

Benjamin K. Poulouse, MD, MPH, FACS
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October 23, 2013

Dear SAGES Research Committee:

Please accept this grant proposal entitled: "**Cholelithiasis Management in America: Do Rural Surgeons Need Different Skills than Urban Surgeons?**" for review. As the responsible Co-PI for the proposed study, I agree to assume full responsibility for the grant should the Candidate Member leave Vanderbilt University Medical Center and be unable to transfer the grant in the event of a move.

We did submit similar proposals to SAGES in 2010 and 2012. Since the initial proposal, we have made significant changes. We have modified the survey extensively after multiple expert reviews and have performed a pilot study in the Nashville community testing the usability of the survey. In addition, we have performed a much more robust power and sample size calculation. The application process this year allows us to submit the survey instrument as an appendix to the application. Our team hopes these changes will result in a successful application. We are also excited to resubmit this proposal at a time when SAGES has renewed its focus on the management of common bile duct stones.

Sincerely,

A handwritten signature in black ink, appearing to read "Benjamin Poulouse". The signature is fluid and cursive, written in a professional style.

Benjamin K. Poulouse, MD, MPH

Statement of Funds

We currently do not have funds for this study. We have not submitted this proposal for other funding mechanisms.

Summary

Choledocholithiasis (CDL) management remains challenging even in the age of advanced laparoscopy and interventional endoscopy. Often, management is dictated by locally available resources and expertise rather than recognized best practices. Our previous work has identified a strikingly consistent variation pattern in CDL management: more operations and less endoscopic interventions are performed in rural communities. In urban areas however, less operations and more endoscopic interventions are performed. The main goal of this proposal is to ascertain why this variation exists and to target potential opportunities for improving access to less invasive techniques of CDL management.

We will evaluate why surgeons choose to manage preoperatively discovered CDL either by open common bile duct exploration (OCBDE), laparoscopic common bile duct exploration (LCBDE), or endoscopic retrograde cholangiopancreatography (ERCP). We will evaluate similar responses for CDL discovered incidentally at the time of cholecystectomy. The results of this research can help determine if surgeons in rural communities should strive to obtain additional training in laparoendoscopic techniques to manage CDL. In addition, these results may help policymakers target interventional endoscopic services to rural areas of the country.

We hypothesize that surgeons in rural communities are more likely to perform operative interventions than their urban counterparts for CDL. In order to test this hypothesis, a 22 item, web-based survey tool will be administered to general surgeons in the AMA Physician Masterfile. Surgeons will be contacted via email and the survey will be completed using Vanderbilt University's REDCap Survey system. Respondents will be classified into one of six NCHS urban-rural classes based on the location of their primary practice. These classes will be collapsed into 3 groups for analysis: metropolitan areas (NCHS 1-4), micropolitan areas (NCHS 5), and rural areas (NCHS 6). Exploratory analysis will be performed amongst the collected variables to assess consolidation of responses for simplification of analysis. Descriptive statistics and frequencies will be reported. Chi-square statistics and tests of correlation will be performed as appropriate.

Background

Current Problems in the Management of CDL and Significance

Cholelithiasis (CDL) management remains a challenging problem given the different methods available for treatment, accessibility to these interventions, and costs involved for unnecessary or inefficient care.² The precise role of common bile duct exploration (CBDE) in the age of ERCP still remains to be defined. Usually, patients obtain care near home for benign gallstone pathology, as cholecystectomy remains one of the most common procedures performed by general surgeons in the United States. Rural surgeons are often called upon to manage complex CDL patients with limited resources and training specific to this disease process.^{3,4} In addition, interventional endoscopic care may not be readily available to these surgeons unlike their urban counterparts. As such, identifying CDL management differences and the reasons for these differences could help target interventions to reduce this variation and improve care.

Prior Studies Evaluating Urban-Rural Influence on Management of CDL

To date, only a single study has attempted to address the issue of rural influences on the management of CDL. Bingener et al. administered a survey to 207 rural surgeons in Texas with a 33% response rate.⁵ The preferred approach to manage suspected CDL was reported as ERCP (73%), followed by LCBDE (22%) and OCBDE (5%) with a very similar distribution for unsuspected stones. The two most popular reasons for not performing LCBDE were the time-consuming nature and lack of available equipment. The sole factor predictive of increased performance of LCBDE was a high volume (>50 per year) of laparoscopic cholecystectomy.

Although this study does provide a glimpse into how CDL is managed in rural areas, its inferential validity and generalizability is limited. Given such a small sample in south Texas, it is impossible to generalize results to all rural surgeons. No comparison group of urban surgeons was surveyed, greatly limiting the conclusions. Finally, no information from the non-respondent group was obtained. This would be important to determine if the respondents themselves were somehow biased to complete the survey. This study still leaves a sizable knowledge gap to be addressed.

Preliminary Studies/Progress Report

Our group has performed an initial evaluation of access to surgical and endoscopic care for CDL in the United States.⁶ Patients undergoing inpatient management of CDL in 2007 were identified from the Healthcare Cost and Utilization Project inpatient database. Hospital characteristics, including availability of ERCP, were determined from the 2007 American Hospital Association survey. The proportion of ERCP or CBDE interventions for CDL was determined and compared across U.S. census regions and NCHS urban-rural classes.

Of approximately 111,000 hospitalizations for CDL, 67% had an intervention performed with similar frequencies across census regions. Comparisons across NCHS classes revealed higher proportions of ERCP in metropolitan areas (NCHS 1-4) while a higher proportion of CBDE was seen in micropolitan and rural areas (NCHS 5 and 6, **Figure 1**). ERCP availability was higher in metropolitan areas (available in 35%-44% of NCHS 1-4 hospitals) than in micropolitan and rural areas (25% of NCHS 5 and 5% of

NCHS 6 hospitals). Percutaneous management was similar. From this study, we concluded that rural hospitals and communities need surgeons trained in CBDE techniques, where ERCP may not be readily available. More importantly, this study raised several questions: Why do rural surgeons perform CBDE more often than urban surgeons? How does performance of LCBDE impact this difference? Should more effort be spent in targeting interventional endoscopy in rural areas? Answers to these questions may have an impact on the goals of surgical training. This proposal directly hopes to address these critical questions.

