

Department of Health and Human Services Public Health Services Grant Application <i>Do not exceed character length restrictions indicated.</i>		LEAVE BLANK—FOR PHS USE ONLY.				
		Type	Activity	Number		
		Review Group		Formerly		
		Council/Board (Month, Year)		Date Received		
1. TITLE OF PROJECT (<i>Do not exceed 81 characters, including spaces and punctuation.</i>) Enhanced Recovery Protocols and the Cost and Quality of Colectomy in Michigan						
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (<i>If "Yes," state number and title</i>) Number: Title: ASCRS Research Foundation Career Development Award						
3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR						
3a. NAME (Last, first, middle) Smith, John		3b. DEGREE(S) M.D., M.P.H.		3h. eRA Commons User Name		
3c. POSITION TITLE Assistant Professor		3d. MAILING ADDRESS (<i>Street, city, state, zip code</i>) University of Michigan 1500 E. Medical Center Drive 2124 Taubman Center Ann Arbor, MI 48109-5343				
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Surgery						
3f. MAJOR SUBDIVISION Medical School						
3g. TELEPHONE AND FAX (<i>Area code, number and extension</i>) TEL: 777-777-7777 FAX: 777-777-7777		E-MAIL ADDRESS: email@umich.edu				
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		4a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		If "Yes," Exemption No.		
4b. Federal-Wide Assurance No. FWA00004969		4c. Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		4d. NIH-defined Phase III Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		
5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes			5a. Animal Welfare Assurance No.			
6. DATES OF PROPOSED PERIOD OF SUPPORT (<i>month, day, year—MM/DD/YY</i>) From 07/01/2014 Through 06/30/2016		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) \$75,000		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 8a. Direct Costs (\$) \$150,000 8b. Total Costs (\$) \$150,000		
9. APPLICANT ORGANIZATION Name Regents of the University of Michigan Address 3003 S. State Street Ann Arbor, MI 48109-1274		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input checked="" type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged				
		11. ENTITY IDENTIFICATION NUMBER 38-6006309 DUNS NO. 073133571 Cong. District MI-012				
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Adminstration Name Title Project Representative Address 3003 S. State Street Ann Arbor, MI 48109-1274 Tel: 777-777-7777 FAX: 777-777-7777 E-Mail: email@umich.edu		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Signors Name Title Managing Project Representative Address 3003 S. State Street Ann Arbor, MI 48109-1274 Tel: 777-777-7777 FAX: 777-777-7777 E-Mail: email@umich.edu				
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. (<i>In ink. "Per" signature not acceptable.</i>)		DATE		

PROJECT SUMMARY (See instructions):

Hospitals caring for Medicare beneficiaries face unprecedented pressure to reduce unwanted practice variation and costs of hospitalization. In surgery, a growing number have introduced Enhanced Recovery After Surgery (ERAS) protocols -- multidisciplinary bundles of surgical, anesthetic, nursing, and medical care intended to reduce the physiologic stress of surgery. In studies from highly specialized centers where they were developed, ERAS protocols have achieved faster recovery and shorter length of stay. Yet it remains unclear whether such protocols improve costs and outcomes of surgical episodes overall, or simply shift them from the hospital to outpatient setting. Further, it is unknown whether ERAS will be effective for the most vulnerable, such as older patients with multiple comorbid conditions, who may require ancillary care services after discharge. Capitalizing on the unique data infrastructure in the state of Michigan, with rich surgical outcomes, cost and utilization data, this proposal will evaluate ERAS in real-world surgical care, and assess its clinical, economic, and functional outcomes for frail and elderly patients. The specific research aims are to evaluate: (i) clinical outcomes of ERAS in real-world surgical practice; (ii) effects of ERAS on cost and utilization across the entire surgical episode; and (iii) differential effects of ERAS by age and clinical risk factors. This study will assess the role of ERAS in value-based care delivery and provide payors with a blueprint for efficiency initiatives in surgery in US hospitals. Further, the highly experienced multidisciplinary mentorship team and research environment are ideally suited to the career goals and educational needs of the candidate. The proposal includes a detailed educational plan with training that will be essential both for successful completion of this research and toward Dr. Smith's career development. The training includes graduate level courses in organizational culture and health care delivery systems, quantitative methods for causal inference, and gerontology and the epidemiology of aging, as well as site visits to local ERAS centers of excellence. This award will lay the groundwork for Dr. Smith to become an independent investigator and national leader in quality improvement in surgery in vulnerable patients.

RELEVANCE (See instructions):

As the first population-based assessment of ERAS protocols for inpatient surgery, this study will have immediate impact on efforts to improve efficiency of inpatient surgical care, and will provide a generalizable assessment of the viability of ERAS for value-based care delivery in US hospitals.

PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page)

Project/Performance Site Primary Location			
Organizational Name: Regents of the University of Michigan			
DUNS: 00000000			
Street 1: 3003 S. State St		Street 2:	
City: Ann Arbor	County: Washtenaw		State: Michigan
Province:	Country: USA		Zip/Postal Code: 48109
Project/Performance Site Congressional Districts: MI-012			
Additional Project/Performance Site Location			
Organizational Name:			
DUNS:			
Street 1:		Street 2:	
City:	County:		State:
Province:	Country:		Zip/Postal Code:
Project/Performance Site Congressional Districts:			

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

SENIOR/KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

Name	eRA Commons User Name	Organization	Role on Project
John Doe, MD	John Doe	University of Michigan	Primary Mentor
Jane Doe, MD, PhD	Doe	University of Michigan	Co-Mentor
Susan Smith, PhD	Smith	University of Michigan	Co-Mentor
Greg Smith, PhD	GMith	University of Michigan	Co-Mentor

OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Role on Project
Sally Smith, MD	University of Michigan	Collaborator
Edward Smith, MCh, PhD	Case Western Reserve University	Collaborator

Human Embryonic Stem Cells No Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp>. *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

Cell Line

The name of the program director/principal investigator must be provided at the top of each printed page and each continuation page.

**RESEARCH GRANT
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7. Inclusion of Women and Minorities	_____
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Appendix (<i>one CD copy</i>)	<input type="checkbox"/> Check if Appendix is Included

* Follow the page limits for these sections indicated in the application instructions, unless the Funding Opportunity Announcement specifies otherwise.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 07/01/2014	THROUGH 06/30/2015
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List PERSONNEL (*Applicant organization only*)
 Use Cal, Acad, or Summer to Enter Months Devoted to Project
 Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
John Smith	PD/PI				No Salary Requested	0	0	0
John Doe	Mentor				No Salary Requested	0	0	0
TBA	Data Analyst	6.0			66,000	33,000	10,560	43,560
Abby Smith	Research Assistant	3.0			57,000	14,250	4,560	18,810
SUBTOTALS →						47,250	15,120	62,370

CONSULTANT COSTS	
EQUIPMENT (<i>Itemize</i>)	
SUPPLIES (<i>Itemize by category</i>) Research Consumable Supplies and Software	1,930
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>)	
OTHER EXPENSES (<i>Itemize by category</i>) Medicare Data	10,700

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (<i>Item 7a, Face Page</i>)		\$ 75,000
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$ 75,000

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>	62,370	64,241			
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES	1,930	59			
TRAVEL					
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	10,700	10,700			
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i>	75,000	75,000			
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	75,000	75,000			
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					\$ 150,000

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

BUDGET JUSTIFICATION

A. Unpaid Personnel (Candidate, Co-Mentors and Collaborators)

John Smith, MD, MPH (Principal Investigator). Dr. Smith is Assistant Professor of Surgery at the University of Michigan. With the guidance of his primary mentor, he will conduct and oversee all aspects of the research plan, including data collection, analysis and interpretation, and manuscript preparation. Dr. Smith has 50% protected research time available. An institutional support letter from his department chairman attests to the Department of Surgery's commitment to his time allocation. No salary requested

John Doe, MD (Primary Mentor): Dr. Doe is the George D. Zuidema Professor of Surgery and Director of the University of Michigan's Center for Healthcare Outcomes and Policy (CHOP). He has a senior-scientist award and an established track record as both an independently-funded scientist and a mentor for young investigators who establish careers that include clinically meaningful and policy-relevant health services research, and he has mentored many K award recipients. He has extensive experience with and access to both Medicare claims data and the Michigan Surgical Quality Collaborative (MSQC) registry, and is the principal investigator of the Michigan Value Collaborative. As Dr. Smith's primary mentor, Dr. Doe has committed to a weekly, one-hour meeting, in addition to daily ad hoc interactions (their research offices are only a few feet apart) and group meetings (weekly CHOP research in progress meetings). The goals of these meetings are to ensure research and educational progress, and to help plan a series of high-impact publications to disseminate this research. Dr. Doe will also mentor the candidate toward independent (R01) research funding. No salary requested.

Jane Doe, MD, PhD (Co-Mentor): Dr. Doe is a Professor of Internal Medicine, Gerontology, and Health Management and Policy. He is also Associate Director of the NIA-funded Health and Retirement Study and Lead Investigator for the Aging, Demographics, and Memory Study. Dr. Smith will provide mentorship that complements the expertise of the primary mentor, Dr. John Doe. He will provide monthly guidance throughout the grant period in designing the candidate's training around care needs of the elderly and will direct his independent study in this area. He will also contribute to the evaluation of clinical outcomes for geriatric patients in the study and will increase Dr. Smith's interactions with the gerontology and aging research group at UM. No salary requested.

Susan Smith, PhD (Co-Mentor): Dr. Smith is Associate Professor of Health Management and Policy at the University of Michigan School of Public Health, Director of the Griffith Leadership Center and Chief Academic Officer of the National Center for Healthcare Leadership. With experience as the Principal Investigator of three major project grants, including a project funded by The Center for Healthcare Research and Transformation to study organizational factors predicting high and low surgical quality performance among hospitals in the MSQC, she will provide guidance in the evaluation of hospital organizational factors contributing to ERAS implementation and outcomes. She has committed to monthly meetings to assist with evaluation of safety and teamwork culture data, and data analysis for Aims 1 and 2. No salary requested.

Greg Smith, PhD (Co-Mentor): Dr. Smith is a Professor of Economics and Health Management and Policy, and is Director of Health Economics at CHOP. He will bring extensive experience in advanced statistical techniques required for the measurement of efficiency. Relevant to this proposal, he teaches courses in applied econometrics and health economics. He will meet regularly with the candidate to supervise the design and conduct of analyses. He will also ensure educational progress in Dr. John Smith's analytic career development goals. No salary requested.

Sally Smith, MD (Collaborator): Dr. Smith is a Professor of Surgery, Chief Medical Officer of the University of Michigan Health System, and Director of MSQC, the research setting for this proposal. A leader in regional and national surgical quality improvement, he has committed to providing infrastructure support and access to key clinical data, engaging participating hospitals in the survey administration, and to helping me develop leadership skills. We will meet at least monthly, as part of the MSQC administrative meetings, to ensure integration of this project within the larger goals and progress of the collaborative.

Edward Smith, MD, PhD (Collaborator): Dr. Smith is a Professor of Surgery, Vice Chairman and Chief of Colorectal Surgery at University Hospital and Case Western Reserve University. He is an international leader in the development and dissemination of ERAS, and has more than 100 publications focused on performance improvement in colorectal surgery, including a national survey of surgeons' use of fast-track recovery practices. Through remote meetings, he will provide guidance in development and interpretation of the survey and to orient findings with national progress in dissemination of enhanced recovery

B. Paid Personnel

Data Analyst TBD (6 Calendar Months). The budget includes support for a half-time data analyst who will be housed and supervised within the Center for Healthcare Outcomes and Policy (CHOP) central offices. This person will be trained and supervised by Dr. John Smith, with additional supervision provided by the CHOP data manager. The responsibilities include maintenance and updating of the specific process of care database for the enhanced recovery project (Aim 1), and merging of these data from the Michigan Surgical Quality Collaborative with the episode cost data derived from Medicare claims (Aims 2&3). This individual will clean, develop, and maintain the analytic datasets, and will assist in completion of analyses designed by Dr. Smith and his mentors.

Abby Smith (Research Assistant, 3 Calendar Months). Ms. Smith is a Clinical Health Research Coordinator in the Department of Surgery. She is housed in the CHOP offices and will serve as a Research Assistant for this project. Her responsibilities will include administration of data use and regulatory agreements, data warehouse maintenance and integration, assistance with manuscript composition and coordination, and administrative duties specifically related to the conduct of the research herein. Her share of time for this project will be supervised directly by Dr. Smith.

Other Direct Costs

Medicare Data. \$21,400 for Years 1 and 2 are requested for the cost of Medicare data (Part D). This includes data extraction from the main Medicare data set and data organization.

Software and Research Consumable Supplies. \$1,930 Y1 and \$59 Y2. Funds are requested to cover the purchase and maintenance of statistical software licenses (SAS Version 9.3), for the data analyst and research consumable supplies which include paper and envelopes, file folders and other supplies related to printing and processing of survey and questionnaires.

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 John Edward Smith, MD, MPH		POSITION TITLE Assistant Professor of Surgery University of Michigan	
eRA COMMONS USER NAME (credential, e.g., agency login) JESMITH			
EDUCATION/TRAINING <i>(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
Princeton University, Princeton, NJ University of California, San Francisco, CA Harvard School of Public Health, Boston, MA	A.B. M.D. M.P.H. Post-Doc	1993-1997 1998-2002 2005-2007 2005-2008	Psychology Medicine Clinical Effectiveness Health Services Resrch.
<u>Residency Training</u> Massachusetts General Hospital, Boston, MA Lahey Clinic, Burlington, MA		2002-2010 2010-2011	General Surgery Colon & Rectal Surgery
<u>Professional Certifications</u> American Board of Surgery American Board of Colon and Rectal Surgery		2010 2011	General Surgery Colon & Rectal Surgery

A. Personal Statement

The goal of the proposed research is to evaluate the use of enhanced recovery protocols in real-world surgical care, and assess their clinical, economic, and functional outcomes in Michigan hospitals. As the first population based assessment of this approach, we seek to determine its viability for value-based care delivery in US hospitals. The project focuses specifically on the costs and outcomes of colorectal resections, which are very common, high-risk operations, performed in a wide variety of hospitals. We capitalize on the unique data infrastructure in the state of Michigan, with a rich surgical outcomes data and quality improvement platform. This proposal involves the analysis of administrative claims data and clinical outcomes registries, and their application to collaborative quality improvement initiatives. I have a solid foundation in clinical epidemiology and biostatistics and a broad practical background in surgical quality improvement, with specific training and expertise in several key research areas for this application.

The research project, multidisciplinary mentorship team, unparalleled research environment and detailed educational plan are designed to meet my career development goals. The training includes graduate level courses in organizational culture and health care delivery systems, quantitative methods for causal inference, as well as site visits to local, national, and international ERAS centers of excellence. This career development award will lay the groundwork for ongoing, innovative health services research, and help me become an independent investigator and national leader in quality improvement around major inpatient surgery.

B. Positions and Honors

Employment

1996-1997	Researcher, Dept. of Psychology, Princeton University, Laboratory of Dr. Charles Gross.
1997-1998	Project Manager & Co-Founder, Tuberculosis Initiative, Princeton Project 55, Princeton, NJ
1999-2000	ENZO Biochem Research Fellow, Pediatric Bone Marrow Transplant Unit, University of California San Francisco, San Francisco, CA. Laboratory of Dr. Morton Cowan.

2002-2010	Resident, Department of Surgery, Massachusetts General Hospital; Clinical Fellow in Surgery, Harvard Medical School, Boston, MA
2005-2008	AHRQ Postdoctoral Fellow, Department of Health Policy & Management, Harvard School of Public Health, Boston, MA. Research group of Dr. Atul Gawande.
2010-2011	Resident, Department of Colon and Rectal Surgery, Lahey Clinic, Burlington, MA; Clinical Instructor in Surgery, Tufts Medical School, Boston, MA
2011-Present	Assistant Professor of Surgery, University of Michigan, Center for Healthcare Outcomes and Policy, Ann Arbor, MI. Research group of Dr. John Birkmeyer.

Honors

1997	Phi Beta Kappa, Highest Honors, Princeton University
2002	Graduating Class Speaker, University of California San Francisco
2005–2007	Edward D. Churchill Research Fellowship in Surgery, Massachusetts General Hospital
2005–2008	NIH Kirschstein National Research Service Award T32-HS000020 Institutional Training Grant, Agency for Healthcare Research and Quality, Postdoctoral Fellowship
2009	Best Research Paper, New England Society of Colon and Rectal Surgeons Annual Spring Meeting, Manchester, NH, June 2009
2011	Commendation for Accomplished Teaching. Tufts University School of Medicine.
2012	Silver Scalpel Medical Student Teaching Award, Dept. of Surgery, University of Michigan
2013	Hour Detroit Magazine 2013 Top Doctor, Colon and Rectal Surgery

Other Experience and Professional Memberships

Associate Member, GI Oncology Research Program, UM Comprehensive Cancer Center, 2011 – Member, Quality Assessment & Safety Committee, American Soc. of Colon and Rectal Surg., 2012 – Cancer Liason Physician, American College of Surgeons' Commission on Cancer, 2013 – Member, UM Comprehensive Cancer Center Patient Safety/Quality Improvement Committee, 2013 – Member, National Comprehensive Cancer Network Colorectal Cancer Screening Panel, 2013 – American College of Surgeons: Resident Member, 2005 – 2011; Associate Fellow, 2011 – Association for Academic Surgery; Candidate Member, 2005 – 2009; Active Member, 2009 – Surgical Outcomes Club, Member, 2005 – American Medical Association, Resident Member, 2007 – 2011 American Society of Colon and Rectal Surgeons, Candidate Member, 2009 – 2011; Member, 2011 –

B. Publications (selected from 24 peer-reviewed publications)

Most relevant to the current application

1. **Smith JE**, Gust C, Smith JD. Hospital surgical volume and the cost of inpatient surgery in the elderly. *Journal of the American College of Surgeons* 2012;215(6):758-765. PMID: 22921326.
2. **Smith JE**, Bordeianou L, Hutter MM, Gawande AA. The intraoperative Surgical Apgar Score predicts post-discharge complications after colon and rectal resection. *Surgery* 2010;148(3):559-66. PMID: 20227100, PMCID: PMC2924468.
3. ElBardissi AW, **Smith JE**, Greenberg CC, Berry W, Arriaga A, Moorman D, Retik A, Warshaw AL, Zinner MJ, Gawande AA. Communication practices on four Harvard surgical services: a surgical safety collaborative. *Annals of Surgery* 2009;250(6):861-5. PMID: 19855264.
4. Arriaga AF, Lancaster RT, Berry WR, **Smith JE**, Lipsitz SR, Kaafarani HMA, Elbardissi AW, Desai P, Ferzoco SJ, Bleday R, Breen E, Kastrinakis WV, Rubin MS, Gawande AA. The Better Colectomy Project: Association of best-practice adherence rates to outcomes in colorectal surgery. *Annals of Surgery* 2009;250(4):507-513. PMID: 21173696.
5. Arriaga AF, ElBardissi AW, Berry W, **Smith JE**, Greenberg CC, Lipsitz SR, Moorman D, Kasser J, Warshaw AL, Zinner MJ, Gawande AA. A policy-based intervention for the reduction of critical communication breakdowns in inpatient surgical care: Results from a Harvard surgical safety collaborative. *Annals of Surgery* 2011;253(5):849-854. PMID: 19734778.

Additional selected publications of importance to the field (in chronological order)

1. Gawande AA, Kwaan MR, **Smith JE**, Lipsitz SR, Zinner MJ. An Apgar score for surgery. *Journal of the American College of Surgeons* 2007;204(2):201-208. PMID: 17254923.
2. Greenberg CC, **Smith JE**, Studdert DM, Lipsitz SR, Rogers SO, Zinner MJ, Gawande AA. Patterns of communication breakdowns resulting in injury to surgical patients. *Journal of the American College of Surgeons* 2007;204(4):533-540. PMID: 17382211.
3. **Smith JE**, Greenberg CC, Studdert DM, Lipsitz SR, Zinner MJ, Gawande AA. Patterns of technical error among surgical malpractice claims: an analysis of strategies to prevent injury to surgical patients. *Annals of Surgery* 2007;246(5):705-711. PMID: 17968158.
4. Weiser TG, **Smith JE**, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, Gawande AA. An estimation of the global volume of surgery: a modeling strategy based on existing data. *Lancet* 2008;372(9633):139-44. PMID: 18582931.
5. **Smith JE**, Lancaster RT, Lipsitz SR, Greenberg CC, Hutter MM, Gawande AA. Does the Surgical Apgar Score measure intraoperative performance? *Annals of Surgery* 2008;248(2):337-341. PMID: 18650644, PMCID: PMC2562699.
6. **Smith JE**, Ehrenfeld JM, Lipsitz SR, Greenberg CC, Hutter MM, Gawande AA. Utility of the Surgical Apgar Score: validation in 4,119 patients. *Archives of Surgery* 2009;144(1):30-36. PMID: 19153322.
7. **Smith JE**, Greenberg CC, Resch SC, Kollengode A, Cima RR, Zinner MJ, Gawande AA. Prevention of retained surgical sponges: a decision-analytic model predicting relative cost-effectiveness. *Surgery* 2009;145(5):527-535. PMID: 19375612, PMCID: PMC2725304.
8. **Smith JE**, Gawande AA, Lipsitz SR, Greenberg CC, Jha AK. Do differences in hospital and surgeon quality explain racial disparities in lower-extremity vascular amputation? *Annals of Surgery* 2009;250(3):424-431. PMID: 19652590.
9. **Smith JE**, Hirose M, Imanaka Y, Oh E-H, Fukuda H, Gawande AA, Takemura T, Yoshihara H. A comparative analysis of incident reporting lag times in academic medical centers in Japan and the United States. *Quality and Safety in Health Care* 2010;19(6):e10,1-4. PMID: 20194219
10. **Smith JE**, Read TE, Roberts PL, Marcello PW, Schoetz DJ, Ricciardi R. Urinary Tract Infection After Colon and Rectal Resections: More Common Than Predicted By Risk-Adjustment Models. *Journal of the American College of Surgeons* 2011;213(6):784-792. PMID: 21945417

C. Research SupportOngoing Support

P01AG019783 (Skinner)

12/01/2012 – 11/30/2017

NIH/NIA

Causes and Consequences of Health Care Efficiency

Based on national Medicare data, this study is examining variation in hospital payments for inpatient surgery and relationship between cost and quality.

