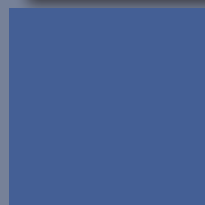


# AHSQC FOUNDATION ANNUAL REPORT 2016



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# PRESIDENT'S MESSAGE



The AHSQC has made significant progress this year thanks to the hard work, support and dedication of all our stakeholders. On behalf of the AHSQC leadership, I sincerely thank the patients, surgeons, FDA leaders and Foundation partners who have come together as a focused community dedicated to improving care and enhancing the practice of hernia surgery.

The AHSQC grew to over 13,000 cases in 2016, becoming a leading comprehensive data source for outcomes information. Keeping the patient at the forefront of our efforts, several easily implemented, quality improvement opportunities stemming from AHSQC analyses have been identified and were presented from the podium at the AHS Annual Meeting and the ACS Clinical Congress. Many have already been published in esteemed peer reviewed journals and we anticipate more to follow in the coming years.

The AHSQC remains focused on enhancing value to hernia surgeons and inherent in our mission is ongoing professional development. It is our hope that the AHSQC will ultimately become the source of truth, trusted to provide balanced, clinically meaningful answers to hernia related questions. In 2016, AHSQC funded two Resident/Fellow research grants for research related to ventral hernias utilizing the AHSQC data set. Recipients will present their research findings in March 2017 at the AHS Annual Meeting. The AHSQC has recently been recognized by the American Board of Surgery as a quality improvement effort satisfying the Maintenance of Certification Part 4 requirement. This is a significant landmark for us, as very few society based collaboratives have achieved that distinction.

This year brought AHSQC leaders to Washington to advocate for meaningful legislative programs which promote and support the delivery of healthcare, improve our patients' quality of life and assists us in delivering the highest level of service. The importance of real-world data as part of regulatory decision processes continues to evolve and the AHSQC has developed a strong relationship with representatives of the FDA who offer support and guidance. The AHSQC was recently endorsed as an MDEpiNet approved program, placing AHSQC among a select group to receive this designation. We look forward to working collaboratively with the MDEpiNet Public Private Partnership leadership to further our mission and strengthen our relationships with regulatory and private stakeholders.

On the development front, building on the momentum and lessons learned from the ventral hernia registry, the Collaborative set out this year to expand to other areas of hernia management. I'm pleased to share that the AHSQC Inguinal module was designed, built and beta tested in 2016. We look forward to introducing this module to the full membership in early 2017.

As 2016 comes to a close and I look ahead to 2017, I find myself filled with gratitude and awe at the power of Collaboration and what can be achieved through partnership, perseverance and commitment. I thank all of you who are current participants and partners in the AHSQC for your efforts and support this year. We have made tremendous progress and are poised for much more to come! I invite those who have questions or may be interested in joining the Collaborative on our journey to contact me directly.

A handwritten signature in black ink, appearing to read 'mf', with a long, sweeping underline.

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

# 2016 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

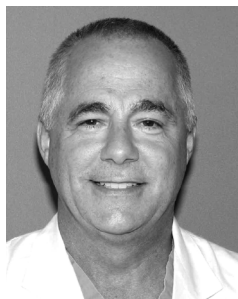
## MEMBERS AT LARGE



Ajita Prabhu, MD



Jake Greenberg, MD



Guy Voeller, MD



Stephen McNatt, MD



William Hope, 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

### INGUINAL HERNIA TASK FORCE

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

### QCDR TASK FORCE

Gina Adrales, MD, MPH  
J. Scott Roth, MD, MBA  
Jacob Greenberg, MD  
Dana Telem, MD, MPH  
Karl LeBlanc, MD, MBA  
Brent Matthews, MD  
Eric Pauli, MD  
Benjamin Poulouse, MD, MPH  
Kristi Harold, MD  
Guy Voeller, MD  
William Hope, MD

# MISSION

*To provide health care professionals real-time information for maximizing value in hernia care.*