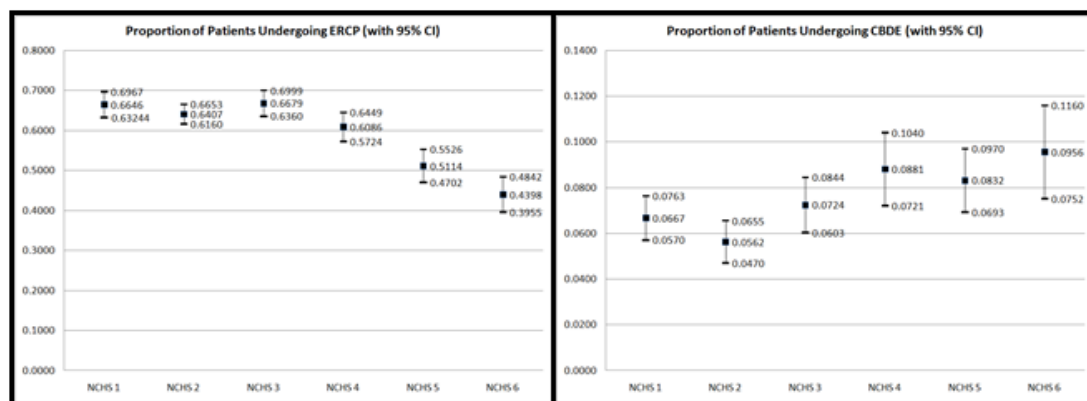


Figure 1 – Proportion of patients undergoing ERCP and CBDE for CDL in 2007 Healthcare Cost and Utilization Project inpatient database. In rural areas (NCHS 1) a significantly reduced proportion of endoscopic interventions were performed for CDL compared to urban areas (NCHS 6).

Pilot Study

We have performed a pilot study testing the usability of the survey locally. Clinical faculty in the general surgery departments at Vanderbilt University Medical Center, Nashville VA Medical Center, Williamson Medical Center, and St. Thomas Hospital were surveyed in an initial effort to quantify practice patterns in the greater Nashville area. Eight-two individuals were contacted by email and 17 completed the survey (20.7%). Respondents ranged in age from 31 to 64 years old and have been in practice for an average of 13 years. Fifteen respondents were male and 2 were female.

As expected, the majority of respondents prefer to manage CDL by referral for pre- or postoperative ERCP. Of note, a high percentage of respondents (29.4%) identified LCBDE as the preferred method for managing incidentally discovered CDL despite 100% ERCP availability at their home institution. Respondents overwhelmingly identified lack of comfort with performing the procedure as a limiting factor in performing LCBDE when indicated (70.6%). Additionally, lack of appropriate equipment (35.3%), time constraints (23.5%), lack of support staff (11.8%), insufficient reimbursement (5.9%), increased morbidity (5.9%), and size of stone (5.9%) were influential. Fear of losing referrals for not referring out for ERCP was not influential. These results may reflect the highly academic nature of the sample population since all individuals surveyed practice in a university hospital or university-affiliated community hospital.

Hypothesis

We hypothesize that surgeons in rural communities are more likely to perform operative interventions for CDL than their urban counterparts, and that this is due to resource availability. Two specific aims are derived from this hypothesis:

Specific Aim 1: Using a national web-based survey, determine whether a difference exists between urban and rural management of CDL.

Specific Aim 2: Determine factors that influence the preference of CDL management of practicing general surgeons.

Methods

Design Summary

A 22 item, web-based survey tool will be administered to general surgeons in the AMA Physician Masterfile. Surgeons will be contacted via email and the survey will be completed using Vanderbilt University's REDCap Survey system. Respondents will be classified into one of six NCHS urban-rural classes based on the location of their primary practice. These classes will be collapsed into 3 groups for analysis: metropolitan areas (NCHS 1-4), micropolitan areas (NCHS 5), and rural areas (NCHS 6). Descriptive statistics and frequencies will be reported. Chi-square statistics and tests of correlation will be performed as appropriate.

Survey Inception and Design

Given the lack of a standardized centralized database that could provide reliable information to address the specific aims of this project, a national survey was chosen as the methodology for implementation. Administrative datasets, although rich in information, do not reflect the reasons why certain management options were chosen. As such, a survey design was chosen with prospective collection of data. To this end, iterative focus groups were conducted at our institution over a 6 month period with participation from our minimally invasive General Surgery faculty, senior surgical residents, and medical students to help formulate survey items to address the hypothesis and specific aims. After 6 rounds of refinement, a 22 item survey was developed addressing items of surgical experience, endoscopic experience, resources available, technical factors, training, and demographics (see survey instrument). All 22 survey items are required for completion with an optional prompt for the respondent's email address and entry into a raffle. One question (survey item 7) uses branching logic that will enable a follow-up question (survey item 7b) depending upon the original response.

Targeted Population

The population of interest to complete this survey will be practicing surgeons designated as either 'General Surgeons' or 'Abdominal Surgeons' in the AMA Physician Masterfile. Access to the AMA Physician Masterfile is facilitated by Direct Medical Data, which acts as the clearinghouse for AMA data. Surgeons in all 50 states and territories of the United States and the District of Columbia will be invited to participate. Currently 24,694 surgeons have valid email addresses within the Masterfile; this represents 76.3% of 'General' or 'Abdominal' surgeons.