Role: Co-I, Subproject #3 (Subproject Leader: Birkmeyer)

Completed Support

2 T32-HS000020 (Weinstein)

7/1/2005 - 6/30/2008

NIH/AHRQ

Harvard University Health Services Research Training Program

National Research Service Award Institutional Training Grant

Role: Postdoctoral Trainee

L30 DK075553 (Regenbogen) 7/1/2006 - 6/30/2008
NIH/NIDDK
Loan Repayment Program in Clinical Research
Two years of loan repayment support for work on "The Safer Surgery Project".
Role: P.I.

(No grant number) (Gawande) 7/1/2005 - 5/31/2008
Harvard Risk Management Foundation
The Safer Surgery Project
The aim of this project was define and develop new approaches to improve outcomes in surgery and reduce serious injuries to patients and it has succeeded in supporting the CRICO/RMF Surgical Safety Collaborative's development of evidence-based approaches to reducing injury to surgical patients. 1) Implement and evaluate the communications guidelines developed by the CRICO/RMF Surgical Safety Collaborative. 2) Design and implement processes to reduce patient injury and malpractice exposure in high-risk surgery, starting with colectomy. 3) Support the continuing quality and safety improvement efforts of Harvard Surgical Chairmen and the CRICO/RMF Surgical Safety Collaborative through our research and data synthesis.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

NAME John Doe	POSITION TITLE Professor of Surgery		
eRA COMMONS USER NAME John Doe			
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Boston College	A.B.	1981 -1985	Mathematics
Harvard Medical School, Boston, MA	M.D.	1985 - 1989	Medicine
Dartmouth Medical School, Hanover, NH		1991 - 1993	NLM-funded Medical Informatics Fellowship

A. Personal Statement

The proposed research and training program has two broad aims: (i) to evaluate the clinical and economic consequences of Enhanced Recover After Surgery protocols for elderly surgical patients in Michigan hospitals; and (ii) to provide research, mentoring, and didactic experience to support the career development of Dr. Scott Regenbogen. As Dr. Regenbogen's primary mentor, I will supervise all aspects of this research proposal. The goals of this project complement my research interests and take advantage of my expertise in several areas. Specifically, I have extensive experience in the analysis of Medicare claims data and surgical episode costs in older patients, and I have served as primary mentor for 14 career development awards, including 5 who have made transition to R01 or R21 awards. With regards to evaluating Medicare payments around episodes of care, I am currently the Project PI on a P01 grant, "Causes and Consequences of Health Care Efficiency" which uses 100% Medicare data to examine the hospital drivers of quality and efficiency of surgical care. I am also Director of the Michigan Value Collaborative, which provides a laboratory for statewide data on episode efficiency, and is one of the key data sources for this study. In addition to supervising Dr. Regenbogen's research and training, I will ensure that he has access to the data and analytic infrastructure necessary for him to complete his complete his research. As Director of the Center for Healthcare Outcomes & Policy at the University of Michigan, I oversee a large database managements and analytics core and thus am well positioned to provide him with such resources.

B. Positions and Employment

1989-1996 Surgical Resident, Dartmouth-Hitchcock Medical Center
 1996 -2001 Departments of Surgery and of Community and Family Medicine, Dartmouth Medical School (Assist Professor 1996-2001), Associate Prof (2001-3)
 1999-2002 Chief of Surgery, VA Medical Center, White River Junction, VT
 2002-2003 Chief, Section of General Surgery, Dartmouth-Hitchcock Medical Center
 2004- George D. Zuidema Professor and Chair, Surgical Outcomes Research, University of Michigan, Ann Arbor, MI
 2005- Medical Director, Michigan Bariatric Surgery Collaborative
 2010- Director, Center for Healthcare Outcomes & Policy, University of Michigan
 2012- Director, Michigan Value Collaborative

Other Experience and Professional Memberships

1998-2001 Editor, Specialty Care Series, *Dartmouth Atlas of Health Care*
 1999-2002 Literature selection technical review committee (LSTRC), National Library of Medicine (Chair 2002-3)
 2000- Chair, Expert Panel for Evidence-based Hospital Referral, The Leapfrog Group

Honors

2006-	Institute of Medicine Elected, 2006-, Section co-chair, 2009-11, Section chair, 2011-
2008	Thomas G. Sheen Award (Bank of America)—given to one US physician each year for outstanding contributions to health and biomedical science

C. Selected Peer-reviewed Publications (Selected from 200+ peer-reviewed publications)

Most relevant to the current application

1. Regenbogen SE, Gust C, **Doe JD**. Hospital Surgical Volume and Cost of Inpatient Surgery in the Elderly. *J Am Coll Surg*. 2012;215(6):758-765. PMID: 22921326.
2. **Doe JD**, Gust C, Dimick JB, Birkmeyer NJ, Skinner JS. Hospital Quality and the Cost of Inpatient Surgery in the United States. *Ann Surg*. 2012 Jan;255(1):1-5. PMID: 22156928.
3. Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, **Doe JD**. Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. *Health Aff (Millwood)*. 2011 Nov;30(11):2107-15. PMID: 22068403.
4. **Doe JD**, Gust C, Baser O, Dimick JB, Sutherland JM, Skinner JS. Medicare payments for common inpatient procedures: implications for episode-based payment bundling. *Health Serv Res*. 2010 Dec;45(6 Pt 1):1783-95. PMID: 20698899.
5. Nicholas LH, Osborne NH, **Doe JD**, Dimick JB. Hospital process compliance and surgical outcomes in medicare beneficiaries. *Arch Surg*. 2010 Oct;145(10):999-1004. PMID: 20956770.

Additional recent publications of importance to the field

1. **Doe JD**, Finks JF, O'Reilly A, Dimick JB, Oerline M, Carlin AM, Banerjee M, Birkmeyer NJO. Surgeon skill and complication rates after bariatric surgery. *N Engl J Med* 2013 (in press).
2. Miller DC, Ye Z, Gust C, **Doe JD**. Anticipating the Effects of Accountable Care Organizations for Inpatient Surgery. *JAMA Surg*. 2013 Feb 20;1-6. PMID: 23426556.
3. Birkmeyer NJ, Finks JF, Greenberg CK, McVeigh A, English WJ, Carlin A, Hawasli A, Share D, **Doe JD**. Safety Culture and Complications After Bariatric Surgery. *Ann Surg*. 2013 Feb;257(2):260-5. PMID: 23047607.
4. Finks JF, Osborne NH, **Doe JD**. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med*. 2011 Jun 2;364(22):2128-37. PMID: 21631325.
5. Ghaferi AA, **Doe JD**, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med* 2009;361:1368-1375. PMID: 19797283
6. Wong SL, Ji H, Hollenbeck BK, Morris AM, Baser O, **Doe JD**. Hospital lymph node examination rates and survival after resection for colon cancer. *JAMA*. 2007;298:2149-54. PMID: 18000198.
7. Birkmeyer NJO, Birkmeyer JD. Strategies for improving surgical quality. Should payers reward excellence or effort? *N Engl J Med*. 2006;354:864-70. PMID: 16495401.
8. **Doe JD**, Sun Y, Goldfaden A, Birkmeyer NJO, Stukel TA. Hospital volume and process of care in high risk cancer surgery. *Cancer*. 2006;106: 2476-2481. PMID: 16634089.
9. **Doe JD**, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003;349:2117-2127. PMID: 14645640.
10. **Doe JD**, Finlayson EVA, Siewers AS, Stukel TA, Lucas FL, Batista I, Welch HG, Wennberg DE. Hospital volume and surgical mortality in the United States. *N Engl J Med*. 2002;346:1137-1144. PMID: 11948273

D. Research Support

Ongoing Research Support

NIH R01AG042340 09/30/2012 – 08/30/2015
Understanding Variation in Failure to Rescue in the Elderly
This project will have direct, population-level impact as our findings inform interventions aimed at reducing surgical mortality in the elderly in Michigan, and ultimately elsewhere.

P01AG019783 (Skinner) 12/01/2012 – 11/30/2017
NIH/NIA
Causes and Consequences of Health Care
Based on national Medicare data, this study is examining variation in hospital payments for inpatient surgery and relationship between cost and quality
Role: Co-I

K05CA115571 (Birkmeyer) 09/14/07 – 08/31/13 NCTX
NIH/NCI
Understanding Racial Disparities in Cancer Surgery
This project will serve as a platform for mentoring several surgeon scientist interested in quality of care issues and racial disparities in bladder, breast, colorectal and other cancers.

AHRQ R01HS018050-01A1 (Birkmeyer, N.-PI, Birkmeyer, Co-I) 04/01/10 – 01/31/14 NCTX
Optimizing Prophylaxis Against Venous Thromboembolism in Bariatric Surgery
The goals of this project are to reduce variation in VTE propylaxis among hospitals performing bariatric surgery in Michigan, with the ultimate goal of improving outcomes and reducing costs.

AHRQ R01HS18728-01 (Birkmeyer, N. – PI, Birkmeyer, Co-I) 04/01/10 – 01/31/14 NCTX
Return on Investment for Quality Improvement Collaboratives In Surgery
This project will assess relationships between hospital quality and costs and the return on investment of collaborative quality improvement.

HS18726 (Hollenbeck) 09/30/10 – 09/29/14
AHRQ
Ambulatory Surgery Centers and Medicare Expenditures for Outpatient Procedures
This project has the following aims: 1) to characterize the delivery of outpatient surgery in the United States, 2) to determine the impact of regional delivery systems on procedure use, and 3) to assess Relationships between regional delivery systems and Medicare payments.

R01AG039434 (Dimick, PI) 04/15/11 – 03/31/15
National Institute of Aging (NIA)
Evaluating policies for improving surgical care in the elderly
The specific aims of this project are to evaluate the relative effectiveness of several competing policy options for improving care and reducing costs in surgical patients.

Completed Research Support

2 R01 CA098481-05A1 (Birkmeyer) 09/1/08 – 08/31/12
NIH/NCI
Structure, Process and Outcomes in Cancer Surgery
In this national, multi-center study, we are examining clinical mechanisms underlying variation in hospital mortality with major cancer surgery.

1R21DK084397-01A1 (Dimick, PI, Birkmeyer, Co-I) 05/01/10 – 04/30/13

Better Measures of Bariatric Surgical Quality

This project will assess that better measures of quality for bariatric surgery will help ensure the success of the growing number of accreditation and quality improvement of payers, policymakers and providers.

1 R21 AG032155-01A1 (Nallamothe, PI, Birkmeyer-Co-I)

09/30/08 – 08/31/10

NIA

Carotid angioplasty and stenting in the elderly

Based on national Medicare claims data, this study is examining dissemination of carotid angioplasty in the elderly and factors underlying variation in utilization and outcomes.

1 R21 AR056988-01 (Chung, PI, Birkmeyer-Co-I)

07/10/08 – 04/30/10

NIAMS

Understanding Treatment Variation of Distal Radius Fractures in the US Elderly

Based on national Medicare data, this study is exploring variation in the operative and non-operative treatment of elderly patients with wrist fractures.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Jane Doe, MD, PhD		POSITION TITLE Professor of Medicine	
eRA COMMONS USER NAME (credential, e.g., agency login) Jdoe			
EDUCATION/TRAINING <i>(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
Amherst College, Amherst, Massachusetts	BA	05/85	Sociology
Harris School of Public Policy, U. of Chicago	PhD	08/92	Health Policy
Pritzker School of Medicine, U. of Chicago	MD	06/94	Medicine

A. Personal Statement

I am a Professor of Medicine at the University of Michigan, an Associate Director of the Institute of Gerontology (IoG), and an Associate Director for the nationally-representative Health and Retirement Study (HRS), an NIA-funded longitudinal study of aging in the United States. My research has focused on the risk factors and outcomes for chronic disease in older adults, with a special emphasis on Alzheimer's disease and other dementias, and I have published more than 130 peer-reviewed articles on these topics. I have also been continuously funded by the National Institute on Aging since 2001. I have been a senior mentor to more than 20 junior faculty at the University of Michigan, and was recently awarded the Michigan Institute for Clinical and Health Research Distinguished Research Mentorship Award. My expertise in survey research and the epidemiology of chronic disease, leadership positions in geriatrics and the HRS, and experience as a mentor will all be useful in supporting Dr. Smtih's successful completion of this K23 project.

B. Positions and Honors

Positions and Employment

1993 Lecturer, Harris Graduate School of Public Policy Studies, University of Chicago
1994 – 1997 Internship and Residency, Internal Medicine, University of Michigan, Ann Arbor
1997 – 1999 Robert Wood Johnson Clinical Scholar, University of Michigan, Ann Arbor
1999 – 2000 Lecturer, Department of internal Medicine, University of Michigan, Ann Arbor
1999 – Research Scientist, VA Center for Practice Management and Outcomes Research, Ann Arbor
1999 – Faculty Associate, Institute for Social Research, University of Michigan, Ann Arbor
2000 – 2006 Assistant Professor, Department of Internal Medicine, University of Michigan, Ann Arbor
2001 – 2002 Clinical Fellow, Cognitive Disorders Clinic, University of Michigan Geriatrics Center, Ann Arbor
2006 – 2009 Associate Professor (with tenure), Departments of Internal Medicine, Health Management and Policy, and Institute of Gerontology, University of Michigan, Ann Arbor
2007 Visiting Professor, Department of Psychiatry and Institute of Public Health, University of Cambridge, Cambridge, England
2009 – Professor, Departments of Internal Medicine, Health Management and Policy, and Institute of Gerontology, University of Michigan, Ann Arbor

Honors

1981 National Merit Scholarship
1985 *Phi Beta Kappa* (Amherst College)
1985 *Summa cum Laude* (Amherst College)
1986 – 1988 John Woodruff Simpson Medical Studies Fellowship (Amherst College)

- 1988 – 1992 Pew Fellowship in Medicine, Arts, and the Social Sciences (University of Chicago)
- 1993 Association for Public Policy Analysis and Management (APPAM) PhD Dissertation Award
- 1997 – 1999 Robert Wood Johnson Clinical Scholar
- 1999 Mack Lipkin Award for outstanding scientific presentation, Society of General Internal Medicine
- 2001 – 2002 Research Mentorship Award (with Eric B. Larson, MD), Society of General Internal Medicine
- 2001 – 2003 New Investigator Award, Alzheimer's Association
- 2001 – 2006 NIH Career Development Award (K08), National Institute on Aging
- 2003 – 2008 Paul Beeson Physician Faculty Scholars Award, American Federation for Aging Research
- 2007 Visiting Fellow, Clare Hall College, University of Cambridge, Cambridge, England
- 2011 Visiting Scholar, Institute on Aging, University of Pennsylvania
- 2007, 2012 National Academy of Sciences Keck Futures Conference
- 2013 Michigan Institute for Clinical and Health Research Distinguished Research Mentorship Award

C. Selected Peer-reviewed Publications (Selected from 131 peer-reviewed publications)

Most relevant to the current application

1. **Doe JM**, Foster N, Larson EB. (2004) Mixed dementia: emerging concepts and therapeutic implications. JAMA, 292(23): 2901-2908.
2. **Doe JM**, Larson E, Karlawish J, Cutler D, Kabeto M, Kim S, Rosen A. (2008). Trends in the prevalence and mortality of cognitive impairment in the United States: Is there evidence of a compression of cognitive morbidity? Alzheimer's & Dementia, 4(2): 134-144. PMC2390845.
3. Lang I, Llewellyn D, **Doe JM**, Wallace R, Melzer D. (2008) Neighborhood deprivation and incident disability in older people: Population-based prospective cohort study. Age and Ageing, 37(4): 403-410. PMC2574954
4. Iwashyna T, Ely EW, Smith D, **Doe JM**. (2010). Long-term cognitive impairment and functional disability among survivors of severe sepsis. JAMA, 304(16): 1787-1794. PMC3345288
5. Hurd M, Martorell F, Delevande A, Mullen K, **Doe JM**. The monetary costs of dementia in the United States. New England Journal of Medicine. 2013; 368(14): 1326-1334.

Additional recent publications of importance to the field (in chronological order)

1. Katz S, Kabeto M, **Doe JM**. (2000). Gender disparities in the receipt of home care for elderly people with disability in the United States. JAMA, 284(23), 3022-3027.
2. Plassman B, **Doe JM**, Fisher G, et al. (2008). Prevalence of cognitive impairment without dementia in the United States. Annals of Internal Medicine, 148(6): 427-434. PMC2670458
3. Rogers M, Plassman B, Kabeto M, Fisher G, McArdle J, Llewellyn D, Potter G, **Doe JM**. (2009). Parental education and late-life dementia in the United States. J. of Geri Psych and Neuro; 22(1): 71-80. PMC2670459
4. **Doe JM**, Llewellyn D, Lang I, et al. (2009). Cognitive health among older adults in the United States and in England. BMC Geriatrics, 9: 23. PMC2709651
5. Gure T, Kabeto M, Plassman B, Piette J, **Doe JM**. (2010). Differences in functional impairment across subtypes of dementia. J. of Gerontology: Medical Sciences, 65(4): 434-441. PMC2844058
6. Llewellyn D, Lang I, **Doe JM**, et al. (2010). Vitamin D and risk of cognitive decline in the elderly. Archives of Internal Medicine, 170(13):1135-1141.
7. Rogers M and **Doe JM**. (2010). Untreated poor vision: a contributing factor to late-life dementia. American Journal of Epidemiology, 171(6): 728-735. PMC2842219
8. Llewellyn D, Lang I, Mathews F, Plassman B, Rogers M, Morgernstern L, Fisher G, Kabeto M, **Doe JM**. (2010). Vascular health, diabetes, ApoE, and dementia in the US. Alzheimer's Res and Therapy, 2(3): 19. PMC2919699
9. Silveira M, Kim S, **Doe JM**. (2010). Advance directives and outcomes of surrogate decision-making before death. New England Journal of Medicine, 362(13): 1211-1218. PMC2880881
10. Nicholas L, **Doe JM**, Iwashyna T, Weir D. Regional variation in the association between advance directives and end-of-life Medicare expenditures. JAMA. 2011; 306(13): 1447-1453. PMC3332047

D. Research Support

Ongoing Research Support

U01 AG09740 Weir (PI) 1/01/12 - 12/31/17
NIH / NIA

Health and Retirement Study

This project is for three additional waves of data collection on an established panel designed to study development throughout the second half of life. Special emphasis is given to the measurement of economic and health status variables.

Role: 1) Associate Director; 2) Co-Investigator

P01 1AG031098 Cutler (PI) 4/01/09 – 3/31/14
NIH / NIA

Expanding the National Health Accounts

The major goal of this project is to develop a national framework to systematically track trends in health alongside health care spending to better understand the productivity of medical care. Within select diseases, we will look at the specific drivers of value and forecast the impact on both health and spending of policy interventions aimed at improving value

Role: Co-Investigator

R01 AG030155 Hurd (PI) 9/15/07 - 5/31/13
NIH/NIA

Costs of Dementia

The major goal of this project is to use data from the Health and Retirement Study (HRS) and Aging, Demographics and Memory Study (ADAMS) to determine the costs of dementia in the United States.

Role: Co-Investigator

IIR 11-109-1 Iwashyna (PI) 9/1/11 – 8/31/14
VA HSR&D

Longterm Consequences for Veterans with Sepsis

This project will examine the extent to which VHA hospitals systematically vary in their risk- and reliability-adjusted long-term outcomes of their patients after acute illness, using severe sepsis as a model system.

Role: Co-Investigator

R01 AG018418 House (PI) 6/15/11 – 5/31/16
NIA

Understanding Social Disparities in Health and Aging

Fifth wave study gathering information about processes related to stress, socioeconomic and racial disparities in health, and the extent to which education causes morbidity to be compressed to a short period at the end of life.

Role: Co-Investigator

SDR 10-180 Langa (PI) 3/1/12 – 2/28/14
VA HSR&D

VA-HRS Data Linkage Project

Create a unique and comprehensive data source to support innovative research on crucial issues regarding Veterans' health, their utilization of VA and non-VA healthcare services, and the impact of illness on Veterans and their families.

Role: Principal Investigator

Ongoing Research Support (cont'd)

R01 AG043960

NIH / NIA

Shih (PI)

9/1/12 – 8/31/15

Neighborhood Characteristics and Cognitive Decline in U.S. Older Adults

This project will fill develop objective neighborhood characteristics for neighborhoods across the nation, link these data with longitudinal data on cognitive function assessed in the HRS, and examine the relationship between objective and perceived psychosocial neighborhood characteristics and cognitive functioning.

Role: Co-Investigator

Completed Research Support

R01 AG027010

NIH / NIA

Langa (PI)

4/15/06 - 3/31/10

Patterns and Predictors of Cognitive Decline

The major goals of this project are to use data from the Health and Retirement Study (HRS) and Aging, Demographics and Memory Study (ADAMS) to: 1) provide new information on the longitudinal trajectories of cognitive decline over a 12-year period in a nationally representative sample of older Americans; and 2) identify risk factors from across the life span (childhood, middle-age, and older-age) that increase the likelihood for developing cognitive impairment and dementia as one ages.

Role: Principal Investigator

R21 HL093129

NHLBI / NIH

Rogers (PI)

7/1/09 – 6/30/11

Blood Transfusions: Gender Differences in Utilization, Predictors, and Outcomes

The goal of the project is to examine the profiles of elderly women and men in the United States who receive blood transfusions. Predictors of utilization will be assessed, as well as post-transfusion outcomes such as infection and thrombotic events.

