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**TITLE:** Gaps in Gastric Cancer Risk Factor Management: Analysis of Electronic Health Data and Provider/Patient Perspectives

**PRINCIPAL INVESTIGATOR:** Dorothy Long Parma, MD, MPH

**CONTRACTING ORGANIZATION:** University of Texas Health Science Center at San Antonio

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**1. REPORT DATE**

JUNE 2021

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Gaps in Gastric Cancer Risk Factor Management: Analysis of Electronic Health Data and Provider/Patient Perspectives

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Dorothy Long Parma, MD, MPH

Raquel Romero, MD, MPH

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**13. SUPPLEMENTARY NOTES****14. ABSTRACT**

This study addressed factors and their interactions contributing to disparities in testing and treatment of *H. pylori* (HP) infection and related gastric disorders (atrophic gastritis, gastric ulcer), and gastric cancer [GC; gastric adenocarcinoma (GCA), gastric non-Hodgkin's lymphoma (GL) and gastric MALT lymphoma (gMALT) diagnosis and treatment, among Latinos relative to non-Latinos at two affiliated but independent health systems in San Antonio, Texas. Continued secondary data analysis showed a very small proportion of patients developed GC but were diagnosed within 1 month of their index diagnosis. Time from diagnosis to referral was within 5 months for 80% of patients; referral time was shorter for female gender, Hispanic ethnicity and low insurance but not poverty, income or education. In contrast, time from referral to actual encounter was longer for those with lower income. Qualitative interviews for providers in primary care, gastroenterology and oncology have been completed and analysis is underway.

**15. SUBJECT TERMS**

*Helicobacter pylori* (*H. pylori*), gastric cancer, atrophic gastritis, gastric ulcer, health disparities, Hispanic, health insurance, time to diagnosis, time to referral, qualitative interviews

<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  UU	<b>18. NUMBER OF PAGES</b>  14	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
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**1. INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

My central research question is: what factors and their interactions contribute to disparities in testing and treatment of *H. pylori* infection and related gastric disorder (atrophic gastritis, gastric ulcer), and gastric cancer [GC; gastric adenocarcinoma (GCA), gastric non-Hodgkin's lymphoma (GL) and gastric MALT lymphoma (gMALT) diagnosis and treatment, among Latinos relative to non-Latinos? Study goals are to be met via a mixed methods approach of secondary data collection/analysis of electronic health records (EHR) from two affiliated but independent health systems (Quantitative); and semi-structured interviews of providers, administrators and a random sample of eligible patients in primary care, gastroenterology and oncology clinics on their experiences of facilitators of and barriers to care for these disorders (Qualitative).

**2. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

*Helicobacter pylori (H. pylori), gastric cancer, atrophic gastritis, gastric ulcer, health disparities, Hispanic, health insurance, time to diagnosis, time to referral, qualitative interviews*

