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## Development and Assessment of an *H. pylori* Medication Adherence and Stomach Cancer Prevention Curriculum for a Chinese American Immigrant Population

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### Background

Stomach cancer is the fifth most common cancer and the third leading cause of cancer mortality in the world with the highest mortality rates in Eastern Asia [1]. In the US, Asian Americans, including Chinese Americans, experience a disproportionate burden of stomach cancer mortality [2]. Stomach cancer incidence for Chinese Americans (69.1% of whom are foreign born) [3] is nearly twice that of non-Hispanic whites (13.8 vs 8.5 per 100,000 per year among men and 8.4 vs 3.7 among women) [4]. Up to 75% of all US stomach cancer cases present with late-stage disease, with poor 5-year survival rates (30.6%) [5]. Cancer is the leading cause of death among Chinese New Yorkers, which they experience at a much higher rate than the overall New York population (9.0 vs. 5.3 per 100,000 population) [6]. These findings underscore cancer disparities among Chinese Americans and the need for more prevention and early detection for this high-risk population.

The bacterium *Helicobacter pylori* (*H. pylori*), a Grade I human carcinogen, is the strongest risk factor for stomach cancer [7]. While data on *H. pylori* infection rates in Chinese Americans are limited, an observational study found 70.1% of NYC East Asian-born populations were *H. pylori*-infected [8]. Eradication of *H. pylori* through triple antibiotic therapy is the most effective prevention method for stomach cancer, however, it is a complicated medication regimen, with several adverse side-effects [9]. *H. pylori* treatment is

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#### Compliance with Ethical Standards

Disclosure of Potential Conflicts of Interest:

The authors have no conflicts of interest to report.

Research involving human participants and/or animals:

This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent:

This article does not contain any studies with human participants performed by any of the authors.

effective and feasible; however, it requires patient education and provider support to yield high adherence, especially for populations with limited English proficiency (LEP) and low health literacy. *H. pylori* eradication as a targeted stomach cancer prevention effort is internationally recommended for high-risk Asian communities [10]. Efforts in the US, however, are limited in practice and poorly integrated within health systems, resulting in poor medication adherence, which undermines treatment effectiveness for stomach cancer prevention. Many patients at high-risk for stomach cancer enter endoscopy clinics for dyspepsia (chronic pain or discomfort in the upper abdomen) associated with *H. pylori*, thus representing a key window for prevention. For immigrant communities, the risk of stomach cancer is compounded by difficulties in accessing healthcare services, and attendant linguistic, cultural, economic and social barriers, which may result in poor medication compliance and disease self-management skills [11].

Community health worker (CHW)-led interventions have been shown to improve screening and treatment [12, 13], yet no studies have investigated the impact of integrating these strategies into a test-and-treat *H. pylori* approach to achieve optimal medication adherence. To address this need, we developed a culturally adapted curriculum, delivered by community health workers (CHWs). This curriculum was developed to be a practical tool, specifically designed to engage limited English proficient (LEP), low health literacy and limited resource populations. The goal of the curriculum is to provide education and support to Chinese Americans who test positive for *H. pylori* as they begin treatment, with a specific focus on increasing medication adherence to eradicate *H. pylori* and therefore prevent stomach cancer.

The purpose of this article is to present the stakeholder engaged development, review, assessment, refinement and finalization of this *H. pylori* treatment adherence and stomach cancer prevention curriculum.

## Methods

### Overview

The curriculum was created through an iterative process of review and revision. The first step involved an in depth review of existing literature and online resources of current curricula in English and Chinese languages. Utilizing this knowledge, we created a draft curriculum based upon templates from our successful culturally tailored hypertension and diabetes CHW interventions [14, 15]. The second iterative step, involved a formal curriculum assessment to elicit feedback from key content experts and other stakeholders which were incorporated into subsequent revisions, until a final curriculum was developed.