Role: Co-Investigator

RC2 AG036554

NIH / NIA

Weir (PI)

9/30/09-9/29/11

National Trends in Brain Health: a Follow-Up Study of CIND and Dementia in the US

The proposed ADAMS 2010, in conjunction with the original ADAMS and the on-going HRS, will provide the first nationally representative data to assess the prevalence and trends of CIND and dementia in the US

Role: Co-Principal Investigator

RC2 AG036495

NIH / NIA

Weir (PI)

9/30/09-9/29/11

Creating a National Resource for Genetic Research in Behavioral & Health Sciences

This ARRA project will create a genetic database on 13,142 individual participants in an ongoing longitudinal study of older Americans, and create mechanisms by which qualified researchers can access the data.

Role: Co-Investigator

IR-07-185-1

VA HSR&D

Piette (PI)

7/01/08 – 6/30/12

Enhancing Caregiver Support for Heart Failure Patients: The CarePartner Study

The purpose of this randomized trial is to evaluate the impact of extending the reach of health information technology by incorporating a protocol-driven model for improved monitoring and self-management support by a CarePartner (informal caregiver).

Role: Co-Investigator

BIOGRAPHICAL SKETCH

NAME Susan Smith	POSITION TITLE Associate Professor of Health Management and Policy
eRA COMMONS USER NAME ssmith	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of Illinois, Urbana-Champaign	B.S.	1982 - 1986	Health Planning/Admin
University of Missouri, Columbia	M.B.A	1986 - 1988	Business
University of Missouri, Columbia	M.H.A.	1986 - 1988	Health Administration
University of Michigan, Ann Arbor		1993 -1994 1996 -1997	AHRQ-funded Pre-doctoral Health Services Research Fellowship
University of Michigan, Ann Arbor	Ph.D.	1993 - 1998	Health Services Organization & Policy

A. Personal Statement

The goal of this study is to conduct a population-level evaluation of dissemination of enhanced recovery after surgery (ERAS) protocols for major inpatient surgery and support Dr. Smith's development as an independent investigator with the longitudinal skills to obtain R01-level research grants, while he maintains a clinical practice in colon and rectal surgery. My entire career in health services research has focused on understanding environmental and organizational factors related to hospitals, physicians, and other healthcare providers. I have conducted site visits and informant interviews, developed and selected survey instruments of organizations, and conducted qualitative research on funded projects studying hospitals, health plan organizations, a Medicaid agency, and substance abuse treatment organizations. Since early 2009, I have been involved with the Michigan Surgical Quality Improvement Collaborative, including participation in hospital site visits and several quarterly collaborative meetings. Partnering with Dr. Smith, I will be involved in all scientific and logistical aspects, and in particular, I will provide guidance in the evaluation of hospital organizational factors contributing to ERAS implementation and outcomes.

B. Positions and Honors

Positions and Employment

1988-1989 Management Fellow, Mercy Health Services, Farmington Hills, MI
 1989-1993 Director of Marketing and Client Services, Sachs Group, Inc., Evanston, IL
 1994-1998 Graduate Research Assistant, Institute for Social Research, Ann Arbor, MI
 1998-2005 Assistant Professor, Health Services Research, Management and Policy, University of Florida,
 2005-2008 Associate Professor, Health Services Research, Management and Policy, University of Florida, Gainesville, FL
 2005-2008 Associate Department Chair, Health Services Research, Management and Policy, University of Florida, Gainesville, FL
 2005-2008 Michael O. and Barbara Bice Term Professor in Health Services Research, Management and Policy University of Florida, Gainesville, FL
 2008- Associate Professor, Health Management and Policy, University of Michigan, Ann Arbor MI
 2011- Director, Griffith Leadership Center in Health Management and Policy, Ann Arbor MI
 2011- Chief Academic Officer, National Center for Healthcare Leadership, Chicago IL

Other Experience and Professional Memberships

2008-2009 Division Chair (Elected), Health Care Management Division, Academy of Management

2009- Board Member (Elected), Association of University Programs in Health Administration

Honors

1997-1998 Rackham Graduate Fellow, University of Michigan Horace A. Rackham Graduate School.
2001 Teaching Excellence Award, University of Florida College of Health Professions.
2005 Faculty Leadership Award, University of Florida College of Public Health & Health Professions
2011 Excellence in Teaching Award, Healthcare Management Division, Academy of Management
2011 Fellow, American College of Healthcare Executives

C. Selected Peer-reviewed Publications (Selected from 40 peer-reviewed publications)

Most relevant to the current application:

1. Hall, A.G., Smith, C.H., Landry, A.Y., and Duncan, R.P. (2013). Reported Experiences with Medicaid Managed Care Models among Parents of Children. *Maternal and Child Health Journal*. Published on-line April 19, 2013. DOI 10.1007/210995-013-1270-5.
2. Smith, C.H., Cohen, G.R., and Erb, N. (2013). Engaging Primary Care Physicians in Quality Improvement: Lessons from a Payer-Provider Partnership. *Journal of Healthcare Management*. In Press.
3. Griffith, JR., Fear, K.M., Lammer, E., Zheng, K., Banaszak-Holl, J., Lemak, C.H. (2013). A Positive Deviance Analysis of Baldrige Award Recipients 2002-2008. *Journal of Health Care Management*. In Press.
4. Hall, A.G., Smith, C.H., Landry, A.Y., and Duncan, R.P. (2012). Incentives for Healthy Behaviors: Experience from Florida Medicaid's Enhanced Benefit Rewards Program. *Journal of Primary Care and Community Health* 4(2), 112-118. DOI: 10.1177/2150131912456437.
5. Cohen, G.R., Erb, N. and Smith, C.H. (2012). Physician Practice Responses to Financial Incentive Programs: Exploring the Concept of Implementation Mechanisms. Annual Review of Health Care Management: Strategy and Policy Perspectives on Reforming Health Systems. *Advances in Health Care Management* 13, 29-58. DOI 10.1108/S1474-8231(2012)0000013007. PMID: 23265066.
6. Parker, V.A. and Smith, C.H. Navigating Patient Navigation: Crossing Health Services Research and Clinical Boundaries. *Biennial Review of Health Care Management* 2011, 11: 149-183.
7. Johnson, CE, Lemak, C.H., Hall, AE, Saxena, P, Harman, J, and Edwards, C. Outsourcing Administrative Functions: Service Organization Demonstrations and Florida Medicaid PCCM Program Costs. *Journal of Health Care Finance* 2010, 37(1): 1-12. McKay, N.L., Lemak, C.H. and White, A. Variations in Hospital Administrative Costs. *Journal of Healthcare Management* 2008; 53(3): 153-168.
8. McKay, N. and Lemak, C.H. Analyzing Administrative Costs in Hospitals. *Health Care Management Review* 2006; 31 (4): 347-354.
9. Lemak, C.H., Johnson, C.E. and Goodrick, E. Collaboration to Improve Services for the Uninsured: Exploring the Concept of Health Navigators as Interorganizational Integrators. *Health Care Management Review* 2004; 29 (3): 196-206.

Additional recent publications of importance to the field:

1. Harman, J., Lemak, C., Al-Amin, M., Hall, A., Duncan, R. (2011). Changes in Per Member Per Month Expenditures after Implementation of Florida's Medicaid Reform Demonstration. *Health Services Research*, 46(3): 787-804. Doi: 10.1111/j.1475-6773.2010.01226.x.
2. Hall, A.G., Landry, A.Y., Lemak, C.H., Duncan, R.P. (2012). Incentives for Healthy Behaviors: Experience from Florida Medicaid's Enhanced Benefit Rewards Program. *Journal of Primary Care and Community Health*. In Press.
3. Landry, A.Y., Lemak, C.H., and Hall, A.G. Successful Implementation in the Public Sector: Lessons Learned from Florida's Medicaid Reform Program. *Journal of Public Health Management Practice* 2011, 7(2): 154-163.
4. Duncan, R.P., Lemak, C.H., Vogel, W.B., Johnson, C.E., Hall, A.G. and Porter, C.K. Florida's Medicaid Provider Services Network (PSN) Demonstration and Medicaid Reform. *Health Services Research* 2007; 43:1, Part II, 384-400.

5. Campbell, C., Wells, R., Alexander, J.A., Jiang, L. Nahra, T.A., and Lemak, C.H. Tailoring of Outpatient Substance Abuse Treatment to Women: 1995-2005. *Medical Care*, Volume 45(8): 775-780. (2007).
6. Wells, R., Lemak, C.H., Alexander, J.A., Campbell, C., Nahra, T.A., and Ye, Y. Do Licensing and Accreditation Matter in Outpatient Substance Abuse Treatment Programs? *Journal of Substance Abuse Treatment* 33: pp. 43-50. (2007).
7. Wells, R., Lemak, C. H., & D'Aunno, T. A. Factors associated with interorganizational relationships among outpatient drug treatment organizations 1990-2000. *Health Services Research* 2005; 40(5) Part I: 1356-1378.
8. Lemak, C. H. and Alexander, J. A. Factors Influencing Staffing of Outpatient Substance Abuse Treatment Programs. *Psychiatric Services* 56(8), pp. 934-940. (2005).
9. Lemak, C.H., Alexander, J.A. & Campbell, C. Administrative Burden and its Implications for Substance Abuse Treatment Organizations. *Psychiatric Services* 54(5), pp. 705-711. (2003).
10. Lemak, C.H., Alexander, J.A., & Roy, J. Why Do Organizations Use Contingent Staffing Arrangements? An Analysis of Market and Social Influences in the Drug Treatment Sector. *Journal of Health and Social Behavior* 44(2): pp. 182-199. (2003).
11. Alexander, J.A. & Lemak, C.H. The Effects of Managed Care on Administrative Burden in Outpatient Substance Abuse Treatment Organizations. *Medical Care*, 35 (10), pp. 1060-1068. (1997).
12. Lemak, C.H. & Goodrick, E. Strategy as Simple Rules: Understanding Success in a Rural Clinic. *Health Care Management Review* 28(2): pp. 90-99. (2002).
13. Johnson, C.E., Kralewski, J.E., Lemak, C.H., Cote, M.J., & Deane, J. Medical Group Practice Information Systems Use within Managed Care Environments. *Journal of Ambulatory Care Management* 25:1, pp. 40-51. (2002).
14. Lemak, C.H., Alexander, J.A., & D'Aunno, T.A. An Organizational Analysis of Selective Contracting in Managed Care: The Case of Substance Abuse Treatment. *Medical Care Research and Review*, Vol. 58 (4), pp. 455-481. (2001).
15. Lemak, C.H. & Alexander, J.A. Managed Care and Drug Treatment Practices: A Model of Organizational Response to External Influence. *Advances in Health Care Management*, Vol. 2, pp. 131-159. (2001).

D. Research Support

Ongoing

Grant, NIA (Smith, PI) 9/30/12 – 8/31/2015
 Understanding Variation in Failure to Rescue in the Elderly
 Examine context, attitudes, and behaviors underlying Failure to Rescue (FTR) and how they relate to risk-adjusted, hospital-specific FTR rates. Gain a deeper understanding of organizational factors related to FTR.
 Role: Investigator

Completed

Grant, The Commonwealth Fund (Smith, PI) 5/01/10 – 03/31/13
 Evaluation of the Physician Group Incentive Program: From Partisanship to Partnership. Comprehensive Evaluation of physician group incentive program using mixed methods, including (1) in-depth physician and other stakeholder interviews and focus groups; (2) health care environmental data collection and analyses; and (3) quantitative analyses of PGIP, physician organization, and physician practice data.
 Role: PI

Grant, Center for Healthcare Research and Transformation (Smith, PI) 5/01/10 – 4/31/11
 Understanding Environmental and Organizational Factors Related to Surgical Quality in Michigan Hospitals. Understand the cultural, organizational, and environmental factors associated with high and low surgical quality performance among the hospitals in the Michigan Surgical Quality Collaborative.
 Role: PI

Grant, Gilbert Whitaker Fund, University of Michigan (Smith, PI) 10/01/09 – 7/31/10
Building Crosscutting Leadership Competencies into Professional Health Education
Institutionalize leadership development activities and competency-based curricula in the Department of Health Management and Policy.
Role: PI

Contract, Thompson Reuters (Griffith, PI) 11/15/09 – 8/31/10
Analysis of "Top 100" Hospital Performance Data
Use Data Envelopment Analyses to construct relative technical efficiency for each hospital and examine correlations between efficiency and performance.
Role: Investigator

Project Grant, Florida Agency for Health Care Administration (Duncan, PI) 12/19/05 – 12/31/10
Evaluating Medicaid Reform in Florida
Comprehensive 5-year evaluation of Florida's Medicaid Reform initiative. Project lead for Organizational Analyses, which focus on (1) reform implementation process; (2) reform health plans (managed care organizations and provider service networks); and (3) choice counseling organization and process.
Role: Consultant

Grant, McNearney Research Award, University of Michigan (Zheng, PI) 12/01/09 – 11/30/10
Knowledge Management of Management Knowledge: Current Best Practice among Healthcare Organizations.
Understand how knowledge is currently managed in healthcare organizations, particularly leading organizations that have demonstrated excellent clinical and organizational performance.
Role: Investigator

Grant, Gilbert Whitaker Fund, University of Michigan (Cooke, PI) 5/01/09 – 4/30/10
Development of an Interdisciplinary Leadership Curriculum for Medical Residents.
Develop leadership curricula for University of Michigan's Department of Family Medicine Residency Program.
Role: Consultant
Role: PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Greg Smith, Ph.D.	POSITION TITLE Professor, Health Management and Policy		
eRA COMMONS USER NAME Gsmith	Professor, Economics		
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
Princeton University, Princeton, NJ	A.B.	1986	Economics
M.I.T, Cambridge, MA	Ph.D.	1990	Economics

A. Personal Statement

Greg Smith joined the faculty at the University of Michigan in 2008 as Professor in both the SPH Department of Health Management and Policy and in the Department of Economics. He is the Director of the Robert Wood Johnson Foundation Scholars in Health Policy Research at the University of Michigan, and a Research Affiliate of the Population Studies Center. In addition to his affiliations with the University of Michigan, Prof. Norton is a Research Associate of the National Bureau of Economic Research in the Health Economics Program. Before coming to Michigan, he taught at UNC at Chapel Hill and at Harvard Medical School. His research interests in health economics include long-term care and aging, obesity, and econometrics. In 2003, UNC at Chapel Hill awarded him the Phillip and Ruth Hettleman Prize for Artistic and Scholarly Achievement by Young Faculty.

Prof. Smith has specific expertise relevant to this grant proposal. He has considerable experience using claims data to implement quasi-experimental design policy evaluations. He has worked with numerous large claims data sets, including Medicare and Medicaid claims. He has published many papers that use instrumental variables and other advanced econometrics. He has worked with clinicians at the University of Michigan on several projects, including projects using instrumental variables published in *JAMA* and in *Journal of Urology*. His articles on interaction terms in logit and probit models changed how researchers estimate and interpret econometric models with interaction terms, a common issue. As a co-investigator, Prof. Smith will advise Dr. Smith on all aspects of the project, with a particular emphasis on multivariable model estimation and ensuring appropriate implementation of econometric techniques for analyses.

B. Positions and Honors

Positions and Employment

1990–1993	Assistant Professor (1992–1993), Instructor (1990–1992), Department of Health Care Policy, Harvard Medical School
1993–1996	Senior Economist (1995–1996), Research Economist (1993–1995), Center for Economics Research, Research Triangle Institute
1994–2008	Professor (2005–2008), Associate Professor (2000–2005), Assistant Professor (1996–2000), Adjunct Assistant Professor (1994–1996), Department of Health Policy and Administration, School of Public Health, University of North Carolina at Chapel Hill
2004–2008	Professor (2007–2008), Adjunct Associate Professor (2004–2007), Department of Economics, University of North Carolina at Chapel Hill
2008–	Professor (2008–), Department of Health Management and Policy, School of Public Health, University of Michigan
2008–	Professor (2008–), Department of Economics, University of Michigan

Other Professional Experience

1990–1992 Postdoctoral Fellow, National Bureau of Economic Research
1994–2005 Part-time Lecturer, Center for Health Policy, Law and Management, Duke University
1997–2008 Research Fellow, Cecil G. Sheps Center for Health Services Research, UNC at Chapel Hill
1999–2003 Associate Editor, **Southern Economic Journal**
2000–2003 Director of the Doctoral Program, Dept. Health Policy and Administration, UNC at Chapel Hill
2004–2011 Board of Trustees, American Society of Health Economists
2008–2011 Associate Director, Robert Wood Johnson Foundation Scholars in Health Policy Research
2007– Associate Editor, **Health Economics**
2008– Research Affiliate, Population Studies Center, University of Michigan
2009– Research Associate, National Bureau of Economic Research’s Health Economics Program
2009– Editorial Board, **Health Services Research**
2011– Director, Robert Wood Johnson Foundation Scholars in Health Policy Research

Awards

2003 Phillip and Ruth Hettleman Prize for Artistic and Scholarly Achievement by Young Faculty
2005 Giddon Award for Distinguished Research in the Behavioral Sciences

C. Peer-Reviewed Publications (selected from more than 100)

Most relevant to the current application

1. Norton, E.C., S.A. Garfinkel, L.J. McQuay, D.A. Heck, J.G. Wright, R. Dittus, and R.M. Lubitz. 1998. “The Effect of Hospital Volume on the In-Hospital Complication Rate in Knee Replacement Patients.” **Health Services Research** 33(5):1191–1210.
2. Van Houtven, C.H. and E.C. Norton. 2008. “Informal care and Medicare expenditures: Testing for heterogeneous treatment effects.” **Journal of Health Economics** 27(1):134–156.
3. Yang, Z., D.B. Gilleskie, and E.C. Norton. 2009. “Health Insurance, Medical Care, and Health Outcomes: A Model of Elderly Health Dynamics.” **Journal of Human Resources** 44(1):47–114.
4. Tan, H.J., E.C. Norton, Z. Ye, K.S. Hafez, J.L. Gore, D.C. Miller. 2012. “Long-term Survival Following Partial vs Radical Nephrectomy Among Older Patients With Early-Stage Kidney Cancer.” **Journal of the American Medical Association** 307(15):1629–1635.
5. Hollingsworth, J.M., E.C. Norton, S.R. Kaufman, R.M. Smith, J.S. Wolf, Jr., B.K. Hollenbeck. Forthcoming 2013. “Expulsive therapy versus early stone-directed surgery for acute renal colic: An instrumental variable analysis.” **Journal of Urology**.

Additional recent publications of importance to the field

1. Norton, E.C., and D.O. Staiger. 1994. “How Hospital Ownership Affects Access to Care for the Uninsured.” **RAND Journal of Economics** 25(1):171–185.
2. Norton, E.C. 2000. “Long-term Care.” In **Handbook of Health Economics, Volume IB**, A.J. Culyer and J.P. Newhouse, eds, pp. 956–994. New York, NY: Elsevier Science B.V.
3. Ai, C. and E.C. Norton. 2003. “Interaction Terms in Logit and Probit Models.” **Economics Letters** 80(1):123–129.

Program Director/Principal Investigator:
(Last, first, middle)

4. Van Houtven, C.H. and E.C. Norton. 2004. "Informal care and health care use of older adults." **Journal of Health Economics** 23(6):1159–1180.
5. Ai, C. and E.C. Norton. 2008. "A Semiparametric Derivative Estimator in Log Transformation Models." **The Econometrics Journal** 11(3):538–553.
6. Kleinman, L.C. and E.C. Norton. 2009. "What's the Risk? A simple approach for estimating adjusted risk ratios from nonlinear models including logistic regression." **Health Services Research** 44(1):288–302.
7. Han, E., E.C. Norton, and S.C. Stearns. 2009. "Weight and Wages: Fat versus Lean Paychecks" **Health Economics** 18(5):535–548.
8. French, M.T., E.C. Norton, H. Fang, and J.C. Maclean. 2010. "Alcohol consumption and body weight." **Health Economics** 19(7):814–832.
9. Cawley, J., E. Han, and E.C. Norton.. 2011. "The Validity of Genes Related to Neurotransmitters as Instrumental Variables." **Health Economics** 20(8):884–888.
10. Werner, R.M., E.C. Norton, R.T. Konetzka, D. Polsky. 2012. "Do consumers respond to publicly reported quality information? Evidence from nursing homes." **Journal of Health Economics** 31(1):50–61.

D. Research Support

ACTIVE

67949 & 70202 (Norton) 8/1/2006-7/31/2014
Robert Wood Johnson Foundation
Scholars in Health Policy Research Program

This is an interdisciplinary post-doctoral training program for recent PhDs in economics, political science and sociology in their early careers. During their two years in the program, Scholars participate in an integrative 6-week seminar on health and health care issues, a research seminar series, individual mentoring, and independent research and scholarship with a focus on health policy.

RSG-12-269-01-CPHPS (Wong) 7/1/2012-6/31/2015
American Cancer Society

Understanding Variation in Treatment Intensity of Poor Prognosis

This project will (1) examine variation in the intensity of care for patients with poor prognosis cancers and (2) identify the main determinants (patient- and systems-level) of variation in treatment intensity.

(Birkmeyer) 1/1/2013-12/31/13
Blue Cross Blue Shield Foundation of Michigan
MVC Michigan Value Collaborative

To work collaboratively with Michigan hospitals to improve cost and quality of care.

PENDING

(Birkmeyer) 9/1/13-8/31/16
PCORI
Patient-Centered Outcomes Research Institute

Program Director/Principal Investigator:
(Last, first, middle)

The goals of this research proposal are to develop, implement, and evaluate an informed decision support tool for treatment of morbid obesity

(Miller) 7/1/13-6/30/17

American Cancer Society

Understanding optimal delivery systems for cancer care

This national study will evaluate comprehensively the relationship between care delivery models and the quality, outcomes, and cost of cancer care in the United States.

