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Aims and Scope

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Contents

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Correction: Perceived neighborhood social cohesion and cervical and breast cancer screening utilization among U.S.-born and immigrant women

Quynh Nhu (Natasha) B. La Frinere-Sandoval*, Catherine Cubbin and Diana M. DiNitto

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1. The fifth paragraph in section 1 has been updated.

"In the United States, disparities in cervical and breast cancer screening between U.S.-born women and the rapidly growing population of immigrant women call for further examination of social factors, including community and neighborhood factors, that in addition to individual level factors (e.g., income, race/ethnicity, education), may be associated with health behaviors, such as preventive care utilization. Previous research has highlighted both individual and structural factors as important social determinants of health and underlined their relevance for influencing efforts to encourage cancer screening utilization [23]. The Social Determinants of Health conceptual framework [24] illustrates the means by which social, economic and political forces contribute to the socioeconomic stratification of populations based on various factors such as income, gender, employment, education level, marital status, and race/ethnicity. One's socioeconomic status influences these health status drivers since those with low socioeconomic status are generally more susceptible to situations that are harmful to their health. Guided by this conceptual framework, we examined the extent to which neighborhood social cohesion and sociodemographic characteristics influence screening utilization among immigrant and U.S.-born women."

2. Subsections 2.1 and 2.2 in section 2 have been updated.

2.1. Data source and study sample

Data came from the 2018 National Health Interview Survey (NHIS), a nationally representative, cross-sectional household interview survey of the U.S. civilian, non-institutionalized population. NHIS's primary goal is to continuously monitor the U.S. population's health through large scale data collection across a wide spectrum of health issues [25]. The overall sample for this population-based study was the 7801 women ages 21–64 without a hysterectomy. Of them, 7722 (99%) reported Pap test data. The overall sample also included 4211 women ages 40–64 without a hysterectomy, of whom 4087 (78%) reported mammogram data. Of the 7801 women, 1477 (19%) reported being born outside the United States and are considered immigrants. Since virtually all adults age 65 and older in the United States are eligible for Medicare, a federal health insurance program, women in this age group were excluded from

the study due to insufficient variance in their insurance status. Participants who identified as belonging to a racial group other than Non-Hispanic Asian, Non-Hispanic Black, Hispanic, or Non-Hispanic White were excluded from our study sample because their numbers were too small for multivariable statistical analyses. The University of Texas at Austin Institutional Review Board reviewed this study's protocol and determined that this is not research involving human subjects and is therefore exempt from IRB oversight.2.2. MeasuresDependent variables were Pap test and mammogram utilization meeting American Society (ACS) or U.S. Preventive Services Task Force (USPSTF) guidelines. USPSTF recommends that women ages 21−65 of average risk have a Pap test every three years [26]; therefore, we gauged Pap test screening utilization using NHIS's query about "Most recent Pap test, time categories," excluding cases that reported having a hysterectomy. Those reporting that they were screened "a year ago or less," "more than 1 year but not more than 2 years," or "more than 2 years but not more than 3 years," were coded as "Yes"; the rest were coded as "No." For mammograms, recommendations are that women ages 40 and older be screened every year [27] or every two years [28]. Using NHIS's query about having had a mammogram "a year ago or less" or "more than 1 year but not more than 2 years," we coded those in this age group who responded affirmatively to either query as "Yes" and those who chose another answer as "No."

The independent variable was perceived neighborhood social cohesion. NHIS queried participants on various neighborhood factors by asking whether they agree or disagree with each of the following four statements using a scale from 1 (definitely agree) to 4 (definitely disagree): 1) "People in this neighborhood help each other out"; 2) "There are people I can count on in this neighborhood"; 3) "People in this neighborhood can be trusted"; and 4) "This is a close-knit neighborhood." In prior studies, these four items were used to form a neighborhood social cohesion scale that demonstrated high internal consistency (Cronbach's alpha 0.93) [20,29]. Each social cohesion scale item is first reverse coded so that a higher score indicates higher social cohesion; the value of each of the four items is then summed to form a continuous variable with scores ranging from4to 16. In our study, we then standardized the summed scores so that in the multivariable analyses the odds ratios indicate neighborhood social cohesion scores as standard deviations from the mean [18]. We imputed any missing or not reported cases for each question separately as the mean of the reported cases for that specific question.

We selected control variables based on previous cancer screening utilization research [15,30,31].

Sociodemographic variables were age (years), marital status (divorced/separated/widowed, never married, married/cohabiting), and race/ethnicity (Asian, Black, Hispanic, White). Socioeconomic status (SES) variables included education (less than high school degree, high school degree, some college, or college degree), employment status (worked last week or not), family income as a share of the federal poverty level (FPL) (FPL <100%, 100–199%, 200–399%, >400%), and health insurance status

(uninsured or insured). The Census Bureau defines threshold levels of income based on family size (one or more) and age, adjusted for inflation. This base income level is uniform throughout the United States. Total family income is calculated by summing the incomes of all members of the family. The income for an individual or family can be normalized by transforming it to a percentage of the FPL. Individuals or families with income below 100% FPL are considered the lowest income group and those at or above 400% FPL, are the highest income group [32]. Nativity was defined as U.S.-born vs. immigrant, and acculturation level among immigrants was defined as years living in the United States (less than 5 years, 5–less than 10 years, 10–15 years, and >15 years).

