SPECIFIC AIMS

Inflammatory bowel disease (IBD), which includes Crohn's and Ulcerative Colitis, is a chronic and costly disease of unknown etiology that now affects over **3.1 million people** in the United States [5]. Patients suffer from lifelong malnutrition, pain and bleeding with added risks of cancers, obstructions and fistulas. For these reasons, over 75% of IBD patients will face major, high-risk surgery with consequences ranging from permanent loss of intestines to ostomies [6, 7]. Although IBD is prominent among Caucasians, over 30% of contemporary IBD populations may now be African-American [8-10]. As this population grows, **significant disparities in surgical outcomes** are also emerging. Nationally, our studies have found that African-Americans with IBD have two-fold higher readmission rates, 20% longer length-of-stays and 30% higher complication rates after surgery than Caucasians [11-14]. The contributing factors are not well understood but would be crucial to development of interventions, and advancement of current NIH-initiatives, focused on reducing surgical disparities [15].

Studies, including our own, have observed that better patient education, understanding and engagement in surgical processes lead to better surgical outcomes and even reduced disparities [16, 17]. These observations suggest a potential role for **health literacy**, or an individual's capacity to obtain, process and understand health information [18], in determining surgical outcomes. Under the Health Literacy and Outcomes Framework [19], this determination occurs through **modifying factors** at the healthcare system, provider and patient-level. Patients with low health literacy are therefore *not* fated to have poorer health outcomes – factors such as readability of education material and effective communication may positively impact outcomes. While established in many non-surgical fields [20], the role of health literacy in surgical outcomes remains unclear [21, 22].

The overall goal of this project is to explore the role of health literacy in determining surgical outcomes among African-American IBD patients. We hypothesize that health literacy is associated with surgical outcomes (and disparities) and that modifying factors can be identified. These findings would inform future development of health literacy-based surgical care models. **These findings may have additional impact** in broader surgical populations and support national action plans to improve health literacy led by the National Academy of Medicine [23] and Department of Health and Human Services [24]. To achieve our goal, this project will be conducted at a high-volume IBD center that serves a 20% African-American IBD population and have the following aims:

Specific Aim 1. Assess health literacy levels in a contemporary adult IBD surgical population.
Approach: Using the Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF), Newest Vital Sign (NVS) and Short Test of Functional Health Literacy in Adults (STOFHLA), Caucasian (n=300) and African-American (n=150) IBD patients who have undergone at least one surgical procedure will be assessed during routine clinic visits for health literacy levels and patient characteristics including social determinants of health (SDOH). *Hypothesis*: Compared to Caucasian-Americans, African-American IBD patients will have lower health literacy levels as determined by REALM-SF, NVS and STOFHLA stratifications.

Specific Aim 2. Determine the association of health literacy to surgical outcomes in IBD patients.
Approach: Using a prospective surgical registry (n=1,236 IBD patients), multivariate analyses will be used to identify independent predictors of three surgical outcomes (30-day readmissions, post-operative length-of-stay (LOS) and post-operative complications (POCs)). Covariates will include patient factors (including race and SDOH), procedure characteristics and health literacy levels (REALM-SF, NVS and STOFHLA). *Hypothesis*: Low health literacy will be associated with higher rates of readmissions, longer LOS and more POCs.

Specific Aim 3. Explore potential factors that impact low health literacy in IBD patients.
Approach: Focus groups (of patients and caregivers) and key informant interviews (of healthcare providers and community educators) will be used to identify potential barriers and facilitators that impact a patient's capacity to obtain, process and understand surgical information in the perioperative periods. From the Health Literacy and Outcomes Framework, these factors occur at the healthcare system, provider and patient-level.

Training/Career Goals: To gain the knowledge and skills to lead interdisciplinary teams dedicated to reducing health disparities in surgical outcomes. To make a substantial impact in reducing surgical disparities, I need to learn new techniques outside the operating room and apply work from innovative fields like health literacy to surgery. These gains will occur through an MSPH program, health literacy training, and this mentored project.

Expected Outcomes: This study will determine health literacy levels in a racially-diverse IBD surgical population and its associations with surgical outcomes. It will also identify potential modifying, and actionable, factors in the surgical process that may impact health literacy. These data will guide development of novel, literacy-based surgical care models that improve outcomes, and reduce disparities, for African-Americans with IBD.

A. CANDIDATE QUALIFICATIONS. My extensive training thus far has provided a strong foundation to begin an academic career. To reach my goal of becoming an independent researcher, however, I require more knowledge and research skills. Receipt of the K12 award would accelerate my progress in reaching this career goal.

A.1.1 Background. I am a first-generation Asian-American born in Lansing, Michigan to immigrant Chinese-American parents from Taiwan. I trained at Yale, Johns Hopkins, Boston University, and the Mayo Clinic. After completing my colorectal surgery fellowship, I joined UAB as an Assistant Professor of Surgery in July 2014.

A.1.2. Evidence of broad scientific foundation. My broad experience in both basic and clinical research has spanned across five major institutions. This foundation began at Yale in a pediatric hookworm laboratory. There, I characterized a unique protein secreted by hookworms that protect them from host digestion. This work resulted in a first-author publication in *Infection and Immunity* [25]. At Hopkins, my interests transitioned from pediatrics to surgery and I entered surgical residency at Boston University with the intent to pursue research. I was accepted to a 2-year research fellowship and during that time, my work on abdominal adhesions and surgical outcomes resulted in 3 first-author [26-28] and 2 co-author publications [29, 30]. At the Mayo Clinic, I balanced my intensive colorectal training with clinical research that resulted in a first-author publication on surgical site infections [31]. Since starting at UAB, I have further strengthened my foundation in clinical research with 9 first or senior-author publications [11, 13, 17, 32-37] and 5 collaborative ones [12, 38-41] in high-impact journals including *Annals of Surgery*. Much of this work has now focused on surgical disparities. As I seek to understand and reduce disparities however, I have realized that using big data-alone will not suffice. I need additional knowledge and skills in other research methods and constructs such as health literacy – needs that can be acquired with this K12 opportunity.

A.1.3. Commitment to improving health outcomes and reducing disparities. As a double-board certified general and colorectal surgeon at the only tertiary-referral center for Alabama, I care daily for disadvantaged and complex surgical patients. I chose UAB over two other academic institutions, Boston University and University of Wisconsin, because I felt there would be greater clinical and research opportunities to make a difference. In one of my first projects as faculty, I implemented an institution-wide surgical recovery pathway that has reduced disparities and improved outcomes for African-American patients undergoing major surgery. This project won the 2016 UAB Health System Innovations Award, attracted news articles [42, 43] and has led to three small grants [44-46] and a recently-accepted publication in the highest impact surgical journal, *Annals of Surgery* [17]. This on-going work, which has directly impacted over 1,000 surgical patients at UAB and now other surgical services lines, has motivated this proposed project as I am finding that factors such as education and engagement play important roles in determining surgical outcomes and potentially disparities.

A1.4. Evidence of academic potential in surgical disparities research. Since joining UAB, I have established a research program within the Division of GI Surgery with a focus on disparities and health outcomes for surgical patients. In the last year, this work has resulted in over 12 presentations at national meetings, 5 awards, 4 publications [11, 13, 17, 37] and three pilot grants on surgical disparities [44-46]. In 2016, I was also designated an Associate Scientist at the UAB Minority Health and Health Disparities Research Center (MHRC). In response to my needs for more knowledge and skills, I was selected as a current scholar in the 2016-2017 MHRC Health Disparities Research Training Program and have also begun part-time coursework in the School of Public Health for an MSPH (I have completed 3 classes thus far). **I have been challenged in balancing my clinical duties** with these academic and training pursuits, however, and seek more protected time, as provided by the K12 opportunity, to gain the knowledge and skills I realize I need to reach my research and career potential.

