MEDSTAR HEALTH RESEARCH INSTITUTE INC
APPLICATION SUMMARY

Charles and Mary Latham Fund Board Meeting

Request Date:	November 1, 2021
Project Title:	PI:VictoriaLai Diving deep into the social factors that affect outcomes and quality of life in endocrine surgery patients: a qualitative study of patients and clinicians
Request Amount:	$15,000.00
Program Area:	Medical Research

Organization Information	**Contact Person for Application**
Medstar Health Research Institute Inc 6525 Belcrest Road www.medstarresearch.org HYATTSVILLE, MD 20782 Tel: (301) 560-7300 Fax: 301-560-7373	Mr. Michael Collins Director, OCGM (301) 560-7300 mri-ocgm@medstar.net

Organization's annual operating budget: $3,800,000.00

Background
MedStar Health Research Institute (MHRI), founded in 1963, is the research division of MedStar Health. MHRI provides scientific, administrative, and regulatory support for clinical research throughout the MedStar Health system. Led by Dr. Neil Weissman, MHRI supports more than 1,000 associates dedicated to advancing health through research.

MHRI's core services include a biostatistics and epidemiological center, clinical research centers, a research pharmacy, two accredited pre-clinical laboratories, biochemistry and biomarker core laboratories, a core platelet center, a cardiac and vascular pathology center, a genetics/genomics/proteomics research core, a cardiovascular core imaging center, an institutional review board, and an office of research integrity. In the last year, more than 1,000 active studies, involving thousands of patients, resulted in nearly 1,000 peer-reviewed publications. MHRI is in the top 20% of U.S. institutions receiving funds from the National Institutes of Health and other federal agencies, with approximately 60% of its studies being federally funded.

Wherever you look throughout the MedStar Health system, you're likely to find the highly qualified scientists and investigators conducting leading edge clinical research. MedStar Health Research Institute researchers cover many areas and types of research. From bench to bedside and into the community, associates across MHRI work to advance the scientific understanding of disease and point the way toward better and more effective treatments. As the research-focused entity of MedStar Health, this is our contribution to the healing work performed throughout the system and in the communities we serve.

Project/Program Budget (if applicable):

Project/Program Title: PI:VictoriaLai
Diving deep into the social factors that affect outcomes and quality of life in endocrine surgery patients: a qualitative study of patients and clinicians

Project Summary (250 words or less)
We aim to identify the nuanced individual and contextual social factors that influence the quality of life of endocrine surgery patients living in the metropolitan Washington, DC area. Our prior work in this patient population showed that many patients face social factors that negatively affect their quality of life and that Black patients are disproportionately affected by such factors. For this proposal we will leverage and build on our prior quantitative work and conduct a multi-level qualitative study that includes patients and clinicians to define the factors that affect medical care and quality of life.
First, we will conduct semi-structured interviews with 24 patients. We will recruit from our prior pool of racially, ethnically and socioeconomically diverse participants and purposively sample participants with high (n=12) and low (n=12) quality of life. We will compare responses across these two groups of participants, identifying themes using content analysis.
Second, we will evaluate clinicians' perspectives of the patient experience with semi-structured interviews. This will include 10 clinicians from different specialties who care for endocrine surgery patients (e.g. surgery, endocrinology, nephrology, primary care). We will investigate whether clinicians' perspectives align with or differ from patients' reports.
We are unaware of any prior efforts to collect rich, multi-level qualitative data on the social determinants of quality of life among endocrine surgery patients. Results will complement our existing and compelling quantitative data and inform future research aimed to design interventions to improve endocrine surgery outcomes and reduce care disparities.

Statement of Problem
Endocrine surgery patients—those with neoplastic conditions of the thyroid, parathyroid and adrenal glands—are common: thyroid cancer survivors will make up to 10% of all cancer survivors in the future and primary hyperparathyroidism affects 1-3% of the population.1,2 Compared to the general United States (US) population, endocrine surgery patients face unique challenges, both socioeconomic and psychological. For example, thyroid cancer patients have higher rates of bankruptcy and lower quality of life (QOL) than the general US population.1,2 Ethnic/racial minorities and the poor with endocrine

surgery conditions face additional inequities.3 They are more likely to experience care delays and surgical complications, and are more likely to have surgery with less experienced surgeons, although the reasons are unclear.4

Individual (e.g. financial, education, race) and contextual (i.e. neighborhood) social determinants of health affect outcomes. In other medical conditions, patients living in more socially vulnerable neighborhoods were more likely to experience surgical complications and have greater financial burdens, an effect that is greater among ethnic/racial minorities than in non-Hispanic Whites.5 However, social determinants of health, at the individual or contextual level, and their impact on outcomes have been understudied in endocrine surgery patients.

Our group has helped fill this literature gap, with research supported in part by the Latham Fund: among 244 endocrine surgery patients in the metropolitan Washington, DC area, we found that 10-15% of patient report social challenges even before undergoing surgery, and we found that Black patients were disproportionately represented. We found that having specific individual social stressors, such as trouble paying for food, was associated with worse QOL in the Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) health-related QOL questionnaire. Paradoxically, we also found that while individual social factors influenced QOL, living in socially vulnerable neighborhoods did not translate to worse QOL.

The factors that influence QOL and well-being are clearly complex, but we lack granular details about the lived experience of patients that influence their care, QOL, overall well-being and decision-making for their medical care. We also lack the clinician perspective, critical because referrals drive care for most endocrine surgery patients, affecting if and to whom a patient gets referred. We also do not know if the clinicians' perception of the patient experience aligns with the patients' realities, which could lead to missed opportunities to better support and care for patients. Our initial work has pointed to what social factors are related to poor QOL; we now need to better understand how social factors affect outcomes or contribute to care inequities so that we can work to improve both.

Specific Aims

Although endocrine surgery patients face unique psychosocial challenges, and although ethnic/racial minorities with these conditions also harbor inequitable outcomes, we do not know patients' lived experiences to understand why. Our overall goal is to improve outcomes for all endocrine surgery patients and reduce care inequities among marginalized patients. For this proposal we will conduct semi-structured interviews to discern and compare patient and clinician perspectives about the individual and contextual factors that influence patients' care experiences, medical care decisions and QOL outcomes. We will use content analysis qualitative approaches to compare the themes that emerge from patients with low vs. high QOL.

This qualitative research will build on the quantitative survey-based work our group has conducted with support from the Latham Fund where we met target recruitment (n=244), enrolled >85% of eligible patients, and matched subject demographics to clinical demographics. Our clinical group performs >800 operations yearly, serving patients of metropolitan Washington, DC. We identified topics of import to patients, but lacked rich details that surveys cannot provide; interviews from this proposed research will. We will sample from our prior participants to recruit 24 patients. We will also recruit 10 clinicians who care for endocrine surgery patients to better understand how their perspectives and choices may influence patient outcomes.

- Aim 1: Evaluate the social factors, priorities and experiences among endocrine surgery patients to obtain data that influenced (1) decisions they made in their care, including barriers and promoters, and (2) outcomes. We will recruit our prior participants and conduct semi-structured interviews. We hypothesize that patients will have a wide breadth of individual and contextual factors beyond medical/clinical factors that influenced their decisions, outcomes and experiences (e.g. employment concerns, anxiety), and that these will differ based on whether patients had low or high QOL.

Aim 2: From clinicians who care for endocrine surgery patients (e.g. surgeons, endocrinologists, nephrologists, primary care providers), (1) identify through semi-structured interviews the social and clinical factors that influenced their patient care decisions and their perceptions of the promoters and barriers to care that patients experience; and (2) compare clinician responses to patient responses. We hypothesize that individual and contextual factors (e.g. health insurance) contribute significantly to decision-making and that clinician perspectives of the patient experience will differ from that of patients.