## NOTABLE ACHIEVEMENTS

### THE AHSQC HIT A NUMBER OF NOTABLE MILESTONES IN 2016:

- Enrollment surpassed 13,000 ventral hernia cases

**13,715** Enrolled Patients



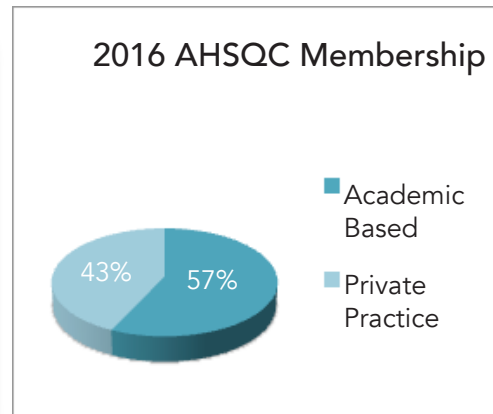
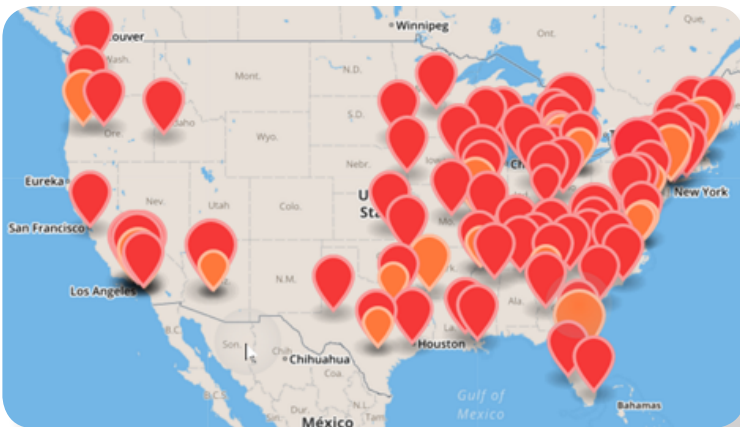
**193**

Participating Surgeons

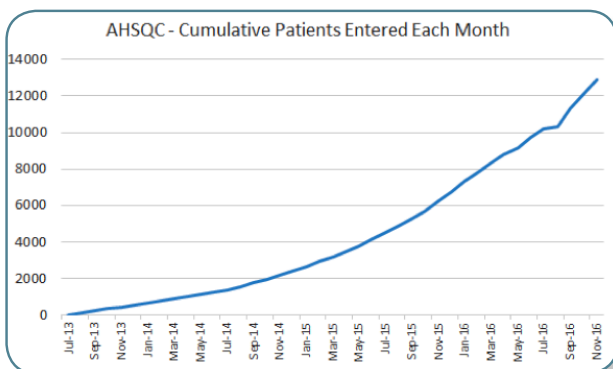
- Established and funded the AHSQC Resident/Fellow Research Grant Program
- Established AHSQC as a CMS QCDR (Qualified Clinical Data Registry)
- Improved value & quality of care through analyses of key metrics
  - Identified actionable ways to reduce wound events
  - Moved the needle in reducing early readmissions
  - Six Peer Reviewed Publications In Press
- AHSQC Endorsed as an MDEpiNet Approved Program
- Development of an Inguinal Hernia Module
- MOC part IV recognition by American Board of Surgery

# MEMBERSHIP

In 2016, the AHSQC continued to expand, with over 180 sites participating in the Collaborative. Participants are split 57% academic based and 43% private practice.

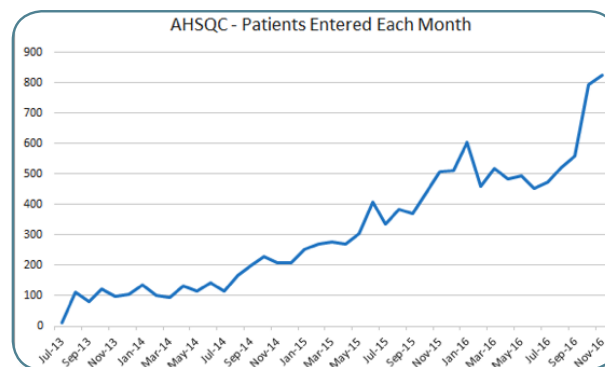


As participation grows, so does the Registry data set. The AHSQC ended 2016 with 13,715 subjects entered, representing 104% growth from December 2015.