### Identifying Theoretical Frameworks

Several theoretical frameworks and theories were integrated to inform the curriculum and enhance meaningful engagement of a traditionally hard to reach population. Health behavior change theories, including Social Cognitive Theory, provide a robust theoretical framework for explaining and predicting medication adherence and healthy behavior change. It comprises 3 primary constructs: *self-efficacy* (an individual's confidence to be in control of

their health); *outcome expectations* (an individual's understanding of the consequences of a behavior); and *socio-structural factors* (the facilitators and challenges to behavior that may indirectly influence health behavior and goal setting, e.g., socio-cultural norms and environment) [16]. Social Cognitive Theory addresses the complex interactions between individual factors (such as skills, knowledge, self-efficacy, including goal setting, and outcome expectancy behaviors) and the environment (models for learning and available materials) [17] and was used to guide the development of behavioral strategies. Health communication theory informed curriculum messaging to foster positive outcome expectations, beliefs about the likelihood and value of the consequences of taking medication, as well as self-efficacy, to enhance the likelihood of a desired action (goal setting) [18]. Goal setting strategies, such as maintaining a daily medication chart, were developed to improve self-efficacy and outcome expectancy behaviors to ultimately improve medication adherence to prescribed triple therapy.

Fundamental to our curriculum design was adult learning theory, which posits that for adults, learning is best accomplished through the translation of new material through individual experiences [19]. For example, in our curriculum sessions begin with an invitation for individuals to share their current knowledge and experiences with *H. pylori* and stomach cancer. Furthermore, the curriculum utilizes an asset-based approach designed to build upon existing cultural networks and norms at the community, interpersonal, and individual level, thereby empowering individuals and improving self-efficacy. The curriculum builds knowledge and health literacy on the importance of medication adherence and provides opportunities for the participant to explore his/her own experiences and challenges to guide him/her to create a personalized medication adherence plan. It also incorporates links to existing community resources such as smoking cessation programs and culturally relevant healthy eating strategies to reduce stomach cancer risks.

The curriculum was adapted to be culturally relevant to this population using an ecological validity framework, which is based on eight domains: language, persons, metaphors, content, concepts, goals, methods and context [20]. In order to ensure maximum feasibility and efficacy, the curriculum is culturally-centered, incorporating both deep (efficacy) and surface (feasibility) structure to increase relevancy and engage Chinese American immigrants. Surface structure adaptation is defined as “matching intervention materials and messages to observable, superficial (though nonetheless important) characteristics of the target population,” [21]. Examples of surface structure within this intervention include using culturally specific food on plate planners, recruiting participants using language concordant CHWs and providing the curriculum in both Chinese and English. Deep structure adaptation is defined as “understanding the cultural, social, historical, environmental and psychological forces that influence the target health behavior in the proposed target population,” [21]. Our formative research with this population has informed our deep structure adaptations. We have incorporated and acknowledged cultural beliefs regarding cancer and western and traditional medicine into our curriculum and trans-created existing tools to adapt texts to include culturally appropriate idioms.

The adaptation process was supported by the principles of social marketing through the identification of culturally appropriate messages for this population. Previous research has

shown message framing to be effective in influencing health behaviors and decision-making processes, such as cancer screening [22]. For instance, Gerend and Shepard [23] found that women presented with a loss-framed message, emphasizing the costs of not receiving a vaccine, reported higher vaccine acceptance than women presented with a gain-framed message, emphasizing the benefits of receiving the vaccine. Present-minded participants (including immigrant populations) responded more favorably to loss-framed messages.[24] Within our curriculum, completing *H. pylori* treatment correctly was described not simply as a way to resolve the infection, but as a stomach cancer prevention tool.

Community based participatory research approaches to adapting population specific interventions can increase flexibility in goal setting aspects of the program and provide a more patient centered approach, allowing participants to set and attain realistic and practical goals. The ability to adjust “restrictive, burdensome and impractical” practices, including responses to a variety of emotional needs, psychological needs, living situations and socioeconomic statuses, help focus the curriculum to the specific needs of a population [25]. Our curriculum applies some principles of community-based participatory research and uses a patient-centered approach [26]. Interactions with the CHW will be personalized to individual s preferences, needs, strengths, and natural and family supports and will include multiple examples of how the information can be incorporated into their daily lived experience. For example, some individuals may prefer daily reminders for medication adherence, while others may request and benefit from family members also receiving texts. Moreover, the curriculum is flexible so that it may be employed both in-person and over the phone taking into account the highly mobile life of this immigrant participant population.