(Norton) 7/1/13-6/30/15

NIH

Improving Cost-Benefit Analysis of Tobacco Regulation

We propose to address the question: how should the FDA estimate the value of smokers' lost consumer surplus—that is, foregone enjoyment—associated with regulation-induced changes in smoking?

(Dimick) 12/1/13-11/30/15

NIH

Long-Term Comparative Effectiveness of the Lap Band

The goal of this project is to evaluate the comparative long-term safety and effectiveness of Lap Band Surgery in Medicare patients.

(Chen) 9/1/13-8/31/15

NIH

Medical Consultants and the Value of Hospital Care

We propose to use national Medicare claims to examine the association between routine medicine consult use and three outcomes: quality performance, utilization, and total expenditures

(Hollenbeck & Norton) 9/30/13-9/29/18

NIH

Accountable care organizations and the diffusion of surgical technology

To assess the impact of ACOs on the substitution of surgical technologies for existing therapies, and to measure the impact of ACOs on treatment expansion associated with surgical technologies.

(Miller) 9/1/13-8/31/18

NIH

Understanding optimal delivery systems for cancer care

This national study will evaluate comprehensively the relationship between care delivery models and the quality, outcomes, and cost of cancer care in the United States.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME [REDACTED]		POSITION TITLE Professor of Surgery Chief Medical Officer	
eRA COMMONS USER NAME			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Michigan State University, Lansing, MI	B.S.	1968	Zoology
George Washington University, Washington, D.C	M.D.	1972	Medicine

As the Project Director for the Michigan Surgical Quality Collaborative, I am charged with ensuring collaboration among hospitals aiming to improve the quality of surgical care and patient outcomes in the state of Michigan. Currently 55 hospitals participate, most of which are small community based and non-academic. The objective of MSQC is to share data, best practices, and quality improvement opportunities, so that overall quality is improved. Best practices are determined by data analysis and site visits to hospitals, and this information is shared by all hospitals at quarterly meetings, via a web site, and hard copy newsletter. This approach has been successful on many levels, particularly in lowering all cause morbidity and mortality, length of stay, and in reducing cost. I am in full support of [REDACTED] K award application.

A. Positions and Honors

Positions and Employment

- 1972-73 Intern in Surgery, University of Michigan
- 1973-74 Resident in Surgery, University of Michigan
- 1974-76 Guest Investigator, Laboratory of Immunodiagnosis, National Cancer Institute, National Institutes of Health, Ronald B. Herberman, Laboratory Chief
- 1976-78 Resident in Surgery, University of Michigan Medical Center
- 1978-83 Assistant Professor, Department of Surgery, University of Michigan
- 1983-90 Associate Professor, Department of Surgery, University of Michigan
- 1989-97 Section Head of General Surgery, University of Michigan
- 1990- Professor, Department of Surgery, University of Michigan Medical Center
- 1990-00 Associate Chair, Department of Surgery, University of Michigan Medical Center
- 1994-02 Assistant Component Director, Component III & IV, Medical School Curriculum, University of Michigan
- 1998-01 Associate Chief of Staff, University of Michigan Hospitals and Health Centers
- 1999-01 Interim Chief, Division of Transplantation, Section of General Surgery, University of Michigan Medical Center
- 2001- Chief of Clinical Affairs, University of Michigan Health System
- 2002- Henry King Ransom Professor of Surgery, Department of Surgery, University of Michigan
- 2002- Assistant Dean for Clinical Affairs, University of Michigan Health System
- 2004- Senior Associate Director for Clinical Affairs, University of Michigan Health System
- 2010- Chief Medical Officer, University of Michigan Health System

Honors and Awards

- 1971 Alpha Omega Alpha Medical Honor Society, George Washington University School of Medicine
- 1972 President, Chapter of Alpha Omega Alpha, George Washington University School of Medicine
- 1972 Smith-Reed Russell Honor Medical Society, George Washington University School of Medicine
- 1972 Lange Book Award for Outstanding Student in the Class of 1972, George Washington University School of Medicine

- 1972 Alec Horowitz Prize for Outstanding Student in the Field of General Surgery, George Washington University School of Medicine
1972 Graduation "With Distinction", George Washington University School of Medicine
1988 Young Surgeon Representative, Michigan Chapter, American College of Surgeons
2001 Clinical Kaiser-Permanente Excellence in Teaching Award finalist.
2005 Patient Safety and Quality Leadership Award, MHA Keystone Center for Patient Safety and Quality
2007 John E. Eisenberg Award for Patient Safety and Quality
2013 Named by Becker's Hospital Review as "50 Experts Leading the Field of Patient Safety."

B. Selected peer-reviewed publications (in chronological order and selected from 168 publications)

██████████, Henderson WG, Englesbe MJ, et al. Surgical Site Infection Prevention: The importance of operative duration and blood transfusion. Results of the first American College of Surgeons/National Surgical Quality Improvement Program best practices initiative. *J Am Coll Surg* 2008; 207(6): 810-820.

Lynch RJ, Englesbe MJ, Sturm L, Bitar A, Budhiraj K, Kolla S, Polyachenko Y, Duck MG, ██████████. Measurement of Foot Traffic in the Operating Room: Implications for Infection Control. *Am J Med Qual* 2009; 24(1): 45-52

██████████, Dellinger EP: Multihospital collaborations for surgical quality improvement. *JAMA* 2009; 302(14): 1584-5.

Lynch RJ, Englesbe MJ, Sturm L, Bitar A, Budhiraj K, Kolla S, Polyachenko Y, Duck MG, **Campbell DA, Jr.** Measurement of Foot Traffic in the Operating Room: Implications for Infection Control. *Am J Med Qual* 2009; 24(1): 45-52.

Darrell A Campbell; Michael Englesbe; Marty Luchtefeld Don't Give Up on Bowel Preps-Yet. *Annals of Surgery* 2010;252(1):200; author reply 200-1.

Moote M, Englesbe M, Bahl V, Hu HM, Thompson M, Kubus J, ██████████. PA driven VTE risk assessment improves compliance with recommended prophylaxis. *JAAPA*. 2010; June; 23(6): 27-35

██████████, Englesbe MJ, Kubus JJ, Phillips LR, Shanley CJ, Velanovich V, Lloyd LR, Hutton MC, Arneson WA, Share DA. Accelerating the Pace of Surgical Quality Improvement: The Power of Hospital Collaboration. *Arch of Surg*. 2010; Oct, 145(10):985-991

Share DA, ██████████, Birkmeyer N, Prager RL, Gurm HS, Moscucci M, Udow-Phillips M, Birkmeyer JD. How a regional Collaborative of Hospitals and Physicians in Michigan Cut Costs and Improved the Quality of Care. *Health Affairs*, 30. 2011; April (4):636-645.

Hendren S, Englesbe MJ, Brooks L, Kubus JJ, Yin H, ██████████. Prophylactic Antibiotic Practices for Colectomy in Michigan. *Am J Surg*. 2011, Mar, 2011(3): 290-294.

Share DA, ██████████, Birkmeyer N, Prager RL, Gurm HS, Moscucci M, Udow-Phillips M, Birkmeyer JD. How a regional Collaborative of Hospitals and Physicians in Michigan Cut Costs and Improved the Quality of Care. *Health Affairs*, 30, 2011; April (4):636-645.

Lee JS, Terjimanian MN, Tishberg LM, Alawieh AZ, Harbaugh CM, Sheetz KH, Kowalsky DB, Holcombe SA, ██████████, Wang SC, Sonnenday CJ, Englesbe MJ. Surgical site infection and analytic morphometric assessment of body composition in patients undergoing midline laparotomy. *J Am Coll Surg*. 2011 Aug;213(2):236-44. Epub 2011 May 20

Krapohl GL, Phillips LR, ██████████, Hendren S, Banerjee M, Metzger B, Morris AM. Bowel Preparation for Colectomy and Risk of Clostridium Difficile Infection. *Dis.of the Colon and Rectum* 2011;54(7):810-7.

Hendren S, [REDACTED] Non-fatal adverse events after colorectal operations. *Seminars in Colon & Rectal Surgery* 2011 Dec; 22(4):203-209.

Hayanga AJ, Lee JS, Kubus, JJ, Makepeace H, Hutton M, [REDACTED], Englesbe MJ. Local Anesthesia: A Strategy for the Reduction of Surgical Site Infections? *World Journal of Surgery*. 2011 Dec; 35(12):2596-602.

Englesbe MJ, Lee JS, He K, Fan L, Schaubel DE, Sheetz KH, Harbaugh CM, Holcombe SA, Campbell DA, Sonnenday CJ, and Wang SC. "Analytic morphomics, Core Muscle Size, and Surgical Outcomes." *Ann Surg* . 2012 Aug;256(2):255-61.

Englesbe MJ, Terjimanian MN, Lee JS, Sheetz KH, Harbaugh CM, Hussain A, Holcombe SA, Sullivan J, Campbell DA Jr., Wang SC, Sonnenday CJ. Morphometric Age and Surgical Risk. *J Am Coll Surg*. 2013 Mar 20. doi:pil:S1072-7515(13)00109-9.10.1016/j.jamcollsurg.2013.01.052[Epub ahead of print]

Smith M, Hussain A, Xiao J, Scheidler W, Reddy H, Olugbade K, Jr, Cummings D, Terjimanian M, Krapohl G, Waits S, **Campbell DA, Jr.**, Englesbe M. The Importance of Improving the Quality of Emergency Surgery for a Regional Quality Collaborative. *Ann Surg*. 2013 April; 257(4):596-602. doi: 10.1097/SLA.0b013e3182863750.

C. Research Support

[REDACTED]
Total Direct Costs

4/1/2013 – 3/31/2014
\$1,200,000.00

Blue Cross/Blue Shield of Michigan
Michigan Surgical Quality Collaborative

Project Goals: To share data, best practices, and quality improvement opportunities, so that overall quality is improved. This approach has been successful on many levels, particularly in lowering all cause morbidity and mortality, length of stay, and in reducing cost.

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 Edward Smith, MB MCh PhD FRCSI FACS	POSITION TITLE POSITION TITLE Professor of Surgery Chief, Division of Colorectal Surgery Vice-Chair, Department of Surgery
eRA COMMONS USER NAME (credential, e.g., agency login) edwardsmith	

EDUCATION/TRAINING <i>(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
University College Dublin Medical School	MB BCh BAO	06/89	Medicine and surgery
Royal College of Surgeons in Ireland	FRCSI	06/93	General surgery
University College Dublin Medical School	MCh	12/95	Immunology
Inter-Collegiate Boards of Surgery	FRCSI(Gen)	02/99	General / Colorectal
University College Dublin Medical School	PhD	12/00	Cell biology

A. Personal Statement

I have been an active clinical and basic science researcher for 20 years, and published more than 140 peer-reviewed manuscripts, 50 chapters and review articles, two textbooks, and given over 200 national and international lectures. My clinical and research interests include cost efficiency, laparoscopic colorectal surgery, surgery for colorectal cancer, re-operative surgery and surgical education. Over the last decade a primary focus of my research has involved enhanced recovery pathways, and I have been national PI on several such randomized controlled trials, and published several single center randomized controlled trials in this field. I am Past-President of the International Society of Laparoscopic Colorectal Surgery, and serve on the Editorial Boards of 10 journals, as well as the administrative committees and Council of many professional societies. I have extensive administrative commitments in my roles as Director of the Digestive Health Institute and Vice-Chair of Surgery. This collaborative study builds on past research experience in this field.

B. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

Positions and Employment

- 1989-93 Basic Surgical Training, Mater Hospital Dublin, and Royal College of Surgeons in Ireland
- 1993-95 Research Fellowship, University of Pittsburgh Medical Center, Pittsburgh, PA
- 1995-99 Higher Surgical Training Scheme, Royal College of Surgeons in Ireland, Dublin, Ireland
- 1999-00 Fellowship in Colorectal Surgery, Cleveland Clinic Foundation, Cleveland, Ohio
- 2000-05 Staff Surgeon, Dept. of Colorectal Surgery, Cleveland Clinic Foundation, Ohio
- 2004-05 Professor of Surgery, Cleveland Clinic Lerner School of Medicine, CWRU, Ohio
- 2005 - Chief of Colorectal Surgery, Vice-Chair of Surgery, University Hospitals of Cleveland, Ohio
- 2005 - Professor of Surgery, Case Western Reserve University, Cleveland, Ohio
- 2005 - Director, Institute for Surgery and Innovation, University Hospitals Case Medical Center and Case Western Reserve University, Cleveland, Ohio
- 2009 - Director, Digestive Health Institute, UHCMC, Cleveland, Ohio

Other Experience and Professional Memberships

Fellow: American Society of Colorectal Surgeons; American College of Surgeons

Editorial Boards include: World J Gastroenterol, Dis Colon Rectum (Associate Editor), World J Surgery, Colorectal Disease, Polish Journal of Surgery, Am J Surgery

Active Member: Central Surgical Association; Midwest Surgical Association (Council & Committee member); SAGES (Committee member); American Society of Colorectal Surgeons (Council & Committee member); American Surgical Association.

Founding Member and Past-President: International Society of Laparoscopic Colorectal Surgery

Prizes and Honors

1987 Henderson Prize, Mater Hospital and University College Dublin, Ireland

1988 Leonard Prize, Mater Hospital and University College Dublin, Ireland

1989 Gold Medal in Surgery, University College Dublin, Ireland

1995 Ortho Biotech Transplant Fellow

1996 European School of Oncology Fellowship

1998 Irish Travelling Fellowship

1999 Surgical Travelling Fellowship of the Royal College of Surgeons in Ireland

2000 Outstanding Colorectal Clinical Fellow Award, Cleveland Clinic

2000 ACG/Astra Zeneca Senior Fellow Award

2001 Millin Medal of Royal College of Surgeons in Ireland

2003 Best of the Best for 2002. Best colorectal paper of international literature by *Archives of Surgery*.

2004 New England Society of CR Surgeons award for best oral presentation, ASCRS.

2005-2009 Best Doctors in America, Americas Top Doctors, and Top Doctors for Cancer.

2007 Northwest Soc CR Surgeons award for best oral presentation, ASCRS.

2009 Honorary Fellowship American Society of Colorectal Surgery

2009 Jeffrey L. Ponsky MD Professorship in Surgical Education, CWRU, Cleveland, OH

2011 Master Clinician Award, University Hospitals Case Medical Center

C. Selected peer-reviewed publications. (Selected from a total of 3 books, 153 peer-reviewed articles, 64 chapters/reviews.)

Most relevant to the current application

1. Fast-track post-operative management protocol for patients with high comorbidity undergoing complex abdominal and pelvic colorectal surgery. Delaney CP, Fazio VW, Senagore AJ, Robinson B, Halverson A, Remzi FH. *Br. J. Surg.* 2001; 88: 1533-8.
2. Randomized controlled trial comparing the Controlled Rehabilitation with Early Ambulation and Diet (CREAD) pathway vs. CREAD with pre-emptive epidural anesthesia/analgesia after laparotomy and intestinal resection. Zutshi M, Delaney CP, Senagore AJ, Mekhail N, Lewis B, Connor JT, Fazio VW. *American Journal of Surgery.* 2005; 189(3): 268-72.
3. Outcome of discharge within 24-72 hours of colorectal surgery. Delaney CP. *Dis Colon Rect.* 2008; 51: 181-5.
4. Clinical Outcomes and Resource Utilization Associated with Laparoscopic and Open Colectomy Using a Large National Database. Delaney CP, Chang E, Senagore AJ, Broder M. *Ann Surg.* 2008; 247(5): 819-24.
5. Association of surgical care practices with length of stay and use of clinical protocols after elective bowel resection (BR): results of a national survey. Delaney CP, Senagore AJ, Gerkin TM, Beard TL, Zingaro WM, Tomaszewski KJ, Walton LK, Poston SA. *Am J Surg.* 2010; 199(3): 299-304.

Additional recent publications of importance to the field (in chronological order)

6. Case matched comparison of clinical and financial outcome after laparoscopic or open colectomy. Delaney CP, Kiran RP, Brady K, Fazio VW. *Annals of Surgery.* 2003; 238: 67-72.
7. Prospective randomized controlled trial between a pathway of Controlled Rehabilitation with Early Ambulation and Diet (CREAD) and traditional postoperative care after laparotomy and intestinal resection. Delaney CP, Zutshi M, Senagore AJ, Remzi F, Hammel J, Fazio VW. *Diseases of the Colon and Rectum.* 2003; 46: 851-9.

8. Prospective randomized controlled trial evaluating epidural anesthesia/analgesia in laparoscopic segmental colectomy. Senagore AJ, Delaney CP, Mekhail N, Fazio VW. British Journal of Surgery. 2003;90: 1195-9.
9. Prospective, randomized, double-blind, multicenter, placebo-controlled study of alvimopan, a novel peripherally acting mu opioid receptor antagonist, for postoperative ileus after major abdominal surgery (Study 14CL302). Delaney CP, Weese JL, Hyman NH for the Alvimopan Postoperative Ileus Study Group. Dis Colon Rectum. 2005; 48(6): 114-25.
10. A critical analysis of laparoscopic colectomy at a single institution: lessons learned after 1000 cases. Senagore AJ, Delaney CP. Am J Surgery. 2006; 191(3): 377-80.
11. Alvimopan for postoperative ileus following bowel resection: a pooled analysis of Phase III studies. Delaney CP, Wolff BG, Viscusi E, Senagore AJ, Fort JG, Du W, Techner L, Wallin B. Ann Surg. 2007; 245: 355-63.
12. A national comparison of laparoscopic vs open colectomy using the National Surgical Quality Improvement database. Senagore AJ, Stulberg J, Byrnes J, Delaney CP. Dis Colon Rectum, 2009; 52: 183-6
13. Adherence to surgical care improvement project measures and the association with postoperative complications. Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, Koroukian SM. JAMA, 2010; 303(24): 2479-85.
14. Enhanced recovery pathways optimize health outcomes and resource utilization: a meta-analysis of randomized controlled trials in colorectal surgery. Adamina M, Kehlet H, Tomlinson GA, Senagore AJ, Delaney CP. Surgery, 2011, 149: 830-40.
15. A randomized trial comparing cost and effectiveness of bipolar vessel sealers vs clips and vascular staplers for straight laparoscopic colorectal resections. Adamina M, Champagne BJ, Hoffman L, Ermlich B, Delaney CP. Br J Surg, 2011; 98(12): 1703-12.
16. Towards optimizing perioperative colorectal care: outcomes for 1000 consecutive laparoscopic colorectal procedures using enhanced recovery pathways. Delaney CP, Brady K, Woconish D, Parmar SP, Champagne BJ. Am J Surg, in press.

D. Research Support

Ongoing Research Support

Funding source: Norwegian Government Role: International Collaborator
Project title: M# Mobile Mentor
Period: 2011-2013

Peer Reviewed Funding – Cleveland Foundation:

2010 – 11 : “Development of a cost efficiency database: Socrates project”.
 Role: PI

University Hospitals Case Medical Center Faculty Support:

2009 – 11 : “Socrates Knowledge Management System”.
 Role: PI

Completed Research Support

Other Research Funding:

2007-9 : Ohio Savings Bank
 “Development of software to integrate administrative databases for evaluation of IBD”
 Position: PI

NIDDK T32-DK61917

2003-7 : "Training programs in academic gastroenterology"
Role: Co-investigator PI: Dr Greg Cooper

Commercial Research Funding:

2008-9 : WL Gore and Associates
"Study of bioabsorbable staple line reinforcement in colorectal and coloanal anastomoses"
Position: PI
2008-9 : Covidien
"Randomized controlled trial of energy-based devices vs staplers in laparoscopic colectomy"
Position: PI

Storz Endosurgery

2005-9 : Surgical Skills Trainer.
Role: Institute Director.

US Army Telemedicine and Advanced Technology Research Center (TATRC) Grant

2005-7 : Development of remote control and simulation for telementoring and telemedicine.
\$2,700,000
Role: Collaborator and Steering Committee member.

United States Surgical, Tyco Healthcare

2005-9 : Funded Laparoscopic Clinical Fellowship.
Role: Primary Training Surgeon.

International Congress of Laparoscopic Colorectal Surgery

2004 : Meeting and Educational support
2007 : Meeting and Educational support
2008 : Meeting and Educational support
2009 : Meeting and Educational support
Role: Program Chair.

Commercial Research Funding:

2002-3 : Adolor Corporation
"Placebo controlled trials in the study of mechanisms of post-operative ileus".
Position: PI

Research Programs Council, Cleveland Clinic Foundation

2000-1 : Project Grant
"Prospective randomized trial comparing fast track and traditional pathways."
Position: PI

Mater College Foundation

1997-8 : Project Grant (Principal Applicant)
"Micro metastatic disease in breast cancer."
Position: PI

Biotrin, Ireland

1997-8 : Research Funding (Organised Irish division of multi-center trial)
"Trypsinogen activation peptide as a predictor of disease severity in acute pancreatitis."
Position: PI

National Institutes of Health, USA

1994-7 : R-01 Research Project Grant
"Effects of orthotopic liver transplantation."
Role: Collaborator PI: Dr Thomas Starzl.

RESOURCES

Follow the 398 application instructions in Part I, 4.7 Resources.

The University of Michigan and UM Department of Surgery

The candidate is on the faculty of the University of Michigan, which ranks second in the United States in federal research and development funding, amongst all colleges and universities. The Department of Surgery has a strong track record of commitment to protected research time for tenure-track faculty. The Department of Surgery has ranked in the top 5 for NIH funding for the last several years, currently second among surgery departments. These statistics reflect the institutional commitment to academic career development, including resources and protected time for research.