*"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 adjustments is phenomenal."*



According to a mid-year surgeon survey, the ability to routinely measure performance and outcomes versus peers as well as participate in real-world research were key factors driving the majority of surgeons to join the AHSQC. An overwhelming majority (92%) of AHSQC participants would recommend joining to other hernia surgeons not yet members of the Collaborative. This is a strong testament to the usefulness of the AHSQC and the desire of hernia surgeons to enrich their practice through collaborative learning.

# QUALITY IMPROVEMENT INITIATIVES

## **NATIONWIDE AHSQC REDUCTION IN READMISSIONS INITIATIVE**

In an effort to identify best practices to reduce readmission rates, 30-day readmissions, a detailed analysis of cases entered between July 2013 – May 2015 was performed. Findings indicated that patient contact between discharge and 30-days seemed to play a role in reduced readmissions. To prospectively evaluate this observation, beginning in November 2015 the entire AHSQC was invited to participate in a quality improvement initiative which involved patient contact via a questionnaire or a clinic visit prior to 30-days. From November 2015-May 2016, 3007 patients were entered; 1242 receiving some form of contact prior to 30-days and 1765 not. A comparison of outcomes clearly indicated that questionnaire or clinic visit administered prior to routine 30 day post-op follow up reduces readmissions. Within the AHSQC alone, 29 readmissions were avoided, saving approximately \$337,270. Thus AHSQC now can provide a post-discharge, pre-30 day patient contact questionnaire and protocol to reduce readmission following ventral hernia repair.

## **ROBUST DATA ANALYSES**

The AHSQC encourages all participants to request AHSQC data reports for research and QI projects of interest across the continuum of the hernia patient's journey – from pre-operative assessment, the operative procedure and post-operative course. Each proposal is evaluated by independent reviewers to assure high caliber, well designed projects. Many AHSQC data requests result in national presentations at clinical meetings and ultimately peer reviewed journal publications.

In 2016, AHSQC surgeons presented findings and offered actionable suggestions to positively impact real world situations during dedicated clinical sessions at the 17th Annual Americas Hernia Society Meeting in March and the American College of Surgeons 2016 Clinical Congress in October. Additionally, manuscripts prepared from many of these projects were accepted in high impact peer reviewed publications this year.

## **AREAS OF IMPROVEMENT TO PATIENT OUTCOMES**

### **ROBOTICS**

Several analyses of robotic assisted hernia repair using AHSQC data have been performed. In elective Class I retromuscular repairs, when matched patient sets were evaluated, results indicated the length of stay (LOS) for robotic cases was significantly lower than LOS for open cases (mean 2.1 days vs 5.1 days). Additionally, no significant differences in wound outcomes or readmissions between the two groups were identified. Based on these findings, it is suggested that the benefit of robotic retromuscular VHR to reduce hospital stay should be taken into consideration when evaluating approaches for VHR in appropriate patients.

### **DRAINS**

An analyses of drain use in 1,100 patients (915 drains, 185 no drains) who underwent open retromuscular sublay VHR found that when adjusted for confounding variables, odds ratios reflected that retromuscular drain use was protective against Surgical Site Occurrences (SSOs) ( $p < 0.05$ ). A second analysis of a 2:1 matched cases (357 drains:182 no drains) demonstrated that drains are being used in more complex cases – patients with higher BMI, longer OR time, and TAR procedures. Analysis of matched groups noted no statistically significant differences in Surgical Site Infections (SSI), SSO or Surgical Site Occurrences requiring Procedural Intervention (SSOPI) rates. Thus use of drains – even in complex cases - does not convey an increased risk of wound complications- and retromuscular drain use may in fact be protective against SSOs such as cellulitis and seroma.

## **BOWEL PREP**

Analysis of bowel prep use in Class I hernia repairs compared outcomes using 3:1 matched groups finding that patients who received bowel prep had a significantly higher rate of post-operative Surgical Site Infections (SSI) and Surgical Site Occurrences (SSO). No difference in SSI/SSO rates was identified when comparing Class II/III hernia groups. Based on these findings, it appears that bowel prep can be safely avoided in pre-operative protocols in elective VHR.