### Developing the Curriculum (see Figure 1)

**Phase 1, January 2017 – March 2017**—Using a team based approach, we convened a curriculum development team meeting, which included researchers, content experts (such as GI experts and experts in Chinese immigrant populations), and community health workers (CHWs), to discuss the development and implementation of this intervention curriculum.

**Phase 2, January 2017 – March 2017**—Phase 2 consisted of a literature and online resource review to inform the draft curriculum. The first step undertaken in this process was a formal literature and internet review of English and Chinese language materials to provide a foundation of understanding, up-to-date knowledge, and current recommendations. Research staff searched 12 U.S. and Chinese-based web-based search engines and health information web resources using words and phrases that included “*H. pylori*” and “stomach cancer” only and in combination with other related health terms such as “treatment,” “prevention,” “risk factors.” Words and phrases included Chinese and English search terms. As there is little information about medication adherence related to treatment of *H. pylori*, we looked to previous work in tuberculosis treatment and medication adherence (a similarly difficult regimen required through completion that affects a similar target population) to enhance our evidence base to guide curriculum development.

Once this process was complete, we used our extensive experience in community-based participatory research (CBPR) and health interventions in Asian communities, including two

previous culturally tailored CHW interventions for hypertension and diabetes [14, 15] to develop a draft curriculum (flip chart) for *H. pylori* treatment and stomach cancer prevention.

**Phase 3, April 2017 – May 2017**—During phase 3, we conducted a systematic assessment of the draft curriculum. Once a draft curriculum was complete, an electronic draft and an evaluation rubric were distributed to eight professionals and experts, including a community health worker education content expert, a health education director from a community clinic that serves the Chinese immigrant patient population in NYC, a GI physician with *H. pylori* expertise, a health communications content expert with expertise in social marketing, a community based organization leader who serves the target patient community, and a community health worker. The evaluation tool utilized a Likert scale (Score 1–4) and open-ended comments fields (Ideas/Action Steps for Improvement) to collect feedback on the curriculum. The evaluation tool focused on the following domains: understandability and actionability. All questions were prefaced by the following statement: “Please indicate on a scale from 1-[Not at all] to 4-[Completely] how much you agree or disagree with the following characteristics. Please note any ideas/action steps for improvement of the characteristics.” Understandability was assessed through questions such as: *To what extent does the curriculum address the risk and protective factors of H. pylori and stomach cancer?* and *To what extent are the H. pylori and stomach cancer topics covered in a logical order?* Actionability was assessed through questions such as: *To what extent does the curriculum focus on specific behaviors for adhering to H. pylori treatment and provide clear messages about these behaviors?* and *To what extent does the curriculum focus on specific behaviors for preventing stomach cancer and provide clear messages about these behaviors?*”

**Phase 4, June 2017 – July 2017**—During phase 4, we refined the curriculum based upon assessment findings. Assessment findings were entered into a REDCap database, coded for content and analyzed for general themes using Atlas.ti (Version 7.0, Scientific Software Development, Berlin). Themes were identified and based upon the analysis the curriculum was revised by the study team, including the head researcher and CHW.

**Phase 5, September 2017 – October 2017**—During phase 5, the revised curriculum was distributed to 3 experts for final review. The three reviewers, including a GI doctor, a community clinic volunteer (neither of whom reviewed the curriculum previously), and a CHW education content expert, were provided with the major themes and scores from the first assessment analysis and were asked to provide open ended feedback and comments. Based upon their comments, the curriculum was revised again. The final curriculum was translated into Chinese by the bilingual, bicultural CHWs using a modified parallel translation process in which two translators independently translate the materials. The results were compared and differences were discussed using a team approach. The translation was completed using a consensus process [27]. This method was chosen over back translation because commonly used cultural idioms require translation of meaning and not words, which is prioritized in back translation. The final curriculum is being pilot tested and will be integrated into a community-based randomized controlled trial.