3. Table 1 has been updated.

Table 1. Descriptive statistics for women ages 21–64, National Health Interview Survey, 2018, N = 7722.

	Immigrant (19%)	1477	U.S.-Born (81%)	6324	T or Statistic	Chi-Square	Significance Level
Age (mean)	42.3 (0.4)		40.5 (0.2)		1.77		0.0769
Race/Ethnicity					2616.00		0.0001
Asian	351 (27%)		116 (2%)				
Black	138 (11%)		894 (14%)				
Hispanic	700 (47%)		576 (11%)				
White	274 (16%)		4638 (72%)				
Marital Status					63.54		0.0001
Divorced/Separated/Widowed	271 (13%)		1280 (13%)				
Never Married	267 (15%)		1696 (26%)				
Married/Cohabiting	937 (72%)		3335 (61%)				
Education					356.63		0.0001
Less than high school degree	304 (20%)		386 (6%)				
High school degree	304 (22%)		1216 (20%)				
Some college	291 (20%)		2077 (33%)				
College graduate	569 (38%)		2631 (41%)				
Employment Status					28.64		0.0001
Did not work last week	548 (39%)		1895 (30%)				
Worked last week	927 (61%)		4427 (70%)				
Income (% of Federal Poverty Level)					101.33		0.0001
<100%	293 (17%)		864 (11%)				
100%–199%	341 (24%)		1,017 (15%)				
200%–299%	212 (15%)		944 (15%)				
300%–399%	163 (11%)		850 (14%)				
>400%	468 (32%)		2649 (45%)				
Health Insurance					152.94		0.0001
Not covered	307 (21%)		593 (9%)				

	Immigrant (19%)	1477	U.S.-Born (81%)	6324	T or Statistic	Chi-Square	Significance Level
Covered	1164 (79%)		5708 (91%)				
Years living in U.S.							
<5 years	182 (12%)						
5–less than 10 years	141 (11%)						
10–15 years	183 (12%)						
>15 years	950 (64%)						
Perceived neighborhood social cohesion							
	11.9 (0.1)		12.4 (0.1)		−5.13		0.0001
Pap-test last 3 years (ages 21–64)					21.31		0.0001
Yes	1120 (76%)		5120 (82%)				
No	348 (24%)		1170 (18%)				
Mammogram last 2 years (ages 40–64)					2.04		0.1537
Yes	514 (62%)		2168 (66%)				
No	312 (38%)		1093 (34%)				

4. Updated the subtitle of section 3 by deleting 3.1.

Participants' characteristics

5. The third paragraph and the rest of section 3 have been updated.

"Racial/ethnic disparities emerged in the sociodemographic models for Pap test utilization. Both U.S.-born and immigrant Hispanic women and U.S.-born Black women had higher odds of having a Pap test than their White counterparts. Other results were similar to the unadjusted models. An additional racial/ethnic disparity emerged in the full model with immigrant Asian women having lower odds of Pap test use than immigrant White women. Other results were similar to the unadjusted and sociodemographic models, except that for U.S.-born women, being previously married or unemployed was no longer statistically significant. For both groups, older age was associated with lower odds of getting a Pap test. Table 3 presents odds ratios and confidence intervals for mammogram utilization (for women ages 40–64).

In the unadjusted models, among immigrant women, those who had less than a high-school education, or income lower than 200% had significantly lower odds of mammogram utilization, while among U.S.-born women, those who were Asian, were previously or never married, had high-school degree or less education, were unemployed, or had income lower than 400% had lower odds of having a mammogram.

As with Pap test utilization, racial/ethnic disparities emerged in the sociodemographic model. Both U.S.-born and immigrant women who lacked insurance had lower odds of mammogram utilization. Immigrant Black women and Asian women had higher odds of mammogram utilization than their White counterparts. Among immigrant women, those who had lived in the United States for less than 10 years had lower odds of having a mammogram than those living in the United States for more than 15 years. Among U.S.-born women, those who were Asian and those who never married had lower odds of

mammogram utilization. Perceived social cohesion was associated with higher odds of mammogram utilization among U.S.-born women (OR = 1.63, CI = 1.02, 2.60).