## **CHLORHEXIDINE SCRUB**

The use of pre-hospital chlorhexidine gluconate (CHG) scrub was evaluated on 30-day post-operative wound events in 3,924 patients. Multiple analyses demonstrated that pre-hospital CHG was associated with a significant increase in wound events. This investigation has led to a compelling larger question: "Do we need to preserve 'good bacteria' of our skin microbiome to combat surgical site infections?"

## **MESH POSITION**

Mesh positioning options – onlay, underlay, sublay – remains a surgical preference with no strong rationale for selecting one method over the others. Evaluation of a matched cohort of patients within the AHSQC receiving onlay with fibrin glue fixation (90 patients) or sublay mesh placement (171 patients) found no significant differences in wound events (SSI, SSO, SSOPI) between the groups. While surgeon leaders believe in selected patients there may be advantages to utilization of the Chevrel approach with immediate adhesive fixation of the entire mesh, technique is critical and should be considered in appropriate situations.

## **EPIDURAL ANALGESIA**

The use of epidural analgesia in patients undergoing clean, open elective ventral hernia repair was evaluated with length of stay (LOS) and 30-day postoperative wound events assessed. Using propensity scores to balance variable factors between the epidural and non-epidural groups, outcomes from 1404 procedures were compared (707/group). Findings indicated the epidural analgesia was associated with increased LOS and greater risk of any postoperative complications, although clinically significant 30-day wound morbidity was not impacted.

## **ACTIONABLE CONCLUSIONS OF AHSQC ANALYSES:**

- Post-discharge, pre-30 day patient contact -via questionnaire or clinic visit –can significantly reduce readmissions following ventral hernia repair
- In 442 patients, robotic retromuscular repairs in Class I VHR was associated with reduced length of stay compared to open (2.1 days vs 5.1 days)
- In 1,100 patients, retromuscular drain use did not increase wound morbidity or mesh infections
- In 1,227 patients, bowel prep associated with increased SSI/SSO in wound Class I VHR, no effect on wound Class II/III VHR
- In 3,924 patients, pre-hospital chlorhexidine scrub associated with increased wound events in wound Class I VHR
- In 1404 patients undergoing clean elective ventral repairs, epidural anesthesia showed no benefit in length of stay

# PUBLICATIONS

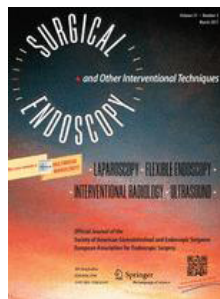
Many AHSQC data requests result in podium presentations at national clinical meetings and ultimately peer reviewed journal publications.

## PEER REVIEWED PUBLICATIONS UTILIZING AHSQC DATA IN 2016 INCLUDE:

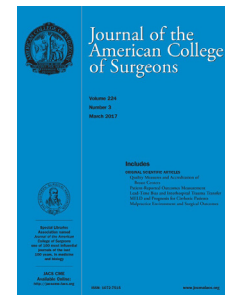
- Design and implementation of the Americas Hernia Society Quality Collaborative (AHSQC): improving value in hernia care. Poulouse BK, Roll S, Murphy JW, Matthews BD, Todd Heniford B, Voeller G, Hope, WW, Goldblatt MI, Adrales GL, Rosen MJ. *Hernia*. 2016 Apr;20(2):177-89. doi: 10.1007/s10029-016-1477-7.
- Standard laparoscopic versus robotic retromuscular ventral hernia repair. Warren JA, Cobb WS, Ewing JA, Carbonell AM. *Surg Endosc*. 2016 Jun 10. [Epub ahead of print]
- The clinical significance of postoperative tachycardia following ventral hernia repair. Haskins IN<sup>1</sup>, Krpata DM<sup>2</sup>, O'Rourke CP<sup>3</sup>, Rosenblatt S<sup>2</sup>, Rosen MJ<sup>2</sup>. *Surgery*. 2016 Aug;160(2):418-25. doi: 10.1016/j.surg.2016.02.030. Epub 2016 Apr 13.
- Using Quality Improvement Principles to Enhance Long-Term Completion of Patient-Reported Outcomes after Ventral Hernia Repair. Ganesh KN et al. *J Am Coll Surg*. 2016 Oct 20. pii: S1072-7515(16)31565-4. doi: 10.1016/j.jamcollsurg.2016.10.031. [Epub ahead of print]
- Does Preoperative Bowel Preparation Surgical Site Infections During Elective Ventral Hernia Repair? Krpata, DM et al. *J AM Coll Surg*. 2016 Nov 3. pii: S1072-7515(16)31595-2. doi: 10.1016/j.jamcollsurg.2016.10.049. [Epub ahead of print]
- Development of a Disease-based Hernia Program and the Impact on Cost for a Hospital System. Krpata DM, Haskins IN, Rosenblatt S, Grundfest S, Prabhu A, Rosen MJ. *Ann Surg*. 2016 Nov 30. [Epub ahead of print]