Survey Procedures and Data Collection

Direct Medical Data (DMD) will be sent the text of the introductory email (see survey instrument). The introductory email will be sent as an initial email blast by DMD to surgeons with valid email addresses. The email will contain a link which will send participants to the Vanderbilt REDCap web-based survey system where survey responses will be managed. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.⁷ Participants will complete the 3-5 minute survey and will then be presented an option to enter a raffle for a \$500 Visa gift card as an incentive for participation. Participation in the raffle is optional and the winner will be selected at random.

Two weeks after the initial email blast, a second email blast will be sent to those who did not click on the link sent in the first email blast. Participants who did complete the survey will not be sent a second email. After an additional two weeks, response rates will be assessed and if greater than 20%, the survey will be closed. If less than 20% response still remains, another 2 weeks will be allowed for survey completion.

Potential Limitations and Possible Solutions

Several potential limitations will be taken into consideration with this study. First, the study design itself (i.e. administered survey) does not produce inferential validity similar to randomized controlled trials or well-designed cohort studies. However, the methods used in this study are felt to be the only feasible way of obtaining information from such a wide range of general surgeons in a reasonable period of time. In addition, the survey method allows investigation of reasons behind decisions made by caregivers. This would be very difficult, if not impossible, to achieve with traditional study methods. Self-reporting of procedural volumes can overestimate or underestimate the true numbers of a particular procedure performed. We anticipate a higher chance of overestimation with this particular group surveyed, however we do not expect these differences to vary between urban and rural surgeons. As such, the relative differences between the two groups should still be maintained. In addition, the survey is designed to force the choice between ranges of procedural volumes which should minimize misreporting to some degree.

Given the electronic nature of the survey administration, the respondents may be a group more biased toward high technology applications and services. The AMA Masterfile has 76.3% of email addresses for 'Abdominal' or 'General' surgeons. It is within reason that this group of individuals would be more likely to perform "higher technology operations" (i.e. laparoscopic common bile duct exploration) than those surgeons who do not routinely use email or other technology intensive services. We recognize this as an essentially unavoidable bias as the alternative would be a paper and mail administered survey. The latter would likely have a much lower response rate and data integrity would be difficult to ensure. As such, we accept this bias with the assumption that both rural and urban surgeons have similar access to email. We do feel that contacting 76.3% of general surgeons will produce a reliable sample. At the time of

study initiation, it is expected that an even higher proportion of email addresses will be obtained.

Although we expect at least a 20% response rate, there is a chance that a smaller percentage would be achieved. Assuming a 'worst case' scenario of 10% response rate, we would still achieve 2,469 estimated responses. We will have ZIP code information on the non-respondents as well and can characterize differential non-response by NCHS classes to help determine if there was a response bias from urban or rural surgeons.

Study Timeline

Step 1 involves finalization of the survey tool, webhosting, and two email blasts to general surgeons (1.5 months). In step 2, data synthesis will incorporate data gathered from specific aims and classification of respondents by NCHS class (9 months). Step 3 proceeds with descriptive statistics, analysis of proportions, and correlations (3 months). Reports and manuscript preparation will be performed in Step 4 (4.5 months).

Sample Size Justification and Statistical Analysis Plan

To correctly assign NCHS class for each completed survey, individual ZIP codes collected from survey data (survey item 14) will be mapped to county-level Federal Information Processing Standard (FIPS) codes. This will be accomplished using software from CD Light LLC at www.zipinfo.com. The county level FIPS codes will then, in turn, be categorized into NCHS classes 1 (most urban) through 6 (most rural) using public access data files from the Center for Disease Control and Prevention NCHS website http://www.cdc.gov/nchs/data_access/urban_rural.htm#resources. At the conclusion of this data processing step, a fully analyzable file of all completed surveys will result. These classes will be collapsed into 3 groups for analysis: metropolitan areas (NCHS 1-4), micropolitan areas (NCHS 5), and rural areas (NCHS 6).

We will begin with an exploratory analysis of survey item responses to determine if multiple response items can be condensed into simpler groupings. For example, items 1-6 include 5 ordinal responses; if this many responses are not needed, the data will be collapsed into a smaller group of responses while maintaining the ordinal nature of the item. Data analyses will include descriptive statistics (proportion of respondents by response options) for demographic characteristics, ZIP code (of primary practice), training, and practice-related questions (e.g. items 1 – 8). Potential differences in the clinical management of common bile duct stones: item 9 (5 discrete response options) and item 10 (4 discrete response options) will be tested using the chi-square statistic. Tests of correlation will be performed as appropriate.

In terms of the original hypothesis and specific aims of this study, rural surgeons will be compared to urban counterparts based on NCHS classification. The responses to survey items 9 and 10 serve as the crucial outcomes pertinent to specific aims 1 and 2, respectively. These items ask surgeons about their preferred method of managing CDL either preoperatively or incidentally discovered at the time of cholecystectomy. All other items essentially serve as covariates to help determine the influence of surgical experience, endoscopic experience, resources available, technical factors, training, and demographics on these outcome measures.

Power Calculation

To estimate power for this study, we assume a total response rate of at least 20% of our targeted population (n=24,694) based on prior surveys administered to surgeons.^{8, 9} These prior surveys had response rates ranging from 23-72%. King et al. reported that surgeons in a typical U.S. population area included 71.1% practicing in metropolitan areas (NCHS 1-4), 21.1% in micropolitan areas (NCHS 5), and 7.7% in rural areas (NCHS 6).¹⁰ We assume that the smallest overall response will be from rural surgeons and base our power calculation on this group. Based on the anticipated minimum response rate of 20%, published data that indicate about 8% of likely respondents will come from rural areas, and expected patterns of clinical management preferences by practice setting (see attached power calculations), this sample will provide adequate power (>95% at the 0.05 alpha level) to detect an effect size of 0.12 – 0.27, i.e. a small to medium effect.