Center for Healthcare Outcomes & Policy

The majority of the proposed research will be conducted at the Center for Healthcare Outcomes & Policy (CHOP) at the University of Michigan. CHOP is a large, multi-disciplinary consortium of 110 clinical and non-clinical faculty and staff sharing common interests in population-level health services research, including research based on clinical registries and large claims databases. Housed within the University's newly-established Institute for Healthcare Policy and Innovation (IHPI), in a 100,000 square foot research building recently acquired by the University, CHOP has a well-organized administrative data management infrastructure, including programmers/analysts, secure computer systems, and a variety of clinical databases spanning many years. Members of CHOP include economists, epidemiologists, statisticians, and clinician-scientists, representing at least eight major clinical departments from the School of Medicine. CHOP is directed by Dr. John Doe, the Primary Mentor on this proposal, and the candidate's primary research office is located at CHOP. As a member of the group, he will have access to the abundant data and human resources available.

CHOP is home to several statewide collaborative quality improvement programs, including the Michigan Surgical Quality Collaborative, the research setting for this proposal. These programs collect detailed clinical data on more than 200,000 patients annually, provide regular feedback on performance to providers, and oversee quality improvement activities at more than 50 Michigan hospitals. Outcomes research and policy evaluation based on clinical registries comprise a large component of CHOP's research portfolio, including multiple R01 grants related to collaborative quality improvement programs and the analytics of healthcare quality comparisons. CHOP investigators have mentored numerous junior faculty members through career development awards and have a track record of candidates progressing to R01-funded independent research efforts.

Advantages of Research Environment for the Proposed Project

IHPI is an ideal setting for this project. The rich intellectual environment and regular seminars will provide the candidate ample opportunity to present his research and elicit feedback from a diverse group of scientists and clinicians. From a practical standpoint, the candidate's primary office at IHPI is just steps away from the offices of Drs. Smith, Doe, Smith and Smith. The physical co-location of the central offices of the MSQC in the IHPI headquarters will facilitate success of the collaboration.

OTHER SUPPORT

Ongoing

Project Number: P01 AG019783
Source: NIH / NIA
Title of Project: **Causes and Consequences of Health Care Efficiency**
Dates of Project: 12/01/2012 – 11/30/2017
Annual Direct Costs: \$147,725 (Subcontract)
Percent Effort: 1.20 calendar months
Major Goals: Based on national Medicare data, this study is examining variation in hospital payments for inpatient surgery and relationship between cost and quality. Subproject #3 is based at the University of Michigan Center for Healthcare Outcomes and Policy, and uses Michigan's extensive data infrastructure to evaluate the effects of technical quality, payment reform and market forces on cost and quality in episodes of acute inpatient surgical care.

Role: Co-Investigator (PI: Skinner; Subproject Leader: Birkmeyer)
Overlap: This Program Grant provides the source of funds for most of the Medicare data required for the current proposal. There is no overlap in the research aims or methods.

CAREER DEVELOPMENT PLAN

A. Candidate's Background

In my clinical and research training, I have established an interest in improving care for vulnerable patients, especially those outside major academic centers where most research takes place. During a three year postdoctoral fellowship, I focused on analytic methods, quality improvement and operations management, mentored by Drs. Ashish Jha and Atul Gawande. My early research included investigations of a novel metric of intraoperative performance, strategies to prevent retained surgical equipment, error-reporting systems, and the role of hospital and surgeon expertise in surgical outcome disparities for disadvantaged patients. Later, my agenda involved themes represented in this proposal – quality improvement through standardization of best practices for colectomy and perioperative communication improvement after surgery in teaching hospitals. These initiatives showed me the value of surgeon leadership in quality improvement.

Since joining the faculty at University of Michigan, I have explored variation in perioperative care practices, care transitions and ancillary care utilization around inpatient surgery. Ongoing work seeks to understand relationships between care practices, technical quality, and episode efficiency, including utilization of post-discharge ancillary care. I am also a member of the ASCRS Quality Assessment & Safety Committee and was nominated to represent ASCRS to the American College of Surgeons' (ACS) Surgical Quality Alliance. I am also the University of Michigan's Cancer Liaison Physician to the ACS Commission on Cancer and representative to the NCCN Colorectal Cancer Screening Panel.

B. Career Goals and Objectives

In Michigan's quality improvement collaboratives, I have observed the benefits of multi-institutional collaboration for quality improvement. Inspired by these initiatives, and my previous experiences, my overarching career mission is *to improve the cost and quality of surgical care for vulnerable patients in all clinical settings -- whether large or small, academic or community*. In this proposal, I will perform population-level evaluation of enhanced recovery after surgery (ERAS) protocols for major inpatient surgery in three ways:

- Evaluating clinical outcomes of ERAS initiatives to improve value and efficiency;
- Evaluating effects of ERAS on transitions of care, utilization and overall episode costs with colectomy;
- Understanding patient-specific differences in the effects on ERAS among vulnerable populations.

These inquiries support my career goal to become an independent investigator with longitudinal skills to obtain R01-level research grants, while maintaining an active colorectal surgery practice. With skills acquired in this proposal I intend to become a national opinion leader in surgical quality and performance improvement.

C. Educational Plan

The educational plan for this award includes mentorship, project-based research, and focused didactics to develop skills in three areas essential to the work plan and my success as an independent investigator:

- 1. Organizational culture and health care delivery systems (Aims 1-2)**
- 2. Quantitative methods for enhancing causal inference (Aims 1-2)**
- 3. Gerontology and the health care needs of older adults (Aim 3)**

C.1. Mentorship

I have assembled a multidisciplinary team with expertise in these key disciplines. The mentors have extensive experience with federal research grants and high-impact scientific publications. Semi-annual meetings of the entire mentorship team will ensure the successful attainment of defined benchmarks for progress in this proposal.

John Doe, MD (Primary Mentor) is Director of the University of Michigan's Center for Healthcare Outcomes and Policy (CHOP). He has a senior-scientist award and an established track record as an independently-funded scientist and he has mentored many K award recipients toward R-level funding and independence. As a member of the Institute of Medicine, he is a recognized leader in health services research with expertise in the organization of health care systems and the measurement and improvement of health care quality. I will meet with Dr. Doe weekly to discuss all aspects of study design, data management, analysis, and interpretation, manuscript and grant writing, and career development.

Jane Doe, MD, PhD (Co-Mentor) is Professor of Internal Medicine, Gerontology, and Health Management and Policy. Dr. Langa's research focuses on the epidemiology and costs of chronic disease in older adults. He was recently awarded the Michigan Institute for Clinical and Health Research Distinguished Research Mentor Award. We will meet monthly, for guidance in evaluating clinical outcomes in Aim 3.

Susan Smith, PhD (Co-Mentor) is Director of the Griffith Leadership Center and Chief Academic Officer of the National Center for Healthcare Leadership. Her research focuses on management, leadership and organizational strategy. She will provide monthly guidance in the evaluation of hospital organizational factors contributing to ERAS implementation and outcomes (Aim 1).

Greg Smtih, PhD (Co-Mentor) is Professor of Economics and Health Management and Director of Health Economics at CHOP. He has extensive experience in statistical techniques to measure efficiency of health care delivery and will provide oversight and guidance twice monthly in the complex causal inference techniques for cost and outcome analyses used in all three Aims of this proposal.

C.2. Coursework

Although the focus of career development in this proposal entails mentorship and project-based learning, we have selected coursework to increase acquisition of skills in the three focus areas:

Organizational culture and health care delivery systems. Though my MPH included coursework in healthcare quality improvement, I will require additional training in health care operations management to better understand the relationships between organizational culture and the implementation and success of efficiency measures such as ERAS. During the first year, I will take a full semester course "Organization and Management of Healthcare Systems" (HMP603), taught by Dr. Lemak, focused on theories of organizations, the use of leadership, management processes, and organizational structures and outcomes. I will also attend the NIH Conference on the Science of Dissemination and Implementation in 2014 and enroll in the UM Department of Surgery Leadership Training Program – a year-long seminar series in team building, implementing innovation, measuring and improving performance, finance and accounting, operations management, and systems modeling.

Quantitative methods for enhancing causal inference. My MPH curriculum included courses in regression and cost-effectiveness analyses, but did not include advanced econometric methods of causal inference. Thus, I will enroll in Dr. Norton's "Program Evaluation in Public Health" (HMP640), which teaches analytic methods for public health programs, policies and interventions. This will be supplemented by summer seminars at UM's Center for Statistical Consultation and Research ("Causal Inference in the Social Sciences" and Applied Multilevel Models Using SAS and SPSS").

Gerontology and the health care needs of older adults. I will broaden my experience with the science of health care evaluation for older patients through participation in UM's Older Americans Independence Center seminars and "Advanced Seminar on Public Health and Aging" (EPID813), which covers methodological approaches to aging-related clinical epidemiology. I will also observe inpatient care in the newly-established Acute Care for Elders unit, a collaboration between UM and a local community hospital to support the functional recovery of hospitalized older adults.

D. Future Directions

Success in this proposal will inform development of applications (R01 and equivalent) for statewide design, dissemination and implementation of high-value practices for inpatient surgery. If we find that ERAS reduces overall costs and complications, we will actively promote its adoption through a mentored implementation program in a cluster-randomized trial among Michigan hospitals to evaluate the outcomes of this program implementation. If, on the other hand, we find that ERAS incurs increased complications, readmissions, or cost-shifting in older patients it would then lead to an R01 proposal around identifying high-value post-discharge ancillary care practices for elderly patients, and a limited project grant (GEMSSTAR R03, R21, or similar) involving primary survey research with elderly patients and their caregivers, to detail personal costs, impact on family, and the burdens and cost of informal care for older adults subjected to different perioperative care and discharge protocols – outcomes not be available in secondary data for this study.

A. SPECIFIC AIMS

Hospitals are facing unprecedented pressure to improve the efficiency of inpatient care, including major surgery. With the advent of Accountable Care Organizations, bundled payments and the expectation of declining reimbursement with health care reform, hospitals caring for Medicare beneficiaries must reduce unwanted practice variation and length of stay. An increasingly common strategy to achieve these ends is the use of so-called Enhanced Recovery After Surgery (ERAS) protocols – evidence-based, multidisciplinary bundles including surgical, anesthetic, nursing, and medical management around surgery. Studies from high-volume, specialty practices in several countries demonstrate that ERAS can minimize physiologic stress from surgery, hasten recovery and shorten length of stay.

Despite early promise, the real-world effects of ERAS dissemination remain uncertain, however. First, the expected benefits of ERAS on surgical outcomes, quality, and efficiency may not extrapolate beyond the highly selected centers in which they have been studied. Second, ERAS appears to reduce utilization of hospital services, but no study has thoroughly evaluated its effect on costs of the entire surgical episode. Concern remains, therefore, that unanticipated consequences, such as late complications or readmissions might increase the use of post-discharge ancillary services and substitute ambulatory care costs for those of the index hospitalization. Finally, there may be individuals, such as older adults with comorbidities or limited social support, who are particularly vulnerable to adverse repercussions of early discharge, for whom ERAS might cause increased utilization of post-discharge care.

To address these knowledge gaps, we propose the first population-based assessment of enhanced recovery protocols for inpatient surgery. We leverage Michigan's unique data infrastructure, including rich clinical registry data from the statewide, 52-hospital Michigan Surgical Quality Collaborative (MSQC), comprehensive payment data from the Michigan Value Collaborative and Medicare claims, and organizational culture and safety data from the Michigan Hospital Association's Keystone Surgery project.

This proposal has three specific aims:

Aim 1: To assess the clinical outcomes of enhanced recovery protocols in Michigan hospitals.

Through prospectively collected process of care data, we will characterize adoption of, and compliance with ERAS guidelines and the association of ERAS use with hospital and practice characteristics and organizational and safety culture. We will examine associations of ERAS use with 30-day complication rates, length of stay, and adherence to process of care quality metrics, as measured in the Michigan Surgical Quality Collaborative's robust clinical data registry. Capitalizing on natural experiments in hospitals that adopt or augment the use of ERAS, we will assess incremental effects on trends, using difference-in-difference methods.

Aim 2: To understand the influence of enhanced recovery protocols on efficiency of the entire surgical episode.

Using complete payment and utilization data from Medicare claims, we will evaluate the contribution of ERAS to differences in overall episode payments, focusing on the potential for cost-shifting from inpatient care to post-discharge services. Again, difference-in-difference methods will be used to evaluate natural experiments in hospitals that have adopted or augmented ERAS practices.

Aim 3: To evaluate patient-specific heterogeneity in the benefits or harms of enhanced recovery.

Using data from the Michigan Value Collaborative, which focuses on cost and utilization among privately insured patients, to supplement utilization data for Medicare beneficiaries, we will assess differential effects of ERAS on post-discharge outcomes, costs, and utilization of ancillary services by age and other factors. We hypothesize that vulnerable older patients—frail, high comorbidity, low socioeconomic status, limited social support—may be particularly susceptible to unintended consequences and cost-shifting in an ERAS protocol.

This research will have immediate impact on efforts to improve the efficiency of inpatient surgical care for older adults. Critical evaluation of value-driven practices will guide the design of efficient, patient-centered perioperative care, and provide payors with a blueprint for the design of value-based care delivery in inpatient surgery. Further, the project, mentorship, and educational plan will prepare the candidate to be an independent investigator and leader in surgical quality improvement.

B. SIGNIFICANCE

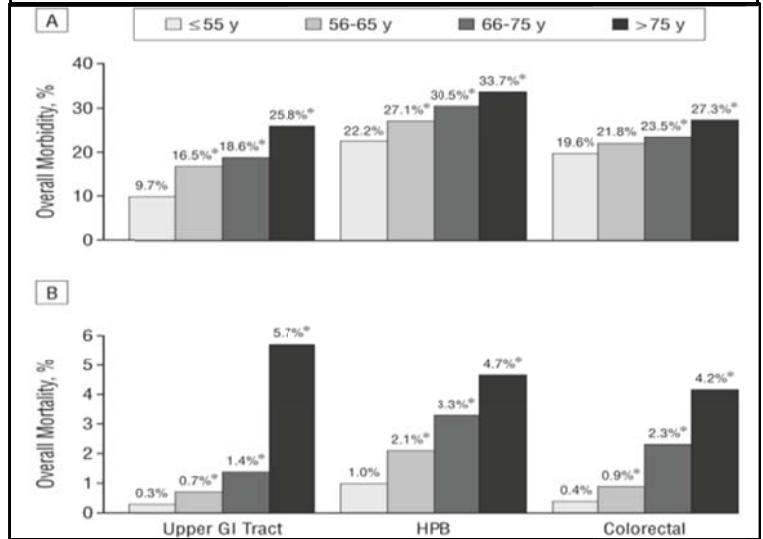
B.1. Pressure to improve the efficiency of inpatient surgery

Nearly 48 million inpatient operations are performed each year in US hospitals^{1,2} accounting for 40% of all hospital and physician payments from Medicare – approximately \$500 billion annually.³ Older adults undergo surgery far more often than younger patients,⁴ accounting for the majority of major inpatient operations,⁵ with disproportionately higher rates of surgical morbidity and mortality (Figure 1).⁶⁻⁸ Elderly patients incur greater risk for hospital readmission,⁹⁻¹⁴ discharge to inpatient nursing care,¹⁴ long-term functional dependence,¹⁵ and prolonged utilization of health care services after major surgery.^{7,8,16}

Evidence that clinical quality, surgical outcomes and costs of inpatient surgery vary widely between hospitals and surgeons suggests considerable opportunities for improvement.¹⁷ In our group’s recent studies of inpatient surgery among Medicare beneficiaries, for example, median postoperative length of stay⁹ and short-term complication rates¹⁸ after major surgical procedures varied at least two-fold between hospitals. Total payments for episodes of inpatient surgery in Medicare beneficiaries varied by more than 50% between the lowest and highest hospital quintiles.^{3,19} And high cost institutions tended to have overall higher complication rates¹⁸ and low procedure volumes.²⁰

As a consequence of the Affordable Care Act and associated reimbursement reforms, the financial consequences and risks associated with cost and quality variation are moving from payers to providers. Hospitals are therefore redoubling their efforts to improve the efficiency of inpatient surgery by reducing postoperative length of stay and minimizing unnecessary tests and services during hospitalization.

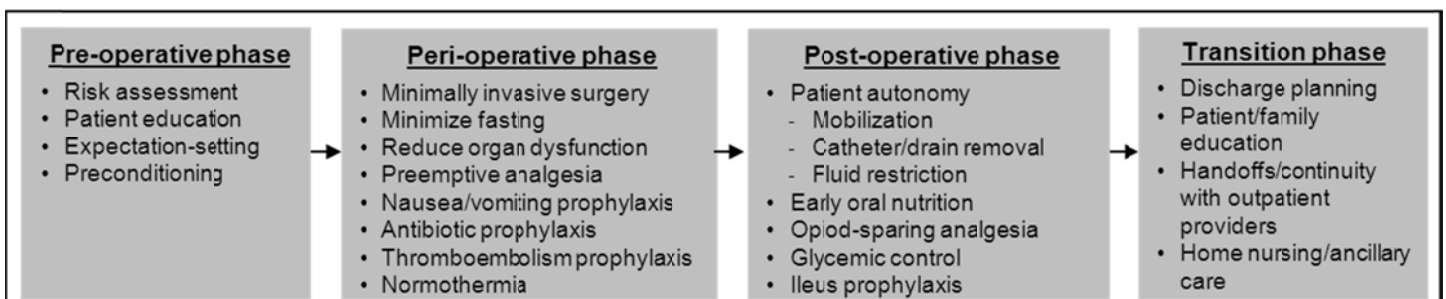
Figure 1: Morbidity and mortality by age, from the National Surgical Quality Improvement Program. (Ref #6)



B.2. Enhanced Recovery After Surgery (ERAS)

To improve efficiency in the perioperative period, many institutions have adopted standardized fast-track care pathways that ensure compliance with quality of care metrics, and reduce postoperative length of stay.²¹⁻²⁴ Among the most prevalent of these approaches is the “Enhanced Recovery After Surgery” (ERAS) program.^{25,26} The ERAS Study Group, composed mainly of European surgeons and anesthesiologists, promotes a 20-point protocol including preoperative, intraoperative, and postoperative care elements to reduce postoperative pain, hasten recovery of intestinal function, and reduce postoperative morbidity after intestinal surgery (Figure 2).^{27,28} ERAS was introduced for colorectal resections,^{28,29} and the lion’s share of evidence for its use comes from these common, high risk operations, but is gradually being adapted to other specialties.³⁰⁻³⁵

Figure 2: Examples of components of ERAS protocols, by phase of care



Many of these processes run counter to traditional surgical dogma, but the key guiding principles of these protocols are minimization and prevention of pain, physiologic stress and metabolic disturbance. Achieving these goals requires effective non-narcotic analgesic strategies, avoidance of unnecessary drains, tubes and other physical hindrances, early mobilization and encouragement of early oral nutrition, among other features.^{21,27} Six randomized trials,³⁶⁻⁴¹ three meta-analyses,^{21,42,43} and a Cochrane Collaboration review⁴⁴ have concluded that ERAS protocols reduce complications and length of postoperative ileus and hospital stay, without increasing readmissions (Figure 3).^{21,37,42,45,46} Cost savings are found across a range of operations and subspecialties, and derive from reductions in length of hospitalization, use of laboratory and imaging tests, and variability in equipment and medication use.^{37,47-56} These effects are particularly notable in high-volume, high-risk, high-complexity care, with substantial practice variation²² – such as colectomy in older adults. Reductions in resource utilization have been achieved without decrement in patient satisfaction or short term quality of life.^{37,45,57,58} Patients in ERAS programs report less postoperative fatigue and earlier functional recovery,⁵⁹⁻⁶¹ provided that they achieve early discharge from the hospital²¹ and remain free from complications.⁶²

Figure 3: Summary of randomized trials of clinical outcomes of ERAS in colon surgery. Adapted from ref #21.

Author	Year	# patients	Length of stay (median days)		Readmission Rate		Morbidity Rate	
			ERAS	Traditional	ERAS	Traditional	ERAS	Traditional
Anderson et al.	2003	25	3	7	0%	0%	29%	46%
Delaney et al.	2003	64	5	5	10%	18%	22%	30%
Gatt et al.	2005	39	5	7.5	5%	20%	47%	75%
Khoo et al.	2007	70	5	7	9%	3%	26%	51%
Muller et al.	2009	161	5	9	4%	3%	22%	48%
Serclova et al.	2009	103	7	9	0%	0%	21%	49%

With this mounting evidence, there is increasing pressure to rapidly disseminate ERAS methods. In the United Kingdom, national associations have signed a consensus statement that “enhanced recovery should be considered as standard practice for most patients undergoing major surgery across a range of procedures and specialties”⁶³ and the National Health Service has endorsed ERAS throughout its institutions.⁶⁴ The ERAS Study Group has developed a Partnership Programme to guide and troubleshoot implementation in new institutions, and includes a framework for data collection and feedback.⁶⁵ Although there are no population-based data on use in the US, clinical observation suggests that ERAS is becoming more widely adopted here as well. Within our Michigan Surgical Quality Collaborative, there are at least five centers that have adopted comprehensive ERAS programs for colectomy in recent years, and there is a groundswell of interest among other member institutions statewide.

