Coordinating Center and MDEpiNet to provide essential real-world data collected from across the health ecosystem.

Currently, there are 14 CRNs operating or under development, including the **Abdominal Core Health CRNSM**.

AHSQC has taken the lead in the Abdominal Core Health Coordinated Registry Network (CRN). Through this initiative, the AHSQC and our collaborators will spearhead projects focused on development and utilization of real world data by identifying and maintaining the common key variables important to hernia patients and patient outcomes.

This Abdominal Core Health CRN attempts to fill the knowledge gap related to post market surveillance of devices utilized in hernia surgeries with the goal of ensuring maximal effectiveness and minimal harm long term – particularly in vulnerable subpopulations.

“The promise of NEST is clear: real-time device safety information means better outcomes for patients who depend on devices to improve their health. We’re committed to making the promise a reality by prioritizing NEST’s development and ensuring it’s set up for long-term success to advance public health.”

- Scott Gottlieb, MD
FDA Commissioner

-Jeff Shuren, MD
Director of the Center for Devices and
Radiological Health

ABDOMINAL CORE HEALTH CRN COLLABORATING AGENCIES:

- FOOD AND DRUG ADMINISTRATION
- AMERICAS HERNIA SOCIETY QUALITY COLLABORATIVE (AHSQC)
- AMERICAS HERNIA SOCIETY (AHS)
- CLEVELAND CLINIC FOUNDATION
- OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER
- VANDERBILT UNIVERSITY MEDICAL CENTER
- CORNELL
- MDEPINET

FOUNDATION PARTNERS

It is with sincere appreciation and thanks that AHSQC recognizes our 2018 industry Foundation Partners who provide ongoing support, commitment and devotion to the AHSQC Foundation, hernia patients and their care teams. The support of Foundation Partners furthers our mission to enhance patient care and allows the AHSQC to continue to offer quality improvement programs and access to the AHSQC registry free of charge to hernia care teams across the country.

GOLD LEVEL



SILVER LEVEL