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November 19, 2010

Benjamin K. Poulouse, M.D.,MPH
General Surgery - Medicine
D-5203 MCN 37232-2637

William J. Lee, MS

Nashville, TN

RE: IRB# 101468 "Choledocholithiasis Management Variation in America: Do Rural Surgeons Need Different Skills than Urban Surgeons?"

Dear Benjamin K. Poulouse, M.D.,MPH:

A designee of the Institutional Review Board reviewed the Request for Exemption application identified above. It was determined the study poses minimal risk to participants. This study meets 45 CFR 46.101 (b) category (2) for Exempt Review. Approval is extended for the Request for Exemption application dated 11/4/2010.

Any changes to this proposal that may alter its exempt status should be presented to the IRB for approval prior to implementation of the changes. In accordance with IRB Policy III.C, amendments will be accepted up to one year from the date of approval. If such changes are requested beyond this time frame, submission of a new proposal is required.

DATE OF IRB APPROVAL: 11/19/2010

Sincerely,

Erin L Hutchins, BS
Behavioral Sciences Committee

ELH/elh

Electronic Signature: Erin L Hutchins/VUMC/Vanderbilt : (806F9C80B5EFE3CF281478F3A1615582)

Signed On: 11/19/2010 10:32:51 AM CST

Available Resources

Key Study Personnel:

Benjamin K. Poulouse, MD, MPH (Principle Investigator) is an MD graduate of the Johns Hopkins University School of Medicine who also holds a Master of Public Health degree from Vanderbilt University. He is an active, fellowship-trained General Surgeon at Vanderbilt University Medical Center with specialty interest in abdominal wall reconstruction and hernia repair. Dr. Poulouse has a robust clinical practice in General Surgery, and his research efforts focus on Health Services Research in General Surgery with an emphasis on quality improvement, cost-effectiveness analysis, and comparative effectiveness. Dr. Poulouse is the founder and director of the Vanderbilt Procedural Outcomes Database that serves to integrate administrative data, patient-centered data, cost data, and health utility/quality of life data using an Enterprise Data Warehouse approach. As PI on the proposed project, he will have responsibility for the overall direction and administration of the project, coordinating its various phases, and orchestrating the efforts of all personnel involved.

Rebecca B. Baucom, MD (Research Fellow) is an MD graduate of the University of Texas Southwestern Medical School at Dallas where she finished near the top of her class. She has completed three years of General Surgery at Vanderbilt University Medical Center and one year of dedicated research. She has already demonstrated great clinical intuition, as well as a strong interest in research and academic medicine. During her time at UT Southwestern, she participated in basic science research. As she has spent more time in patient care, her interests have grown in the area of health services research. For the proposed project, she will serve as the study contact, and she will be responsible for survey distribution, data collection, analysis and publications. She will have 100% protected time to devote to her research, and the Department of Surgery is committed to providing any additional support that is necessary for the completion of this project.

Irene Feurer, PhD (Research Professor of Surgery) is a graduate of the University of Pennsylvania where she received her Masters in Health Professions Education and completed a PhD in Measurement, Evaluation, and Techniques of Experimental Research. She joined the faculty at Vanderbilt in 1997 and has been a Research Professor of Surgery since 2003. She currently serves as the Director of Quantitative Services and Outcomes Research and is an active member of the Center for Surgical Quality and Outcomes Research at Vanderbilt University. She independently collaborates as a member of research teams, and assists with design, implementation, analysis, and publication of research. She will provide statistical expertise for this project, and was instrumental in development of the survey tool for the pilot study. She will participate in data verification as well as intensive analysis for the project.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Benjamin K. Poulouse, MD, MPH		POSITION TITLE Assistant Professor, Vanderbilt University Medical Center, Department of Surgery	
eRA COMMONS USER NAME POULOSBK			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	B.S.	1994	Biology
Johns Hopkins University School of Medicine, Baltimore, MD	M.D.	1999	Doctor of Medicine
Vanderbilt University School of Medicine, Nashville, TN	M.P.H.	2005	Master of Public Health

A. Personal Statement

I am an active general surgeon and health services researcher. I work in a busy surgical practice in an academic setting that is committed to excellence in patient care, research, and teaching. I see patients every week with abdominal wall hernia, foregut, and biliary disease. My research has focused heavily on health services research and epidemiology in efforts to help improve the real-world care of surgical patients. My practice and my Department are committed to our efforts within the Vanderbilt Surgical Health Services Research group. We have successfully mentored both medical students and surgical residents pursuing academic careers. As a successful clinician-researcher, I have developed several relationships that lend itself well to clinical research as it is easy for me to access colleagues who are stakeholders for patient advocacy, health care providers, insurance companies, hospital administrators, industry, and professional societies. Most importantly, I am very fortunate to work in a collegial and innovative research environment with so many talented people who are experts in their respective fields of stakeholder engagement, epidemiology, bioinformatics, biostatistics, and qualitative methods.

B. Positions and Honors**Positions and Employment**

1993-1994 Cancer Education Fellow, University of North Carolina at Chapel Hill, Chapel Hill, NC
 1997-1998 Predoctoral Research Fellow, Johns Hopkins University School of Medicine, Baltimore, MD
 1999-2000 Internship in General Surgery, Vanderbilt University Medical Center, Nashville, TN
 2002-2005 Fellowship in Surgical Research, Vanderbilt University Medical Center, Nashville, TN
 2003-2005 Health Services Research Fellowship, Vanderbilt University School of Medicine
 2001-2007 Residency in General Surgery, Vanderbilt University Medical Center, Nashville, TN
 2007-2008 Fellowship in Minimally Invasive Surgery and Surgical Endoscopy, University Hospitals Case Medical Center, Cleveland, OH
 2008- Assistant Professor, Department of Surgery, Vanderbilt University Medical Center, Nashville, TN