## Results

Findings from the literature and online resource review identified some health education information on *H. pylori* infection and links to stomach cancer for Chinese patients; however, no comprehensive patient curricula were found on *H. pylori* treatment adherence or on *H. pylori* infection and stomach cancer prevention. Our review of the peer-reviewed articles yielded limited articles focused on patient education interventions for *H. pylori* for Chinese or Chinese immigrant patients. These articles, for the most part, included strategies focused on providing *H. pylori* medication instructions and telephone follow-up calls for treatment adherence for the general patient population. A review of online resources using English and Chinese language search engines yielded varying sources including physician generated health blogs, hospital websites, online health magazines, social media based health forums, and online news websites of web postings, news articles and brochures. Information within these sources were developed for patients in China, Taiwan and Hong Kong and presented general *H. pylori* information such as the symptoms, transmission of *H. pylori*, and potential treatment options. Online resources were in Chinese and the available resources were not tailored for the Chinese American population.

Quantitative scores (see Figure 2) and themes from the curriculum assessment tool noted several areas for development, including: improving messaging to address the low literacy and health literacy levels of this population; enhancing the patient-centered approach; simplifying the curriculum; adding more tools and activities to improve the educational materials; and presenting more culturally appropriate examples. All respondents indicated that the curriculum clearly addressed at least one of the stated health goals, clearly informed the priority population about risk factors associated with *H. pylori* and stomach cancer, and provided multiple activities to address these risk and protective factors. From the qualitative feedback recorded in ATLAS.ti, general themes for improvement were determined and the curriculum was updated (see Table 1).

Furthermore, utilizing a consensus process of translation helped clarify curriculum meaning. For example, when adapting 10 tips for medication adherence, Tip 7: Bring another set of ears, has no meaning in Chinese and therefore had to be changed.

## Discussion

Chinese American immigrants carry a significantly elevated burden of both *H. pylori* infection and stomach cancer. Despite this high risk disparity, there remains a lack of evidence-informed education resources on *H. pylori* and stomach cancer prevention. In order to address this disparity, we developed a community health worker based *H. pylori* medication adherence and stomach cancer prevention curriculum, specially designed to engaged, inform, and empower this population.

Due to the limited information on *H. pylori* medication adherence and a lack of previous curriculums related to Chinese Americans and *H. pylori*/stomach cancer, we began curriculum development by utilizing previous templates we developed, referencing our prior experiences working with the Chinese American population, adapting existing evidence-



based materials and curricula on similar health topics, and gathering input from key stakeholders. By grounding the curriculum in theoretical frameworks, such as adult learning theory and social cognitive theory, we were able to emphasize the value of self-efficacy and goal setting. Furthermore, by utilizing an ecologic validity framework, the curriculum has both deep and surface structure relevant to the population. These documented and embedded cultural adaptations enhance the potential effectiveness of the curriculum for this LEP and low health literacy Chinese American immigrant population.

By applying a systematic review, we ensured that the curriculum will be usable for widespread adoption and dissemination. The team-based and participatory approach to developing and assessing the curriculum has allowed us to gain perspectives and assessments from a variety of stakeholders to ensure that we were creating a relevant, user-friendly, and actionable curriculum. Specifically, the active engagement of the CHWs in the development and revision process enabled us to determine key components necessary to deliver the information in an effective and culturally relevant manner. The overall process has provided individual and practical insights into how the curriculum can be modified and which aspects should be retained. The open ended questions enabled us to more richly collect feedback and comments to make culturally meaningful refinements to the curriculum. This curriculum development and assessment process can serve as a useful tool in creating curricula for low income, low health literacy, and LEP communities.

## Conclusion

Through our review, assessment, refinement, and finalization process, we were able to develop an *H. pylori* treatment adherence and stomach cancer prevention curriculum, specifically designed to engage LEP, Chinese American immigrants in NYC. Using a participatory approach, which values the input of various people within the health delivery continuum, we have maximized the potential for this tool to be both effective and adaptable.