The results of this study will provide needed insight on how individual and contextual social factors contribute to outcomes and care disparities. Combined with our prior work, we will have the necessary information to test interventions against the relevant social factors (e.g. employment concerns) that negatively affect clinical and QOL outcomes. Some of the social factors that affect endocrine surgery patients may also affect other surgical patients, a broader community plagued with outcomes disparities, where the evidence is limited by the use of administrative databases.3-5 The lessons here can be tested and applied to those patients too. The surgical disparities literature suffers from being descriptive and not prescriptive – our work would help move the field—both ours and the broader surgical community—towards the latter.

Research Strategy: Significance

Endocrine surgery patients experience unique socioeconomic, psychological, and clinical challenges. The challenges they face depend on their particular disease. Thyroid cancer patients have material and psychological financial challenges.1 They are more likely to experience psychological financial burdens than other cancer survivors (46.1% vs 23.0%, p=0.04), and they have higher rates of bankruptcy than the general population (3% vs. 0.6%).1,2 They are more likely to have mental health problems.6 Given that thyroid cancer tends to have low mortality rates (98% five-year survival), one would expect that thyroid cancer patients have better QOL than cancer patients who have more mortal or morbid conditions, but this is not the case. Compared to colon cancer, breast cancer, and glioma survivors, thyroid cancer survivors have worse spiritual well-being QOL scores.6 Patients with primary hyperparathyroidism face negative potential clinical and QOL harm because primary hyperparathyroidism is underdiagnosed and under-referred for curative surgery.7 This is problematic given the potential negative effects of the disease on the bone and renal system, some of which can be ameliorated with surgery. Furthermore, patients with primary hyperparathyroidism have greater neuropsychological symptoms and lower QOL than the general population.8

Ethnic and racial minorities with endocrine surgery conditions are more likely than non-Hispanic White patients to experience care disparities. Those with thyroid cancer are more likely to have worse surgical outcomes, and are more likely to undergo surgery with less-experienced surgeons who have higher complication rates.9 Black patients with primary hyperparathyroidism are more likely to experience care delays than white patients.10

The reasons for these stark disparities are unclear. Without understanding the factors that contribute to the disparities, the medical community is unable to design useful and effective interventions to mitigate adverse health outcomes. Our research seeks to overcome this barrier by performing the required first steps: engaging with endocrine surgery patients and the clinicians who care for them. By conducting semi-structured interviews to understand the factors that either promote or hinder optimal medical care, we will obtain a rich, nuanced understanding of the individual, contextual and medical system factors that contribute to patients' experiences and outcomes.

Results from the proposed study will add considerably more depth to the current literature on endocrine surgery disparities and the field of surgical disparities in general. Evidence to date from the surgical disparities field has come largely from retrospective chart reviews of institutional or large administrative datasets without attention to the individual patient experience.3-7,9-10 Our approach that combines our prior quantitative data with the proposed qualitative data to identify intervention approaches to address health disparities can serve as a model for other surgical patients. Although endocrine surgery patients have their own specific challenges, issues of disparate surgical access, timeliness of care, and outcomes are rife throughout the surgical community – thus, not only the approach, but the lessons from this proposed work can be tested within other surgical specialties.

Research Strategy: Innovation

This research is innovative because it seeks to gather an in-depth understanding from endocrine surgery patients the factors that may influence their care, outcomes, and QOL—research that has not been done much before in this field or in the much broader research field of surgical disparities. Our proposed multi-level approach is also innovative because we seek to understand both the patient experience and the clinician perception of the endocrine surgery patient experience. We are not aware of any other work that has taken this approach to understand health disparities among endocrine surgery patients.

Our proposed work moves the field forward by moving beyond what surveys or chart reviews can accomplish, which are the research designs of most published surgical disparities studies.3-7,9-10 Many of the surgical disparities literature identifies risk factors that are unchangeable (race and ethnicity), difficult to change (socioeconomic status), or not actionable. Others have also studied the role of contextual social factors in other conditions, which has not been done within endocrine surgery. Hyer et al found that patients who live in the most socially vulnerable neighborhoods were more likely to experience complications after undergoing colon, lung, esophageal or rectal surgery.11 The degree of social vulnerability was determined by the Social Vulnerability Index, and neighborhoods are grouped based on US Census tracts. In contrast, we found in our quantitative study that patients living in the most socially vulnerable neighborhoods had better QOL. This may be because endocrine surgery patients are affected differently by contextual social factors than other patients, but more likely, it highlights the limits of relying only on constructed means of categorizing patients without consideration of individual social factors. Our current proposal builds on our original findings to better understand the complex factors that contribute to QOL that others have not yet delved into.

Research Strategy: Approach

Overview:

Our research approach is informed by preliminary research we performed with support from the Charles and Mary Latham Fund. We performed one of the few prospective QOL studies in 244 endocrine surgery patients using validated QOL questionnaires in a racially/ethnically diverse population. Through patient reports, we found that 10-15% of our patients had difficulty paying for daily necessities in the three months before surgery, which is prior to incurring significant medical bills. We identified that these social determinants of health predicted worse preoperative QOL, and we identified that Black patients were more likely to be represented in this group. Paradoxically, while Black patients were more likely to live in the most socially vulnerable neighborhoods, those living in such neighborhoods were more likely to have better QOL. Our prior research adds previously unreported data about the experience of ethnic/racial minorities with endocrine surgery conditions and also demonstrates the complexity of the relationship between QOL, individual social determinants of health and contextual social vulnerability. These findings compel the next steps to better understand how these social factors intersect for endocrine surgery patients.

A conceptual framework, adapted from the World Health Organization conceptual framework,12 for the interactions is that social determinants of health likely affect intermediary factors, which together work to affect QOL and clinical outcomes. This research proposal seeks to identify the relevant individual and contextual social determinants of health that affect QOL in endocrine surgery patients.

Patient Recruitment and Interviews:

We aim to perform semi-structured interviews of endocrine surgery patients and clinicians to understand how social factors influence outcomes. Interview guides will be informed by findings from our prior quantitative research and input from a multidisciplinary team (surgery, behavioral science, oncology survivorship). For this qualitative research, the strategy consists of purposively recruiting 24 adult endocrine surgery patients from the metropolitan Washington, DC area from our prior study. We will recruit patients with high (n=12) and low (n=12) QOL based on their prior responses to the PROMIS-29 questionnaire. The PROMIS-29 is scored with T-scores; a T-score of 50 corresponds to the general US mean, with a standard deviation of 10.13 We will inquire about the factors that contributed to the decision-making about their medical care, and the factors that contributed to or detracted from their outcomes and well-being. We will identify the themes that emerge from these semi-structured interviews.

Clinician Recruitment and Interviews:

We will recruit 10 clinicians from different fields (e.g. surgery, endocrinology, nephrology, primary care) who care for endocrine surgery patients because of the central role that they play in what kind of care patients receive, and when and how they get it, and because they may have insight into the challenges that patients face. Those in different fields will have different perspectives based on the different points in the patients' medical journey they participate in. We will inquire about factors they perceive influence patients' decision-making, and factors that contribute to their decision-making for their patients. We will compare the themes that emerge from the patients' and clinicians' responses.

Research Design and Methods
The research design is a qualitative one and employs the use of semi-structured interviews of adult endocrine surgery patients and clinicians who care for them.