Other Experience and Professional Memberships

1992-1994 Undergraduate Research in Cancer Biology, University of North Carolina at Chapel Hill, Chapel Hill, NC
 1995 Predoctoral Research in Microbiology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India
 2008-present Active Member, Society of American Gastrointestinal Endoscopic Surgeons
 2008-present Associate Fellow, American College of Surgeons
 2008-present Fellow, Southeastern Surgical Congress

Honors

- 1990 Phi Eta Sigma Freshman Honor Society
1990-1994 Dean's List, University of North Carolina at Chapel Hill, Chapel Hill, NC
1993 Phi Beta Kappa
1994 Bachelor of Science (Biology) with Highest Distinction and Highest Honors, University of North Carolina at Chapel Hill, Chapel Hill, NC
2002 H. William Scott, Jr. Research Scholarship in Surgery, Vanderbilt University School of Medicine, Nashville, TN
2007 Alfred Blalock Surgical Resident Award, Vanderbilt University School of Medicine, Nashville, TN

C. Selected peer-reviewed publications (in chronological order)

- 2005** Grogan EL, Morris JA, Moore DE, Dittus RS, Poulose BK, Diaz JD, Speroff T. Plain Films Should be Eliminated in the Evaluation of the Cervical Spine in Urban Trauma Centers : Results from Decision Analysis Using an Institutional Cost Perspective. *Journal of the American College of Surgeons*, 200:160-165, 2005.
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- 2006** Poulose BK, Arbogast PG, Holzman MD. National analysis of in-hospital resource utilization in choledocholithiasis management using propensity scores. *Surgical Endoscopy*, 20:186-190, 2006.
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2012 Shelton J, Kummerow K, Phillips S, Griffin M, Holzman MD, Nealon W, Pinson CW, Poulose, BK. An Urban-Rural Blight? Choledocholithiasis Presentation and Treatment. *Journal of Surgical Research*, 173 :193-197, 2012.

Kummerow K, Shelton J, Phillips S, Holzman MD, Nealon W, Beck W, Sharp K, Poulose BK. Predicting Complicated Choledocholithiasis. *Accepted to the Journal of Surgical Research*, 2012.

Principal Investigator/Program Director (Last, First, Middle):

Poulose BK, Shelton J, Phillips S, Moore DE, Nealon W, Penson D, Holzman MD.
Epidemiology and Cost of Ventral Hernia Repair: Making the Case for Hernia Research.
Hernia, 16:197-183, 2012.

D. Research Support

Completed Research Support

Health Services Research Fellowship 7/1/2003 – 6/30/2005
T32, HS 13833-01

Vanderbilt University School of Medicine, Nashville, TN

Role: Health Services Research Fellow

Principal Investigator: Marie R. Griffin, M.D., M.P.H.

Provided salary support for two years and 60% tuition for Master of Public Health degree

Natural Orifice Surgery Consortium for Assessment and Research 7/1/2008-6/30/2009
Cost Effectiveness Analysis of Transgastric Cholecystectomy, Transvaginal Cholecystectomy, and
Laparoscopic Cholecystectomy: Projected Long Term Outcomes and Complications Evaluation
University Hospitals Case Medical Center, Department of Surgery, Cleveland, OH
Vanderbilt University School of Medicine, Nashville, TN
Role: Principal Investigator
\$20,000

Current Research Support

Karl Storz, U.S.A. 10/1/2011-

Barriers to Microlaparoscopy

Vanderbilt University School of Medicine, Nashville, TN

Role: Principal Investigator

\$48,000

American Hernia Society 7/1/2012-6/30/2013
Prospective Randomized Trial of Biologic Mesh versus Synthetic Mesh for the Repair of Complex Ventral
Hernias
University Hospitals Case Medical Center, Cleveland, OH and Vanderbilt University School of Medicine,
Nashville, TN, Departments of Surgery
Role: Co-Investigator (Principal Investigator Michael Rosen, M.D.)
\$25,000

Vanderbilt Initiative in Surgery and Engineering 7/1/2012-6/30/2013
Towards an Image Guided Classification System for Ventral Abdominal Wall Hernia
Vanderbilt University School of Medicine, Department of Surgery, Nashville, TN
Role: Principal Investigator; (Co-Investigator Bennett Landman, Ph.D, Department of Biomedical Engineering)
\$35,000

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Baucom, Rebeccah B.	POSITION TITLE General Surgery Research Fellow		
eRA COMMONS USER NAME (credential, e.g., agency login) BAUCOMR			
<i>EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Texas A&M University, College Station, TX	BS	05/05	Mathematics
UT Southwestern Medical Center, Dallas, TX	MD	06/09	Medicine

A. Personal Statement

The proposed research project aims to determine whether a difference exists between urban versus rural management of choledocholithiasis. I am fortunate to be a surgery resident at an academic institution committed to excellence in clinical training as well as patient care. Additionally, I have the support of the General Surgery Department at Vanderbilt University Medical Center to have two years of 100% devoted research time. My qualifications demonstrate that I have the motivation and aptitude to complete the proposed project. While in my junior clinical years as a General Surgery resident, I successfully published a review article on the surgical management of Hereditary Nonpolyposis Colorectal Cancer (HNPCC). As a research fellow at UT Southwestern I participated in research involving corneal transplantation in mice. This required meticulous attention to detail, as well as dedication to develop the initial protocol for the project. I have demonstrated that I have the qualifications necessary to complete the proposed project, including clinical aptitude, attention to detail, dedicated research time, and motivation.