A.1.5. Evidence of expertise in inflammatory bowel disease (IBD). IBD is a devastating disease that has received comparatively little public attention or funding. I have worked with IBD patients in all my training grounds including Boston University and the Mayo Clinic, which is an international referral-center for challenging IBD cases. I performed over 600 cases in my one-year fellowship at the Mayo Clinic and have gained significant skills and experience in IBD in both clinical and research domains [11, 12, 29, 33, 35]. Since joining UAB, I have performed over 1,000 cases and developed a busy clinical practice at the UAB IBD Center. I have significant access to IBD patients. I also work with the Crohn's and Colitis Foundation (CCF) and serve on patient education panels. Anecdotally, I take care of many African-American IBD patients who have major challenges in their care and outcomes. Their stories are the inspiration for this research proposal as I see significant opportunities to address disparate outcomes in this population.

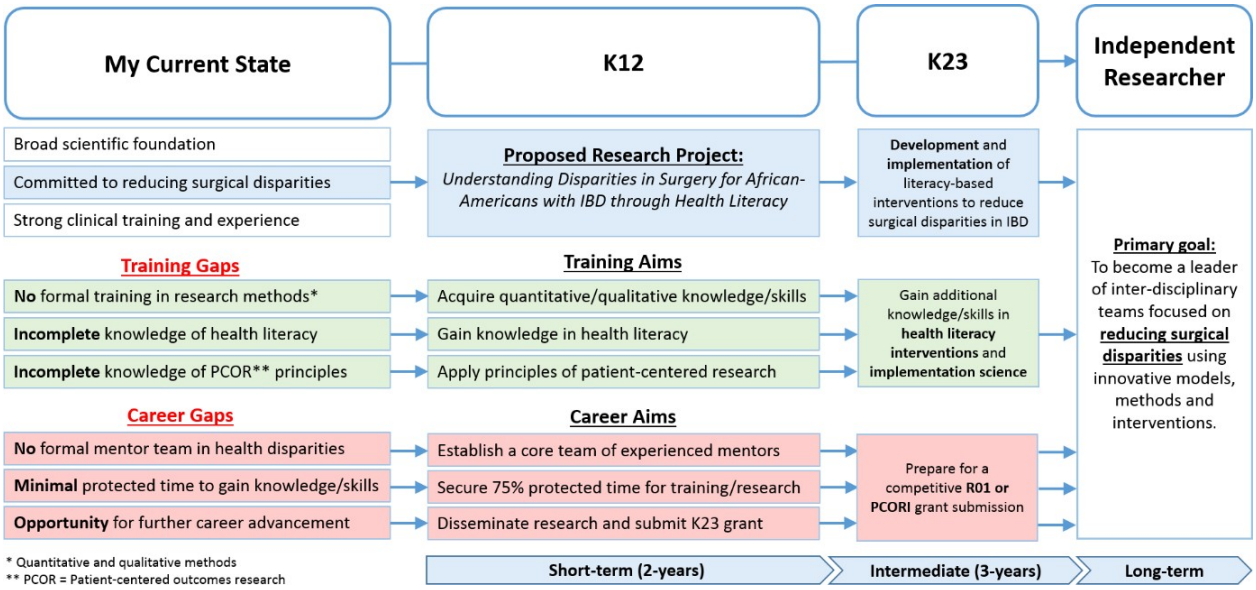

Figure 1. Summary of progression from current state to independent researcher.

A.1.6. Need for more knowledge, skills and time. To make an even greater positive impact on IBD patients, and to advance our understanding of disparities in surgery, I need more protected time to gain knowledge/skills and to conduct innovative research as proposed in this K12 award. I have had no formal training in outcomes research, learning primarily from informal mentorship and publications, and would benefit from a rigorous training program. I am currently 55% clinical effort (2.75 days) but could be quickly reduced to 25% clinical effort (1.25 days) should I receive this K-award (*see support letters from Drs. Kennedy/Chen*). My previous three years as an attending surgeon has increased my confidence and ability to independently care for complex surgery patients and I am ready to decrease my clinical efforts and focus on becoming a successful independent investigator.

A.2. Career goals and objectives. My career goal is to become an independently-funded researcher who can lead inter-disciplinary teams focused on reducing disparities among high-risk surgical populations, such as IBD, using innovative approaches (**Figure 1**). To achieve this goal, several objectives will need to be achieved:

A.2.1. Short-Term Objectives (years 1-2). My short-term objectives will focus on acquisition of additional knowledge and skills through the completion of this proposed mentored project.

Objective 1. Conduct and complete a 2-year mentored project on surgical disparities. (Research)
Objective 2. Acquire knowledge/skills in quantitative and qualitative research methods. (Training)
Objective 3. Gain knowledge in health literacy-based research and competencies. (Training)
Objective 4. Apply principles of PCOR methods through patient/stakeholder engagement. (Training)
Objective 5. Establish core team of mentors. (Career)
Objective 6. Disseminate research through publications (2-3/yr) and presentations (2-3/yr). (Career)
Objective 7. Gain external funding (K23). (Career)

A.2.2. Intermediate-Term objectives (years 3-5). My intermediate-term objectives will focus on maturing my knowledge and skills through a K23 and preparing for an R01 or PCORI grant submission.

Objective 1. Conduct 3-year project developing/implementing literacy-based interventions.
Objective 2. Obtain advanced training in health literacy-based interventions.
Objective 3. Obtain advanced training in implementation science.
Objective 4. Submit an R01 or PCORI application.

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A.2.3. Long-Term objectives (years > 5).

Objective 1. To become an independent researcher on surgical disparities.
Objective 2. To become an expert on surgical disparities with a focus in health literacy.

A.3. Role in promoting career. The proposed K12 award will promote my career by these provisions:

Role 1. Provide protected time for career development through intramural support. The K12 award will allow me to train, conduct and disseminate research in surgical disparities with protected resources and time (*see letter by Drs. Kennedy/Chen*). I have capacity to decrease my clinical workload with financial support.

Role 2. Provide a rich, inter-disciplinary research experience. The proposed project will use both quantitative and qualitative methods to better understand disparities in surgery. It will also focus on health literacy, a construct that is not well understood in surgery. This research will complement my training and career development plans and result in a strong research foundation upon which other innovative projects will be built.

Role 3. Provide training opportunities. The training programs proposed in this project will include an MSPH, seminars/workshops, conferences, a mini-sabbatical, and mentored training. Acquiring knowledge and skills is my most critical need and the key asset provided by the K12 award.

Role 4. Provide formal mentorship. The K12 award would provide an opportunity to be formally taught and mentored by health service professionals with diverse expertise and skills. Mentorship would sharpen my analytical approach to problems such as health disparities and health literacy. It would also establish long-term relationships for anticipated future projects.

Role 5. Provide opportunities to engage patients and stakeholders. By intention, the K12 award will encourage me to learn about PCOR research principles and apply them through this proposed project. Through engagement of patients and stakeholders, I will learn from their stories and perspectives. These experiences in PCOR methods would prepare me for competitive future applications in patient-centered research.

Role 6. Build my capacity for competitive extramural grant applications. Through this proposed project, I will gain the data, training and experience that I need to develop literacy-based surgical care models. The acquired experience and knowledge/skills will help me be competitive in R01/PCORI grant applications.

A.4. Commitment to a research career.

I am fully committed to a research career focused on eliminating health disparities in surgery.

B. CAREER DEVELOPMENT AND TRAINING PLAN. To achieve my career goal, I need further career development with training in three areas: research methods (quantitative and qualitative), health literacy, and PCOR research principles. My proposed 2-year training plan will fill these gaps through the MSPH program and health literacy training via didactics, seminars/conferences, mini-sabbaticals and mentored training (**Table 1**).