- Aim 1:

Methods
We will recruit 24 adult endocrine surgery patients who were participants from our quantitative study. We will recruit 12 patients with high and 12 with low QOL based on their PROMIS-29 results. We aim to be representative in age, sex, race, and ethnicity. We will schedule individual interviews. Study personnel will conduct semi-structured interviews using an interview guide. Based on our quantitative study results, these will include questions about the individual (e.g. food security) and contextual factors that contributed to their outcomes, QOL, and medical care decision-making. We will ask patients to reflect on aspects within the healthcare system (e.g. access, care coordination) and its impact on their outcomes; potential helpful interventions and when these would have been helpful. We will inquire about patients' priorities.
Given the COVID-19 pandemic, the interviews will be primarily conducted virtually with video-based calls, unless for clear and practical reasons it needs to be done over the phone or in-person (e.g. lack of reliable internet connection). We will make available certified medical interpreters as needed. Interviews will last 60-90 minutes and will be recorded. We will compensate subjects with $50 gift cards.
Analysis
We will transcribe, store, and analyze interviews with NVivo 12 software. Two trained research personnel will independently review the interview transcripts and perform line by line coding, creating a codebook. We will categorize the findings into early themes. Researchers will then refine the themes until there is agreement about the concepts. Data will be presented as themes and exemplary quotes will be collected. We will compare themes generated from patient interviews of patients with QOL above the US mean to those with QOL below the US median.
Anticipated results:
We anticipate that patients will report and expand on individual and contextual social determinants of health that impact their QOL and would allow us to design interventions aimed at improving clinical outcomes and QOL. We anticipate that those with lower QOL will report different factors than those with higher QOL.
We anticipate that such patients will be able to expand on whether, when, and how individual (e.g. food security) and contextual (e.g. housing concerns) social factors affected their medical care decision making, clinical outcomes and QOL. These lived experiences will provide the basis for us to design interventions to improve outcomes, be it a legal counselor who can advise patients of their housing rights or a social worker who can help patients access food banks, for example.

Our prior work showed that contextual social factors, such as the social vulnerability of a patient's neighborhood, did not translate into lower QOL and living in more socially vulnerable neighborhoods predicted higher QOL. We anticipate that patients will provide insight into these counterintuitive findings and the relative import of certain factors over others.

- Aim 2:

Methods

We will recruit 10 clinicians in different fields (e.g. surgery, endocrinology, nephrology, primary care) who care for endocrine surgery patients of the metropolitan Washington, DC area. We will use a combination of e-mail and mailed research advertisements, and individual word of mouth to recruit participants. Interviews will be conducted similarly as for patient participants. Clinician questions will pertain to clinical and social factors that they perceive affect patient decision-making and outcomes. We will inquire about factors that influenced the clinicians' medical care decision-making for the patients, from diagnostic work-up to recommended treatment. We will provide $50 gift cards in appreciation for participants' efforts.

Analysis

The process will be similar to the analysis outlined in Aim 1. We will compare clinician and patient responses.

Anticipated results

We anticipate that clinicians will focus on clinical factors that affected their decision-making for patients but will also have insight into the social factors (e.g. health insurance coverage) they believe negatively affected patient outcomes. We hypothesize that clinicians' perspectives of the patient experience will differ in certain areas from what patients report, such as QOL,14 which can serve as potential areas of research to improve patient outcomes and well-being. In areas of agreement, these too would be potential targets for intervention, as they may have greater acceptance from both patients and clinicians.

Challenges

One potential challenge will be subject recruitment. To address this, we will purposively recruit prior research participants from our quantitative study. We will try to promote inclusion by compensating subjects for their time and providing language translators as needed. For clinician recruitment, we will send follow-up notices about the opportunity to participate, and make use of group meetings or conferences to advertise the research project.

We may encounter time challenges. With regards to scheduling challenges with recruited subjects, we will seek the assistance of a research assistant to help coordinate schedules. We will also request the purchase of the NVivo software package to reduce the time required to manage the data. The research team will also include a general surgery resident spending dedicated time as a research fellow in our department and a medical student who previously worked as a clinical research coordinator conducting qualitative research. The PI has 20 % of time dedicated to research.

Future Plans

We will continue to work towards our overall goal of improving outcomes and reducing care disparities. Based on the themes and lessons that emerge from the patient and clinician interviews and analyzed in light of the quantitative data acquired from our prior research study, we aim to design interventions aimed at the social determinants of health that impact QOL and patient outcomes.

To give an example, our original work suggested that those who had difficulty paying for medical bills had lower QOL. What's unclear: if these financial needs change over time; what would be most helpful with regards to their medical bills; and whether medical bills affected their decisions to comply with recommended care. We would clarify these issues in our semi-structured interviews. If we identified in this proposed research that paying for medical bills not only contributed to worse QOL, but also reduced the likelihood of complying with recommended treatment and predicted worse clinical outcomes, and if patients expressed a desire for help both before and after surgery, we would have acquired richer details than what the surveys alone would have found.

Taking this information, we would design this intervention within a real-world workflow. One potential intervention for the hypothetical scenario above would be to refer patients to financial counselors who could help patients create plans to afford their care, or with social workers who can help patients assess, understand, and optimize their current health insurance coverage. We would get feedback about the relevance, helpfulness, and ease of use from stakeholders such as patients and clinical staff throughout the process to allow us to evaluate and iterate on the design.

After designing the intervention, we would then create an implementation study. The primary outcomes would be whether the interventions improve patient QOL, improve clinical outcomes by reducing complications or care delays, and reducing ethnic/racial disparities in both. Other ways that we would evaluate such interventions would be patient satisfaction, staff satisfaction and work burden, degree of integration within existing clinical workflows and electronic health systems, and cost for the healthcare system. We would evaluate these interventions to historical and published controls. We will also assess the intervention based on aspects of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework.15

Based on these results of our implementation study, we can either continue to iterate on the intervention or move in a different direction. We will eventually study it in other clinical settings, such as other endocrine surgery offices, surgical specialty offices, or institutions.

Budget Breakdown

Research assistant

We are requesting a percentage of effort from an institutional research assistant to help with the administrative aspects of the project, including recruitment, schedule coordination, and data management. This assistance will help to address the potential challenge of time.

o 15.3% effort of 1.84 calendar months effort = $9,942.00 salary
o 20.3% Fringe = $2,018.00
o Total = $11,960.00

- Gift cards

We will request gift cards to compensate for patient and clinician participation in this study. We will provide $50 for each participant.
o Estimated # of patients: 24 x $50/patient = $1200.00
o Estimated # of clinicians: 10 x $50/clinician = $500.00
o Total: $1700.00
- Postage for recruitment and administrative tasks
o Includes envelopes and stamps: $200.00
- NVivo 12 Plus software

This is a widely-used software product for qualitative research used for data storage and organization. It is intended to facilitate the data capture and analysis and aimed to address the challenge of time for this project. Will request the software package as well as the one-year transcription service.
o Software package cost as a faculty member through the Georgetown University Information Services: $640.00
o Cost of one-year transcription subscription: $500.00
o Total: $1140.00
- Total requested: $15,000.00

Recommendation/Notes

MedStar Health

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March 30, 2021

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BIOGRAPHICAL SKETCH

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

NAME: VICTORIA LAI

eRA COMMONS USER NAME (credential, e.g., agency login): VICTORIA LAI

POSITION TITLE: Attending Surgeon, MedStar-Georgetown Department of Surgery, Division of Endocrine Surgery; Assistant Professor of Surgery, Georgetown University Medical Center

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale College, New Haven, CT	BA	05/2004	History
Albert Einstein College of Medicine, Bronx, NY	MD	06/2008	Medicine with distinction in research
Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY	Residency	06/2013	General surgery
Medical College of Wisconsin, Milwaukee, WI	Fellowship	06/2014	Endocrine surgery
Georgetown-Howard Universities Center for Clinical & Translational Science, Washington, DC	MS	12/2018	Clinical and Translational Research

A. Personal Statement

As a general surgery resident and then as an endocrine surgery fellow, my interest in clinical outcomes research in the field of endocrine surgery began. I further developed my analytical skills through a Master of Science in Clinical and Translational Research. I am keenly interested in understanding and reducing health care inequities, particularly in endocrine surgery conditions. Advocating for and highlighting the experience of minorities and immigrants was an interest that began as an undergraduate. After fellowship I worked in a community hospital until 2019 when I started my position with the MedStar-Georgetown Department of Surgery.