B. Positions and Honors

Positions and Employment

2006 Medical Student Research Fellow, UT Southwestern Medical Center
 2008-09 Tutor, Human Anatomy and Medical Physiology, UT Southwestern Medical Center
 2009- General Surgery Resident, Vanderbilt University Medical Center
 2012- General Surgery Research Fellow, Vanderbilt University Medical Center

Professional Memberships

2005- Member, Phi Beta Kappa
 2009- Member, Alpha Omega Alpha
 2009- Member, American Medical Association
 2009- Resident Member, American College of Surgeons
 2012- Candidate Member, Society of American Gastrointestinal and Endoscopic Surgeons
 2013- Candidate Member, American Society of Colon and Rectal Surgeons

Awards and Honors

2005-07 Southwestern Medical Foundation Scholarship
 2011-12 Lester F. Williams, Jr. Research Scholarship

C. Selected Peer-reviewed Publications

Publications

1. Xu Z, Allen WM, Baucom RB, Poulouse BK, Landman BA. *Texture Analysis Improves Level Set Segmentation of the Anterior Abdominal Wall*. Med Phys (accepted). 2013.
2. Baucom RB, Wise PE. *Endoscopic and Surgical Management of Hereditary Nonpolyposis Colorectal Cancer*. Clin Colon Rectal Surg 2012;25:90-96.
3. Robertson DM, Kalangara JP, Baucom RB, Petroll WM, Cavanagh HD. *A reconstituted telomerase-immortalized human corneal epithelium in vivo: a pilot study*. Curr Eye Res. 2011 Aug;36(8): 708-12.

D. Research Support

No current or previous research support.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Feurer, Irene Debra		POSITION TITLE Research Professor of Surgery and Biostatistics	
eRA COMMONS USER NAME (credential, e.g., agency login) FEURERID			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Ursinus College, Collegetown, PA	B.S.	06/76	Biological Sciences
University of Pennsylvania, Philadelphia, PA	M.S.Ed.	05/83	Health Professions Education
University of Pennsylvania, Philadelphia, PA	Ph.D.	05/97	Measurement, Evaluation, and Statistical Methods

A. Personal Statement

The primary aim of this proposal is to ascertain variables associated with variations in the management of choledocholithiasis, particularly factors contributing to differences in the use of operative and endoscopic methods. I have broad experience in research design, statistical methods, and person-reported outcomes research. Additionally, I collaborated with Dr. Poulouse in the early development of the proposed study and would be pleased to participate in this project.

B. Positions and Honors

Positions and Employment

- 1976-79 Upper school instructor in mathematics and science, The Stevens School, Philadelphia, PA
- 1979-85 Coordinator, Metabolic Testing Services, Clinical Nutrition Center, Hospital of the University of Pennsylvania, Philadelphia, PA
- 1985-88 Education Specialist, Clinical Nutrition Center, Hospital of the University of Pennsylvania
- 1988-90 Associate Director, Graduate Medical Education Division, Department of Surgery, University of Pennsylvania
- 1990-92 Research Coordinator for Practice Guidelines, American Psychiatric Association, Washington, DC
- 1995-2000 Statistician, John F. Kennedy Center for Research on Human Development (NICHD-funded Mental Retardation Research Center), Vanderbilt University, Nashville, TN
- 1997-2000 Research Assistant Professor of Psychiatry, Vanderbilt University School of Medicine
- 2000- Director of Quantitative Services and Outcomes Research, Vanderbilt Transplant Center
- 2000-03 Research Associate Professor of Surgery, Vanderbilt University School of Medicine
- 2001-03 Research Associate Professor of Preventive Medicine, Division of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN
- 2003- Research Professor of Surgery, Vanderbilt University School of Medicine, Nashville, TN
- 2003-06 Research Professor of Preventive Medicine, Vanderbilt University School of Medicine
- 2004- Research Professor of Biostatistics, Vanderbilt University School of Medicine, Nashville, TN
- 2004- Faculty Statistician, Vanderbilt-Ingram Cancer Center, Nashville, TN
- 2008- Adjunct Professor of Nursing (Research), Vanderbilt University School of Nursing, Nashville, TN

Other Experience and Current Professional Memberships

- 1993- Member, American Psychological Association
- 2001- Member, American Statistical Association (Secretary, 2002 and President, 2003, Middle Tennessee Chapter)
- 2001- Member, Americas Hepato-Pancreato-Biliary Association
- 2005- Member, *ad hoc* expert panel on quality of life measurement, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
- 2005- Member, clinical study planning and oversight committee, "Islet Transplantation in Type 1 Diabetic Kidney Allograft Recipients: Efficacy of Islet after Kidney Transplantation", NIDDK, NIAID, and Juvenile Diabetes Research Foundation
- 2009- Member, International Hepato-Pancreato-Biliary Association
- 2009- Member, Vanderbilt Center for Surgical Quality and Outcomes research, Nashville, TN
- 2011- Invited faculty member, Vanderbilt Center for Quantitative Sciences, Nashville, TN