B.3. Questions and concerns about ERAS

Generalizability beyond specialty centers. To date, the preponderance of literature examining effects of ERAS on clinical outcomes^{36-39,41} and costs^{47,49,52,57,66,67} has come from select institutions, with high volume practices, effective care coordination, and highly motivated surgeons and ancillary care providers.⁴⁴ Small trials from single clinical units are subject to important selection bias at the institution level, as the investigators may not be representative of hospitals and surgeons at large. Less than one in three US colon surgeons make use of any standardized perioperative care protocol at all⁶⁸ and continued use of practices demonstrated to prolong recovery time – mechanical bowel preparation, routine nasogastric intubation, restriction of oral intake, etc. – is prevalent.⁶⁹ Thus, there is particular concern about whether ERAS successes can be replicated in the average hospital practice, and in lower-resource settings with lesser care coordination. Further, in the nonrandomized, pre/post comparison trials that predominate the literature,^{52,57,67,70,71} there is likely selection bias at the patient level, affecting which patients are treated with ERAS, and regression to the mean, when groups that perceive a need to improve are the ones that adopt new protocols. These uncertainties, as well as concern for publication bias favoring studies with positive findings, led the Cochrane reviewers to grade as low the overall quality of evidence supporting ERAS dissemination.⁴⁴

Heterogeneity of ERAS components. There is uncertainty about which elements of ERAS protocols are responsible for their effects. There is great variability between trials in the details of the perioperative protocols and what processes are included,⁴⁴ making it difficult to parse their individual contributions. Standardization of care practices in some studies is associated with reduced length of stay and hospital costs, even when the elements of the protocol are quite traditional, and not particularly consistent with ERAS principles.^{52,57,70,71} Perhaps standardization itself, with the attendant focus on efficiency, coordination of care, and early discharge may be more important than the specific clinical interventions involved.⁷² Considering the published trials on ERAS, the Evidence Based Reviews in Surgery Group concluded that the wide variation in definitions, included practices, outcome measures, and methodology limits the confidence with which conclusions can be drawn from this body of literature to date.⁷³

Cost-shifting to outpatient care. Third, in-hospital efficiencies from ERAS could be undermined if early discharge incurs increased late complications or substitution with outpatient ancillary care services.^{59,60,74-76} When complications arise outside the hospital,^{77,78} there is risk for delayed recognition, increased readmission and more severe morbidity.⁶⁴ It is recognized that decreasing duration of hospital care is associated with increased readmissions for older patients with medical conditions such as heart failure,^{79,80} And many complications after colectomy arise only after discharge,^{77,78,81-83} making unplanned readmission both common and difficult to predict.⁸⁴⁻⁸⁷ In evaluating costs of care, however, most ERAS studies rely solely on submitted charges^{48,56,57} – an unreliable indicator of actual payments made – and focus on charges during the index hospitalization only.^{47,49,52,56,57,67,88} Because readmissions and post-discharge ancillary care are consistent, major contributors to variation in surgical episode payments, hospital charges alone cannot account for the possibility of cost-shifting to the outpatient phase of care.^{10,19,20} Even complete episode costs will not account for the effect that early discharge may have on indirect costs from informal care provided by family and other caregivers for older patients,⁸⁹ especially those with cognitive impairment.⁹⁰ Thus, ERAS proponents expecting savings from early discharge^{21,74} may overlook broader effects on overall costs.

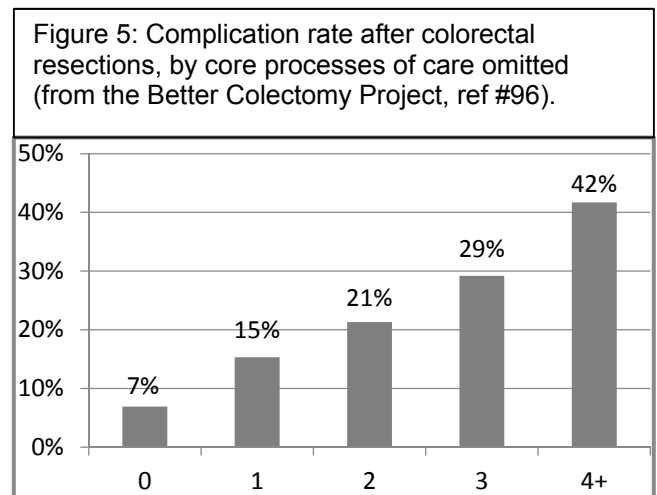
Effects on vulnerable patients. Despite scattered studies of the use of ERAS in older patients,^{91,92} there is particular concern for unintended consequences of early postoperative discharge in these patients. There is even more uncertainty about the efficiency and costs associated with ERAS for elderly patients. Studies that have included older adults^{37,91-93} have not evaluated late post-discharge outcomes, costs, or utilization of post-discharge care at all. Recognizing that that the principles of high-quality postoperative care management may differ for elderly surgical patients,^{94,95} and that the morbidity of major inpatient surgery increases with age,⁶⁻⁸ it is not clear from the published studies that ERAS will improve overall costs and outcomes for older patients. Rather, they are particularly likely to require increased outpatient resources to overcome the burden of early hospital discharge. Summarizing these uncertainties, a Cochrane Collaboration review concluded that ERAS trials have not been adequately assessed in these patient groups and insufficient data exist to support their safety for older patients.⁴⁴

C. PRELIMINARY STUDIES

C.1. Experience in evaluating processes of care and their effects on efficiency of inpatient surgery.

In previous work, the candidate demonstrated the value of care standardization in the “Better Colectomy Project”.⁹⁶ Surgeons convened from three partnering hospitals ratified and implemented a set of 37 process measures for colectomy, including components of ERAS. In a pilot implementation, non-compliance with core measures monotonically increased the rate of postoperative complications,⁹⁷ suggesting an important link between process and outcome (Figure 5).

The candidate’s interest in the primary predictor for this project – the use of ERAS – is specifically influenced by



data from the Michigan Surgical Quality Collaborative (MSQC) Colectomy Project, which has found substantial variation in perioperative processes of care in colorectal surgery,⁹⁸⁻¹⁰¹ especially as institutions have recently introduced ERAS protocols. Differences in bowel preparation,¹⁰⁰ perioperative antibiotics,⁹⁸ and ileus prophylaxis,¹⁰¹ are associated with substantial variation in wound infection rates and other clinical outcomes. Average length of stay and readmission rates after uncomplicated colectomy varies twofold in the state, and is closely related to hospitals' technical quality and aggregate complication rates, suggesting broad opportunities for quality improvement.¹⁰²

C.2. Experience in evaluating episode costs around inpatient surgery

In addition to Dr. Birkmeyer's expertise exploring relationships between models of care delivery and the cost, quality, and outcomes of inpatient surgery,^{3,18,19} the candidate has accrued substantial experience in assessing variation in episode payments.²⁰ Members of our team have similarly extensive experience with methods for micro-accounting payments to account for intended differences in pricing across provider groups, obscure reimbursement formulas, differences in case mix and the use of services unrelated to the primary diagnosis.¹⁰³ We have found that overall costs of inpatient surgery in the elderly vary widely between hospitals,¹⁹ that readmissions and post-discharge ancillary care account for the lion's share of variation in payments,²⁰ and that technical quality, as reflected by complication rates, is an important determinant of these expenditures.¹⁸ We have also examined correlations in hospitals' cost "signatures" across specialties, which suggest that both hospital-wide practice patterns and specialty-specific variation in physicians' decision-making drive variation in episode payments.³

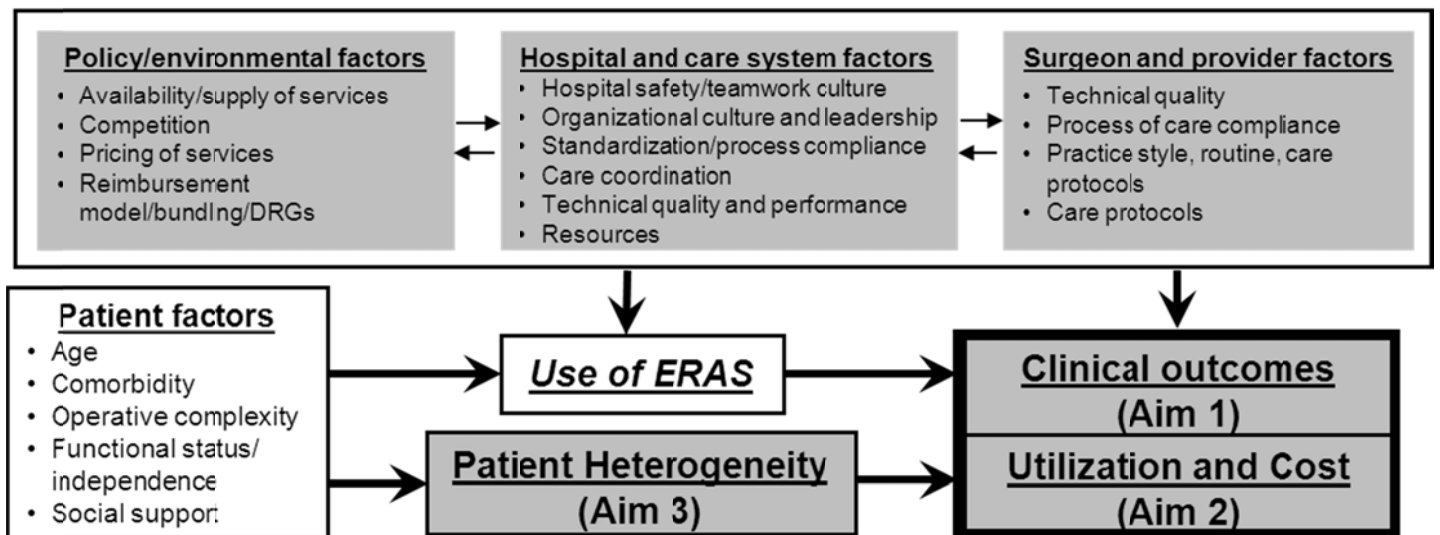
D. PROJECT DESIGN AND METHODS

D.1. Overview and Conceptual Model

The overarching goal of this research is to identify and implement strategies for optimizing outcomes and cost of inpatient surgery, while avoiding harms to vulnerable individuals, including elderly patients. We hypothesize that ERAS may influence episode costs and outcomes in contrasting ways. By hastening return of function, it may reduce length of stay, resource use and complications (Aim 1). But early discharge may trade inpatient costs for outpatient services, late complications or readmissions (Aim 2). These tradeoffs may be even more important among older adults with multiple comorbid conditions (Aim 3).

Although patient and procedure-specific factors can define both the quantity and type of services needed, external policy, hospital systems, and provider-specific patterns of care are often greater determinants of variation in overall health care utilization. The particular features of both patients and providers may influence the likelihood of using ERAS. Thus, there are multiple pathways by which these factors may affect outcomes and costs, as displayed in the conceptual model in Figure 4.

Figure 4: Conceptual Model – determinants of efficiency of inpatient surgery



This study focuses on colorectal resections as a generalizable model for inpatient surgery, because they are common (250,000/year in the US¹⁰⁴), account for the largest share of morbidity, death and prolonged hospitalization in general surgery,¹⁰⁵ and they have been hospitals' primary target for ERAS implementation to date.²⁸ Colorectal surgery provides a unique opportunity – urgent need for improvement, wide variation in perioperative care practices, and highly specific process of care data available in Michigan hospitals.

D.2. Study Setting and Data Sources

Successful execution of this study will be facilitated by our unparalleled access to rich, population-based clinical, cost, and culture data from three statewide collaborations, and by our group's extensive experience evaluating outcomes and cost using Medicare claims data.^{3,5,18-20,106} Although the analytic demands represented in Figure 4 are extensive, the Center for Healthcare Outcomes and Policy possesses all data management and analytic resources required to satisfy its effective completion (see Table below), as well as the computational skills and procedural experience to link these data sources at the patient-observation level.

Measure	Source	Comments
Use of ERAS	MSQC core process measures	MSQC recently began recording ERAS-specific care components around colorectal resections.
Covariates <ul style="list-style-type: none"> - Patient characteristics - Hospital characteristics - Hospital safety and teamwork culture 	MSQC AHA Survey MHA Keystone	Demographics, comorbidities, surgery information Structural characteristics and resources 27-item measure of safety & teamwork climate – the Safety Attitudes Questionnaire ¹⁰⁷
Clinical outcomes	MSQC	Length of stay, readmission, complications, etc.
Episode costs <ul style="list-style-type: none"> - Age 65 and older - Under age 65 	Medicare Part A&B BCBSM	Including facility costs, diagnostic tests, professional fees, home health, skilled nursing, rehabilitative services, etc. “Fully loaded” claims on Blue Cross-insured patients including payments, readmissions, utilization.

Michigan Surgical Quality Collaborative. MSQC includes 52 Michigan hospitals participating in a quality improvement program focused on improving care for approximately 100,000 patients undergoing general and vascular surgery in Michigan each year. The hospitals account for the vast majority of major surgery performed in the state, a population-based representation of community hospitals (62%) and tertiary-care and academic sites.^{108,109} Financial support for data collection is provided by Blue Cross and Blue Shield of Michigan (BCBSM), the insurer for nearly half of the state’s residents. MSQC uses an audit and feedback approach in which trained individuals in each hospital collect rigorously-defined patient and surgical data, including over 80 patient-level variables related to demographics, comorbidity, and acuity (patient factors/heterogeneity), and outcomes up to 30 days after surgery (clinical outcomes, surgeon and hospital factors), with purposive oversampling of operations of interest, such as colectomy. MSQC’s Colectomy Project evaluates processes of care around colectomy, including antibiotic use, bowel preparation, and thromboembolism prophylaxis and is now supplementing these measures with ERAS-specific process data (use of ERAS, surgeon factors). These programs have been remarkably successful in improving hospital safety and quality. In the first four years of the program, complication rates fell 37% while trends in non-Michigan hospitals were flat (p<0.001).¹⁰⁸

Michigan Value Collaborative. MVC was launched by BCBSM in 2011, to provide a measurement infrastructure for improving care transitions, and reducing variation in episode payments around hospitalization. In the collaborative, BCBSM provides the coordinating center with “fully loaded” claims on BCBSM-insured patients acute care Michigan hospitals (utilization/cost). Comparative data on episode payments, readmissions, and other services are reported to hospital leadership and clinicians in the collaboratives, and will provide utilization data for privately insured patients under 65.

Keystone Surgery. Since 2007, the Michigan Hospital Association's Keystone Surgery collaborative has been using the Safety Attitudes Questionnaire¹⁰⁷ to assess hospitals' safety and teamwork organizational culture. This survey is distributed electronically to all caregivers involved in postoperative care on the wards and in the ICU. Reflecting the strong institutional commitment to this initiative, the overall response rate for this survey has been approximately 70% (range 40% to 85% across hospitals). Data from this initiative will inform our understanding of *hospital and care system factors*, their relationship to the use of high-efficiency care processes around colectomy, and their impact on coordination of care, costs and outcomes.

AHA: American Hospital Association; BCBSM: Blue Cross Blue Shield of Michigan MHA: Michigan Hospital Association; MSQC: Michigan Surgical Quality Collaborative; SAF: Standard Analytic Files

D.3. Characterizing Hospitals' Use of Enhanced Recovery After Surgery Protocols

The primary exposure variable for this study is the use of ERAS protocols in colorectal surgery. To assess the use of ERAS we will capitalize on an initiative within MSQC to collect ERAS-specific process of care data. The ERAS data instrument in MSQC is modeled after the ERAS Study Group's well-established Interactive Audit System,⁶⁵ which documents compliance with each of the core elements of the protocol:^{27,29}

- **Preoperative:** counseling; oral carbohydrate loading; avoidance of fasting; prophylaxis against thromboembolism and wound infection
- **Intraoperative:** prophylaxis against nausea/vomiting; use of regional or local analgesia; maintenance of normothermia and normovolemia
- **Postoperative:** early ambulation and feeding; stimulation of gut motility; early urinary catheter removal; nasogastric tube avoidance; opioid-sparing analgesia; normoglycemia; normovolemia.

For hospital-level analyses, use of ERAS will be defined by implementation of these core elements within a codified perioperative care protocol, and will be considered as a binary predictor, setting aside local variations not involving core processes. We will separately evaluate whether a hospital's compliance rate with the core processes influences the fidelity of effects from ERAS, as care protocols may improve outcomes either from their introduction alone,⁷² or from actual achievement of their key components.¹¹⁰

D.4. Analytic Plan

Our primary exposure variable, the use of ERAS, will be assessed primarily at the hospital level. We will first examine relationships between the primary exposure variables and outcomes for the entire surgical population at participating hospitals. We will then assess these relationships among older patients and other high risk subgroups, such as those identified based on covariates derived from risk adjustment models.

Clinical quality outcomes (Aims 1 and 3). We will test the relationship between Michigan hospitals' ERAS use and perioperative outcomes in colorectal surgery. The unit of analysis will be patients nested within hospitals. We will estimate hierarchical logistic regression models (the generalized linear mixed model, SAS PROC GLIMMIX,¹¹¹ with logit link for discrete outcomes and log link for Poisson regression for length of stay) with hospital random effects to account for clustering. In this framework, $Y_{ijk} = 1$, if the j th patient in the i th hospital had an event (e.g. postoperative complications and readmission) in the k th care protocol (levels of k will be defined by the indicator variable for traditional care versus ERAS), and $Y_{ijk} = 0$ otherwise. The probability that the j th patient seen at the i th hospital had an event in the k th care protocol is modeled as:

$$\text{logit}(P(Y_{ijk}=1)) = \beta_{00} + \beta_{0i} + \gamma_k I_k + X_{ijk} \theta \quad (1)$$

where β_{00} is the population-averaged log-odds of the event, β_{0i} is the hospital-specific random effect (*i.e.* random departure for each hospital in the log-odds scale), assumed to follow a normal distribution with mean zero and variance $\sigma^2_{\text{hospital}}$, I_k are indicator/dummy variables corresponding to use of ERAS practices and hospital culture characteristics from the SAQ; X_{ijk} is a matrix of covariates (patient characteristics), γ_k , represents changes in the log-odds of event due to intervention k (baseline is traditional non-ERAS care), and the parameter vector θ represent changes in the log-odds of event corresponding to each unit change in the covariate values. Model estimates will be obtained using likelihood based approach (marginal or penalized quasi-likelihood). Hypothesis-testing will be based on the direction and amplitude of γ and patient-level heterogeneity (Aim 3) will be evaluated by coefficients of X , and interaction terms $X \times \gamma$. Analyses will be fully

adjusted for patient risk characteristics in the MSQC database. From previous analyses, we expect final risk adjustment models with 10-15 covariates and c-indices of approximately 0.82-0.85.^{112,113}

Episode cost outcomes (Aims 2 and 3). The candidate and mentors have extensive experience in evaluating relationships between care delivery and surgical episode costs for Medicare beneficiaries.^{3,18-20} With NIA support (P01, J. Skinner, PI), members of our team have developed micro-accounting methods to account for intended differences in pricing across provider groups, obscure reimbursement formulas, differences in case mix and the use of services unrelated to the primary diagnosis.¹⁰³ In this study, we will adopt the payors' perspective, focusing on payments made to hospitals, rather than estimating costs from charges. We will determine total payments for clinical services in the surgical episode, as empirically defined previously.^{3,19,20} Linear mixed effects regression (PROC MIXED in SAS version 9.3) will model cost as a continuous variable, with hospital random effects to account for clustering. In this framework, if Y_{ijk} is costs associated with the j th patient in the i th hospital at the k th care protocol, then Y_{ijk} is modeled as:

$$Y_{ijk} = \beta_{00} + \beta_{0i} + \gamma_k I_k + X_{ijk} \theta + \varepsilon_{ijk} \quad (2)$$

where β_{00} is the population-averaged cost, β_{0i} is the hospital-specific random effect (i.e. random departure for each hospital), assumed to follow a normal distribution with mean zero and variance $\sigma^2_{\text{hospital}}$, I_k are indicator variables for ERAS use and hospital culture characteristics from the SAQ; X_{ijk} is a matrix of covariates (patient characteristics), γ_k represents changes in the log-odds of event due to intervention (versus traditional care), the parameter vector θ represent changes in the mean cost associated with each unit change in the covariate values, and ε_{ijk} represents random error which is assumed to follow a normal distribution with mean zero and variance σ^2_{ε} . Additionally, we assume that β_{0i} and ε_{ijk} are independent. Hypotheses for Aim 2 will be evaluated by the direction and amplitude of the coefficient γ . Hypotheses for Aim 3 regarding patient-level heterogeneity will be evaluated by components of the various coefficients X , and interaction terms $X^* \gamma$.

Sample size and power. The sample will include colorectal resections enrolled in MSQC. Extrapolating from case numbers in 2009-2011, we expect at least 12,000 cases (about half over 65 years old), assuming 10% loss rate for missing data or mis-categorized cases. For the generalized linear mixed model, there is no closed form calculation for sample size. Simulation suggests that 30 groups (hospitals) with at least 50 observations (events per hospital) produce reliable estimates in hierarchical logistic regression models.¹¹⁴ The overall complication rate averages 23% across the 52 hospitals, ranging from a risk and reliability adjusted rate of 14% to 36%. Thus, the average number of patients with complications in the overall group is conservatively estimated to be 1,800 (15% of 12,000). Likewise, the risk and reliability adjusted costs of colectomy vary more than 11%,^{18,19} and lengths of stay vary twofold¹⁰² in our previous studies. If we assume ERAS use at least as prevalent as in surveys,^{25,68} there will be sufficient sample size to detect variation of these magnitudes in clinical and cost outcomes for both the overall and subgroup analyses.¹¹⁵

D.5. Limitations

Endogeneity. Characteristics of hospitals and surgeons may be associated with both adoption of ERAS and other features of technical performance that determine patient outcomes and efficiency, as displayed in Figure 4 above. We have at least two approaches to address these complexities, however. First, from MSQC and the Keystone Surgery project, we have rich data sets to characterize the core quality, safety and teamwork attributes of participating hospitals, and will have a unique ability to account for factors associated with both technical quality and adoption of ERAS. Second, because hospitals are implementing and adopting ERAS practices at different points in time, we will use difference-in-difference methods for causal inference, to account for intrinsic features of the institutions, as well as temporal trends in the outcomes of interest. Specifically, hospitals may serve as their own controls by comparing differences in outcomes before and after ERAS adoption with before and after differences in non-adopters. Further, we can use non-colorectal operations in MSQC (such as vascular surgery, for which ERAS has not disseminated in Michigan) as secondary controls. If we compare differences in outcome trends between colorectal and non-colorectal surgery before and after ERAS adoption in ERAS hospitals against these between-specialty differences in trends in non-ERAS hospitals, the resulting "difference-in-difference-in-difference" estimation¹¹⁶⁻¹¹⁸ isolates the ERAS-specific effect, independent of hospital factors correlated with implementation of ERAS in colon surgery.