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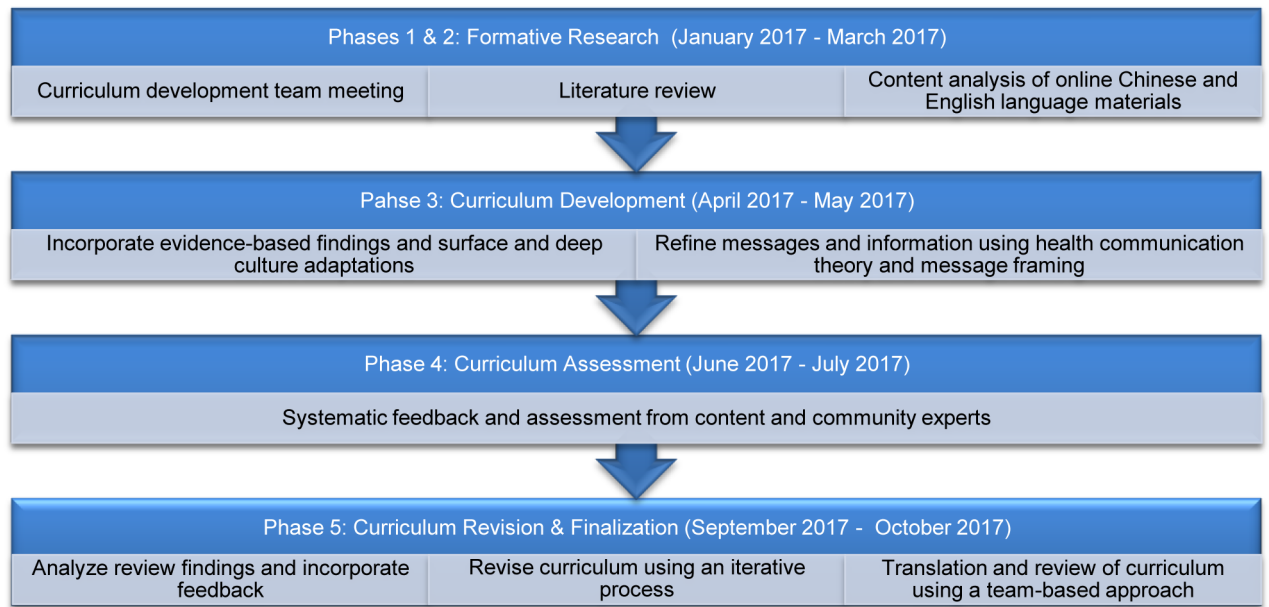
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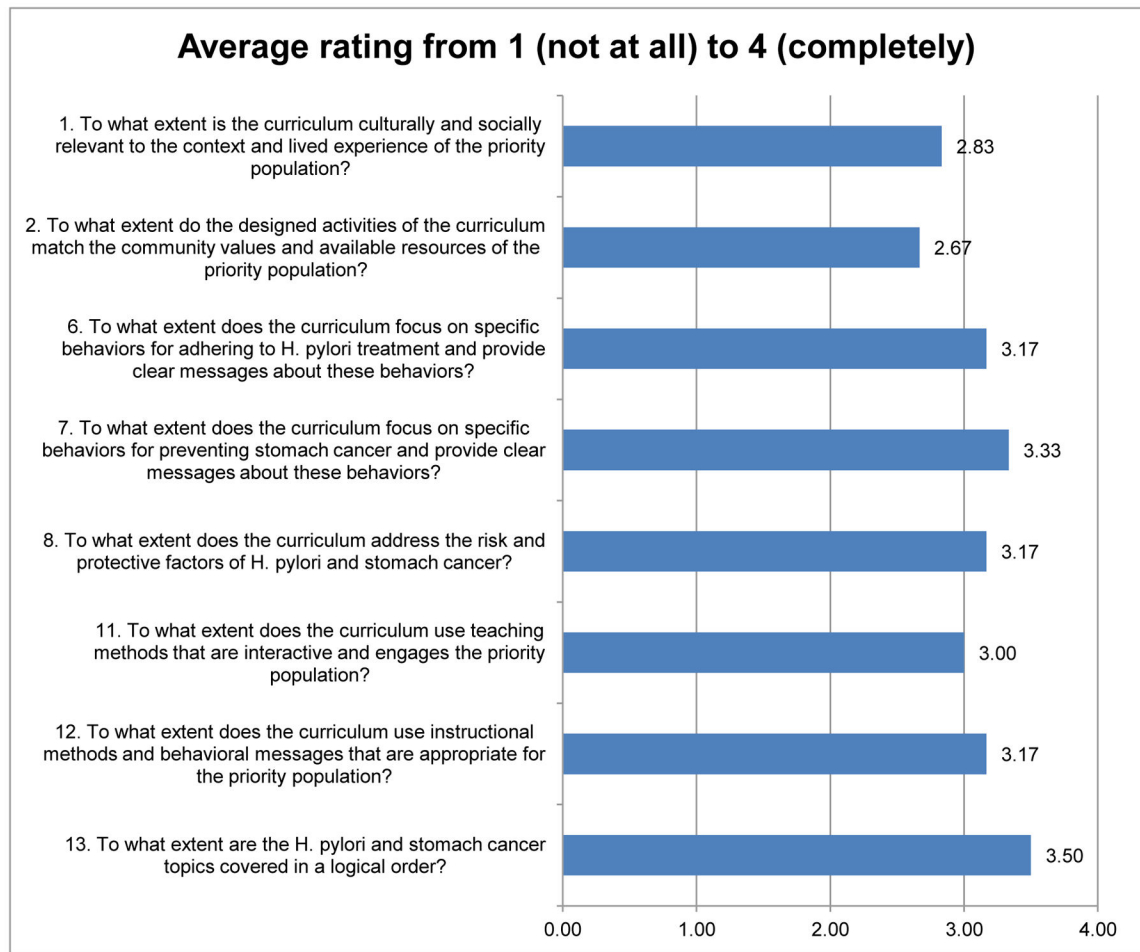
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**Fig. 1.**  
Curriculum Development Process