Training Plan	6-month	12-months	18-months	24-months
Acquire knowledge and skills in research methods				
Quantitative Method Coursework	BST612	BST613/EPI610	HCO687	HCO693
Qualitative Method Coursework	HCO628	HCO621		
Seminars	Lister Hill Center Health Policy Methods, COERE Works-in-Progress, Surgical Outcomes Club			
Off-site seminar	QRSIC – UNC-Chapel Hill			
Additional Training	Mentored Training	Mentored Training	Mentored Training	Mentored Training
Gain knowledge in health literacy				
Coursework	CDC Health Literacy Training Course		HB730	
Conferences	NHLRC		NHLRC	
Off-site seminar		Tufts HLL Institute		
Mini-sabbatical		CHSR-EHCP - Vanderbilt		
Additional Training	Mentored Training	Mentored Training	Mentored Training	Mentored Training
Apply principles of PCOR methods				
Engagement	HCO677	IBD Advisory Panel	IBD Advisory Panel	IBD Advisory Panel
Implementation & Dissemination			HB625	HB636
Presentations/Publications		2-3 publications	2-3 presentations	2-3 publications
Seminars	PCORI webinars/panels	PCORI webinars/panels	PCORI webinars/panels	PCORI webinars/panels
Off-site seminar			NIH TIDIRH	
Additional Training	Mentored Training	Mentored Training	Mentored Training	Mentored Training

Table 1. Specific training plans with 6-month benchmarks. MSPH program – blue-colored box.

B.1. TRAINING AIM 1. Acquire knowledge and skills in quantitative and qualitative research methods. While I have more experience in quantitative analysis, I have never been formally trained. I also have no training in qualitative methods. Our proposed project will require application of both research methods.

B.1.1. Acquiring Quantitative Knowledge and Skills.

a. Didactic Training: Biostatistics (BST612 and 613), Epidemiology (EPI610), Empirical Research Methods (HCO687), Modeling and Simulation (HCO693). *I completed BST611 (Biostatistics I) in Spring 2017*.
b. Seminar: I will supplement my coursework with on-campus seminars including the Lister Hill Center for Health Policy Methods, the Center for Outcomes and Effectiveness Research (COERE) Works-in-Progress meetings, and the monthly on-line seminar Surgical Outcomes Club (www.surgicaloutcomesclub.com/didactic-sessions).
c. Mentored Training*:* My entire mentor team is very experienced with quantitative methods.

B.1.2. Acquiring Qualitative Knowledge and Skills.
a. Didactic Training: Qualitative/Mixed Methods Research (HCO628), Clinical Decision-making (HCO621).
b. Seminar: I will attend the off-site UNC-Chapel Hill Qualitative Research Summer Intensive Course (QRSIC). Content will include learning about qualitative techniques, study design, analytical approaches and codebooks.
c. Mentored Training: Dr. Knight will provide mentored training in mixed-methods with a focus on qualitative approaches. I have 2 on-going mixed-method studies with Dr. Knight that will provide parallel learning [44, 45].

B.2. TRAINING AIM 2. Gain knowledge in health literacy. I have had no formal training on health literacy and will obtain the knowledge as detailed below.

a. Didactic Training. Health Communications (HB730)
b. Additional Courses*:* I will take the Centers for Disease Control and Prevention (CDC) Health Literacy Training program. These six online courses are designed for health professionals.
c. Seminar*:* I will take an off-site seminar: The Tufts University Health Literacy Leadership Institute (June 2018, 1-week course on health literacy and communication).
d. Conferences: I will attend the 2017 and 2018 National Health Literacy Research Conference (NHLRC) which is an interdisciplinary meeting for investigators dedicated to health literacy research.
e. Mini-Sabbatical*:* I plan to attend the Center for Health Services Research Effective Health Communication Program (CHSR-EHCP) with Dr. R. Rothman at Vanderbilt. I will learn about health literacy including patient centered communication, addressing cultural/language barriers, and developing effective education material.
f. Mentored Training: Drs. Gakumo and Davis will provide expert mentored training in this domain. I am already working with both on a qualitative review of the current state of health literacy research in surgery.

B.3. TRAINING AIM 3. Apply principles of patient-centered research methods. To successfully gain extramural funding from NIH and PCORI, I need further training in patient/stakeholder engagement, implementation and dissemination of research. Through this proposed training program, I will better understand and utilize these principles in my current and future research.

B.3.1. Engagement of Patients/Stakeholders.
a. Didactic Training. Patient-Based Outcomes Measurement (HCO677).
b. Seminar/Workshops: I will participate in PCORI Advisory Panel meetings, online Webinars and Regional workshops which are open to off-site researchers. I will learn about new advances in PCORI research and better prepare for future PCORI grant applications.
c. Mentored Training: Dr. Davis is a PCORI-funded mentor experienced in engagement and PCOR principles. Through this project, we will also develop, establish and meet with an IBD Advisory Panel composed of patients and stakeholders including the nation's largest IBD patient-advocacy organization, the Crohn's and Colitis Foundation (*see letter of support from CCF*).

B.3.2. Implementation and Dissemination.
a. Didactic Training*:* Dissemination/Implementation in Health (HB625), Intervention Development (HB636)
b. Seminars/Workshops: I will apply for the 2019 NIH Training Institute for Dissemination and Implementation Research in Health (TIDIRH) which is a one-week intensive course for young investigators in Babson Park, MA.
c. Publications*:* To share our research findings with peers, I aim to publish at least 2-3 peer-reviewed manuscripts per year in addition to presenting our work at key national meetings held by the American College of Surgeons (ACS), American Society of Colon and Rectal Surgeons (ASCRS) and NHLRC.

C. MENTORING. My mentor team consists of academic clinician-scientists who have comprehensive and successful experience in mentoring, research techniques, training, and career development (**Figure 1**).

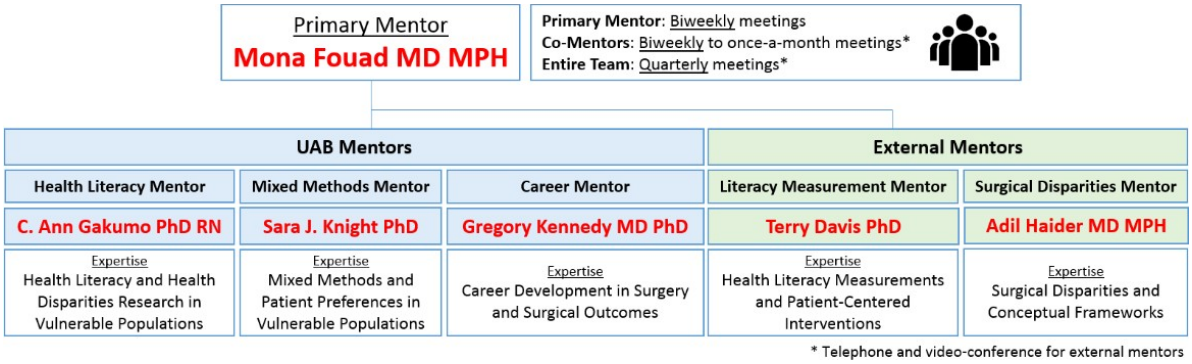

Figure 1. Mentor team including UAB and external mentors.

C.1. Mentor Qualifications.

Dr. Mona Fouad MD MPH *Professor and Associate Dean of the School of Medicine, Director of the UAB Division of Preventive Medicine, Director of the UAB Minority Health and Health Disparities Center (MHRC)*. **Dr. Fouad will be my primary mentor.** Dr. Fouad is an internationally-recognized, NIH-funded leader in health disparities research. Dr. Fouad has extensive experience mentoring previous K-award recipients including prior surgeons. As Director of the UAB MHRC, Dr. Fouad will ensure my participation in MHRC enrichment activities, including monthly health disparities seminars and workshops and opportunities to present in-progress research data. I have met with Dr. Fouad regularly over the last two years and she has been invaluable in framing my approach to this study design. She will direct me to resources from the MHRC to successfully implement this project.