Hernia  
The World Journal of Hernia  
& Abdominal Wall Surgery



Surgical Endoscopy  
Journal of SAGES & EAES



Journal of the American  
College of Surgeons



Surgery  
Journal of the University Surgeons, Central  
Surgical Association & the American  
Association of Endocrine Surgeons



Annals of Surgery  
A Monthly Review of  
Surgical Science Since 1885

# PROFESSIONAL DEVELOPMENT

The AHSQC Foundation is honored to award Resident/Fellow Research Grants for research related to ventral hernias utilizing the AHSQC database. All resident and fellows in surgical training in North, Central or South America are eligible and invited to apply for this grant.

This year, the AHSQC Foundation awarded two Resident/Fellow Research Grants. Grant awardees will present their research findings at the AHS 18th Annual Hernia Repair Meeting in March 2017.

## 2016 GRANT RECIPIENTS:

- Dr. Ivy Haskins (Cleveland, Ohio)  
'Development and Validation of a Ventral Hernia Decision Support Tool using the AHSQC.'
- Dr. Thomas Gavigan (Charlotte, NC)  
'Prospective Cohort Study of Patients Undergoing Parastomal Hernia Repair using the AHSQC.'

## BOARD CERTIFICATION

In 2016, the AHSQC was recognized by the American Board of Surgery (ABS) as a quality improvement effort satisfying the Maintenance of Certification (MOC) Part 4 requirement. ABS MOC is a national, surgeon-defined program for staying up to date in surgical practice. MOC Part 4 requires ongoing participation in a local, regional or national outcomes registry or quality assessment program. The AHSQC is identified by the ABS as meeting the Essential Characteristics to measure practice performance outcomes. Few society based collaboratives have achieved this distinction.



# STRATEGIC EXPANSION

## INGUINAL HERNIAS

With over 700,000 inguinal hernia surgeries performed annually in the US, there are still many unanswered questions that rigorous assessment of real world data may address. Thus, the AHSQC embarked on development of an inguinal module. In 2016, the Inguinal Hernia Task Force, comprised of five hernia surgeons, worked diligently to design this module which focuses on the most important measures – surgical outcomes, pain and function. The inguinal module was beta-tested in the fourth quarter of the year and will be released to the full AHSQC membership in early 2017.

# ADVOCACY

AHSQC is committed to advocating for hernia surgeons and patients at the federal level. In just a few years, we have made measurable inroads in Washington. In 2016, our efforts focused on work with CMS and the FDA.

## CMS

In 2016, AHSQC was established as a CMS Qualified Clinical Data Registry (QCDR) and the AHSQC QCDR task force worked diligently to create 8 outcome measures specific to hernia surgery that could be used for value based payments. Individual providers and group practices who satisfactorily participate in 2016 PQRS (Physician Quality Reporting System) through a QCDR may avoid the 2018 negative payment adjustment (-2.0%) penalties with the upcoming value based payment model. As is often the case, third party payers and state Technical Advisory Groups may follow CMS and adjust their payment models to encourage reporting of outcome measures.