**Fig. 2.**  
Average Likert Ratings from Curriculum Assessment

Table 1

Themes Generated, Example Comments and Revisions made to Curriculum

Themes	Example comments	Changes made to curriculum
Curriculum Content <i>The curriculum content is complete or missing certain topics. The content is useful and informative.</i>	"I can tell that you tried to cover the foundation of gastric/stomach cancer, but I felt that it can be trimmed more." – Health education expert in target population "It's very comprehensive and informative... All the pertinent pieces of information is within the text" – Gastroenterology doctor	The information was kept much the same but the language and details were simplified to be more accessible to the readers (see subsequent comments). Feedback also recommended including specific resources, such as hotlines and community resources, which we incorporated in the relevant sections.
Relationship to Audience <i>The curriculum is culturally relevant and reflects the community values of the target audience. The messaging is appropriate or inappropriate for the target audience.</i>	"I think some more content can be tailored for the population, such as the exercises" – CHW education content expert "It would be more culturally adaptable if add the Chinese Hotline for quit smoking" – CHW for target population	The curriculum messaging, imagery and recommended tools were updated to reflect more culturally appropriate information. For example, images not reflecting exercises that participants could easily access (such as, gym-based exercises) were removed and replaced with more general, home based exercises.
Success of Educational Materials and Exercises <i>The educational materials in the curriculum utilize appropriate teaching methods to engage the target audience. The material clearly identifies the health goals of the curriculum.</i>	"I would encourage the inclusion of goal setting using MI techniques Physical activity recommendations should be included, not just descriptions of exercise" – CHW education content expert "The curriculum will definitely help one to seek care, but at times it is hard to change an individual's perspective about seeking care. Hence, combination of curriculum and CHW's effort will help bring one to care." – CHW	CDC recommendations for duration and vigor of exercise for adults were included in the physical activity section. The number of exercise suggestions was also shortened. We included more tools for the CHW to engage their participant, such as detailed examples on sending text messages (when and what to write) and clarifying how to use the medication reminder scheduling sheet.
Reading Level <i>The reading level is appropriate for the level of education and familiarity with the content of this target population.</i>	"I think for the patient population, the verbiage may need to be a bit simpler in session 1. For the typical Bellevue patient I would make it a grade to high school level of understanding" – Gastroenterology doctor	This was a common note of feedback throughout respondents. The reading level was simplified throughout the curriculum and the depth of some of the more detailed biological concepts were removed (such as detailed discuss of different stomach tissues in which gastric cancer can develop).