My current funded research seeks to understand and address health disparities in endocrine surgery patients. This includes successfully completing a prospective survey-based quality of life study of 244 endocrine surgery patients that characterizes the experience of minorities previously underrepresented in such studies (Charles and Mary Latham Fund, 2019) and uncovering the relevant associated social determinants of health, both individual and contextual (Georgetown-Howard Universities Center for Clinical and Translational Science Pilot Award 2020-2021). We submitted our preliminary data as an abstract to the 2022 Academic Surgical Congress meeting. With support from the Georgetown-Howard Universities Center for Clinical and Translational Science Pre-Pilot Team-Building Award (2021), I brought together a multidisciplinary team to address thyroid cancer disparities that includes experts in surgery, behavioral science (Kristen Miller, PhD), and oncology survivorship (Kristi Graves, PhD). I am also working to understand referral delays in patients with primary hyperparathyroidism within a large metropolitan health care system using a mixed-methods approach (American Association of Endocrine Surgeons Crowdfunding Award, 2021). I receive research mentorship in the MedStar Research Scholars program, a multidisciplinary small-group program supported by our local Center for Translational Science center.

For the current research proposal with the Charles and Mary Latham fund, my experience, interests, and prior and current multidisciplinary collaborations allow me to be uniquely able to complete the proposed study. This qualitative study builds on the previously undescribed findings from the original quantitative quality of life study, and the combined results are necessary to form the basis and preliminary data for our subsequent work that seeks to design and implement interventions aimed at improving outcomes and reducing disparities.

B. Positions, Scientific Appointments, and Honors

Positions held

2019 – Present	Surgeon, MedStar Washington Hospital Center, Washington, DC
2015 – Present	Assistant Professor of Clinical Surgery, Georgetown University
2014 – 2019	Surgeon, Virginia Hospital Center, Arlington, VA

Honors

2012	Resident Research Day Poster Winner, Montefiore Medical Center
2010	Resident Teaching Award – Albert Einstein College of Medicine
2008	Dean’s Recognition Award – Albert Einstein College of Medicine
2005	Travel Language Fellowship Award – Albert Einstein College of Medicine
2002, 2003	Leadership Award – Asian American Cultural Center & Yale College Dean’s Office

Professional membership

2012—Present	American Association of Endocrine Surgeons (Education committee, 2020-2022)
2013—Present	Association for Academic Surgery
2013—2015	Association of Women Surgeons
2016—Present	American College of Surgeons, Fellow
2018—Present	Society of Asian Academic Surgeons (Publications committee, 2021-2023)
2019—Present	American Thyroid Association (Development committee, 2020-2023)

Licensures/Board Certifications

2014 – Present	Board Certification: American Board of Surgery
2014 – Present	Virginia Board of Medicine Medical License
2019—Present	District of Columbia Board of Medicine Medical License
2020—Present	Maryland Board of Physicians Medical License

C. Contributions to Science

1. Disparities research: My current research focus is in disparities in endocrine surgery with particular interest in uncovering and understanding potential contributing factors. In addition to the previously-described studies (Section A), I conducted studies that looked at outcomes disparities across race. In a cohort of >300 thyroid cancer patients who underwent RAI, we found no difference across race in the amount of post-thyroidectomy remnant—a marker of surgical thoroughness—or in recurrence rates within a cohort cared for by high-volume surgeons. I conducted a pilot cross-sectional quality of life study of 135 patients that proved the feasibility of conducting a prospective quality of life study in a diverse endocrine surgery patient population; the manuscript has been submitted for publication consideration and we are preparing our revisions. I have also served as co-author on research that explored the role of race on in indeterminate thyroid nodules.

Crepeau PK, Kulkarni K. Martucci JM, **Lai V**. Comparing surgical thoroughness and recurrence in thyroid cancer patients across race/ethnicity. Surgery. 2021. In press.

Zheng H, **Lai V**, Lu J, Kang J, Felger E, Carroll N, Burman K, Wartofsky L, Rosen JE. Comparing the rate and extent of malignancy in surgically excised thyroid nodules across race and ethnicity. Am J Surg. 2021. In press.

Lu J, Zheng H, **Lai V**. Pilot cross-sectional quality of life study of a diverse endocrine surgery patient population. Presented at the annual Society of Asian Academic Surgeons 2021 meeting. Manuscript submitted and peer review feedback received; to submit revisions.

2. Outcomes research in endocrine surgery: I became interested in clinical outcomes research that arose from clinical queries. We studied the clinical import of lymphadenopathy and the lymph node yield in thyroid cancer patients with thyroiditis—patients with thyroiditis had a higher lymph node yield that did not translate to a higher rate of lymph node metastasis. We also studied delayed calcium normalization after curative parathyroidectomy. We found this in 10% of patients, and of these, most normalized within one month and

were not more likely to have persistent or recurrent disease than those who did not have delayed normalization.

Lai V, Yen TW, Misustin S, Evans DB, Wang TS. The effect of thyroiditis on the yield of central compartment lymph nodes in patients with papillary thyroid cancer. Ann Surg Oncol. 2015;22(13):4181-6. PMID: 25851341

Lai V, Yen TW, Doffek K, Carr AA, Carroll TB, Fareau GG, Evans DB, Wang TS. Delayed calcium normalization after presumed curative parathyroidectomy is not associated with the development of persistent or recurrent primary hyperparathyroidism. Ann Surg Oncol. 2016;23(7):2310-4. PMID: 27006125

3. <u>Surgical practice patterns</u>: Surgical and endocrine surgical practice patterns have been changing, both locally and nationally. I was involved with a project that sought to understand the practice patterns of endocrine surgery, gathering data from a national cohort of surgeons—we found that it takes an average of 7 years for endocrine surgeons to become high-volume. I also conducted a study that compared the perspectives of telemedicine use between endocrine surgery patients and endocrinologists during the COVID era. We found that both patients and providers were accepting of telemedicine as a means to deliver healthcare, although they differed in the types of visits to conduct virtually vs. in-person.

Kuo JH, Duh QY, Chen H, **Lai V**, Sorensen MJ, Chabot JA, Lee JA. The evolving practice patterns of academic endocrine surgeons: a cross-sectional analysis of the faculty practice solutions center database 2014 to 2017. Ann Surg. 2018 Nov 6. PMID: 30407204

Zheng H, Rosen JE, Bader NA, **Lai V**. Endocrine surgery patients' and providers' perceptions of telemedicine in the COVID era. J Surg Res. 2022;269:76-82.

Project Budget Request and Budget Justification

- Research assistant
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    - Total: $1140.00

- Total requested: $15,000.00

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Charles and Mary Latham Fund Grant application
Victoria Lai, MD, MS
October 2021

Total requested: $15,000

Project Title:

Diving deep into the social factors that affect outcomes and quality of life in endocrine surgery patients: a qualitative study of patients and clinicians

Project Summary:

We aim to identify the nuanced individual and contextual social factors that influence the quality of life of endocrine surgery patients living in the metropolitan Washington, DC area. Our prior work in this patient population showed that many patients face social factors that negatively affect their quality of life and that Black patients are disproportionately affected by such factors. For this proposal we will leverage and build on our prior quantitative work and conduct a multi-level qualitative study that includes patients and clinicians to define the factors that affect medical care and quality of life.

First, we will conduct semi-structured interviews with 24 patients. We will recruit from our prior pool of racially, ethnically and socioeconomically diverse participants and purposively sample participants with high (n=12) and low (n=12) quality of life. We will compare responses across these two groups of participants, identifying themes using content analysis.

Second, we will evaluate clinicians' perspectives of the patient experience with semi-structured interviews. This will include 10 clinicians from different specialties who care for endocrine surgery patients (e.g. surgery, endocrinology, nephrology, primary care). We will investigate whether clinicians' perspectives align with or differ from patients' reports.

We are unaware of any prior efforts to collect rich, multi-level qualitative data on the social determinants of quality of life among endocrine surgery patients. Results will complement our existing and compelling quantitative data and inform future research aimed to design interventions to improve endocrine surgery outcomes and reduce care disparities.