With the impending shift in 2017 from PQRS to the Merit based Incentive Payment System (MIPS), CMS recently reviewed all the metrics for Qualified Clinical Data Registries and suggested several substantive changes which we believed would erode the clinical relevance and benefit to patient care of our important quality metrics. As a group, we worked diligently to discuss, negotiate and address CMS' requests with substantial dialogue grounded in clinical insight and with our patients and colleagues in mind. Ultimately, our efforts were successful and nearly all of our quality measures were preserved and maintained appropriate risk adjustments to accurately stratify patient and operative risks.

## FDA

The value of robust, real-world data continues to garner significant attention and clinical registries are driving a new paradigm for the FDA for both post-market and premarket assessments.

Over the past several years, we have formed trusted relationships with representatives of the FDA, who share our desire to use real world data to enhance patient care. The AHSQC is honored to have representatives of the FDA sit as ex-officio members of the AHSQC Executive Council, working together with us to develop strategies and pathways which may incorporate AHSQC real world data in regulatory activities.

*"Clinical registries provide useful real-world data to inform health care providers in their clinical practice and help augment the FDA's understanding of the benefit-risk of medical devices."*

Binita Ashar, MD  
Director of the Division of Surgical Devices at the FDA's Center for Devices and Radiological Health.



# COLLABORATIVE ENGAGEMENT



The Medical Device Epidemiology Network Initiative (MDEpiNet) Public-Private Partnership is part of the Epidemiology Research Program (ERP) at the FDA's Center for Devices and Radiological Health (CDRH). MDEpiNet brings together leadership, expertise and resources to build and operate a national device ecosystem supporting the development, regulation, and use of innovative medical devices.

Mid-2016, the AHSQC submitted a proposal for consideration by the MDEpiNet Scientific Oversight Committee (SOC). The SOC found the AHSQC was well aligned with the MDEpiNet mission and recommended its approval to the Executive Committee. In its August 2016 meeting, the Executive Committee accepted the recommendation of the SOC, designating the AHSQC as an MDEpiNet PPP SOC approved program.

AHSQC is honored to be among a select group to receive this designation and will work collaboratively with the Public Private Partnership leadership to further our mission and strengthen our relationships with regulatory and private stakeholders.

## FOUNDATION PARTNERS

The AHSQC welcomes interested individuals, corporations, foundations, and hospital organizations involved in the management of hernia disease to partner with us. The support of Foundation Partners enables AHSQC to fulfill our mission to add value and positively impact the delivery of quality care for patients.

AHSQC sincerely thanks our 2016 industry Foundation Partners for their ongoing contributions, commitment and devotion to hernia patients and those who provide their care.

### 2016 FOUNDATION PARTNERS

#### PLATINUM:



#### GOLD:



#### SILVER:



# FINANCIALS

## 2016 FOUNDATION PARTNER FINANCIAL REPORT

### FP GRANTS: \$525,000

PARTICIPANTS	DECEMBER 31, 2015	DECEMBER 31, 2016
HOSPITALS:	154	227
SURGEONS:	142	193*
PATIENTS:	6,720	13,715

\* The AHSQC created a new policy to remove surgeons who are not entering patients into the AHSQC. After 3 warning emails and months without entering data, surgeons are removed. The AHSQC started removing surgeons at the end of 2015. This number reflects the surgeons both added and removed.

### EXPENSES AND PROGRAMS

#### PROGRAMS AND SERVICES

Research & QI Initiatives	\$ 259,084
Professional Development	\$ 69,772
Membership Engagement	\$ 80,719
Advocacy	\$ 66,100
Grants	\$ 25,000

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Total	\$500,675
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#### OPERATIONS

General Administration	\$ 142,079
IT Development and Maintenance	\$ 86,851
Legal	\$ 67,529
Fundraising / Development	\$ 58,032

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Total:	\$354,491
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Subtotal Operating Expenses:	\$ 855,166
Foundation Partner Reports:	\$ 120,000**
2015 FP Donative Revenue Carried over to 2016	\$ 34,995
2016 FP Donative Revenue Carried over to 2017	\$ (415,171)

\*\* of the \$525,000 in gifts made by Foundation Partners in 2016, \$120,000 of that amount was acknowledged as being the value of reports and data provided by AHSQC Foundation. This report does not include all of the expenses of AHSQC Foundation incurred in creating those reports such as additional consulting time and professional fees associated with producing those reports.