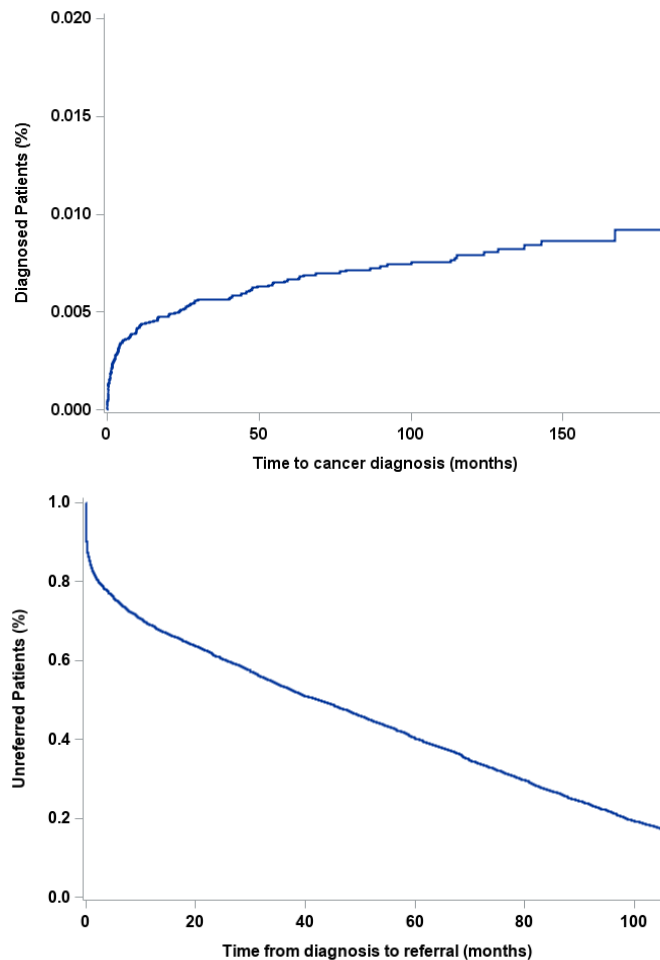
**3. ACCOMPLISHMENTS:**

**What were the major goals of the project?**

1. Gather and analyze electronic health record (EHR) data from two affiliated health systems (UTMed and UHS) – months 1-6 (analysis pending data re-extraction started 10/19; see Challenges)
  - a. IRB approval – months 1-6 (met 08/2019); HRPO approval not applicable
  - b. Prepare and submit manuscript for publication – months 6-8 (in progress; 10%)
2. Compare data from 2 health systems – months 4-12 (in progress; 20%, see 1 above)
  - a. Prepare/present results at national conference – months 6-12 (met 09/2019, 02/2020)
  - b. Prepare and submit manuscript for publication – months 8-12 (in progress; 10%)
3. Design and translate interview guides for providers, administrators and patients – months 13-15 (initial guides approved by IRB 11/2019; translation and amendments in progress 75% - patients)
  - a. HRPO approval – received 10/13/20; Continuing Review LOA submitted 11/5/20
4. Conduct semi-structured interviews with providers, administrators and patients from UTMEd/ UHS – months 15-24 (in progress; 50% -- all provider interviews completed)
5. Analyze interviews for qualitative themes – months 20-28 (in progress; 25% of provider interviews)
  - a. Prepare/present results at national conference – months 24-36 (not started)
  - b. Prepare and submit manuscript for publication – months 28-36 (not started)

## What was accomplished under these goals?

1. Gather and analyze electronic health record (EHR) data from two affiliated health systems (UTMed and UHS) – The PI received pilot funding from the Geographic Management of Cancer Disparities (GMaP) program Region 3 on 7/20 for \$7500 over 1 year to obtain Biostatistics Core support to analyze Aims 1 and 2 data. Analyses of 5/20 cohort dataset began and halted when need for data re-extraction was discovered in 9/20.
  - a. IRB approval (Expedited; PHI present in socioeconomic status and clinic notes data) – months 1-6 (met 08/2019); HRPO approval not applicable
  - b. Prepare and submit manuscript for publication – months 6-8 (in progress; 10%). Further delays in data analysis occurred due to systemic errors discovered by data warehouse personnel. Processes were updated and data re-extraction started 10/20. Due to multiple delays on the data warehouse side, PI received new datasets 6/3/21, and additional variables 6/9/21.
2. Compare data from 2 health systems – final analysis is pending cleaning of re-extracted data. Interim analysis of old dataset involved constructing Kaplan-Meier curve of progression to gastric cancer and time from diagnosis to referral. Figures below show a very small proportion of patients developed GC but were diagnosed within 1 month of their index diagnosis. Time from diagnosis to referral was within 5 months for 80% of patients.