Most of the significant factors remained in the full model. For both immigrant and U.S.-born groups, older age was associated with higher odds of mammogram utilization, while not having insurance coverage and income less than 200% was associated with lower odds. Among immigrants, Black and Asian (compared with White) women had higher odds of mammogram utilization. Those who had lived in the United States for less than 10 years had lower odds of having mammogram utilization than those living in the United States for more than 15 years. Continuing the same trend, among U.S.-born women, Black women had higher odds of mammogram utilization compared to their White counterparts. Those who had less than a high school degree had lower odds of mammogram utilization. For both groups, perceived social cohesion had no effect."6. Title of Table 2 has been updated.

Table 2. Odds ratios of Pap test utilization, NHIS, U.S., 2018, N = 7722

7. Table 3 has been updated.

Table 3. Odds ratios of mammogram utilization, NHIS, U.S., 2018, N = 408

	Unadjusted Model				Sociodemographic Models				Full Models			
	Immigrant		U.S.-Born		Immigrant		U.S.-Born		Immigrant		U.S.-Born	
	O.R.	95% C.I.	O.R.	95% C.I.	O.R.	95% C.I.	O.R.	95% C.I.	O.R.	95% C.I.	O.R.	95% C.I.
Age	1.05	[1.03, 1.08]	1.04	[1.03, 1.05]	1.04	[1.02, 1.07]	1.04	[1.03, 1.06]	1.05	[1.02, 1.07]	1.05	[1.04, 1.06]
Race/Ethnicity												
Asian	1.01	[0.69, 1.47]	0.57	[0.42, 0.77]	1.75	[1.13, 2.70]	0.71	[0.51, 0.98]	2.87	[1.70, 4.85]	0.80	[0.57, 1.13]
Black	1.32	[0.73, 2.41]	0.87	[0.67, 1.13]	2.15	[1.12, 4.11]	1.06	[0.80, 1.40]	2.83	[1.38, 5.80]	1.31	[1.00, 1.72]
Hispanic	0.87	[0.57, 1.33]	1.24	[0.49, 3.13]	0.92	[0.59, 1.42]	1.37	[0.56, 3.35]	0.97	[0.62, 1.51]	1.11	[0.45, 2.76]
White	1.00		1.00		1.00		1.00		1.00		1.00	
Marital Status												
Divorced/Separated/Widowed	0.96	[0.67, 1.36]	0.80	[0.67, 0.96]	0.75	[0.51, 1.11]	0.84	[0.69, 1.01]	0.93	[0.62, 1.42]	1.02	[0.83, 1.25]
Never Married	0.75	[0.44, 1.27]	0.58	[0.46, 0.73]	0.67	[0.37, 1.20]	0.64	[0.49, 0.83]	0.79	[0.42, 1.47]	0.77	[0.59, 1.01]
Married/Cohabiting	1.00		1.00		1.00		1.00		1.00		1.00	
Education												
Less than high school degree	0.50	[0.34, 0.74]	0.39	[0.29, 0.53]					0.69	[0.41, 1.16]	0.69	[0.48, 0.99]
High school degree	0.69	[0.47, 1.02]	0.59	[0.48, 0.74]					0.72	[0.43, 1.18]	0.76	[0.59, 0.98]
Some college	0.89	[0.57, 1.37]	0.68	[0.56, 0.82]					0.98	[0.60, 1.60]	0.76	[0.61, 0.95]
College graduate	1.00		1.00						1.00		1.00	
Employment Status												
Did not work last week	0.87	[0.66, 1.16]	0.74	[0.63, 0.87]					1.11	[0.79, 1.57]	0.83	[0.68, 1.00]
Worked last week	1.00		1.00						1.00		1.00	
Income (% of Federal Poverty Level)												
<100%	0.32	[0.21, 0.51]	0.28	[0.21, 0.36]					0.35	[0.18, 0.65]	0.42	[0.30, 0.58]
100%–199%	0.45	[0.30, 0.68]	0.44	[0.34, 0.56]					0.48	[0.28, 0.84]	0.60	[0.44, 0.82]
200%–299%	0.64	[0.37, 1.11]	0.63	[0.49, 0.81]					0.62	[0.33, 1.14]	0.77	[0.59, 1.01]
300%–399%	0.56	[0.32, 1.00]	0.72	[0.56, 0.94]					0.56	[0.29, 1.09]	0.79	[0.60, 1.04]
≥400%	1.00		1.00						1.00		1.00	
Health Insurance Coverage												
Not covered	0.26	[0.17, 0.39]	0.23	[0.18, 0.30]	0.23	[0.14, 0.36]	0.23	[0.17, 0.31]	0.27	[0.16, 0.43]	0.28	[0.21, 0.37]
Covered	1.00		1.00		1.00		1.00		1.00		1.00	
Years Living in U.S.												
<5 years	0.36	[0.18, 0.73]			0.48	[0.24, 0.95]			0.49	[0.24, 1.01]		
5–less than 10 years	0.36	[0.17, 0.77]			0.36	[0.16, 0.84]			0.41	[0.17, 0.97]		
10–15 years	0.79	[0.47, 1.32]			0.91	[0.53, 1.57]			1.03	[0.59, 1.79]		
>15 Years	1.00				1.00				1.00			
Perceived Neighborhood Social Cohesion												
	0.68	[0.29, 1.63]	1.70	[1.09, 2.65]	0.81	[0.32, 2.08]	1.63	[1.02, 2.60]	0.80	[0.30, 2.12]	1.27	[0.79, 2.04]
Perceived Neighborhood Social Cohesion Squared												
	1.73	[0.71, 4.20]	0.69	[0.44, 1.07]	1.37	[0.53, 3.54]	0.69	[0.43, 1.10]	1.37	[0.51, 3.69]	0.83	[0.52, 1.33]