Generalizability. Our study is limited to Michigan Surgical Quality Collaborative hospitals, which differ from hospitals nationwide, because they already systematically track surgical outcomes, receive feedback on performance, and engage in structured quality improvement activities.^{108,109} There have, however, been no projects focused on utilization or efficiency to date. Thus, the exploratory work herein will not be contaminated by previous interventions and should provide generalizable insights about the effects of ERAS. Our study sample will be limited to colorectal surgery, and therefore may not be representative of inpatient surgery as a whole. Yet colectomy has been cited as a high-priority,^{105,112} model operation^{97,119} for surgical quality improvement, and principles of ERAS have historically spread from colon surgery to other specialties.¹²⁰

D.6. Innovation

This research program will identify the use of Enhanced Recovery After Surgery protocols in 52 hospitals participating in a statewide collaborative quality improvement program, and evaluate their clinical and economic consequences in older patients. The proposal is highly innovative from several perspectives:

- (1) This is the first study to extend evaluation of ERAS beyond highly-selected specialty practices, using a *population-based* collaborative of large and small, academic and community hospitals across the state of Michigan.
- (2) This analysis breaks new ground in assessing the potential for spillover of costs and complications from the hospital to the outpatient arena. We use overall episode payments, rather than just charges for hospital care. This *full spectrum of surgical care* has rarely been studied as a target for value improvement, but is far more relevant to considerations of the impact of national payment reform such as bundled payments, value-based purchasing and Accountable Care Organizations.
- (3) The third specific aim takes a novel, patient-centered perspective on ERAS, evaluating its effects on *vulnerable patients at greatest risk for unintended consequences* from initiatives to increase efficiency in inpatient surgery.

E. HUMAN SUBJECTS

There will be two types of human subjects in this study: (1) patients undergoing surgery in Michigan hospitals, and (2) surgeons and institutions whose practices will be evaluated. For patients, there will be no direct contact or intervention, and risks to them consist only of data security risks. For the providers, risks include data security and any discomfort or inconvenience associated with the data collection. This project is based entirely on analysis of secondary data collected previously by Center for Medicare and Medicaid Services (CMS), the Michigan Surgical Quality Collaborative (MSQC), and Blue Cross and Blue Shield of Michigan (BCBSM). Because Medicare databases released by CMS for research use contain patient identifiers; they are subject to strict confidentiality requirements. IRB approval, and data use agreements between CMS and the Center for Healthcare Outcomes & Policy (CHOP) stipulating such are already in place for other projects; however, we will ensure that these policies are updated specifically for the proposed work. The collection of data by MSQC and BCBSM has already undergone IRB approval at the University of Michigan as well as at each of the participating sites. Data use agreements between the University of Michigan and the participating sites are also already in place. These data use agreements between the MSQC, BCBSM, and hospital sites allow for collection of data by trained personnel in each hospital for quality improvement. A limited data set generated from these resources will be used for all research analyses. Existing data security measures will ensure that patient information remains completely secure.

There are no interventions in this study and no contact with patients since each of the databases used contains retrospective information. Existing data use agreements and data security measures will ensure that patient information remains completely secure. Since we are only using retrospective data from an existing database, there will be no recruitment of subjects. Thus, a waiver of informed consent is appropriate because: 1. The research involves no more than minimal risk; 2. The waiver will not adversely affect the rights and welfare of the subjects; 3. The research could not practicably be carried out without the waiver.

F. VERTEBRATE ANIMALS

Not applicable.

G. LITERATURE CITED

1. National Hospital Discharge Survey. National Center for Health Statistics, 2009. (Accessed October 10, 2012, at http://www.cdc.gov/nchs/data/nhds/4procedures/2009pro4_numberprocedureage.pdf.)
2. Weiser TG, Regenbogen SE, Thompson KD, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet* 2008;372:139-44.
3. Birkmeyer JD, Gust C, Baser O, Dimick JB, Sutherland JM, Skinner JS. Medicare payments for common inpatient procedures: implications for episode-based payment bundling. *Health services research* 2010;45:1783-95.
4. Etzioni DA, Liu JH, O'Connell JB, Maggard MA, Ko CY. Elderly patients in surgical workloads: a population-based analysis. *Am Surg* 2003;69:961-5.
5. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. *N Engl J Med* 2002;346:1128-37.
6. Bentrem DJ, Cohen ME, Hynes DM, Ko CY, Bilimoria KY. Identification of specific quality improvement opportunities for the elderly undergoing gastrointestinal surgery. *Arch Surg* 2009;144:1013-20.
7. Finlayson E, Fan Z, Birkmeyer JD. Outcomes in octogenarians undergoing high-risk cancer operation: a national study. *J Am Coll Surg* 2007;205:729-34.
8. Al-Refaie WB, Parsons HM, Habermann EB, et al. Operative outcomes beyond 30-day mortality: colorectal cancer surgery in oldest old. *Ann Surg* 2011;253:947-52.
9. Hendren S, Morris AM, Zhang W, Dimick J. Early discharge and hospital readmission after colectomy for cancer. *Dis Colon Rectum* 2011;54:1362-7.
10. Schneider EB, Hyder O, Wolfgang CL, et al. Patient readmission and mortality after surgery for hepatopancreato-biliary malignancies. *J Am Coll Surg* 2012;215:607-15.
11. Kassin MT, Owen RM, Perez SD, et al. Risk factors for 30-day hospital readmission among general surgery patients. *J Am Coll Surg* 2012;215:322-30.
12. Martin RC, Brown R, Puffer L, et al. Readmission rates after abdominal surgery: the role of surgeon, primary caregiver, home health, and subacute rehab. *Ann Surg* 2011;254:591-7.
13. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med* 2009;360:1418-28.
14. Nallamotheu BK, Rogers MA, Saint S, et al. Skilled care requirements for elderly patients after coronary artery bypass grafting. *J Am Geriatr Soc* 2005;53:1133-7.
15. Lawrence VA, Hazuda HP, Cornell JE, et al. Functional independence after major abdominal surgery in the elderly. *Journal of the American College of Surgeons* 2004;199:762-72.
16. Finlayson E, Zhao S, Boscardin WJ, Fries BE, Landefeld CS, Dudley RA. Functional status after colon cancer surgery in elderly nursing home residents. *J Am Geriatr Soc* 2012;60:967-73.
17. Davidoff F. Heterogeneity is not always noise: lessons from improvement. *JAMA* 2009;302:2580-6.
18. Birkmeyer JD, Gust C, Dimick JB, Birkmeyer NJ, Skinner JS. Hospital quality and the cost of inpatient surgery in the United States. *Ann Surg* 2012;255:1-5.
19. Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, Birkmeyer JD. Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. *Health Aff (Millwood)* 2011;30:2107-15.
20. Regenbogen SE, Gust C, Birkmeyer JD. Hospital surgical volume and cost of inpatient surgery in the elderly. *J Am Coll Surg* 2012;215:758-65.
21. Adamina M, Kehlet H, Tomlinson GA, Senagore AJ, Delaney CP. Enhanced recovery pathways optimize health outcomes and resource utilization: a meta-analysis of randomized controlled trials in colorectal surgery. *Surgery* 2011;149:830-40.
22. Ronellenfitch U, Rossner E, Jakob J, Post S, Hohenberger P, Schwarzbach M. Clinical Pathways in surgery: should we introduce them into clinical routine? A review article. *Langenbeck's archives of surgery / Deutsche Gesellschaft fur Chirurgie* 2008;393:449-57.
23. Gawande AA. *The Checklist Manifesto*. New York: Metropolitan Books; 2009.
24. Haynes AB, Regenbogen SE, Weiser TG, et al. Surgical outcome measurement for a global patient population: validation of the Surgical Apgar Score in 8 countries. *Surgery* 2011;149:519-24.
25. Kehlet H, Wilmore DW. Evidence-based surgical care and the evolution of fast-track surgery. *Ann Surg* 2008;248:189-98.

26. Nygren J, Hausel J, Kehlet H, et al. A comparison in five European Centres of case mix, clinical management and outcomes following either conventional or fast-track perioperative care in colorectal surgery. *Clin Nutr* 2005;24:455-61.
27. Lassen K, Soop M, Nygren J, et al. Consensus review of optimal perioperative care in colorectal surgery: Enhanced Recovery After Surgery (ERAS) Group recommendations. *Arch Surg* 2009;144:961-9.
28. Francis N, Kennedy RH, Ljungqvist O, Mythen MG. *Manual of Fast Track Recovery for Colorectal Surgery*. London: Springer-Verlag; 2012.
29. Gustafsson UO, Scott MJ, Schwenk W, et al. Guidelines for perioperative care in elective colonic surgery: Enhanced Recovery After Surgery (ERAS((R))) Society recommendations. *World journal of surgery* 2013;37:259-84.
30. Husted H, Troelsen A, Otte KS, Kristensen BB, Holm G, Kehlet H. Fast-track surgery for bilateral total knee replacement. *The Journal of bone and joint surgery British volume* 2011;93:351-6.
31. Lassen K, Coolson MM, Slim K, et al. Guidelines for perioperative care for pancreaticoduodenectomy: Enhanced Recovery After Surgery (ERAS(R)) Society recommendations. *World journal of surgery* 2013;37:240-58.
32. Yamada T, Hayashi T, Cho H, et al. Usefulness of enhanced recovery after surgery protocol as compared with conventional perioperative care in gastric surgery. *Gastric cancer : official journal of the International Gastric Cancer Association and the Japanese Gastric Cancer Association* 2012;15:34-41.
33. Jones C, Kelliher L, Dickinson M, et al. Randomized clinical trial on enhanced recovery versus standard care following open liver resection. *Br J Surg* 2013.
34. Muehling B, Schelzig H, Steffen P, Meierhenrich R, Sunder-Plassmann L, Orend KH. A prospective randomized trial comparing traditional and fast-track patient care in elective open infrarenal aneurysm repair. *World journal of surgery* 2009;33:577-85.
35. Bianchini C, Pelucchi S, Pastore A, Feo CV, Ciorba A. Enhanced recovery after surgery (ERAS) strategies: possible advantages also for head and neck surgery patients? *European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery* 2013.
36. Anderson AD, McNaught CE, MacFie J, Tring I, Barker P, Mitchell CJ. Randomized clinical trial of multimodal optimization and standard perioperative surgical care. *Br J Surg* 2003;90:1497-504.
37. Delaney CP, Zutshi M, Senagore AJ, Remzi FH, Hammel J, Fazio VW. Prospective, randomized, controlled trial between a pathway of controlled rehabilitation with early ambulation and diet and traditional postoperative care after laparotomy and intestinal resection. *Dis Colon Rectum* 2003;46:851-9.
38. Gatt M, Anderson AD, Reddy BS, Hayward-Sampson P, Tring IC, MacFie J. Randomized clinical trial of multimodal optimization of surgical care in patients undergoing major colonic resection. *Br J Surg* 2005;92:1354-62.
39. Khoo CK, Vickery CJ, Forsyth N, Vinall NS, Eyre-Brook IA. A prospective randomized controlled trial of multimodal perioperative management protocol in patients undergoing elective colorectal resection for cancer. *Ann Surg* 2007;245:867-72.
40. Muller S, Zalunardo MP, Hubner M, Clavien PA, Demartines N. A fast-track program reduces complications and length of hospital stay after open colonic surgery. *Gastroenterology* 2009;136:842-7.
41. Serclova Z, Dytrych P, Marvan J, et al. Fast-track in open intestinal surgery: prospective randomized study (Clinical Trials Gov Identifier no. NCT00123456). *Clin Nutr* 2009;28:618-24.
42. Varadhan KK, Neal KR, Dejong CH, Fearon KC, Ljungqvist O, Lobo DN. The enhanced recovery after surgery (ERAS) pathway for patients undergoing major elective open colorectal surgery: a meta-analysis of randomized controlled trials. *Clin Nutr* 2010;29:434-40.
43. Zhuang C-L, Ye X-Z, Zhang X-D, Chen B-C, Yu Z. Enhanced Recovery After Surgery Programs Versus Traditional Care for Colorectal Surgery: A Meta-analysis of Randomized Controlled Trials. *Diseases of the Colon & Rectum* 2013;56:667-78 10.1097/DCR.0b013e3182812842.
44. Spanjersberg WR, Reurings J, Keus F, van Laarhoven CJ. Fast track surgery versus conventional recovery strategies for colorectal surgery. *Cochrane Database Syst Rev* 2011:CD007635.
45. Khan S, Wilson T, Ahmed J, Owais A, MacFie J. Quality of life and patient satisfaction with enhanced recovery protocols. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2010;12:1175-82.

46. Lawrence JK, Keller DS, Samia H, et al. Discharge within 24 to 72 Hours of Colorectal Surgery Is Associated with Low Readmission Rates when Using Enhanced Recovery Pathways. *J Am Coll Surg* 2013;216:390-4.
47. Zehr KJ, Dawson PB, Yang SC, Heitmiller RF. Standardized clinical care pathways for major thoracic cases reduce hospital costs. *Ann Thorac Surg* 1998;66:914-9.
48. Collier PE. Do clinical pathways for major vascular surgery improve outcomes and reduce cost? *J Vasc Surg* 1997;26:179-85.
49. Cooney RN, Bryant P, Haluck R, Rodgers M, Lowery M. The impact of a clinical pathway for gastric bypass surgery on resource utilization. *J Surg Res* 2001;98:97-101.
50. Muller MK, Dedes KJ, Dindo D, Steiner S, Hahnloser D, Clavien PA. Impact of clinical pathways in surgery. *Langenbeck's archives of surgery / Deutsche Gesellschaft fur Chirurgie* 2009;394:31-9.
51. Schwarzbach M, Rossner E, Schattenberg T, Post S, Hohenberger P, Ronellenfitsch U. Effects of a clinical pathway of pulmonary lobectomy and bilobectomy on quality and cost of care. *Langenbeck's archives of surgery / Deutsche Gesellschaft fur Chirurgie* 2010;395:1139-46.
52. Stephen AE, Berger DL. Shortened length of stay and hospital cost reduction with implementation of an accelerated clinical care pathway after elective colon resection. *Surgery* 2003;133:277-82.
53. Vanounou T, Pratt W, Fischer JE, Vollmer CM, Jr., Callery MP. Deviation-based cost modeling: a novel model to evaluate the clinical and economic impact of clinical pathways. *J Am Coll Surg* 2007;204:570-9.
54. Porter GA, Pisters PW, Mansyur C, et al. Cost and utilization impact of a clinical pathway for patients undergoing pancreaticoduodenectomy. *Ann Surg Oncol* 2000;7:484-9.
55. Kulkarni RP, Ituarte PH, Gunderson D, Yeh MW. Clinical pathways improve hospital resource use in endocrine surgery. *J Am Coll Surg* 2011;212:35-41.
56. Kariv Y, Delaney CP, Senagore AJ, et al. Clinical outcomes and cost analysis of a "fast track" postoperative care pathway for ileal pouch-anal anastomosis: a case control study. *Dis Colon Rectum* 2007;50:137-46.
57. Melbert RB, Kimmins MH, Isler JT, et al. Use of a critical pathway for colon resections. *J Gastrointest Surg* 2002;6:745-52.
58. Taylor C, Burch J. Feedback on an enhanced recovery programme for colorectal surgery. *Br J Nurs* 2011;20:286-90.
59. Jakobsen DH, Sonne E, Andreasen J, Kehlet H. Convalescence after colonic surgery with fast-track vs conventional care. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2006;8:683-7.
60. Hjort Jakobsen D, Sonne E, Basse L, Bisgaard T, Kehlet H. Convalescence after colonic resection with fast-track versus conventional care. *Scandinavian journal of surgery : SJS : official organ for the Finnish Surgical Society and the Scandinavian Surgical Society* 2004;93:24-8.
61. Zargar-Shoshtari K, Paddison JS, Booth RJ, Hill AG. A prospective study on the influence of a fast-track program on postoperative fatigue and functional recovery after major colonic surgery. *J Surg Res* 2009;154:330-5.
62. Blazeby JM, Soulsby M, Winstone K, King PM, Bulley S, Kennedy RH. A qualitative evaluation of patients' experiences of an enhanced recovery programme for colorectal cancer. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2010;12:e236-42.
63. Enhanced Recovery. Department of Health, United Kingdom. (Accessed October 24, 2012, at [http://mdbulletin.dh.gov.uk/2012/09/21/enhanced-recovery/.](http://mdbulletin.dh.gov.uk/2012/09/21/enhanced-recovery/))
64. Enhanced recovery programme toolkit. National Health Service. (Accessed October 24, 2012, at [http://www.natcansatmicrosite.net/enhancedrecovery/.](http://www.natcansatmicrosite.net/enhancedrecovery/))
65. ERAS Interactive Audit System. ERAS Society. (Accessed October 24, 2012, at
66. Reurings JC, Spanjersberg WR, Oostvogel HJ, et al. A prospective cohort study to investigate cost-minimisation, of Traditional open, open fAst track recovery and laparoscopic fAst track multimodal management, for surgical patients with colon carcinomas (TAPAS study). *BMC surgery* 2010;10:18.
67. Markey DW, McGowan J, Hanks JB. The effect of clinical pathway implementation on total hospital costs for thyroidectomy and parathyroidectomy patients. *Am Surg* 2000;66:533-8; discussion 8-9.

68. Delaney CP, Senagore AJ, Gerkin TM, et al. Association of surgical care practices with length of stay and use of clinical protocols after elective bowel resection: results of a national survey. *Am J Surg* 2010;199:299-304; discussion
69. Kehlet H, Buchler MW, Beart RW, Jr., Billingham RP, Williamson R. Care after colonic operation--is it evidence-based? Results from a multinational survey in Europe and the United States. *J Am Coll Surg* 2006;202:45-54.
70. Bradshaw BGG, Liu SS, Thirlby RC. Standardized Perioperative Care Protocols and Reduced Length of Stay After Colon Surgery. *Journal of the American College of Surgeons* 1998;186:501-6.
71. Pritts TA, Nussbaum MS, Flesch LV, Fegelman EJ, Parikh AA, Fischer JE. Implementation of a clinical pathway decreases length of stay and cost for bowel resection. *Ann Surg* 1999;230:728-33.
72. Birkmeyer JD. Strategies for Improving Surgical Quality — Checklists and Beyond. *New England Journal of Medicine* 2010;363:1963-5.
73. Mastracci TM, Cohen Z, Senagore A. Canadian Association of General Surgeons and American College of Surgeons Evidence-Based Reviews in Surgery. 24. Fast-track programs in colonic surgery. Systematic review of enhanced recovery programmes in colonic surgery. *Canadian journal of surgery Journal canadien de chirurgie* 2008;51:70-2.
74. King PM, Blazeby JM, Ewings P, et al. The influence of an enhanced recovery programme on clinical outcomes, costs and quality of life after surgery for colorectal cancer. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2006;8:506-13.
75. Jones JW, McCullough LB, Richman BW. The ethics of clinical pathways and cost control. *J Vasc Surg* 2003;37:1341-2.
76. Bohmer RMJ, Newell J, Torchiana DF. The effect of decreasing length of stay on discharge destination and readmission after coronary bypass operation. *Surgery* 2002;132:10-5.
77. Morris M, Deierhoi R, Richman JS, et al. Measuring surgical complications as a quality metric: Looking beyond hospital discharge. *Journal of the American College of Surgeons* 2012;215:S97-S8.
78. Regenbogen SE, Bordeianou L, Hutter MM, Gawande AA. The intraoperative Surgical Apgar Score predicts postdischarge complications after colon and rectal resection. *Surgery* 2010;148:559-66.
79. Bueno H RJSWY, et al. Trends in length of stay and short-term outcomes among medicare patients hospitalized for heart failure, 1993-2006. *JAMA* 2010;303:2141-7.
80. Baker Dw EDHSSCRD. Trends in postdischarge mortality and readmissions: Has length of stay declined too far? *Archives of internal medicine* 2004;164:538-44.
81. Hyman N, Manchester TL, Osler T, Burns B, Cataldo PA. Anastomotic leaks after intestinal anastomosis: it's later than you think. *Ann Surg* 2007;245:254-8.
82. Raval MV, Hamilton BH, Ingraham AM, Ko CY, Hall BL. The importance of assessing both inpatient and outpatient surgical quality. *Ann Surg* 2011;253:611-8.
83. Bilimoria KY, Cohen ME, Ingraham AM, et al. Effect of postdischarge morbidity and mortality on comparisons of hospital surgical quality. *Ann Surg* 2010;252:183-90.
84. Medress Z, Fleshner PR. Can we predict unplanned hospital readmission after colectomy for ulcerative colitis and indeterminate colitis? *The American surgeon* 2007;73:998-1001.
85. Kiran RP, Delaney CP, Senagore AJ, Steel M, Garafalo T, Fazio VW. Outcomes and prediction of hospital readmission after intestinal surgery. *J Am Coll Surg* 2004;198:877-83.
86. Azimuddin K, Rosen L, Reed JF, 3rd, Stasik JJ, Riether RD, Khubchandani IT. Readmissions after colorectal surgery cannot be predicted. *Dis Colon Rectum* 2001;44:942-6.
87. Kariv Y, Wang W, Senagore AJ, Hammel JP, Fazio VW, Delaney CP. Multivariable analysis of factors associated with hospital readmission after intestinal surgery. *Am J Surg* 2006;191:364-71.
88. Sammour T, Zargar-Shoshtari K, Bhat A, Kahokehr A, Hill AG. A programme of Enhanced Recovery After Surgery (ERAS) is a cost-effective intervention in elective colonic surgery. *The New Zealand medical journal* 2010;123:61-70.
89. Hayman JA, Langa KM, Kabeto MU, et al. Estimating the cost of informal caregiving for elderly patients with cancer. *J Clin Oncol* 2001;19:3219-25.
90. Langa KM, Chernew ME, Kabeto MU, et al. National estimates of the quantity and cost of informal caregiving for the elderly with dementia. *J Gen Intern Med* 2001;16:770-8.
91. Day A, Fawcett WJ, Scott MJP, Rockall TA. Fast-track surgery and the elderly. *British Journal of Anaesthesia* 2012;109:124.