Statement of the problem

Endocrine surgery patients—those with neoplastic conditions of the thyroid, parathyroid and adrenal glands—are common: thyroid cancer survivors will make up to 10% of all cancer survivors in the future and primary hyperparathyroidism affects 1-3% of the population.[1,2] Compared to the general United States (US) population, endocrine surgery patients face unique challenges, both socioeconomic and psychological. For example, thyroid cancer patients have higher rates of bankruptcy and lower quality of life (QOL) than the general US population.[1,2] Ethnic/racial minorities and the poor with endocrine surgery conditions face additional inequities.[3] They are more likely to experience care delays and surgical complications, and are more likely to have surgery with less experienced surgeons, although the reasons are unclear.[4]

Individual (e.g. financial, education, race) and contextual (i.e. neighborhood) social determinants of health affect outcomes. In other medical conditions, patients living in more socially vulnerable neighborhoods were more likely to experience surgical complications and have greater financial burdens, an effect that is greater among ethnic/racial minorities than in non-Hispanic Whites.[5] However, social determinants of health, at the individual or contextual level, and their impact on outcomes have been understudied in endocrine surgery patients.

Our group has helped fill this literature gap, with research supported in part by the Latham Fund: among 244 endocrine surgery patients in the metropolitan Washington, DC area, we found that 10-15% of patient report social challenges even before undergoing surgery, and we found that Black patients were disproportionately represented. We found that having specific individual social stressors, such as trouble paying for food, was associated with worse QOL in the Patient Reported Outcomes Measurement Information System-29 (PROMIS-29) health-related QOL questionnaire. Paradoxically, we also found that while individual social factors influenced QOL, living in socially vulnerable neighborhoods did not translate to worse QOL. The factors that influence QOL and well-being are clearly complex, but we lack granular details about the lived experience of patients that influence their care, QOL, overall well-being and decision-making for their medical care. We also lack the clinician perspective, critical because referrals drive care for most endocrine surgery patients, affecting if and to whom a patient gets referred. We also do not know if the clinicians' perception of the patient experience aligns with the patients' realities, which could lead to missed opportunities to better support and care for patients. Our initial work has pointed to *what* social factors are related to poor QOL; we now need to better understand *how* social factors affect outcomes or contribute to care inequities so that we can work to improve both.

Specific aims:

Although endocrine surgery patients face unique psychosocial challenges, and although ethnic/racial minorities with these conditions also harbor inequitable outcomes, we do not know patients' lived experiences to understand why. Our overall goal is to improve outcomes for all endocrine surgery patients and reduce care inequities among marginalized patients. For this proposal we will conduct semi-structured interviews to discern and compare patient and clinician perspectives about the individual and contextual factors that influence patients' care experiences, medical care decisions and QOL outcomes. We will use content analysis qualitative approaches to compare the themes that emerge from patients with low vs. high QOL.

This qualitative research will build on the quantitative survey-based work our group has conducted with support from the Latham Fund where we met target recruitment (n=244), enrolled >85% of eligible patients, and matched subject demographics to clinical demographics. Our clinical group performs >800 operations yearly, serving patients of metropolitan Washington, DC. We identified topics of import to patients, but lacked rich details that surveys cannot provide; interviews from this proposed research will. We will sample from our prior participants to recruit 24 patients. We will also recruit 10 clinicians who care for endocrine surgery patients to better understand how their perspectives and choices may influence patient outcomes.

- Aim 1: Evaluate the social factors, priorities and experiences among endocrine surgery patients to obtain data that influenced (1) decisions they made in their care, including barriers and promoters, and (2) outcomes. We will recruit our prior participants and conduct semi-structured interviews. We hypothesize that patients will have a wide breadth of individual and contextual factors beyond medical/clinical factors that influenced their decisions, outcomes and experiences (e.g. employment concerns, anxiety), and that these will differ based on whether patients had low or high QOL.

- Aim 2: From clinicians who care for endocrine surgery patients (e.g. surgeons, endocrinologists, nephrologists, primary care providers), (1) identify through semi-structured interviews the social and clinical factors that influenced their patient care decisions and their perceptions of the promoters and barriers to care that patients experience; and (2) compare clinician responses to patient responses. We hypothesize that individual and contextual factors (e.g. health insurance) contribute significantly to decision-making and that clinician perspectives of the patient experience will differ from that of patients.

The results of this study will provide needed insight on how individual and contextual social factors contribute to outcomes and care disparities. Combined with our prior work, we will have the necessary information to test interventions against the relevant social factors (e.g. employment concerns) that negatively affect clinical and QOL outcomes. Some of the social factors that affect endocrine surgery patients may also affect other surgical patients, a broader community plagued with outcomes disparities, where the evidence is limited by the use of administrative databases.[3-5] The lessons here can be tested and applied to those patients too. The surgical disparities literature suffers from being descriptive and not prescriptive – our work would help move the field—both ours and the broader surgical community—towards the latter.

Research strategy: significance

Endocrine surgery patients experience unique socioeconomic, psychological, and clinical challenges. The challenges they face depend on their particular disease. Thyroid cancer patients have material and psychological financial challenges.[1] They are more likely to experience psychological financial burdens than other cancer survivors (46.1% vs 23.0%, p=0.04), and they have higher rates of bankruptcy than the general population (3% vs. 0.6%).[1,2] They are more likely to have mental health problems.[6] Given that thyroid cancer tends to have low mortality rates (98% five-year survival), one would expect that thyroid cancer patients have better QOL than cancer patients who have more mortal or morbid conditions, but this is not the case. Compared to colon cancer, breast cancer, and glioma survivors, thyroid cancer survivors have worse spiritual well-being QOL scores.[6]

Patients with primary hyperparathyroidism face negative potential clinical and QOL harm because primary hyperparathyroidism is underdiagnosed and under-referred for curative surgery.[7] This is problematic given the potential negative effects of the disease on the bone and renal system, some of which can be ameliorated with surgery. Furthermore, patients with primary hyperparathyroidism have greater neuropsychological symptoms and lower QOL than the general population.[8]

Ethnic and racial minorities with endocrine surgery conditions are more likely than non-Hispanic White patients to experience care disparities. Those with thyroid cancer are more likely to have worse surgical outcomes, and are more likely to undergo surgery with less-experienced surgeons who have higher complication rates.[9] Black patients with primary hyperparathyroidism are more likely to experience care delays than white patients.[10]

The reasons for these stark disparities are unclear. Without understanding the factors that contribute to the disparities, the medical community is unable to design useful and effective interventions to mitigate adverse health outcomes. Our research seeks to overcome this barrier by performing the required first steps: engaging with endocrine surgery patients and the clinicians who care for them. By conducting semi-structured interviews to understand the factors that either promote or hinder optimal medical care, we will obtain a rich, nuanced understanding of the individual, contextual and medical system factors that contribute to patients' experiences and outcomes.

Results from the proposed study will add considerably more depth to the current literature on endocrine surgery disparities and the field of surgical disparities in general. Evidence to date from the surgical disparities field has come largely from retrospective chart reviews of institutional or large administrative datasets without attention to the individual patient experience.[3-7,9-10] Our approach that combines our prior quantitative data with the proposed qualitative data to identify intervention approaches to address health disparities can serve as a model for other surgical patients. Although endocrine surgery patients have their own specific challenges, issues of disparate surgical access, timeliness of care, and outcomes are rife throughout the surgical community – thus, not only the approach, but the lessons from this proposed work can be tested within other surgical specialties.

Research strategy: innovation

This research is innovative because it seeks to gather an in-depth understanding from endocrine surgery patients the factors that may influence their care, outcomes, and QOL—research that has not been done much before in this field or in the much broader research field of surgical disparities. Our proposed multi-level approach is also innovative because we seek to understand both the patient experience and the clinician perception of the endocrine surgery patient experience. We are not aware of any other work that has taken this approach to understand health disparities among endocrine surgery patients.