8. The third paragraph in section 4 has been updated.

"The sociodemographic model also revealed racial/ethnic disparities in Pap test utilization that are contrary to commonly reported trends. For example, like some previous studies, we found that among both U.S.-born and immigrant groups, Hispanic women had higher odds of Pap test use than White women [36] and that among the U.S.-born, Black women had higher odds of Pap test use than White women [37]. Any obstacles these groups may have faced in obtaining preventive services might have been overcome through increased access and outreach. For example, national and regional programs and initiatives have been launched that are specifically tailored to racial minority populations in an effort to reduce disparities and improve cancer screening among these groups [37]. In the full model for immigrant women, consistent with other studies [11,38], another racial/ethnic disparity emerged in that Asian women had lower odds of Pap test screenings than their White counterparts. However, pooling NHIS data from 4 years (2005, 2008, 2013, 2015), Endeshaw et al. [39] found that the likelihood of having received a Pap test within 3 years for immigrant Southeast Asian women was comparable to U.S.-born women. Although those results suggest that Pap test utilization has increased in recent years among Asian immigrant women, our study indicates that this group remains at risk of underutilization of cervical cancer preventive screenings. In comparing Asian immigrants to White immigrants, we found that disparities in utilization persist."

9. The sixth paragraph in section 4 has been updated.

"Regarding mammogram utilization, racial/ethnic disparities as well as differences by nativity emerged in the sociodemographic model. Recent statistics showed that Black women now have slightly higher mammography use rates than other women [41], and our study also shows this for Black versus White immigrants. Asian women in the United States are reported to have lower rates of mammogram utilization than White women [41]. In our study, U.S.-born Asian women had higher odds of using mammography screening than their White U.S.-born counterparts in the unadjusted model; however, after adjusting for socioeconomic factors in the full model, that finding remained significant for Asian immigrants only. Since Asian Americans are the most diverse racial group in the United States, and significant socioeconomic variation exists across Asian subgroups [10], more research is needed to examine mammography utilization between and within subgroups by nativity and other acculturation measures. In the full model, socioeconomic and demographic factors had varied effects by women's nativity. Immigrant women who had lived in the U.S. between 5 and 10 years and U.S-born women with less than a high-school education had lower odds of mammogram utilization than their comparison groups, White immigrants and White U.S. born, respectively. Future studies should further investigate relationships between these factors so that policy and other interventions can be better tailored to reduce socioeconomic, racial/ethnic, and nativity-based disparities in mammogram use."

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Impact of sex and comorbid diabetes on hospitalization outcomes in acute pancreatitis: A large United States population-based study

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ABSTRACT

Backgrounds: Data on the association between comorbid diabetes mellitus (DM) and acute pancreatitis (AP) remains limited. Utilizing a large, nationwide database, we aimed to examine the impact of comorbid diabetes mellitus on patients admitted for acute pancreatitis. Methods: This was a retrospective case-control study of adult patients with AP utilizing the National Inpatient Sample from 2015–2018, using ICD–10 codes. Hospitalization outcomes of patients admitted for AP with comorbid DM were compared to those without comorbid DM at the time of admission. The primary outcome was a mortality difference between the cohorts. Multivariable-adjusted cox proportional hazards model analysis was performed. Data was analyzed as both sex aggregated, and sex segregated. Results:940,789 adult patients with AP were included, of which 256,330 (27.3%) had comorbid DM. Comorbid DM was associated with a 31% increased risk of inpatient mortality (aOR: 1.31; p = 0.004), a 53% increased risk of developing sepsis (aOR: 1.53; p = 0.002), increased hospital length of stay (LOS) (4.5 days vs. 3.7 days; p < 0.001), and hospital costs ($9934 vs. $8486; p < 0.001). Whites admitted for AP with comorbid DM were at a 49% increased risk of mortality as compared to Hispanics (aOR: 1.49; p < 0.0001). Different comorbidities had sex-specific risks; men admitted for AP with comorbid DM were at a 28% increased risk of mortality (aOR: 1.28; p < 0.0001) as compared to women. Men with comorbid DM plus obesity or hypertension were also at increased risk of mortality as compared to women, whereas women with comorbid DM plus renal failure were at greater risk of mortality as compared to men. Conclusions: Comorbid DM appears to be a risk factor for adverse hospitalization outcomes in patients admitted for AP with male sex and race as additional risk factors. Future prospective studies are warranted to confirm these findings to better risk stratify this patient population.