We also constructed Cox models to identify factors influencing time from diagnosis to referral, and logistic regression models for factors influencing time from referral to encounter. These are shown in the tables below. The first table shows referral time was shorter for female gender, Hispanic ethnicity and low insurance but not poverty, income or education. In contrast, time from

*Time from diagnosis to referral (Cox model)*

Obs	Parameter	Estimate	StdErr	ProbChiSq	HazardRatio	HRLowerCL	HRUpperCL
1	AGE_AT_DIAGNOSIS	0.00999	0.00167	<.0001	1.010	1.007	1.013
2	SEX F VS M	-0.08899	0.03836	0.0203	0.915	0.849	0.986
3	RACE Asian vs White	0.09814	0.12792	0.4430	1.103	0.858	1.417
4	RACE Black vs White	-0.17018	0.08040	0.0343	0.844	0.721	0.987
5	RACE Other vs White	-0.26948	0.10579	0.0109	0.764	0.621	0.940
6	HISPANIC Y VS N	-0.16864	0.04701	0.0003	0.845	0.770	0.926
7	PRIMARY_PAYER_cat CareLink vs Private Insurance	-0.28244	0.05347	<.0001	0.754	0.679	0.837
8	PRIMARY_PAYER_cat Medicaid/Medicare/SCHIP vs Private Insurance	-0.10437	0.05889	0.0764	0.901	0.803	1.011
9	PRIMARY_PAYER_cat Other vs Private Insurance	-1.03144	0.08003	<.0001	0.356	0.305	0.417
10	PRIMARY_PAYER_cat Self-pay vs Private Insurance	-0.18943	0.09480	0.0457	0.827	0.687	0.996
11	DIAGNOSIS AG vs (null)	0.95936	0.04857	<.0001	2.610	2.373	2.871
12	DIAGNOSIS GCA/L/MT vs (null)	1.09596	0.06042	<.0001	2.992	2.658	3.368
13	DIAGNOSIS GU vs (null)	0.96588	0.08789	<.0001	2.627	2.211	3.121
14	Log_MEDINCOME_2017_5	0.04752	0.05091	0.3506	1.049	0.949	1.159
15	BELOWPOVERTY_2017_5Y	-0.11922	0.24332	0.6242	0.888	0.551	1.430
16	NOHS_2017_5Y_BG	-0.66397	0.35592	0.0621	0.515	0.256	1.034

*Time referral to encounter (Logistic model)*

Obs	Effect	OddsRatioEst	LowerCL	UpperCL	Estimate	StdErr	ProbChiSq
1	AGE_AT_DIAGNOSIS	1.005	1.000	1.010	0.00541	0.00252	0.0320
2	SEX F vs M	0.921	0.815	1.042	-0.0818	0.0628	0.1925
3	RACE Asian vs White	0.850	0.558	1.295	-0.1626	0.2148	0.4489
4	RACE Black vs White	0.832	0.635	1.090	-0.1841	0.1378	0.1813
5	RACE Other vs White	0.633	0.428	0.935	-0.4571	0.1992	0.0217
6	HISPANIC Y vs N	0.940	0.809	1.093	-0.0615	0.0765	0.4218
7	PRIMARY_PAYER_cat CareLink vs Private Insurance	0.868	0.731	1.031	-0.1419	0.0877	0.1058
8	PRIMARY_PAYER_cat Medicaid/Medicare/SCHIP vs Private Insurance	1.002	0.838	1.198	0.00182	0.0914	0.9841
9	PRIMARY_PAYER_cat Other vs Private Insurance	0.726	0.553	0.953	-0.3207	0.1389	0.0209
10	PRIMARY_PAYER_cat Self-pay vs Private Insurance	0.387	0.262	0.571	-0.9502	0.1990	<.0001
11	DIAGNOSIS AG vs (null)	3.546	3.093	4.064	1.2657	0.0696	<.0001
12	DIAGNOSIS GCA/L/MT vs (null)	3.933	3.242	4.772	1.3694	0.0986	<.0001
13	DIAGNOSIS GU vs (null)	3.409	2.732	4.255	1.2266	0.1130	<.0001
14	Log_MEDINCOME_2017_5	1.303	1.097	1.549	0.2650	0.0882	0.0026
15	BELOWPOVERTY_2017_5Y	1.107	0.476	2.575	0.1020	0.4306	0.8128
16	NOHS_2017_5Y_BG	1.251	0.367	4.269	0.2243	0.6261	0.7202