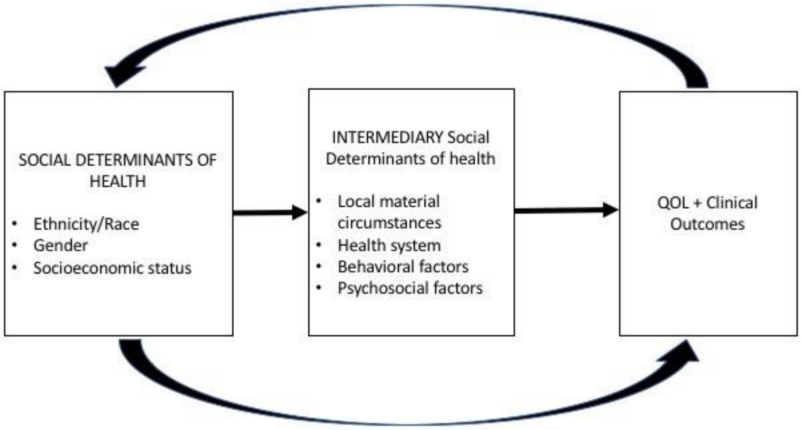
Our proposed work moves the field forward by moving beyond what surveys or chart reviews can accomplish, which are the research designs of most published surgical disparities studies.[3-7,9-10] Many of the surgical disparities literature identifies risk factors that are unchangeable (race and ethnicity), difficult to change (socioeconomic status), or not actionable. Others have also studied the role of contextual social factors in other conditions, which has not been done within endocrine surgery. Hyer et al found that patients who live in the most socially vulnerable neighborhoods were more likely to experience complications after undergoing colon, lung, esophageal or rectal surgery.[11] The degree of social vulnerability was determined by the Social Vulnerability Index, and neighborhoods are grouped based on US Census tracts. In contrast, we found in our quantitative study that patients living in the most socially vulnerable neighborhoods had better QOL. This may be because endocrine surgery patients are affected differently by contextual social factors than other patients, but more likely, it highlights the limits of relying only on constructed means of categorizing patients without consideration of individual social factors. Our current proposal builds on our original findings to better understand the complex factors that contribute to QOL that others have not yet delved into.

Research strategy: approach

Overview:

Our research approach is informed by preliminary research we performed with support from the Charles and Mary Latham Fund. We performed one of the few prospective QOL studies in 244 endocrine surgery patients using validated QOL questionnaires in a racially/ethnically diverse population. Through patient reports, we found that 10-15% of our patients had difficulty paying for daily necessities in the three months before surgery, which is prior to incurring significant medical bills. We identified that these social determinants of health predicted worse preoperative QOL, and we identified that Black patients were more likely to be represented in this group. Paradoxically, while Black patients were more likely to live in the most socially vulnerable neighborhoods, those living in such neighborhoods were more likely to have better QOL. Our prior research adds previously unreported data about the experience of ethnic/racial minorities with endocrine surgery conditions and also demonstrates the complexity of the relationship between QOL, individual social determinants of health and contextual social vulnerability. These findings compel the next steps to better understand how these social factors intersect for endocrine surgery patients.

A conceptual framework, adapted from the World Health Organization conceptual framework,[12] for the interactions is that social determinants of health likely affect intermediary factors, which together work to affect QOL and clinical outcomes. This research proposal seeks to identify the relevant individual and contextual social determinants of health that affect QOL in endocrine surgery patients.



Patient Recruitment and Interviews:

We aim to perform semi-structured interviews of endocrine surgery patients and clinicians to understand how social factors influence outcomes. Interview guides will be informed by findings from our prior quantitative research and input from a multidisciplinary team (surgery, behavioral science, oncology survivorship). For this qualitative research, the strategy consists of purposively recruiting 24 adult endocrine surgery patients from the metropolitan Washington, DC area from our prior study. We will recruit patients with high (n=12) and low (n=12) QOL based on their prior responses to the PROMIS-29 questionnaire. The PROMIS-29 is scored with T-scores; a T-score of 50 corresponds to the general US mean, with a standard deviation of 10.[13] We will inquire about the factors that contributed to the decision-making about their medical care, and the factors that contributed to or detracted from their outcomes and well-being. We will identify the themes that emerge from these semi-structured interviews.

Clinician Recruitment and Interviews:

We will recruit 10 clinicians from different fields (e.g. surgery, endocrinology, nephrology, primary care) who care for endocrine surgery patients because of the central role that they play in what kind of care patients receive, and when and how they get it, and because they may have insight into the challenges that patients face. Those in different fields will have different perspectives based on the different points in the patients' medical journey they participate in. We will inquire about factors they perceive influence patients' decision-making, and factors that contribute to their decision-making for their patients. We will compare the themes that emerge from the patients' and clinicians' responses.

Animal testing:
We have no intention to perform research that involves animals and no funds will be allocated towards medical research involving animals.

Research design and methods

The research design is a qualitative one and employs the use of semi-structured interviews of adult endocrine surgery patients and clinicians who care for them.

- Aim 1:

Methods

We will recruit 24 adult endocrine surgery patients who were participants from our quantitative study. We will recruit 12 patients with high and 12 with low QOL based on their PROMIS-29 results. We aim to be representative in age, sex, race, and ethnicity.

We will schedule individual interviews. Study personnel will conduct semi-structured interviews using an interview guide. Based on our quantitative study results, these will include questions about the individual (e.g. food security) and contextual factors that contributed to their outcomes, QOL, and medical care decision-making. We will ask patients to reflect on aspects within the healthcare system (e.g. access, care coordination) and its impact on their outcomes; potential helpful interventions and when these would have been helpful. We will inquire about patients' priorities.

Given the COVID-19 pandemic, the interviews will be primarily conducted virtually with video-based calls, unless for clear and practical reasons it needs to be done over the phone or in-person (e.g. lack of reliable internet connection). We will make available certified medical interpreters as needed. Interviews will last 60-90 minutes and will be recorded. We will compensate subjects with $50 gift cards.

Analysis

We will transcribe, store, and analyze interviews with NVivo 12 software. Two trained research personnel will independently review the interview transcripts and perform line by line coding, creating a codebook. We will categorize the findings into early themes. Researchers will then refine the themes until there is agreement about the concepts. Data will be presented as themes and exemplary quotes will be collected. We will compare themes generated from patient interviews of patients with QOL above the US mean to those with QOL below the US median.

Anticipated results:

We anticipate that patients will report and expand on individual and contextual social determinants of health that impact their QOL and would allow us to design interventions aimed at improving clinical outcomes and QOL. We anticipate that those with lower QOL will report different factors than those with higher QOL.

We anticipate that such patients will be able to expand on whether, when, and how individual (e.g. food security) and contextual (e.g. housing concerns) social factors affected their medical care decision making, clinical outcomes and QOL. These lived experiences will provide the basis for us to design interventions to improve outcomes, be it a legal counselor who can advise patients of their housing rights or a social worker who can help patients access food banks, for example.

Our prior work showed that contextual social factors, such as the social vulnerability of a patient's neighborhood, did not translate into lower QOL and living in more socially vulnerable neighborhoods predicted higher QOL. We anticipate that patients will provide insight into these counterintuitive findings and the relative import of certain factors over others.

- Aim 2:

Methods

We will recruit 10 clinicians in different fields (e.g. surgery, endocrinology, nephrology, primary care) who care for endocrine surgery patients of the metropolitan Washington, DC area. We will use a combination of e-mail and mailed research advertisements, and individual word of mouth to recruit participants. Interviews will be conducted similarly as for patient participants. Clinician questions will pertain to clinical and social factors that they perceive affect patient decision-making and outcomes. We will inquire about factors that influenced the clinicians' medical care decision-making for the patients, from diagnostic work-up to recommended treatment. We will provide $50 gift cards in appreciation for participants' efforts.

Analysis

The process will be similar to the analysis outlined in Aim 1. We will compare clinician and patient responses.

Anticipated results

We anticipate that clinicians will focus on clinical factors that affected their decision-making for patients but will also have insight into the social factors (e.g. health insurance coverage) they believe negatively affected patient outcomes. We hypothesize that clinicians' perspectives of the patient experience will differ in certain areas from what patients report, such as QOL,[14] which can serve as potential areas of research to improve patient outcomes and well-being. In areas of agreement, these too would be potential targets for intervention, as they may have greater acceptance from both patients and clinicians.