Keywords: acute pancreatitis; diabetes; hospitalization outcomes; race, renal failure; sex differences

1. Introduction

Acute pancreatitis is a common indication for inpatient hospital care in the United States with an annual incidence of 13–45 cases per 100,000 persons [1–3]. The focus of the management of acute pancreatitis has been on rapid diagnosis; the determination of the severity of the disease for determining the level of care required; and consideration of causative factors for addressing during acute management and

planning prevention of recurrent attacks [1]. Sex differences exist in the etiology of pancreatitis; alcohol and tobacco predominate in men, whereas idiopathic and obstructive etiologies predominate in women [4].In addition to severity determination, there are several clinical factors that increase the risk of complications or death with an episode of acute pancreatitis. These factors include advanced age (≥60 years), obesity and a history of heavy alcohol use [5]. Numerous and severe coexisting conditions measured by an increased Charlson comorbidity index (a score of ≥2) are associated with increased morbidity and length of stay with an episode of acute pancreatitis [5–7]. Although the Charlson comorbidity index includes the presence of diabetes and diabetes with complications, we are not aware of any studies that show the specific effect of comorbid diabetes on the course of acute pancreatitis in men and women.

The prevalence of diabetes has increased significantly in the United States over the past three decades [8] suggesting that greater numbers of patients presenting with acute pancreatitis have comorbid diabetes. This trend prompted us to determine the effect of comorbid diabetes on the course of acute pancreatitis. Furthermore, because the prevalence of diabetes is greater in men than women [9], wanted to do determine if there is a sex difference of the impact of comorbid diabetes on outcomes in acute pancreatitis. To address these questions, we utilized a large nationwide database to investigate the impact of comorbid diabetes mellitus (DM) in men and women admitted for management of an episode of acute pancreatitis (AP).

2. Materials and methods

2.1. Data source

In this retrospective case-control study, we utilized the National Inpatient Sample (NIS) database from 2015–2018. The NIS is the largest publicly available database of inpatient stays derived from billing data based upon discharge abstracts. The NIS database contains data from over 4500 hospitals in 48 US states and is thus considered to be nationally representative. It contains de-identified clinical and nonclinical elements at both the patient and hospital level and can be queried based upon International Classification of Diseases, tenth Revision, Clinical Modification (ICD–10 CM) coding terms.

2.2. Ethical consideration

This study did not require institutional review board approval as it uses publicly available de identified data.

2.3. Study population and inclusion criteria

Patients hospitalized for a primary diagnosis of AP (based upon the ICD–10 code K85) between 2015–2018 were selected from the general population. All patients under the age of 18, admissions that were elective, or patients with incomplete information on sex, age, or demographics, were excluded.

Thereafter, those patients admitted for AP were stratified based upon the presence or absence of comorbid DM at the time of hospitalization. Patient and hospital-level characteristics were compared between these two groups (those with vs. without comorbid DM). Additionally, the impact of comorbid DM upon hospitalization outcomes were assessed. Finally, in the cohort of patients admitted for AP who also had comorbid DM, we examined the effect age, sex, demographics, and other common comorbidities had on hospital outcomes.

2.4. Study variables

Variables included patient age (>65 vs. <65); sex (Women vs. Men); race (Black, Hispanic, Native American, Asian-Pacific Islander vs. white); the presence of obesity; the presence of hypertension; and the presence of renal impairment. All variables were assessed for their impact on inpatient mortalityin the cohort of patients hospitalized for AP who also had comorbid DM. Burden of comorbidities was assessed using the Elixhauser comorbidity indices.

2.5. Primary and secondary outcomes

The primary outcome was the inpatient mortality and sex differences in patients admitted for AP with vs. without comorbid DM. Secondary outcomes included the difference in (a) mean hospitalization LOS, (b) mean hospitalization cost, (c) risk of sepsis (based upon the ICD–10 codes A40 and A41), and (d) discharge disposition between these two cohorts.

2.6. Statistical analysis

Statistical analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, North Carolina). Weighting of patient-level observations was implemented. Univariate analysis was initially performed to calculate an unadjusted odds ratio and determine confounders significantly associated with the outcomes. Multivariable-adjusted cox proportional hazards model analysis was used to adjust for potential confounders. A multivariable-adjusted cox proportional hazards regression model was then built by including all confounders that were found to be significant by univariate analysis, to calculate an adjusted odds ratio. Sex was then also used as an independent variable to perform analyses related to the mortality difference amongst cohorts (i.e., those with vs. without the comorbidities of interest). Proportions were compared using chi-square test for categorical variables, and Student's t-test for continuous variables. All p-values were two-sided, with 0.05 as the threshold for statistical significance.
30 comorbidities were taken into account among which: Congestive heart failure, Cardiac arrythmias, Valvular disease, Pulmonary circulation disorders, peripheral vascular disorders, Hypertension, paralysis, neurodegenerative disorders, uncomplicated diabetes, complicated diabetes, hypothyroidism, renal failure, liver disease, peptic ulcer disease excluding bleeding, AIDS/HIV, lymphoma, metastatic

cancer, solid tumor without metastasis, rheumatoid arthritis/collagen vascular diseases, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, blood loss anemia, deficiency anemia, alcohol abuse, drug abuse, Psychoses, and depression.