Dr. C. Ann Gakumo PhD RN *Associate Professor of Nursing, School of Nursing, University of Alabama at Birmingham*. **Dr. Gakumo will be my research mentor.** She will provide expertise on health literacy. Dr. Gakumo is a nationally-recognized, independently-funded health services researcher who focuses on health literacy in the vulnerable HIV population. She is a prior UAB K12-funded researcher and is an expert on research methods, both quantitative and qualitative, in health literacy research. She is PI of a current Robert Wood Johnson Foundation-funded project studying health literacy in African-Americans with HIV. I have met with Dr. Gakumo over the last year to design this study and she will be an important mentor in all parts of this study.

Dr. Sara J. Knight PhD *Professor of Preventative Medicine and Director of Health Services Research and Development Programs for the Birmingham and Tuscaloosa Department of VA Medical Centers.* **Dr. Knight will be my research mentor.** She will provide expertise on mixed-methods and qualitative research. Dr. Knight is an internationally-recognized, NIH/VA-funded researcher who has focused her career on using mixed-methods to investigate patient values and goals. Dr. Knight has previously mentored over 20 junior faculty members. Prior to joining UAB, she served as the Deputy Director of the VA Health Services Research and Development Service in Washington, DC and represented the VA among Federal Agencies and PCORI in a national initiative to build research capacity to advance the implementation of patient values assessment and shared decision-making. Her expertise in mixed-methods and insights into federal funding priorities in patient-centered outcomes research will be valuable to me as I seek federal and NIH/PCORI research funding.

Dr. Gregory Kennedy MD PhD *Professor of Surgery, Director of the Division of GI Surgery*. **Dr. Kennedy will be my career development mentor**. Dr. Kennedy is an NIH R01-funded surgeon-scientist. He is director of my division and direct supervisor. With support from the Chair of Surgery (**Dr. Herb Chen**, *see biosketch and letter*), Dr. Kennedy has a vested interest in my early career development. As director, he has already begun allocating the protected time and resources that I need to become successful in this project and in my research career.

Dr. Terry Davis PhD *Professor of Medicine and Pediatrics, Louisiana State University Health Sciences Center (LSUHSC), Shreveport, LA*. **Dr. Davis will be my external mentor.** She will provide expertise on health literacy and literacy-measurement instruments. Dr. Davis is an internationally-recognized, independently-funded researcher on health literacy and developed the world's most validated and utilized health literacy instrument (Rapid Estimate of Adult Literacy in Medicine, REALM). I have worked with Dr. Davis over the last year developing this project and maintain biweekly calls with her.

Dr. Adil Haider MD MPH *Professor of Surgery, Harvard Medical School and the Brigham and Women's Hospital, Boston, MA.* **Dr. Haider will be my external mentor.** He will provide expertise on the field of surgical disparities. Dr. Haider is an internationally-recognized, independently-funded surgeon-scientist who led the efforts that established the national agenda on surgical disparities research with the American College of Surgeons and NIH [15]. He is a previous K23 awardee and pioneer of this field. Dr. Haider has been invaluable with his mentorship of this study since its inception and will continue to provide guidance.

C.2. Plan for addressing strengths and learning needs. My mentor team recognizes that I have a strong clinical and research background with the potential to become an independently funded researcher. To reach my full potential, however, I need to acquire a formal education in outcomes research (MSPH) and gain additional skills in quantitative/qualitative analysis, health literacy and PCOR methods. Our strategy to address these gaps are well-outlined in my training plan (**Table 1**).

C.3. Plan for providing guidance and advice. Dr. Fouad will be my primary mentor and supervise the entire project. She will meet with me at least biweekly or more frequently if problems arise. I will meet with Drs. Gakumo, Knight and Kennedy on a biweekly or monthly basis in-person. I will hold calls with my external mentors biweekly or monthly as needed. My entire team will meet quarterly in-person w/ video-conference for external mentors. This team has already leveraged their unique strengths in design of this study and will continue in this project.

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C.4. Plan for monitoring and evaluating progress. Dr. Fouad and my mentor team will evaluate me by training/career development benchmarks in 6-month intervals (**Table 1**) and research progress by timeline (**Table 4**). These will include deliverables of publications (2-3/yr), presentations (2-3/yr) and a final K23 submission. I will formally present research findings at the quarterly group meetings.

C.5. Collaborative experience. My mentors are familiar with each other and have collaborated through a mix of research, clinical and administrative channels. Drs. Fouad and Knight are partners in the Division of Preventative Medicine and have served as joint mentors to me in my last two years at UAB. Through these collaborations, we were awarded the SSAT Health Disparities Award [44] and funding from the VA Office of Health Equity [45]. I also have several manuscripts with Drs. Knight [13, 17, 37]. Dr. Gakumo is a former recipient of the K12 award and trained under Dr. Fouad in the MHRC. She is familiar with Drs. Fouad and Knight and especially with Dr. Davis through her health literacy work. Dr. Kennedy is my Division Director and works with Drs. Fouad and Knight at the administrative levels. He interacts closely with Dr. Haider in several national surgical societies. Drs. Davis and Knight overlapped in training years and it was Dr. Knight who first introduced me to Dr. Davis. Together, my mentor team have approved and fully support this proposed project (*see letters*).

D. RESEARCH PLAN.

D.1. SIGNIFICANCE. **Inflammatory bowel disease (IBD) is a significant and costly problem**. In the United States, at least 3.1 million people now suffer from IBD which includes both Crohn's Disease (CD) and Ulcerative Colitis (UC) [5]. Patients are afflicted with lifelong malnutrition, pain and bleeding with added risks of cancers, obstructions and fistulas. IBD is a cruel and burdensome disease with substantial health and economic costs. In 2004, IBD patients generated over 1.3 million physician visits and 92,000 hospitalizations [47]. In 2008, IBD generated over $6.3 billion dollars in direct treatment costs and $5.5 billion dollars in indirect costs such as missed work opportunities [47, 48]. Despite these burdens, research in IBD received only 0.08% of the total NIH research budget in 2016 [49]. There remains no cure and the incidence of IBD is rapidly increasing [50]. An urgent need therefore exists for more clinical innovations and research in IBD.

D.1.1. Most IBD patients will have surgery with major consequences. Over 75% of Crohn's [6] and 25% of UC patients [7] will undergo at least one major abdominal operation during their lifetime with nontrivial consequences including permanent loss of intestines and placement of ostomies [6, 7]. All IBD patients will undergo more "minor" procedures, such as colonoscopies, but in the setting of IBD even these invasive procedures are associated with major, higher-than-average risks such as intestinal perforations [51]. Patients with IBD are continuously faced with difficult choices on the timing of these procedures, the specific type of procedure, and even on how best to prepare/recover from them. Major opportunities exist in this high-risk population to improve these surgical processes and resulting outcomes.

D.1.2. African-Americans with IBD experience worse outcomes. The incidence of IBD in minorities is increasing with over 30% of contemporary IBD populations reported as African-American [8-10]. Compared to Caucasian-Americans, African-American patients with IBD have increased disease severity, poorer medication adherence, higher hospitalization rates, worse quality of life, and delays in surgical treatment [8, 52-56]. As African-Americans undergo more surgery, disparities in surgical outcomes are emerging [8]. Nationally, our studies have shown increased length-of-stay (**Figure 2**) and readmissions [11] for African-American patients after surgery. Efforts to reduce these disparities are limited by a significant lack of understanding of the patient, provider and system-level factors that might drive them [57]. No studies have focused on surgical disparities in IBD populations and this study would target a unique and understudied population.