Anticipated Challenges

One potential challenge will be subject recruitment. To address this, we will purposively recruit prior research participants from our quantitative study. We will try to promote inclusion by compensating subjects for their time and providing language translators as needed. For clinician recruitment, we will send follow-up notices about the opportunity to participate, and make use of group meetings or conferences to advertise the research project.

We may encounter time challenges. With regards to scheduling challenges with recruited subjects, we will seek the assistance of a research assistant to help coordinate schedules. We will also request the purchase of the NVivo software package to reduce the time required to manage the data. The research team will also include a general surgery resident spending dedicated time as a research fellow in our department and a medical student who previously worked as a clinical research coordinator conducting qualitative research. The PI has 20 % of time dedicated to research.

Future Plans

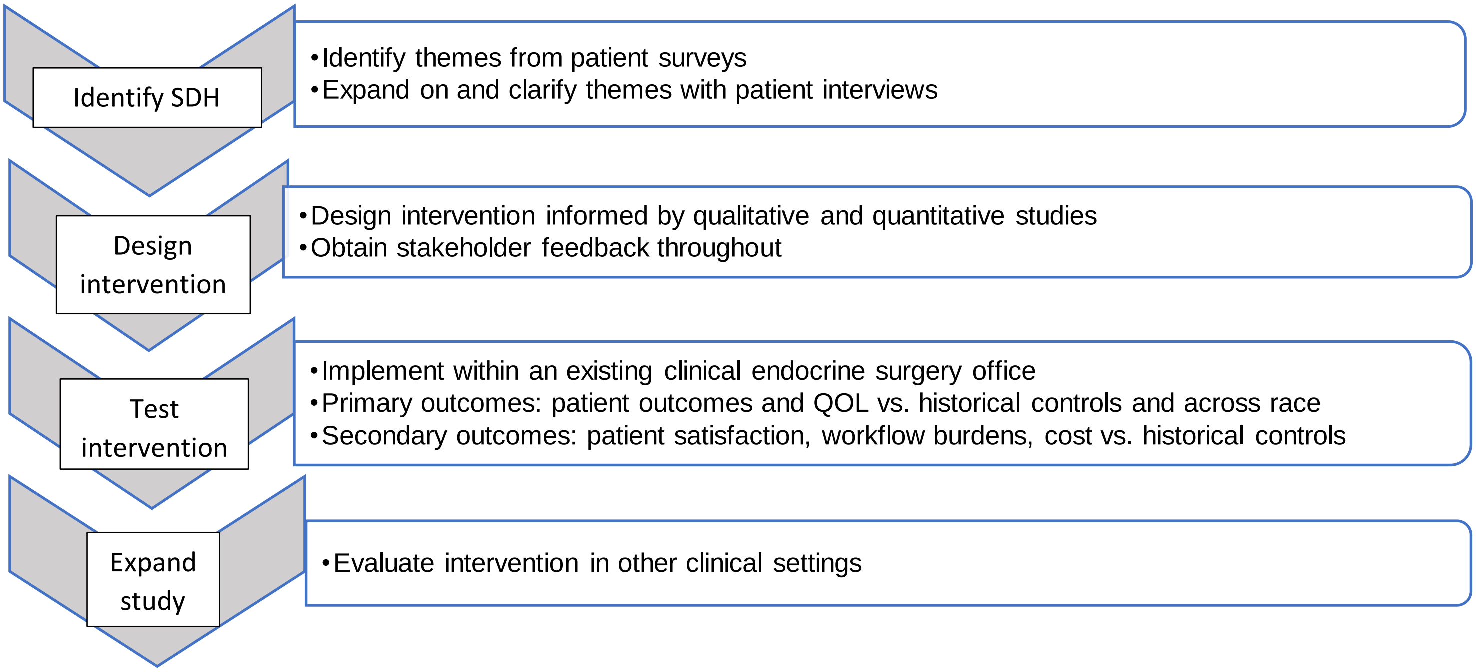
We will continue to work towards our overall goal of improving outcomes and reducing care disparities. Based on the themes and lessons that emerge from the patient and clinician interviews and analyzed in light of the quantitative data acquired from our prior research study, we aim to design interventions aimed at the social determinants of health that impact QOL and patient outcomes.

To give an example, our original work suggested that those who had difficulty paying for medical bills had lower QOL. What's unclear: if these financial needs change over time; what would be most helpful with regards to their medical bills; and whether medical bills affected their decisions to comply with recommended care. We would clarify these issues in our semi-structured interviews. If we identified in this proposed research that paying for medical bills not only contributed to worse QOL, but also reduced the likelihood of complying with recommended treatment and predicted worse clinical outcomes, and if patients expressed a desire for help both before and after surgery, we would have acquired richer details than what the surveys alone would have found.

Taking this information, we would design this intervention within a real-world workflow. One potential intervention for the hypothetical scenario above would be to refer patients to financial counselors who could help patients create plans to afford their care, or with social workers who can help patients assess, understand, and optimize their current health insurance coverage. We would get feedback about the relevance, helpfulness, and ease of use from stakeholders such as patients and clinical staff throughout the process to allow us to evaluate and iterate on the design.

After designing the intervention, we would then create an implementation study. The primary outcomes would be whether the interventions improve patient QOL, improve clinical outcomes by reducing complications or care delays, and reducing ethnic/racial disparities in both. Other ways that we would evaluate such interventions would be patient satisfaction, staff satisfaction and work burden, degree of integration within existing clinical workflows and electronic health systems, and cost for the healthcare system. We would evaluate these interventions to historical and published controls. We will also assess the intervention based on aspects of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework.[15]

Based on these results of our implementation study, we can either continue to iterate on the intervention or move in a different direction. We will eventually study it in other clinical settings, such as other endocrine surgery offices, surgical specialty offices, or institutions.



- Identify themes from patient surveys
- Expand on and clarify themes with patient interviews

- Design intervention informed by qualitative and quantitative studies
- Obtain stakeholder feedback throughout

- Implement within an existing clinical endocrine surgery office
- Primary outcomes: patient outcomes and QOL vs. historical controls and across race
- Secondary outcomes: patient satisfaction, workflow burdens, cost vs. historical controls

- Evaluate intervention in other clinical settings

Future funding opportunities

For our next grant application, an R-series through the Agency for Healthcare Research and Quality or the National Institutes of Health, we need the information from both the quantitative and qualitative research to design an intervention within an endocrine surgery office setting. The intervention will aim to improve patient outcomes and QOL, and reduce care disparities, and must keep the relevant social factors at the forefront to be effectual. To get a clearer understanding of how and when individual and contextual factors promote or detract from QOL, identify patients' priorities, and to understand the role of the clinician in these factors, *so that* we can design an informed intervention, we must build on the prior work with this proposed qualitative research. Both our prior data and what can be generated from this proposal are needed to create the rationale that a competitive grant application requires.

As part of the next proposal, we will bring together a multidisciplinary team to design this intervention. To identify which areas of expertise are needed (e.g. social work, information technology, legal), we would rely on our findings in this proposed study. We will obtain stakeholder feedback before the intervention design and evaluate the design based on follow-up feedback from patients and clinical staff.

The lessons from this proposed project—*the how, when, and why*—interpreted in light of our prior project—*the what*—will create the strong and required pilot data needed to successfully compete for future grant applications.

BIOGRAPHICAL SKETCH

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

NAME: VICTORIA LAI

eRA COMMONS USER NAME (credential, e.g., agency login): VICTORIA LAI

POSITION TITLE: Attending Surgeon, MedStar-Georgetown Department of Surgery, Division of Endocrine Surgery; Assistant Professor of Surgery, Georgetown University Medical Center

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale College, New Haven, CT	BA	05/2004	History
Albert Einstein College of Medicine, Bronx, NY	MD	06/2008	Medicine with distinction in research
Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY	Residency	06/2013	General surgery
Medical College of Wisconsin, Milwaukee, WI	Fellowship	06/2014	Endocrine surgery
Georgetown-Howard Universities Center for Clinical & Translational Science, Washington, DC	MS	12/2018	Clinical and Translational Research

A. Personal Statement

As a general surgery resident and then as an endocrine surgery fellow, my interest in clinical outcomes research in the field of endocrine surgery began. I further developed my analytical skills through a Master of Science in Clinical and Translational Research. I am keenly interested in understanding and reducing health care inequities, particularly in endocrine surgery conditions. Advocating for and highlighting the experience of minorities and immigrants was an interest that began as an undergraduate. After fellowship I worked in a community hospital until 2019 when I started my position with the MedStar-Georgetown Department of Surgery.