C. Selected Peer-Reviewed Publications (Selected from 112 peer-reviewed publications)

1. Feurer, I.D., Russell, R.T. & Pinson, C.W. (2007). Incorporating health-related quality of life and patient satisfaction measures into a transplant outcomes assessment program: technical and practical considerations. *Progress in Transplantation*, 17(2), 121-128. PMID: 17624134.
2. Zaydfudim, V., Feurer, I.D., Moore, D.E., Wisawatapnimit, P., Wright, J.K. & Pinson, C.W. (2009). The negative effects of pre-transplant overweight and obesity on the rate of improvement in physical quality of life after liver transplantation. *Surgery*, 146(2), 174-80. PMID: 19628071.
3. Zaydfudim, V., Feurer, I.D., Moore, D.R., Moore, D.E., Pinson, C.W. & Shaffer D. (2010). Pre-transplant overweight and obesity do not affect physical quality of life after kidney transplantation. *Journal of the American College of Surgeons*, 210(3), 336-344. PMID: 20193898.
4. Dunn, J.P., Cowan, R.L., Volkow, N.D., Feurer, I.D., Li, R., Williams, D.B., Kessler, R.M. & Abumrad, N.N. (2010). Decreased dopamine type 2 receptor availability after bariatric surgery: Preliminary findings. *Brain Research*, 1350,123-30. PMCID: PMC2926260.
5. Saliba, J., Kasim, N.R., Tamboli, R.A., Isbell, J.M., Marks, P., Feurer, I.D., Ikizler, A. & Abumrad, N.N. (2010). Roux-en-Y gastric bypass reverses renal glomerular but not tubular abnormalities in excessively obese diabetics. *Surgery*, 147(2), 282-287. PMCID: PMC2813906.
6. Landman, M.P., Feurer, I.D., Pinson, C.W. & Moore, D.E. (2011). Which is more cost-effective under the MELD system: primary liver transplantation, or salvage transplantation after hepatic resection or loco-regional therapy for hepatocellular carcinoma within Milan criteria? *HPB (Oxford)*, 13(11), 783-791. PMCID: PMC3238012.
7. Hoy, H.M., Feurer, I.D., Alexander, S., Loyd, J., Wells, N. & Pinson, C.W. (2012). Negative effects of pretransplant body mass index on physical health-related quality of life after lung transplant. *Progress in Transplantation*, 22(4)363-268. PMID: 23187053.
8. un, J.P., Abumrad, N.N., Breitman I., Marks-Shulman P.A., Flynn C.R., Jabbour K., Feurer I.D. & Tamboli R.A. (2012). Hepatic and peripheral insulin sensitivity at 1 month after Roux-en-Y gastric bypass surgery. *Diabetes Care*, 35(1), 137-42. PMCID: 22040841.
9. Anderson, C.B., Feurer, I.D., Large, M.C., Steinberg, G.D., Barocas, D.A., Cookson, M.S. & Penson, D.F. (2012). Psychometric characteristics of a condition-specific health-related quality of life survey: the FACT-Vanderbilt Cystectomy Index. *Urology*, 80(1), 77-83. PMID: 3329842.
10. Zaydfudim, V., Feurer, I.D., Landman, M.P., Moore, D., Wright, J.K. & Pinson C.W. (2012). Reduction in corticosteroids is associated with better health-related quality of life after liver transplantation. *Journal of the American College of Surgeons*, 214(2), 14-35. PMID: 22137824.
11. Dageforde, L.A., Landman, M.P., Feurer, I.D., Poulouse, B. Pinson, C.W. & Moore, D.E. (2012). A cost-effectiveness analysis of early vs late reconstruction of iatrogenic bile duct injuries. *Journal of the American College of Surgeons*, 214(6), 919-927. PMID: 22495064.

12. Moore, D.R., Feurer, I.D., Zaydfudim, V., Hoy, H., Zavala, E.Y., Shaffer, D., Schaefer, H. & Moore, D.E. (2012). Evaluation of living kidney donors: variables that affect donation. *Progress in Transplantation*, 22(4), 385-392. PMID: 23187057.
13. Moore, D.R., Feurer, I.D., Zavala, E.Y., Shaffer, D., Karp, S., Hoy, H. & Moore, D.E. (2013). A web-based application for initial screening of living kidney donors: development, implementation and evaluation. *American Journal of Transplantation*, 13(12), 450-457. PMID: 23205926.
14. Landman, M.P., Feurer, I.D., Moore, D.E., Zaydfudim, V. & Pinson, C.W. (2013). The long-term effect of bile duct injuries on health-related quality of life: a meta-analysis. *HPB (Oxford)*, 15(4), 252-259. PMID: 23458623, PMCID: PMC3608978 (available 2014/4/1).
15. Maltais, S., Jaik, N.P., Feurer, I.D., Wigger, M.A., DiSalvo, T.G., Schlendorf, K.H., Ahmad, R.M., Lenihan, D.J., Stulak, J.M. & Keebler, M.E. (2013). Mechanical circulatory support and heart transplantation: donor and recipient factors influencing graft survival. *Annals of Thoracic Surgery*, E-Pub ahead of print, 31 July, 2013. PMID: 23915592

D. Research Support

Ongoing Research Support

- | | | |
|--|----------------|---------------------|
| 1R01 DK091748-01A1 | Abumrad (PI) | 09/01/11 – 08/30/16 |
| RYGB Improves Metabolism by Interrupting the Gastric Adipose Tissue Axis | | |
| This study addresses the mechanisms associated with metabolic improvements immediately following bariatric surgery. | | |
| Role: Co-Investigator | | |
| 5R01 NR011477-04 | Fowke (PI) | 07/01/09 – 04/30/14 |
| A New Instrument to Comprehensively Assess Sedentary Behaviors | | |
| The major goal of this project is to develop a questionnaire of manageable length that comprehensively assesses major sedentary behaviors in the population. | | |
| Role: Co-Investigator | | |
| 3P30 CA068485-15S1 | Pietenpol (PD) | 09/10/10 – 08/31/15 |
| Cancer Center Support Grant | | |
| The goal of this project is to conduct, coordinate and integrate Vanderbilt University's cancer-related activities. | | |
| Role: Co-Investigator | | |

Completed Research Support and Research Training Sponsorship

- | | | |
|--|--------------------------------|---------------------|
| R01 DK70860-01 | Abumrad (PI) | 04/01/05 – 03/31/11 |
| Role of the Omentum in the Treatment of Morbid Obesity | | |
| This grant supported a clinical study assessing the impact of omentectomy during bariatric surgery on metabolic and molecular markers of inflammation in morbid obesity. | | |
| Role: Co-Investigator | | |
| IAF-06-085 Department of Veterans Affairs (HSR&D) | Weinger (PI) | 01/2008 – 09/2011 |
| Operating Room Workload and Quality of Care | | |
| The study evaluated multi-discipline clinician perceptions of workload in the operating room and models relationships among perceived workload and intraoperative quality of care. | | |
| Role: Co-Investigator | | |
| F32 DK077482-02 | Russell (post-doctoral fellow) | 09/15/06 – 06/2008 |
| Evaluating Cognitive Function, Cost Utility, and Outcomes after Liver Transplantation | | |
| This individual fellowship award supported the stipend and MPH program tuition costs of Dr. Robert Russell's | | |

Program Director/Principal Investigator (Last, First, Middle):

post-doctoral research training program in transplant outcomes research.