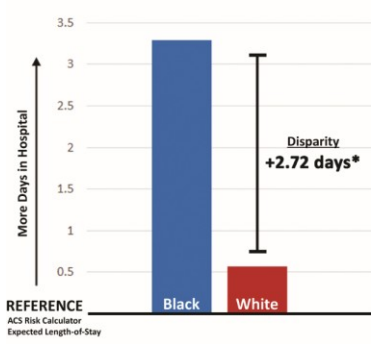

Figure 2. Significant racial/ethnic disparities in post-op length-of-stay (LOS) for patients undergoing surgery.

D.1.3. Potential role of health literacy in determining surgical outcomes and disparities. Studies, including our own, have observed that better patient education, understanding and engagement in surgical processes lead to better surgical outcomes and even reduced disparities [16, 17]. These observations suggest a potential role for **health literacy**, or an individual's capacity to obtain, process and understand health information [18], in determining surgical outcomes. Under the Health Literacy and Outcomes Framework [19] (**Figure 4**), this determination occurs through **modifying factors** at the healthcare system, provider and patient-level. While health literacy has been implicated in many non-surgical fields such as diabetes [20], its role in determining surgical outcomes and disparities remains unclear [21, 22]. Alabama is particularly affected by low health literacy (**Figure 3**) and was ranked 49th out of the 50 states in poor health outcomes by the United Health Foundation in 2016 [58]. This environment provides a unique opportunity to investigate the role of health literacy in surgery.

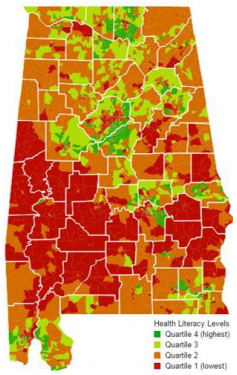

Figure 3. Health literacy levels in Alabama (2003 NAAL) [1]

D.1.5. Implications to patients and families with IBD. Health literacy provides a specific, concrete and actionable way to deliver patient-centered care [59]. Such care could improve outcomes and reduce disparities in surgery for patients, including African-Americans, with IBD. Patients and families would benefit directly from decreased readmissions, shorter lengths-of-stay, and fewer complications and indirectly from gained work opportunities. Healthcare systems would also benefit from these gains with cost-savings and increased patient satisfaction through patient-centered care.

D.1.6. Relevance to improving health outcomes through PCOR domains. This study will address PCOR Domain 1 (health disparities) and use several patient-centered methods (PCOR Domain 5) to generate the data to inform future health system interventions (PCOR Domain 2) through health literacy. As part of this study design, findings will be disseminated to the patient and scientific community (PCOR Domain 4).

D.1.7. National impact of study results. African-American patients with IBD represent two populations at high-risk for poor health outcomes. The findings from this study will directly impact these patients by providing the preliminary data necessary to develop and implement, in future studies, novel patient-centered surgical care models that are specifically tailored to health literacy. Through these efforts, our study will directly support national action plans to improve health outcomes through health literacy led by the National Academy of Medicine [23], Department of Health and Human Services [24], NIH [60], and CDC [61]. This study will also directly support the recent national initiatives put forth by the American College of Surgeons and NIH calling for more research to reduce surgical disparities [15]. If successful, our study may also have additional impact in broader surgical populations (of all specialties) as health literacy affects many, if not all, surgical populations [21].

D.1.7. Summary. This current proposal is significant because it will explore the role of health literacy in determining surgical outcomes and identify potential opportunities for literacy-based interventions to reduce disparities for African-American IBD patients and other low-literate populations. Greater efforts must be made to reduce disparities and improve outcomes in the understudied IBD surgical population. In addition, the training/career development plans proposed in this project will equip me with the capacity to conduct patient-centered research, the tools to advance the field of surgical disparities and the career trajectory to mentor future surgeon-scientists in disparities work.

D.2. INNOVATION. Our study will be innovative in several ways:

Innovation 1. Our study will be the first to study health literacy in African-Americans with IBD. Health literacy is likely deficient in the IBD population [22], but no published studies exist except for an abstract on 53 IBD patients demonstrating low literacy [62]. No studies have focused on African-Americans, which is a growing IBD population. Findings from this study would contribute significant knowledge to this unexplored field.

Innovation 2. Our study will be the first to explore the associations between health literacy, race/ethnicity and surgical outcomes. Studies-to-date in surgery have only measured health literacy levels [21]. No studies have linked literacy-levels to race/ethnicity or to outcomes in surgical populations. This study will be conducted at a minority-serving, high-volume institution that is well-positioned to explore these associations.

Innovation 3. Our study will utilize qualitative approaches to address a surgical problem. Qualitative studies in surgery are not frequently used due to surgeon's lack of knowledge/skills in this approach. Disparities research in surgery cannot be advanced with quantitative studies alone as recognized by the ACS and NIH [15]. This study will therefore apply a mixed-methods approach to understanding surgical disparities in IBD.

Innovation 4. Our study will engage patients/stakeholders, including from the Crohn's and Colitis Foundation (CCF), in a long-term partnership. Using the PCOR rubric for engagement, this study will utilize PCOR principles to establish and sustain patient-centered research in a unique surgical population.

D.3. APPROACH. **Overview of study design**. Our study will use a sequential explanatory mixed-methods approach [63]. This approach is characterized by the initial collection and analysis of quantitative data (Specific Aims 1-2) followed by collection and analysis of qualitative data (Specific Aims 3) (**Figure 4**).

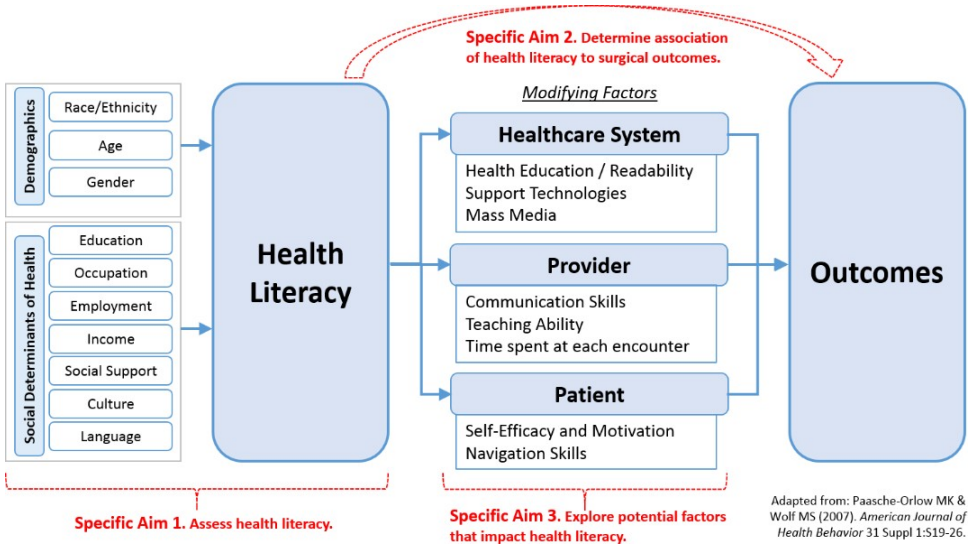

Figure 4. Health Literacy and Health Outcomes Framework with the research goals of this project (Specific Aims 1-3).

D.3.1. Conceptual framework. Under the Health Literacy and Outcomes Framework [19], health literacy drives health outcomes through **modifying factors** at the healthcare system, provider and patient-level. (**Figure 4**). Identifying which factors may be most important is a critical step to development of effective literacy-based interventions. Studies in non-surgical fields have shown that interventions at many of these levels can positively modify effects of low health literacy [64]. Examples of successful interventions include using videos for education and improving readability of text material [65] (healthcare system-level), improving communication through teach-back techniques [66] (provider-level) and developing self-management skills [67] (patient-level).