3. Results

3.1. Patient demographics and hospital characteristics

940,789 adult patients with a diagnosis of AP were included in the study. Of these, 256,330 (27.3%) had comorbid DM and 684,460 (72.7%) did not. The cohort of patients whom had comorbid DM were significantly older (mean age of 55.6 years vs. 49.5; $p < 0.0001$), more likely to be men (56.7% vs. 51.9%; $p < 0.001$), obese (27.2% vs. 13.4%; $p < 0.0001$), have hypertension (77.4% vs. 48.1%; $p < 0.001$), and have renal failure (16% vs. 5.6%; $p < 0.001$); and less likely to be white (54.8% vs. 64.5%; $p < 0.001$) compared to the cohort of patients whom did not have DM upon hospitalization for AP. Additional patient and hospital characteristics for both cohorts are presented in Table 1. A total of 37 different comorbidities were reported in this patient population but only 8 of those comorbidities were associated significantly with DM in AP (Table 1).

3.2. Mortality

The primary outcome, all-cause inpatient mortality in the cohort of patients with comorbid DM, who were admitted for AP, was observed in 0.67% of admissions vs. 0.46% in the cohort who did not have comorbid DM. In an unadjusted analysis comorbid DM was associated with a 58% increased risk of inpatient mortality (OR: 1.58; 95% CI: 1.71–1.98; $p = 0.005$). Upon multivariable analysis, comorbid DM was associated with a 31% increased risk of inpatient mortality (aOR: 1.31; 95% CI: 1.84–1.97; $p = 0.004$) (Table 2).

Men admitted for AP who had comorbid DM were at a 28% increased risk of mortality (0.71% vs 0.61%, (aOR: 1.28; 95% CI: 1.05–1.44; $p < 0.0001$) as compared to women. Patients >65 years of age, admitted for AP who had comorbid DM were at a 219% increased risk of mortality (1.43% vs.0.36%, aOR: 3.19; 95% CI: 2.79–3.67; $p < 0.0001$) as compared to those <65 years of age. Whites admitted for AP whom had comorbid DM were at a 49%, 21%, and 7% increased risk of mortality as compared to Hispanics (0.80% vs. 0.30%, (aOR: 1.49; 95% CI: 1.42–1.62; $p < 0.0001$), Blacks (0.80% vs. 0.60%, aOR: 1.21; 95% CI: 1.11–1.68; $p < 0.0001$), and AP Islanders (0.80% vs. 0.74%, aOR: 1.07; 95% CI: 1.01–1.18; $p < 0.0001$), respectively (Table 2).

Table 1. Baseline patient and hospital characteristics of the study population

NIS 2015–2018 Baseline characteristics N = 940,789	Acute pancreatitis with DM N = 256,330 (27.3%)	Acute pancreatitis without DM N = 684,460 (72.7%)	P-value
Age			<0.0001
Mean years (Mean ± SD)	55.6 ± 15.3	49.5 ± 17.7	
Sex			<0.0001
Men	56.7%	51.9%	
Women	43.3%	48%	
Age groups			<0.0001
<18	0.4%	2.3%	
18–34	8.6%	19.5%	
35–49	25.8%	29.1%	
50–64	36.5%	28.7%	
65–79	22.1%	14.2%	
≥80	6.6%	6.1%	
Race			<0.0001
White	54.8%	64.5%	
Black	19.4%	15.2%	
Hispanic	16.2%	12.9%	
Ap Islander	9.2%	7.2%	
Other	0.04%	0.02%	
Insurance type			<0.0001
Medicare	39.9%	26.5%	
Medicaid	21.3%	25.9%	
Private	28.7%	33.5%	
Other	10.1%	14.1%	
Elixhauser Comorbidities			
Congestive heart failure	9.9%	4.1%	<0.0001
Valvular disease	2.5%	1.9%	<0.0001
Peripheral vascular disease	3.9%	2.8%	<0.0001
Hypertension	77.4%	48.1%	<0.0001
Renal failure	16%	5.6%	<0.0001
Liver disease	19%	16.3%	<0.0001
Rheumatoid arthritis/collagen			
Vascular disease	2.5%	2.3%	<0.0001
Obesity	27.2%	13.4%	<0.0001
Hospital ownership/control			<0.0001
Rural	12.3%	11.7%	
Urban nonteaching	26.6%	26.5%	
Urban teaching	61.1%	61.7%	