Role: Faculty Sponsor

1-R03 HS13036

Feurer (PI)

09/2002 – 08/2004

Measuring Quality of Life in Organ Transplant Patients

The goal was to evaluate the reliability, validity, and responsiveness of measures of patient satisfaction and health-related quality of life in organ transplant candidates and recipients.

Role: Principal Investigator

Participation in SAGES

Dr. Baucom is a newly elected candidate member of SAGES. She attended the 2013 meeting, and was an author of the poster, "Prospective Evaluation of Barriers to Microlaparoscopy."

Dr. Poulouse has participated in SAGES since 1998 and has continued to be actively involved on multiple levels throughout his career. He has participated on multiple committees within SAGES including Resident Education, Flexible Endoscopy, and Fundamentals of Endoscopic Surgery. Dr. Poulouse has presented at the SAGES annual meeting on multiple occasions and has mentored several medical students, residents, and fellows who have also participated in SAGES. Dr. Poulouse has taken an active role in SAGES participating as faculty for post-graduate courses, resident and fellow courses. He has served as the SAGES Annual Meeting Poster Session Co-Chair for 2012 and 2013.

Choledocholithiasis Management Survey - Final Copy3

Dear Surgeon:

We are investigating practice patterns regarding the management of choledocholithiasis and how these may be affected by local resources. In light of changes to national healthcare policy, access to care and physician availability have recently moved into the spotlight. We have created a simple survey to address these issues that we hope you will invest 3-5 minutes to complete.

Please know that although we do ask for demographic information, all information will be de-identified. Data will be kept strictly confidential and will only be presented in its aggregate form.

We are grateful for you taking the time to complete this survey. As a token of our appreciation, you will have the option of entering a raffle for a \$500 Visa gift card upon completion of the survey!

Best Regards,

Rebecca Baucom, M.D.

Benjamin Poulose M.D., M.P.H., Assistant Professor of Surgery

Michael Holzman M.D., M.P.H., Lester and Sara Jayne Williams Chair in Academic Surgery

The following questions address some basic information about you, your surgical practice, and how you address the management of choledocholithiasis. Please read each item carefully and answer according to your practice habits.

1. On average, I perform laparoscopic cholecystectomy:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

2. On average, I perform upper GI endoscopy:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

3. On average, I perform colonoscopy:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

4. On average, I perform open common bile duct exploration:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

5. On average, I perform laparoscopic common bile duct exploration:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

6. On average, I perform ERCP:

- Never < once per month 1-5 times per month 6-10 times per month > 10 times per month

7. I routinely perform intraoperative cholangiography (IOC) during cholecystectomy:

- Yes
 No

7b. If you use IOC selectively, what are your typical indications? (check all that apply)

- History of gallstone pancreatitis
 History of jaundice
 Elevated bilirubin or alkaline phosphatase
 Common bile duct dilation
 Cystic duct dilation
 Anatomic concerns
 Suspected common bile duct stones

8. The closest proceduralist who performs ERCP:

- Is affiliated with one or all of the hospitals in which I practice
 Requires a referral to another hospital

9. My preferred method for managing common bile duct stones discovered preoperatively:

- Laparoscopic common bile duct exploration
 Open common bile duct exploration
 Preoperative ERCP
 Intraoperative ERCP
 Postoperative ERCP

10. My preferred method for managing common bile duct stones discovered during cholecystectomy:

- Laparoscopic common bile duct exploration
 Open common bile duct exploration
 Intraoperative ERCP
 Postoperative ERCP

11. What limitations, if any, prevent you from performing laparoscopic common bile duct exploration when indicated? (check all that apply)

- Time constraints
 Lack of appropriate equipment
 Lack of support staff
 A reliable ERCP proceduralist is available
 Lack of appropriate reimbursement
 Increased morbidity
 Fear of losing referrals if I don't refer out for ERCP
 Size of stone
 Lack of comfort with performing the procedure

12. My age (in years) is: _____

13. My current practice is best described as:

- University hospital/VA
 Community hospital
 Community hospital, university affiliated
 Military

14. Enter 5 digit zip code in which your primary practice is located. The results of this response will be kept strictly confidential and used for demographic groupings only.

15. Since completing my training, I have been in practice for ____ years.

16. My residency program would be best described as:

- University hospital/VA
 Community hospital
 Community hospital, university affiliated
 Military

17. I received the majority of my laparoscopic training:

- In residency
 In fellowship
 Other (e.g. postgraduate course, mini-fellowship, preceptorship, on the job)
 Did not receive laparoscopic training

18. I received the majority of my endoscopic training:

- In residency
 In fellowship
 Other (e.g. postgraduate course, mini-fellowship, preceptorship, on the job)
 Did not receive endoscopic training

19. I consider myself a general surgeon:

- Yes
 No

20. Including myself, there is(are) ____ general surgeon(s) in my practice.

21. Please select your gender:

- Male
 Female
 Transgender

22. Please enter your ethnicity and race: (check all that apply)

- Hispanic, Latino/a, or of Spanish origin
 White
 Black
 American Indian or Alaska Native
 Asian or Pacific Islander
 Prefer not to respond

OPTIONAL: Enter email address if you wish to be entered into a raffle for a \$500 Visa gift card. Your email address will be kept strictly confidential and only used to contact you should you be selected as the winner.