D.3.2. Specific Aim 1. Assess health literacy levels in a contemporary adult IBD surgical population.
Overview: Using the Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF), Newest Vital Sign (NVS) and Short Test of Functional Health Literacy in Adults (STOFHLA), Caucasian (n=300) and African-American (n=150) IBD patients who have undergone surgical procedures will be assessed during routine clinic visits for health literacy levels and patient characteristics including social determinants of health (SDOH).
Hypothesis: Compared to Caucasian-Americans, African-American IBD patients will have a higher proportion of low health literacy levels by REALM-SF, NVS and STOFHLA stratifications.

Instrument	Description	Skills	Items	Time	Interpretation
REALM-SF [2]	Recognition and pronunciation of medical terms	Pronunciation	7 items	1 min	0 = ≤ 3rd grade 1-3 = 4-6th grade 4-6 = 7-8th grade 7 = High school
NVS [3]	Reading & comprehension of a nutrition label	Numeracy	6 items	4 min	0-4 = Low 5-6 = High
STOFHLA [4]	Comprehension	Comprehension	36 items	7 min	0-16 = Inadequate 17-22 = Marginal 23-36 = Adequate

Table 2. Health literacy instruments.

Study Population: This study will enroll all patients 18 years and older with a diagnosis of Crohn's or Ulcerative Colitis by ICD-9/ICD-10 code and history of a surgical procedure for IBD at the UAB IBD Center from 2006-present. Surgical history will be defined as having any abdominal, anorectal or endoscopic procedure.

Survey Instruments: Three well-validated health literacy instruments (REALM-SF, NVS and STOFHLA) will be used (**Table 2**). These instruments test for different literacy skills and are rapidly administered. The three health literacy instruments will be combined into one master survey on RedCap [68]. Based on the Health Literacy and Outcomes Framework, background factors contribute to health literacy; therefore, these elements will also be included in the master survey. These include social determinants of health (SDOH) (**Figure 4**).

Power Calculations to Detect Differences in Health Literacy Levels. Based on a population study of health literacy rates using STOFHLA, 52% of African-Americans had inadequate literacy compared to 19% in Caucasians [69]. Assuming equal numbers of patients, our study will need 37 patients in each racial/ethnicity group for 80% power to detect differences of this size. To address goals of Specific Aim 2, however, our target enrollment will be **150 African-Americans and 300 Caucasian-Americans**. These numbers purposely exceed what is necessary for this Specific Aim 1, but will be needed for Specific Aim 2.

Administration of Surveys: All potential candidates will be approached in clinic and consented. An IRB-trained research assistant (Lauren Goss MSPH), who is experienced in patient recruitment and survey administration, will administer the master survey in-person. Total administration time will be less than 15-minutes.

Analysis. Included patients will be stratified by race/ethnicity and compared by background characteristics and stratified health literacy levels. Health literacy levels are categorical variables and bivariate comparisons with chi-square tests will be conducted. For continuous variables such as age and income, independent t-tests will be utilized. Statistical tests will be conducted with SAS (Cary, NC) and $p<0.05$ deemed as significant.

Expected Finding*:* Compared to Caucasian-Americans, African-American IBD patients may have lower levels of health literacy as measured by REALM-SF, NVS and STOFHLA stratifications. These levels may be associated with lower measures of SDOH including education and income. While no publications have described health literacy levels in the IBD population by race/ethnicity, one abstract reported overall low literacy rates of 38% in 53 IBD patients using the NVS [62].

Potential Difficulties and Alternative Approaches: Potential difficulty may arise in achieving our target numbers. Since 2006, however, the UAB IBD Center has served over 7,500 individuals with IBD and has over 80 unique IBD clinical encounters per week (approximately 25% are African-Americans) for 3 gastroenterologists and 4 colorectal surgeons. All patients have had, or will have, a surgical procedure. Assuming a 20% rate of non-participation, we could reach our targets within 1-year with an accruement goal of 16 African-Americans and 48 Caucasians per month. To ensure success, I will have the full-time support of an experienced research assistant in additional to 4 other research assistants in the Division of GI Surgery. All have significant experience in recruiting surgical patients, including African-Americans, for two of my on-going clinical studies involving focus groups and fecal/tissue sampling [44, 70]. If recruitment slows, we will enlist the aid of the MHRC Recruitment and Retention Shared Facility (RRSF) and our stakeholder group (IBD Advisory Panel) for advice and guidance. It is also possible that Caucasian-Americans with IBD will have low health literacy and not differ from African-Americans. While this finding would not support our hypothesis, it would be important to discover.

D.3.3. Specific Aim 2. Determine the association of health literacy to surgical outcomes in IBD patients.

Overview: Using a prospective surgical registry maintained since 2006 (n=14,318 with 1,236 IBD patients), we will merge and test the association of health literacy levels (REALM-SF, NVS and STOFHLA) to 3 surgical outcomes (30-day readmissions, post-operative length-of-stay (LOS) and post-operative complications (POCs)).

Hypothesis: Low health literacy, as determined by REALM-SF, NVS and STOFHLA, is associated with higher rates of readmissions, longer LOS and more POCs.

Study Population and Database: This study will include all patients 18 years and older in the UAB American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) database with a diagnosis of IBD by ICD9/10 code. Unlike claims-based databases, the ACS-NSQIP is a nationally validated, outcomes-based registry that uses clinically-trained nurses to record over 125 variables that encompasses standardized

patient and procedure-level data [71]. Clinical outcomes including 30-d readmissions, LOS and POCs are specifically included and POCs are categorized.

Selection of Surgical Outcomes: Based on our studies showing that African-American patients have longer post-operative LOS [13], higher 30-day readmissions [11] and more POCs [14], these 3 surgical outcomes will be the primary dependent variables. Mortality in IBD is too rare to detect meaningful differences and will not be included.

Variables: The UAB ACS-NSQIP database includes 125 independent variables defined by ACS-NSQIP (patient and procedure-specific factors) [71]. Because health literacy will be assessed only on IBD patients with surgical procedures after 2006, we will be able to cross-reference and merge health literacy data obtained from Specific Aim 1 to the UAB ACS-NQSIP database.

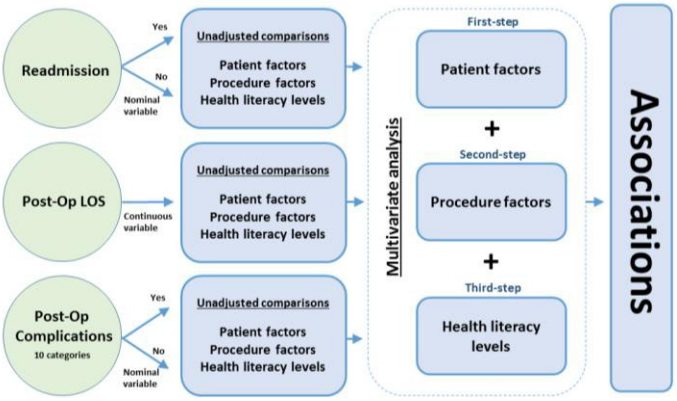

Figure 5. Analytical plan to test for associations.

Power Calculations to Detect Differences. From a minimum of 150 African-American and 300 Caucasian-American patients (a 1:2 ratio), and using two-sided tests with 80% power, we will be able to detect proportions of 10 vs. 20% (for 30-day readmissions and POCs) and effects sizes of 0.28 standard deviations (SD) for LOS (1.7 days assuming a SD of 6-days) between these two racial/ethnic groups. These differences in size have been observed in previous publications on readmissions, LOS and POCs [11, 13, 14].