92. Scharfenberg M, Raue W, Junghans T, Schwenk W. "Fast-track" rehabilitation after colonic surgery in elderly patients—is it feasible? *International Journal of Colorectal Disease* 2007;22:1469-74.
93. DiFronzo LA, Yamin N, Patel K, O'Connell TX. Benefits of early feeding and early hospital discharge in elderly patients undergoing open colon resection. *Journal of the American College of Surgeons* 2003;197:747-52.
94. McGory ML, Kao KK, Shekelle PG, et al. Developing quality indicators for elderly surgical patients. *Ann Surg* 2009;250:338-47.
95. McGory ML, Shekelle PG, Rubenstein LZ, Fink A, Ko CY. Developing quality indicators for elderly patients undergoing abdominal operations. *J Am Coll Surg* 2005;201:870-83.
96. Arriaga AF, Lancaster RT, Berry WR, et al. The better colectomy project: association of evidence-based best-practice adherence rates to outcomes in colorectal surgery. *Ann Surg* 2009;250:507-13.
97. Arriaga AF, Lancaster RT, Berry WR, et al. The Better Colectomy Project: Association of Evidence-Based Best-Practice Adherence Rates to Outcomes in Colorectal Surgery. *Ann Surg* 2009.
98. Hendren S, Englesbe MJ, Brooks L, Kubus J, Yin H, Campbell DA, Jr. Prophylactic antibiotic practices for colectomy in Michigan. *Am J Surg* 2011;201:290-3.
99. Hendren S, Fritze D, Banerjee M, et al. Antibiotic choice is independently associated with risk of surgical site infection after colectomy: a population-based cohort study. *Ann Surg* 2013;257:469-75.
100. Englesbe MJ, Brooks L, Kubus J, et al. A statewide assessment of surgical site infection following colectomy: the role of oral antibiotics. *Ann Surg* 2010;252:514-9.
101. Harbaugh CM, Al-Holou SN, Bander TS, et al. A statewide, community-based assessment of alvimopan's effect on surgical outcomes. *Ann Surg* 2013;257:427-32.
102. Krell R, Girotti M, Fritze D, Campbell D, Hendren S. Readmissions following colectomy: a population-based study. *Dis Colon Rectum* 2013;56:235.
103. Gottlieb D, Zhou W, Song Y, Andrews KG, Skinner J, Sutherland J. A standardized method for adjusting Medicare expenditures for regional differences in prices. . January 2010. (Accessed October 23, 2012, at http://www.dartmouthatlas.org/downloads/papers/std_prc_tech_report.pdf.)
104. National Center for Health Statistics. NCHS FASTATS--Inpatient surgery., 2009. (Accessed October 19, 2012, at http://www.cdc.gov/nchs/data/nhds/4procedures/2009pro4_numberprocedureage.pdf.)
105. Schilling PL, Dimick JB, Birkmeyer JD. Prioritizing quality improvement in general surgery. *J Am Coll Surg* 2008;207:698-704.
106. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003;349:2117-27.
107. Sexton JB, Helmreich RL, Neilands TB, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC health services research* 2006;6:44.
108. Campbell DA, Jr., Englesbe MJ, Kubus JJ, et al. Accelerating the pace of surgical quality improvement: the power of hospital collaboration. *Arch Surg* 2010;145:985-91.
109. Share DA, Campbell DA, Birkmeyer N, et al. How a regional collaborative of hospitals and physicians in Michigan cut costs and improved the quality of care. *Health Aff (Millwood)* 2011;30:636-45.
110. Gustafsson UO, Hausel J, Thorell A, Ljungqvist O, Soop M, Nygren J. Adherence to the enhanced recovery after surgery protocol and outcomes after colorectal cancer surgery. *Arch Surg* 2011;146:571-7.
111. McCulloch C, Searle S, Neuhaus J. Generalized, linear, and mixed models. New Jersey: John Wiley & Sons; 2008.
112. Cohen ME, Bilimoria KY, Ko CY, Hall BL. Development of an American College of Surgeons National Surgery Quality Improvement Program: morbidity and mortality risk calculator for colorectal surgery. *J Am Coll Surg* 2009;208:1009-16.
113. Dimick JB, Osborne NH, Hall BL, Ko CY, Birkmeyer JD. Risk adjustment for comparing hospital quality with surgery: how many variables are needed? *J Am Coll Surg* 2010;210:503-8.
114. Moineddin R, Matheson FI, Glazier RH. A simulation study of sample size for multilevel logistic regression models. *BMC medical research methodology* 2007;7:34.
115. Liu GH, Liang KY. Sample size calculations for studies with correlated observations. *Biometrics* 1997;53:937-47.
116. Gruber J. The Incidence of Mandated Maternity Benefits. *The American Economic Review* 1994;84:622-41.

117. Ravallion M, Galasso E, Lazo T, Philipp E. What Can Ex-Participants Reveal about a Program's Impact? *Journal of Human Resources* 2005;XL:208-30.
118. Rossin M. The effects of maternity leave on children's birth and infant health outcomes in the United States. *Journal of health economics* 2011;30:221-39.
119. Gawande AA, Kwaan MR, Regenbogen SE, Lipsitz SA, Zinner MJ. An Apgar Score for Surgery. *J Am Coll Surg* 2007;204:201-8.
120. Ljungqvist O, Fearon K. Preface. In: Francis N, Kennedy RH, Ljungqvist O, Mythen MG, eds. *Manual of Fast Track Recovery for Colorectal Surgery*. London: Springer-Verlag; 2012:v-vi.

H. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

Not applicable

I. CONSULTANTS

We have assembled a multidisciplinary team with expertise in collaborative quality improvement, gerontology, organizational science and advanced statistical methods. The mentors have extensive experience with federal research grants and high-impact scientific publications. Semi-annual meetings of the entire mentorship team will ensure the successful attainment of defined benchmarks for progress in this proposal.

I.1. Primary Mentor

John Dow, MD, George D. Zuidema Professor of Surgery, University of Michigan: Dr. Doe is Director of the University of Michigan's Center for Healthcare Outcomes and Policy (CHOP). He has a senior-scientist award and an established track record as both an independently-funded scientist and a mentor for young investigators who establish careers that include clinically meaningful and policy-relevant health services research, and he has mentored many K award recipients toward R-level funding and independence. Dr. Doe's research funding and publications include work in variation in costs of surgery, analytical methods for comparing hospitals' performance, and regional surgical quality improvement. As a member of the Institute of Medicine, he is a recognized leader in health services research with expertise in the organization of health care systems and the measurement and improvement of health care quality. He has extensive experience with Medicare claims data and the Michigan Surgical Quality Collaborative (MSQC) registry, and is the principal investigator of the Michigan Value Collaborative, a statewide initiative to improve care transitions and reduce variation in costs around hospital care. I will meet with Dr. Doe weekly to discuss all aspects of study design, data management, analysis, and interpretation, manuscript and grant writing, and career development.

I.2. Co-Mentors

Jane Doe MD, PhD, Professor of Internal Medicine, Gerontology, and Health Management and Policy, University of Michigan. Dr. Doe's research focuses on the epidemiology and costs of chronic disease in older adults. He is Associate Director of the NIA-funded Health and Retirement Study and Lead Investigator for the Aging, Demographics, and Memory Study, examining risk factors, epidemiology, and outcomes of dementia. He was recently awarded the Michigan Institute for Clinical and Health Research Distinguished Research Mentor Award. I will meet with Dr. Doe at least monthly, for guidance in my training around care needs of older adults, and in evaluating unique clinical outcomes in geriatric patients (Aim 3).

Susan Smith, PhD, Associate Professor of Health Management and Policy, University of Michigan School of Public Health. Dr. Smith is Director of the Griffith Leadership Center at Michigan, and Chief Academic Officer of the National Center for Healthcare Leadership. Her research focuses on management, leadership and organizational strategy. She is currently the Principal Investigator of three major project grants, including a project funded by The Center for Healthcare Research and Transformation to study organizational factors predicting high and low surgical quality performance among hospitals in the MSQC. She will provide guidance in the evaluation of hospital organizational factors contributing to ERAS implementation and outcomes (Aim 1).

Greg Smith PhD, Professor of Economics and Health Management, University of Michigan. Dr. Smith is an economist and Director of Health Economics at CHOP. He has extensive experience in advanced statistical techniques to measure efficiency of health care delivery. He teaches courses proposed for this

training program, and will provide oversight of cost analyses and techniques of causal inference used in this proposal. I will meet with Dr. Norton twice-monthly to ensure longitudinal guidance regarding the complex cost and outcome methodologies outlined in this proposal (Aims 1, 2, and 3).

I.3. Collaborators

Sally Smith, MDD, Professor of Surgery, University of Michigan. Dr. Smith is the Chief of Medical Officer at the University of Michigan Health System, and Director of the Michigan Surgical Quality Collaborative (MSQC), the research setting for this proposal. A leader in surgical quality improvement, he has committed to providing infrastructure and data support, engaging participating hospitals in the project administration, and to helping me develop leadership skills. We will meet at least monthly, as part of the MSQC administrative meetings, to ensure integration of this project within the larger goals and progress of the collaborative.

Edward Smith MD, PhDD, Professor of Surgery, Case Western Reserve University. Dr. Delaney is the Vice Chairman of Surgery, and Division Chief of Colorectal Surgery at University Hospital Case Medical Center. He is an international leader in the development and dissemination of ERAS, and has more than 100 publications focused on performance improvement in colorectal surgery, including a national survey of surgeons’ use of fast-track recovery practices. Remote meetings will occur every two months, for guidance in interpretation of process of care data and to orient findings with national progress in dissemination of ERAS.

J. APPENDIX – TIMELINE

The timeline and benchmarks for research and career development activities, organized by the three skill sets to be acquired, are detailed in the Gantt chart below:

Topic	Mentor/Aim	Category	Year 1		Year 2	
Organizational Culture and Delivery Systems	Lemak Spec. Aim 1	Coursework		HMP603		Surg. Leadership Dev't Prog.
		Mentored Research	Process data accrual		Analysis of in-hospital outcomes	NIH Impl. Science
		Seminars	Griffith Leadership Center Leadership Fellows (monthly) MSQC working group (monthly)			
Enhancing Causal Inference	Norton Spec. Aim 2	Coursework		HMP 640		CSCAR
		Mentored Research		Accrual of Medicare cost data	Analysis of post-discharge outcomes and episode costs	
		Seminars	CHOP Research in Progress (weekly)			
Gerontology	Langa Spec. Aim 3	Coursework			EPI 813	
		Mentored Research		Accrual of Michigan Value Collaborative cost data		Analysis of patient-specific heterogeneity
		Seminars	Claude D. Pepper Older Americans Independence Center (bi-weekly)			
		Site Visits	Univ. of Michigan/St. Joseph Mercy Acute Care for Elders unit			

CHOP: Center for Healthcare Outcomes and Policy; CSCAR: Center for Statistical Consultation and Research; EPI: Epidemiology; HMP: Health Management and Policy;



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September 4, 2013

John Munson, MD
President
American Society of Colon and Rectal Surgeons Research Foundation

Re: John Smith's Career Development Award Application

Dear Dr. Munson:

I am very pleased to submit this letter of support for John Smith, MD, MPH, who is applying for the ASCRS Career Development Award. This letter documents our institution's commitment to Dr. Smith and the research and education plan proposed herein. I recruited Dr. Smith to the University of Michigan, and he began his position with us in 2011. He is one of our most promising new tenure-track faculty members. Our commitment to Dr. Smith's career is not contingent upon this grant, but this exciting proposal will be a superb vehicle for his career development into an independent academic investigator.

Dr. Smith's research goal is to improve the quality and costs of surgical care across the wide diversity of hospitals that perform colon and rectal surgery. Our institutional setting is extremely well suited to his success in this goal for three reasons. First, the University of Michigan is one of the best places in the world for surgical outcomes research. The research group led by Dr. John Doe is an incredibly fertile environment, as indicated by the group's extensive grant funding, their high-impact publication record and the number of junior faculty with successful career development grants. Furthermore, under my leadership the Department of Surgery is unwaveringly committed to the academic success of its faculty, with protected time for research, support staff for grant and research development, and mentorship. Second, Michigan is home to more than 10 statewide collaborative quality improvement programs. The research setting for Dr. Regenbogen's project includes two of these successful programs, the Michigan Surgical Quality Collaborative and Michigan Value Collaborative. Dr. Smith is rapidly integrating into the core leadership of these organizations, and has the full support of Dr. Greg Smtih who directs the program. Finally, the University of Michigan has a uniquely rich, multidisciplinary environment, with world-class coursework and mentorship that will allow Dr. Smith to achieve his educational goals to become an expert in development and implementation of high-value surgical care.

Specifically, I am committed to giving Dr. Smtih at least 50% of his full-time professional effort to meeting the requirements of this proposal. I also am fully committed to supporting Dr. Smith with any additional resources needed to fulfill the goals of this award, such as assistance with tuition from discretionary funds for academic development. In summary, I give my strongest support to the grant application of this promising faculty member, and I speak on behalf of the institution in asserting our firm commitment to his career development and to the success of this proposal.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Mulholland'.

Michael W. Mulholland, MD, PhD
Frederick A. Collier Distinguished Professor and Chair
Department of Surgery, University of Michigan



University of Michigan
Hospitals and Health Centers

John D. Birkmeyer, MD

George D. Zuidema Professor of Surgery
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September 4, 2013

John Munson, MD
President
American Society of Colon and Rectal Surgeons Research Foundation

Re: [REDACTED] Career Development Award Application

Dear Dr. Munson:

[REDACTED] has asked me to serve as his sponsor and primary academic mentor for the ASCRS Career Development Award and. Please accept my strongest possible support for his application.

[REDACTED] is an exceptionally well-trained colorectal surgeon and health services researcher. He obtained his clinical surgery training at the Massachusetts General Hospital and Lahey Clinic. During this time, he dedicated three years to coursework in public health and a highly successful research program within an AHRQ-sponsored T32 training grant at the Harvard School of Public Health. I enthusiastically recruited [REDACTED] to join the faculty in surgery at the University of Michigan, and I have served as his primary academic mentor. [REDACTED] has emerged as an extremely promising health services researcher. As outlined in his scientific bibliography, he has over 20 peer-reviewed publications to date, which have appeared in many of the best clinical and academic surgical journals, including *Lancet*, *Annals of Surgery*, and *Journal of the American College of Surgeons*.

Although the majority of [REDACTED] bibliography is focused on assessment and improvement in quality and safety in surgery, his scientific interests have evolved during his time in Michigan, and he is now particularly interested in the interplay between cost and efficiency improvements and the outcomes of care for potentially vulnerable surgical patients. With the advent of bundled payments, and interest in strategies for value-based care delivery occurring in concert with a growing interest in fast-track recovery after surgery, an understanding of the consequences of cost containment efforts in surgery will be crucial. Thus, I am very excited about his proposal to characterize the cost and outcome consequences of enhanced recovery protocols for colectomy in our statewide surgical quality collaborative in Michigan.

I have a longstanding interest and track record in mentoring clinician health services researchers, but only agree to mentor those that I can provide adequate attention. Although most of my mentees are still early in their careers, many of these individuals have been very successful. Fourteen have received NIH K-awards or equivalent career development grants; five have made the transition to R21 or R01 awards. Supporting my commitment to faculty-level mentorship, I am a current recipient of a K05 Senior Scientist/Mentor Award from the National Cancer Institute.

As primary mentor, I am committed to a schedule of formal meetings with [REDACTED] to guide his progress. In addition to meeting with [REDACTED] and his Mentorship Team on a twice-yearly basis, I also commit to a weekly, one-hour meeting with him. These will supplement frequent ad-hoc interactions (our offices are approximately 20 feet apart) and group meetings such as our Center for Healthcare Outcomes and Policy weekly research in progress seminar. I have the following objectives for our meetings:

1. Help [REDACTED] develop a longitudinal research agenda. I will advise him in selection of high-impact research questions which will be both clinically interesting and policy relevant. The research themes outlined in this proposal dovetail closely with my own well-established federally-funded interests in understanding the costs and efficiency of inpatient surgical care (as outlined in my Biosketch), yet are uniquely independent in their focus on the clinical care associated with fast-track recovery.
2. Make sure he sticks to his educational plan. Although he already has a very solid grounding in clinical epidemiology research methods, further statistical training, particularly in causal inference and econometrics will help him blossom as an independent researcher in health services researcher. Given the organizational context of his work, he will also benefit from structured educational experiences in organizations management and cost accounting. His proposal outlines a rigorous educational plan and I will ensure that he follows through on these commitments.
3. Ensure that [REDACTED] completes the proposed analyses. During our weekly meetings, [REDACTED] and I will discuss and troubleshoot both data management issues and the analytic approach to his proposed research. I will push him to defend the analytic choices he makes and guide him when challenges surface. I will also help direct his independent study on topics relevant to the analyses he conducts.
4. Help him disseminate his work. As [REDACTED] completes individual projects, I will serve as an editor to ensure that his manuscripts are clear and effective. I will help him publish his work in journals read not only by surgical peers, but also by other clinicians, health services researchers, administrators, and policy makers. I expect Scott to publish at least three to five papers derived specifically from the results of this proposal, but anticipate he will also publish additional manuscripts from related work. I will ensure that Scott is presenting his work not only to the members of his own specialty society, but also among other relevant audiences, including aging and policy researchers.
5. Facilitate his transition from trainee to independent investigator. In the spirit of the career development award program, I aim to help [REDACTED] develop as an independently-funded scientist. Toward this end, I will advise him on issues related to grantsmanship and the funding process. I am committed to helping him submit his first R01 application toward the end of this award timeline. I will also chair his Mentorship Team meetings and ensure that he takes full advantage of the unique talents of each co-mentor and collaborator.

I will also ensure that [REDACTED] has the resources needed to accomplish the research outlined in this work plan, particularly the required data and programming support. I serve as Director of the Center for Healthcare Outcomes and Policy (CHOP) at U-M, a large multi-disciplinary consortium of clinical and non-clinical faculty and staff (total 110) sharing common interests in population-level health services research, including the use of large claims databases and clinical registries. CHOP has a well-organized administrative data management infrastructure, including 100% fee-for-service Medicare claims for several surgical cohorts spanning many years, Blue Cross and Blue Shield of Michigan claims data, and the Michigan Surgical Quality Collaborative (including all data required to complete this proposal).

Among the many promising junior clinician-researchers I have mentored over the years, [REDACTED] is clearly among the most talented and committed. Given the competing demands on the time of a junior faculty surgeon, a career development award will be instrumental in providing the financial support and educational experience he needs to get to the next level.

Yours sincerely,



John D. Birkmeyer, MD



Arden M. Morris, M.D., M.P.H.
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September 16, 2013

John Munson, MD
President
American Society of Colon and Rectal Surgeons Research Foundation

Re: Reference letter for [REDACTED]

Dear Dr. Munson:

I am very pleased to write this letter of support for [REDACTED]'s career development grant application. I have worked with Scott as a research collaborator and mentor since his arrival at the University of Michigan more than two years ago. Since that time I have come to know him very well and can attest to his personal and professional qualities that make him an outstanding candidate for this career development opportunity.

I believe that [REDACTED] has outstanding potential for conducting independent research, as evidenced by the qualities he displayed in our collaborations. He is highly committed to an academic career. He dedicated three years away from his clinical surgery training to complete an MPH degree and obtain the necessary skills to conduct sophisticated health services research. His drive to pursue an academic surgical career was further displayed in his move to the University of Michigan, the main motivation being the wonderful support for his academic career development.


Since his arrival here, he has developed a very promising research and career development plan under the mentorship of [REDACTED], and has also been an important contributor to my own American Cancer Society-funded research, involving survey-based evaluations of patients with Stage III colorectal cancer. Mentoring [REDACTED] as a part of our research team, I have observed outstanding originality and clarity in his thought process, vision, and communication skills. For example, from our survey instrument he independently conceived, designed and analyzed inquiries into the effects of surgical complications on doctor-patient relationships, financial strain, and receipt of chemotherapy after colorectal cancer surgery. He has consistently demonstrated the ability to brainstorm, design, analyze, compose and present his analyses. We have had the opportunity to author several manuscripts together, and I found his writing skills and ability to work together in a multidisciplinary team are exceptional. In summary, [REDACTED] contributions to our research group are extremely valuable, both as a surgeon and a creative problem-solver. He is a closer.

John Munson, MD
September 16, 2013
Page Two

Most of all, [REDACTED] is absolutely passionate about improving the quality of care provided to the most vulnerable of our patients. His original interests were particularly in low-performing hospitals and the role they play in health outcomes for patients with socioeconomic disadvantage. Upon arrival in Michigan, he immediately recognized the potential for statewide collaboratives to improve the quality of care in these settings, and has taken a specific interest in the use of clinical care standardization and optimization in improving care for vulnerable patients. He has developed a new interest in cost and efficiency, and this proposal seems a very natural evolution of the interests he has developed in our collaborations and in his previous work. I believe this training opportunity will be the final step in his path to independence. The mentorship team he has gathered for the grant is world-class, and will no-doubt result in high-impact research and publications.

In conclusion, I support [REDACTED] in this career development grant with highest enthusiasm. He has outstanding potential to contribute to surgical health services research as an independent investigator, and this grant proposal is an ideal mechanism to develop his research program. Please feel free to contact me with any questions.

Sincerely,



Arden M. Morris, MD, MPH
Associate Professor of Surgery
Chief, Division of Colorectal Surgery
Associate Professor of Health Behavior
And Health Education