NIS 2015–2018 Baseline characteristics N = 940,789	Acute pancreatitis with DM N = 256,330 (27.3%)	Acute pancreatitis without DM N = 684,460 (72.7%)	P-value
Income quartile by zip code			<0.0001
0–25th	36.1%	31.2%	
26–50th	26.9%	26.7%	
51–75th	22.2%	23.8%	
76–100th	14.8%	18.2%	
Geographic region			<0.0001
Northeast	15.7%	17.1%	
Midwest	22.1%	22.5%	
South	43.1%	40%	
West	18.9%	20.4%	
Hospital Bed size			<0.0001
Small	23%	24%	
Medium	30.5%	30.6%	
Large	46.4%	45.4%	

Table 2. Multivariable analyses of factors affecting mortality in Diabetic patients admitted for Acute pancreatitis.

Characteristics	Mortality in patients with Acute Pancreatitis	
	Percentage (%)	95 % CI
		$P = 0.004$
Patients with DM	0.67	aOR: 1.31; (95% CI, 1.84–1.97)
Patients without DM	0.47	
Sex		$P < 0.0001$
Men with DM	0.71	aOR: 1.28; (95% CI, 1.05–1.44)
Women with DM	0.61	
Age		$P < 0.0001$
≥65 with DM	70.9	aOR: 3.19; (95% CI, 2.79–3.67)
<65 with DM	29.1	
Ethnicities comparisons among DM patients		
Whites vs. Hispanics	0.80 vs. 0.30	aOR: 1.49; (95% CI: 1.42–1.62) $p < 0.0001$
Whites vs. Blacks	0.80 vs. 0.60	aOR: 1.21; (95% CI: 1.11–1.68) $p < 0.0001$
Whites vs. Pacific Islanders	0.80 vs. 0.74	aOR: 1.07; (95% CI: 1.01–1.18) $p < 0.0001$
Associated Comorbidities		
DM and obesity	0.72	aOR: 1.17; (95% CI: 1.15–1.19) $p < 0.0001$
DM and Hypertension	0.77	aOR: 1.19; (95% CI: 1.32–1.45) $p < 0.0001$
DM and renal failure	0.93	aOR: 1.31; (95% CI: 1.25–1.63) $p < 0.0001$

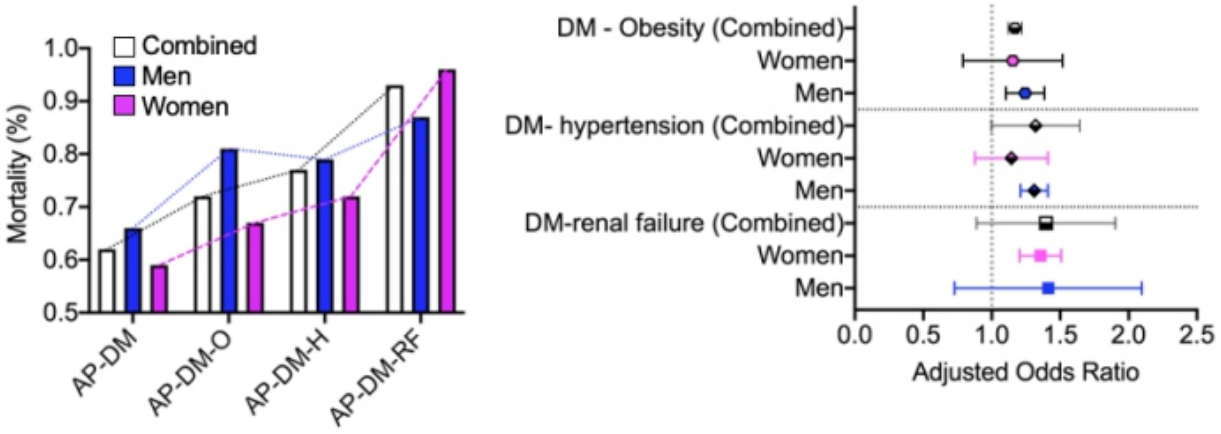

Figure 1. Sex aggregated and segregated data pertaining to mortality associated with comorbid Diabetes mellitus (DM) plus a secondary comorbidity vs. those with only comorbid DM.

Compared to those without comorbid DM, patients admitted for AP whom had comorbid DM were at a 38%, 41%, and 66% increased risk of mortality if they also had comorbid obesity (32% vs. 0.72%, aOR: 1.38; 95% CI: 1.25–1.59; p <0.0001), hypertension (32% vs. 0.77%, aOR: 1.41; 95% CI: 1.32–1.78; p < 0.0001), or renal failure (32% vs. 0.93%, aOR: 1.66; 95% CI: 1.29–1.87; p < 0.0001), respectively. Data segregated by sex showed men and women have different risks for mortality (Figure 2).