Analysis: For each surgical outcome, a series of analyses will be performed (**Figure 5**). Readmission and POCs will be treated as nominal dependent variables. LOS will be treated as an interval-ratio dependent variable. Initial unadjusted comparisons using independent t-tests and chi-squares of covariates will be made, as appropriate, to compare patient, procedure and health literacy characteristics. For each surgical outcome, step-wise multivariate regressions will then be used. Blocks of covariates will be added in sequence to ascertain the contribution of patient-level factors, procedure-level factors and health literacy levels to each outcome. The Oaxaca-Blinder regression decomposition method [72-74] will also be applied to quantify the extent to which disparities in outcomes can (and cannot) be explained by the contributing factors.

Expected Finding: We expect to find disparities in surgical outcomes for African-Americans with IBD with higher 30-day readmission rates, longer LOS and more POCs compared to Caucasian-Americans. We expect to find associations between low health literacy levels and poor surgical outcomes. On multivariate analyses, health literacy may remain an independent predictor of readmissions, LOS and POCs.

Potential Difficulties and Alternative Approaches: By analyzing a large, racially-diverse surgical database, we will gain a more complete picture of African-American IBD patients who undergo surgery. We will, however, be limited to the available covariates in our institutional database. We may also have insufficient power to determine significant differences in surgical outcomes, or associations of health literacy to outcomes, if the differences are smaller than what was assumed *a priori*. This situation may not be immediately addressable within the time frame of this K-award, but will be mitigated by the continued, and anticipated long-term, inclusion of health literacy measurements for all IBD patients seen at the UAB IBD Center. As an exploratory study, any observations made in this project will have utility in shaping future research directions and grant applications.

D.3.4. Specific Aim 3. Explore potential factors that impact low health literacy in IBD patients.

Overview: Focus groups (patients and caregivers) and key informant interviews (providers and community educators) will be used to identify potential barriers and facilitators that impact a patient's capacity to obtain, process and understand surgical information in the perioperative periods.

Study Population: *Patients and Caregivers:* African-American and Caucasian-American IBD patients 18 years and older and their caregivers will be identified from the IBD Center. *Other stakeholders*: Key providers and community educators of IBD will be identified with the IBD Advisory Panel.

Topic and Interview Guide Development: The IBD Advisory Panel will determine questions for focus groups and key informant interviews. The IBD Advisory Panel will be composed of important stakeholders including the largest IBD patient advocacy group (Crohn's and Colitis Foundation), providers, and my research mentors. Separate interview guides will be developed for patients/caregivers and providers/community educators. The guides will be framed by the Health Literacy and Outcomes Framework and include open-ended questions that will probe for barriers and facilitators to obtaining, processing and understanding surgical information (**Table 3**).

Approach: *Focus Groups:* We will conduct at least 4-6 focus groups of patients and caregivers (6-8 per group). We will work with the MHRC RRSF to identify, consent, enroll, schedule and implement these focus groups. To

allow for more open discussion of barriers that may differ by race/ethnicity, we will use purposive sampling to organize 2-3 African-American and 2-3 Caucasian-Americans groups with equitable numbers. Focus groups will last approximately 60-90 minutes and will be conducted in a private location convenient to participants. Participants will be offered $50 gift card for their time and travel. *Key Informant Interviews:* In addition, we will conduct at least 10 semi-structured interviews with key stakeholders that will be identified by the IBD Advisory Panel. Stakeholders may include nurses (3-4), social workers (1-3), physicians (1-3) and community educators (1-3). Interviews will last approximately 60-90 minutes and participants will also be offered $50 gift card for their time and travel. Focus groups and key informant interviews will be conducted by a trained moderator with me present in the first sessions. Final sample size will be determined by thematic saturation.

System-level Probing Questions	Topic
How did you obtain your information about surgery?	Accessibility
What are some things in the materials given to you that make them easy or difficult to understand?	Readability
Provider-level Probing Questions	
How did your doctor help you understand more about the surgery?	Communication
What, if anything, about your clinic visit was confusing?	Communication
Patient-level Probing Questions	
How confident do you feel in taking care of yourself or a sick family member?	Self-efficacy

Table 3. Example of Potential Interview Guide Questions.

Analysis. Focus group sessions and key informant interviews will be recorded using a digital recorder, transcribed (Landmark Associates, http://thelai.com), and transcriptions verified. We will analyze the transcripts using an iterative content analysis and grounded theory approach [75]. NVivo qualitative data analysis software will be used as a tool for coding and analysis. Each team member participating in the analysis will review the transcript independently, convening after the initial review for discussion and build a code book of content categories that reflects the common response patterns and themes that are identified. The team will use the code book to identify content categories in the transcript using the method of constant comparison and discussion to resolve differences in the assignment of coding categories. These categories will be used as a framework for coding those domains (barriers and facilitators) deemed most important to IBD patients faced with surgery.

Expected Finding*:* We expect to identify several barriers at the healthcare system and provider-level that impact a patient's capacity to obtain, process and understand information when faced with surgery. Based on studies in non-surgical fields, these factors could include poor readability of education material [76] and ineffective provider-patient communication [77]. We also expect to find differences in perceived barriers and facilitators between African-Americans and Caucasian-Americans and between providers and patients.

Potential Difficulties and Alternative Approaches: Potential difficulty may arise in recruiting African-American IBD patients and caregivers to focus groups. I have prior experience, however, successfully recruiting African-Americans to two large focus groups [44] with the MHRC RRSF. Alternative approaches include recruitment through the CCF Alabama Chapter. Additional difficulties may arise in coordinating meetings. To address these difficulties, I will work with the MHRC RRSF which has significant experience coordinating group meetings. Alternative approaches may involve providing remote access (telephone) for off-site panel members.

D.4. Progression from K12 to K23. The K12 will equip me with the pilot data and training to competitively apply for a K23 (**Figure 1**). Through this project, I will gain a better understanding of the critical points in surgical care that pose problems for patients with low health literacy. These points will be the focus of the K23 which will concentrate on development and implementation of literacy-based interventions and concurrent training in implementation science.

D.5. TIMELINE. A two-year timeline for project implementation is shown below in **Table 4.**

	Year 1 (2017)				Year 2 (2018)			
Activity	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Research								
IRB approvals (already in-progress)	x							
Establishment of IBD Advisory Panel	x							
Meet with IBD Advisory Panel	x	x	x	x	x	x	x	x
Specific Aim 1. Assess health literacy in IBD patients	x	x	x	x				
Specific Aim 2. Link health literacy to surgical outcomes			x	x	x			
Specific Aim 3. Qualitative studies					x	x	x	x
Training Development *								
Training Plan	x	x	x	x	x	x	x	x
Career Development								
Meet with mentors	x	x	x	x	x	x	x	x
Presentations at national meetings			x				x	
Publications (2-3/year)				x				x
Submit K23 proposal							x	

Table 4. Research and career development timeline. *See Table 1 for Training Plan Details.

LAY SUMMARY

Inflammatory bowel disease (IBD) is a chronic and costly disease that affects the gastrointestinal tract with serious and sometimes fatal consequences. In the United States, at least 3.1 million people suffer from IBD which includes Crohn's Disease and Ulcerative Colitis. Life-long challenges include pain, bleeding, and frequent bowel movements with added risks of cancers and bowel obstructions. **There is no known cure**. Because of these problems, most patients with IBD will face at least one major operation in their lifetime and all patients will face minor, but still risky, procedures like colonoscopies. As more and more people get IBD, including African-Americans, we are starting to see big differences in health outcomes. Compared to Caucasians, for example, African-Americans with IBD do significantly worse with:

- More emergency room visits and hospitalizations
- More days in the hospital
- Worse quality of life
- Delays in surgical treatment

Recently, our research group has found that after surgery, African-Americans with IBD are readmitted to the hospital far more than other IBD patients and spend more days in the hospital even with no complications. We do not know why these differences occur or what factors might be involved. To address this problem, **our project hopes to identify the factors that might cause these differences with a focus on something called *health literacy***. The findings form this project are important because they could help us develop more effective ways to reduce these differences and improve outcomes for all IBD patients.