My current funded research seeks to understand and address health disparities in endocrine surgery patients. This includes successfully completing a prospective survey-based quality of life study of 244 endocrine surgery patients that characterizes the experience of minorities previously underrepresented in such studies (Charles and Mary Latham Fund, 2019) and uncovering the relevant associated social determinants of health, both individual and contextual **(**Georgetown-Howard Universities Center for Clinical and Translational Science Pilot Award 2020-2021). We submitted our preliminary data as an abstract to the 2022 Academic Surgical Congress meeting. With support from the Georgetown-Howard Universities Center for Clinical and Translational Science Pre-Pilot Team-Building Award (2021), I brought together a multidisciplinary team to address thyroid cancer disparities that includes experts in surgery, behavioral science (Kristen Miller, PhD), and oncology survivorship (Kristi Graves, PhD). I am also working to understand referral delays in patients with primary hyperparathyroidism within a large metropolitan health care system using a mixed-methods approach (American Association of Endocrine Surgeons Crowdfunding Award, 2021). I receive research mentorship in the MedStar Research Scholars program, a multidisciplinary small-group program.

For the current research proposal with the Charles and Mary Latham fund, my experience, interests, and prior and current multidisciplinary collaborations allow me to be uniquely able to complete the proposed study. This qualitative study builds on the previously undescribed findings from the original quantitative quality of life study, and the combined results are necessary to form the basis and preliminary data for our subsequent work that seeks to design and implement interventions aimed at improving outcomes and reducing disparities.

B. Positions, Scientific Appointments, and Honors

Positions held

2019 – Present	Surgeon, MedStar Washington Hospital Center, Washington, DC
2015 – Present	Assistant Professor of Clinical Surgery, Georgetown University
2014 – 2019	Surgeon, Virginia Hospital Center, Arlington, VA

Honors

2012	Resident Research Day Poster Winner, Montefiore Medical Center
2010	Resident Teaching Award – Albert Einstein College of Medicine
2008	Dean's Recognition Award – Albert Einstein College of Medicine
2005	Travel Language Fellowship Award – Albert Einstein College of Medicine
2002, 2003	Leadership Award – Asian American Cultural Center & Yale College Dean's Office

Professional membership

2012—Present	American Association of Endocrine Surgeons (Education committee, 2020-2022)
2013—Present	Association for Academic Surgery
2013—2015	Association of Women Surgeons
2016—Present	American College of Surgeons, Fellow
2018—Present	Society of Asian Academic Surgeons (Publications committee, 2021-2023)
2019—Present	American Thyroid Association (Development committee, 2020-2023)

Licensures/Board Certifications

2014—Present	Board Certification: American Board of Surgery
2014—Present	Virginia Medical License
2019—Present	District of Columbia Medical License
2020—Present	Maryland Medical License

C. Contributions to Science

1. Disparities research: My current research focus is in disparities in endocrine surgery with particular interest in uncovering and understanding potential contributing factors. In addition to the previously-described studies (Section A), I conducted studies that looked at outcomes disparities across race. In a cohort of >300 thyroid cancer patients who underwent RAI, we found no difference across race in the amount of post-thyroidectomy remnant—a marker of surgical thoroughness—or in recurrence rates within a cohort cared for by high-volume surgeons. I conducted a pilot cross-sectional quality of life study of 135 patients that proved the feasibility of conducting a prospective quality of life study in a diverse endocrine surgery patient population; the manuscript has been submitted for publication consideration and we are preparing our revisions. I have also served as co-author on research that explored the role of race on in indeterminate thyroid nodules.

Crepeau PK, Kulkarni K. Martucci JM, **Lai V**. Comparing surgical thoroughness and recurrence in thyroid cancer patients across race/ethnicity. Surgery. 2021. In press.

Zheng H, **Lai V**, Lu J, Kang J, Felger E, Carroll N, Burman K, Wartofsky L, Rosen JE. Comparing the rate and extent of malignancy in surgically excised thyroid nodules across race and ethnicity. Am J Surg. 2021. In press.

Lu J, Zheng H, **Lai V**. Pilot cross-sectional quality of life study of a diverse endocrine surgery patient population. Presented at the annual Society of Asian Academic Surgeons 2021 meeting. Manuscript submitted and peer review feedback received; to submit revisions.

2. Outcomes research in endocrine surgery: I became interested in clinical outcomes research that arose from clinical queries. We studied the clinical import of lymphadenopathy and the lymph node yield in thyroid cancer patients with thyroiditis—patients with thyroiditis had a higher lymph node yield that did not translate to a higher rate of lymph node metastasis. We also studied delayed calcium normalization after curative

parathyroidectomy. We found this in 10% of patients, and of these, most normalized within one month and were not more likely to have persistent or recurrent disease than those who did not have delayed normalization.

Lai V, Yen TW, Misustin S, Evans DB, Wang TS. The effect of thyroiditis on the yield of central compartment lymph nodes in patients with papillary thyroid cancer. Ann Surg Oncol. 2015;22(13):4181-6. PMID: 25851341

Lai V, Yen TW, Doffek K, Carr AA, Carroll TB, Fareau GG, Evans DB, Wang TS. Delayed calcium normalization after presumed curative parathyroidectomy is not associated with the development of persistent or recurrent primary hyperparathyroidism. Ann Surg Oncol. 2016;23(7):2310-4. PMID: 27006125

3. <u>Surgical practice patterns</u>: Surgical and endocrine surgical practice patterns have been changing, both locally and nationally. I was involved with a project that sought to understand the practice patterns of endocrine surgery, gathering data from a national cohort of surgeons—we found that it takes an average of 7 years for endocrine surgeons to become high-volume. I also conducted a study that compared the perspectives of telemedicine use between endocrine surgery patients and endocrinologists during the COVID era. We found that both patients and providers were accepting of telemedicine as a means to deliver healthcare, although they differed in the types of visits to conduct virtually vs. in-person.

Kuo JH, Duh QY, Chen H, **Lai V**, Sorensen MJ, Chabot JA, Lee JA. The evolving practice patterns of academic endocrine surgeons: a cross-sectional analysis of the faculty practice solutions center database 2014 to 2017. Ann Surg. 2018 Nov 6. PMID: 30407204

Zheng H, Rosen JE, Bader NA, **Lai V**. Endocrine surgery patients' and providers' perceptions of telemedicine in the COVID era. J Surg Res. 2022;269:76-82.

Project Budget Request and Budget Justification

- Research assistant
  We are requesting a percentage of effort from an institutional research assistant to help with the administrative aspects of the project, including recruitment, schedule coordination, and data management. This assistance will help to address the potential challenge of time.
    - 15.3% effort of 1.84 calendar months effort = $9,942.00 salary
    - 20.3% Fringe = $2,018.00
    - Total = $11,960.00

- Gift cards
  We will request gift cards to compensate for patient and clinician participation in this study. We will provide $50 for each participant.
    - Estimated # of patients: 24 x $50/patient = $1200.00
    - Estimated # of clinicians: 10 x $50/clinician = $500.00
    - Total: $1700.00

- Postage for recruitment and administrative tasks
    - Includes envelopes and stamps: $200.00

- NVivo 12 Plus software
  This is a widely-used software product for qualitative research used for data storage and organization. It is intended to facilitate the data capture and analysis and aimed to address the challenge of time for this project. Will request the software package as well as the one-year transcription service.
    - Software package cost as a faculty member through the Georgetown University Information Services: $640.00
    - Cost of one-year transcription subscription: $500.00
    - Total: $1140.00

- Total requested: $15,000.00

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