- a. prepare and submit manuscript for publication – months 8-12 (in progress; 10%). In the meantime, PI and colleagues submitted 2 related manuscripts (one first-author) on gastric cancer epidemiology in the U.S., Texas and South Texas, and gastric cancer mortality at the local cancer center (see Other Publications below).
3. Design and translate interview guides for providers, administrators and patients – months 13-15 (initial guides approved by IRB 11/2019; translation and amendments in progress 75% - patients)
  - a. HRPO approval – received 10/13/20; Continuing Review LOA submitted 11/5/20

4. Conduct semi-structured interviews with providers, administrators and patients from UTMEd/ UHS – months 15-24 (in progress; 50% -- all provider interviews completed) – with assistance of new RC, PI contacted at least 5 providers and 2 administrators from each of 3 specialties (primary care, gastroenterology, oncology – 26 total interviews). Due to COVID restrictions, PI conducted all interviews via telephone and recorded speakerphone conversations on a data recorder. Audio files were uploaded to Landmark Associates for transcription, and verbatim transcripts downloaded.

5. Analyze interviews for qualitative themes – months 20-28 (in progress; 40% of provider interviews) – PI and RC created transcript summaries of interviews following guidance from publication by Dr. Erin Finley, PI's Qualitative advisor. PI generated document of summary categories identified for use in summarizing future interviews. PI also generated matrix of interview domains by provider to look for common themes across specialties and locations. Analysis of common themes from individual domains in the matrix is ongoing.



**What opportunities for training and professional development has the project provided?**

**Training:** The PI is attending monthly webinars in the Spotlight for Research Integrity series. This takes the place of the course on Responsible Conduct of Research.  
The new Research Coordinator began a one-on-one mentorship with the PI beginning Dec. 2019. This has been primarily focused on recruiting participants for semi-structured interviews and creating transcript summaries of recorded interviews for analysis (Aim 3).  
**Professional development:** The PI presented data from a manuscript in development at the Mays Cancer Center Annual Symposium on Jan. 13, 2021. She also attended the virtual annual conference of the American Society for Preventive Oncology on Mar. 29-Apr. 1, 2021.

**How were the results disseminated to communities of interest?**

Nothing to report

**What do you plan to do during the next reporting period to accomplish the goals?**

Goal 1: acquire final clean dataset from the data warehouse – completed. Will request update in Dec 2021.  
Goal 2: analyze dataset with help of Biostatistics Core; describe changes if any to the cohort; conduct longitudinal data analyses. Prepare/present results at a national conference and submit manuscripts for publication.  
Goal 3: Submit IRB amendments for patient interview guides and surveys - completed. Obtain permission to contact eligible patients from participating providers. Begin patient interviews. Conduct qualitative analyses of all interviews throughout this process. Present preliminary results at a national conference. Prepare and submit manuscript for publication.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report

**What was the impact on other disciplines?**

Nothing to report

**What was the impact on technology transfer?**

Nothing to report

**What was the impact on society beyond science and technology?**

Nothing to Report

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

Due to COVID-19 restrictions, most interviews to date have been conducted via telephone speakerphone with an audio recorder. Patient interviews will be conducted per patient preference but will likely also be via telephone.

**Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

Research Coordinator left the institution in October 2020, leading to delays in Aims 1 and 2 analyses. Further delays resulted from systemic errors discovered in data warehouse, necessitating re-extraction of all datasets. Priority queries and understaffing led to re-extraction process taking longer than expected (almost 8 months). PI was able to obtain funding for Biostatistical Core support of secondary data analysis. She will disburse these funds up front so as not to lose them when funding ends in July 2021. New RC started Dec 2020. Her area of expertise is more on qualitative approaches (Aim 3). PI will request her assistance with simpler aspects of data cleaning.

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Since the ASPO meeting was held virtually, PI did not incur travel expenses and only had to cover meeting registration.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

Nothing to report

**Significant changes in use or care of vertebrate animals**

Not applicable

**Significant changes in use of biohazards and/or select agents**

Not applicable

**6. PRODUCTS:**

- **Publications, conference papers, and presentations**

*Report only the major publication(s) resulting from the work under this award.*

**Journal publications.**

**Dorothy Long Parma**, MD, MPH; Susanne Schmidt, PhD; Edgar Muñoz, MS; Amelie G. Ramirez, DrPH. Gastric cancer burden and late-stage diagnosis in Latino and non-Latino populations in the United States and Texas 2004-2016: a multilevel analysis. Submitted to *Cancer Medicine* 5/4/21. Revise and resubmit due 6/21/21. Acknowledgment of federal support (Yes).  
Madison H. Williams, Ryan A. Williams, Brian Hernandez, Joel Michalek, **Dorothy Long Parma**, Sukeshi P. Arora. Clinicopathologic differences and mortality among Latinos and non-Latino whites with gastric cancer at a majority-minority cancer center in South Texas. Submitted to *J Gastrointestinal Oncology* 2/7/21. Accepted with minor revisions 6/10/21. acknowledgment of federal support (Yes)

**Books or other non-periodical, one-time publications.**

Nothing to report

**Other publications, conference papers and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

**\*Dorothy Long Parma, MD, MPH; Susanne Schmidt, PhD; Edgar Muñoz, MS; Amelie G. Ramirez, DrPH.** Late-stage gastric cancer burden in South Texas, Texas and the U.S., 2004-2016. Mays Cancer Center Annual Conference, Jan. 13, 2021

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Databases/datasets – re-extracted/revised cohort dataset of UTMEd/UHS patients with diagnoses of *H. pylori* (HP) infection, atrophic gastritis, gastric ulcer, gastric adenocarcinoma, gastric (non-Hodgkin’s) lymphoma, gastric MALT lymphoma from 2007-2020. This version of dataset includes antibiotic regimens; repeat HP testing for HP-positive individuals; referrals to specialty services and encounters/completed appointments; census tract/block-level socioeconomic status data for ~65% of the cohort

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name:	Dorothy Long Parma, MD, MPH
Project Role:	PI
Researcher Identifier:	ORCID ID 0000-0001-8059-3392
Nearest person month:	9
Contribution to project:	Supervised data extraction, cleaning, organization and analyses, recruited providers and conducted provider interviews; created transcription summaries; wrote manuscripts/abstracts
Funding support:	Institutional (3 person-months)
Name:	Raquel Romero, MD, MPH
Project Role:	Research Coordinator
Researcher Identifier:	ORCID ID 0000-0002-7716-3364
Nearest person month:	2.4 (Dec 2020-present)
Contribution to project:	assisted in contacting providers for semi-structured interview, creating transcript summaries of transcribed provider interviews, analyzing qualitative interview data
Funding support:	HRSA U5ARH39480 (Allison PI) (1.2 person-months); Elizabeth Dole Foundation (Delgado PI) (1.2 person-months); Bexar County Health Collaborative (Tsevat PI) (0.15 person-months)

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report

**What other organizations were involved as partners?**

Name: Geographical Management of Cancer Disparities (GMAP) Region 3  
Location: University of New Mexico at Albuquerque, NM  
Contribution: financial support

## **8. SPECIAL REPORTING REQUIREMENTS**

**QUAD CHARTS:** see Appendices.

- 9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*