I am a colorectal surgeon with 16-years of training at Yale, Johns Hopkins, Boston University and the Mayo Clinic. I specialize in IBD and see first-hand the difficult challenges that IBD patients face daily. At the University of Alabama at Birmingham (UAB), which serves a state with two-times the average proportion of African-Americans, the effects of IBD on African-Americans and their families are particularly devastating. Recently, we have noticed that improved education and engagement by patients and families in their surgical care seems to improve outcomes. This ability to obtain, process and understand surgical information is called **health literacy**. In many fields outside of surgery, people have shown that improving health literacy is an effective way to improve health outcomes. Based on these studies, we believe that we can similarly improve outcomes, and reduce disparities, for African-American IBD patients undergoing surgery through health literacy.

To explore this idea, we will conduct a three-part study:

- **First**, we will measure health literacy levels in IBD patients at our high-volume IBD center. No one knows what health literacy levels are in IBD populations. In non-IBD populations, however, people have shown that health literacy varies across racial/ethnic groups and is particularly low in African-Americans.
- **Second**, we will test if these health literacy levels can be linked to surgical outcomes. No one has shown this link. But research in fields such as diabetes have shown that low health literacy is linked to poor health outcomes, so we would expect to see this relationship even in surgery.
- **Third**, we will talk with patients, caregivers, providers and community educators to identify factors that might affect low health literacy, whether positively or negatively. This information will help guide future projects that can then target specific points in the surgical process where we can do a better job at educating and engaging patients.

The involvement of patients and other people experienced with IBD will be critical to the success of this project. I will be partnering with African-American and Caucasian-American patients with IBD from the UAB IBD Center, which is a busy referral center for IBD patients in Alabama and surrounding states. Additionally, I will partner with the Crohn's & Colitis Foundation (CCF), which is the nation's largest organization dedicated to finding a cure and improving quality of life for all IBD patients.

As part of this project, I will also work with an experienced team of mentors from different departments at UAB. Together my mentors are experts in all the research techniques that will be used in this study and will be invested in the success of this project. While conducting this research, I will also be obtaining an advanced degree at the School of Public Health to enhance my own research skills. I will take several courses and attend conferences that will make me better equipped to do this research long-term. The additional training and the findings from this study will then be used to develop an even bigger project that will develop and test literacy-based surgical care models to improve outcomes for disadvantaged patients with IBD.

REFERENCES

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM August 1, 2017	THROUGH July 31, 2018

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
	PD/PI	9			120,000	90,000	27,180	117,180
SUBTOTALS						90,000	27,180	117,180

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)* Digital tape equipment for focus group interviews - $200 Portable computer equipment for interview/transcript analysis - $1,000	1,200
TRAVEL Conference - American College of Surgeons (ACS) - $500 per year Conference - American Society of Colon and Rectal Surgeons (ASCRS) - $500 per year Conference - National Health Literacy Conference - $500 per year Conference - Tufts Health Literacy Leadership Institute - $500 once	2,000
INPATIENT CARE COSTS	0
OUTPATIENT CARE COSTS	0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	0
OTHER EXPENSES *(Itemize by category)* Training - UAB MSPH – Tuition - $250 per online course (6 courses per year) - $1500 per year Training (1st year) – UNC Qualitative Research Summer Intensive ($305 per day) x 5d = $1,525 Training (1st year) – Vanderbilt Center for Health Services Research EHCP - $1000 Training (2nd year) – NIH Implementation Training Course - $1,500 Research (2nd year) - Focus Group Incentives - $50 x 8 panelists per group x 6 groups - $2400 Research (2nd year) – Key Informant Interviews - $50 x 10 participants = $500 Research (2nd year) - Transcription Services - $100 x 16 sessions = $1600 Research (2nd year) - MHRC Recruitment and Retention Shared Facility (RRSF) - $4000	4,025

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$** 124,405
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$** 124,405

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	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: *Salary and fringe benefits. Applicant organization only.*	117,180	117,180			
CONSULTANT COSTS					
EQUIPMENT	1,200	0			
SUPPLIES					
TRAVEL	2,000	1,500			
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	4,025	11,500			
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*	124,405	130,180			
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	124,405	130,180			
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					**$ 254,585**

BUDGET JUSTIFICATION

Personnel:

1. Example Scholar, MD (9cm, Principal Investigator) – Dr. XX will be the principal investigator. He will dedicate at least 75% of his time to research, training and career development for this grant. The funding will allow Dr. XX to reduce his clinical duties to focus on the specific research and training aims outlined in this application. Dr. XX has 3 fellow colorectal surgeons (Drs. AA, BB, CC) and 6 gastrointestinal surgeons in his Division (Drs. DD, EE, FF) who have and will continue to share the call and clinical volume to allow him to fulfill the objectives outlined in this proposal.

Supplies:

Digital tape equipment will be purchased ($200) to record focus group and key informant interviews. Purchase of a UAB-encrypted, password-protected computer ($1,000) will be used to store and analyze data from health literacy measurements (Specific Aim 1), clinical databases (Specific Aim 2) and focus groups/key informant interviews (Specific Aim 3).

Travel:

Funds are requested for Dr. XX to travel to three key conferences: the American College of Surgeons (ACS), American Society of Colon and Rectal Surgeons (ASCRS) and National Health Literacy Conference. All three forums will be important opportunities to disseminate findings from this study. In addition, Dr. XX will attend the Tufts Health Literacy Leadership Institute (1-week) in Boston, MA during his first year. Funds requested in this budget will be supplemented with discretionary funds from the Division of GI Surgery.

Other Expenses:

1. Research.

Year 1 (Specific Aims 1-2):
None.

Year 2 (Specific Aim 3):
a. Participant Costs **–** Participants in the focus group will receive a stipend of $50 ($50 x 8 panelists x 6 groups = $2400). Participants in the key informant interviews (Specific Aim 3) will receive a stipend of $50 ($50 x 10 participants = $500). Additional patients will be recruited depending on theme saturation.

b. Interview transcription – Funds are requested to cover the cost for transcription of the focus group meetings and interviews. Costs are estimated at $100 for each 1-hr interview tape (6 focus groups + 10 key informant interviews = $1600). Additional transcriptions may be necessary. We plan to use Landmark Associates (http://thelai.com for our transcription needs.

c. UAB MHRC Recruitment and Retention Shared Facility (RRSF) – We will use the MHRC RRSF to recruit and conduct focus groups. Fees for trained moderators (Elise McLin and Cynthia Johnson) and qualitative analysts/consultants (Ivan Herbey) are estimated to be $4000 total for this study based on prior collaborations.

2. Training.

The core of Dr. XX's training will be the UAB MSPH program (42-credit requirements). In the last year, Dr. XX has already taken and passed 3 MSPH courses (HCO601Q Health Economics, HCO670Q Social/Ethical Issues in Public Health, and BST611Q Intermediate Statistical Analysis I). While Dr. XX receives a tuition discount as a UAB employee, he is responsible for $250 per online course. Dr. XX intends to take 12 courses over the next two years (each 3-credits), or 6 courses per year, to complete his MSPH as shown in **Table 1**.

Additionally, for the 1st year, Dr. XX plans to participate in the UNC Qualitative Research Summer

Intensive course and join the Vanderbilt Center for Health Services Research Effective Health Communication Program (CHSR-EHCP). For the 2nd year, Dr. XX plans to attend the NIH Training Institute for Dissemination and Implementation Research in Health (TIDIRH) in Babson Park, MA.

BIOGRAPHICAL SKETCHES

OTHER SUPPORT