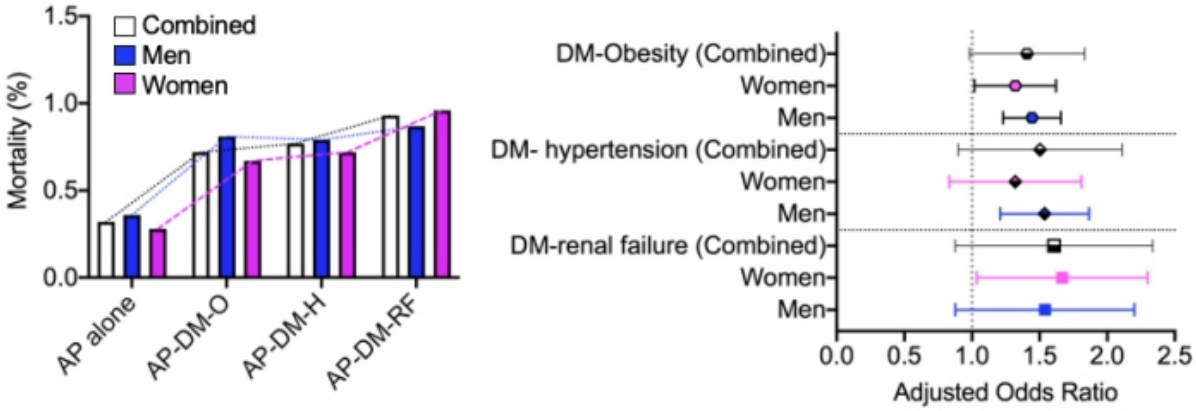

Figure 2. Sex aggregated and segregated data pertaining to mortality associated with Comorbid Diabetes mellitus (DM) plus comorbid obesity, hypertension, or renal failure vs. those without any of these comorbidities.

Compared to those without any of the aforementioned comorbidities, patients admitted for AP who had comorbid DM, obesity, hypertension, and renal failure together were at a 116% increased risk of mortality (0.32% vs. 1.18%, aOR: 2.16; 95% CI: 2.04–2.31; p = 0.007). Data segregated by sex revealed differences in risks for different comorbidities (Figure 3).

Figure 2. Sex aggregated and segregated data pertaining to mortality associated with Comorbid Diabetes mellitus (DM) plus comorbid obesity, hypertension, or renal failure vs. those without any of these comorbidities.

Compared to those without any of the aforementioned comorbidities, patients admitted for AP who had comorbid DM, obesity, hypertension, and renal failure together were at a 116% increased risk of mortality (0.32% vs. 1.18%, aOR: 2.16; 95% CI: 2.04–2.31; p = 0.007). Data segregated by sex revealed differences in risks for different comorbidities (Figure 3).

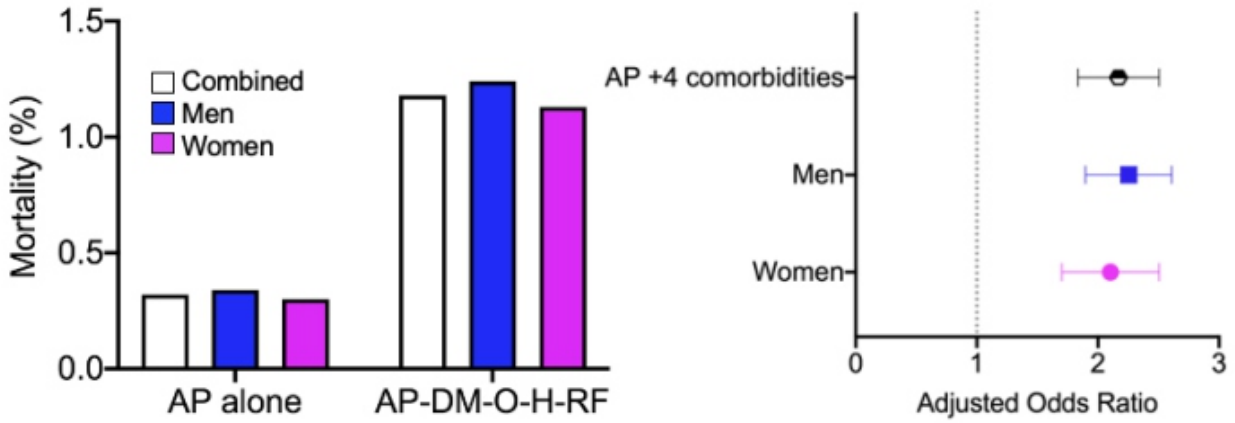

Figure 3. Sex aggregated and segregated data pertaining to mortality associated with Comorbid Diabetes mellitus (DM) plus obesity, hypertension, and renal failure compared to those without any of these comorbidities.

3.3. Sex differences in other comorbidities for AP outcomes

Next, we analyzed if there were sex differences in AP outcomes with or without other comorbidities. Men compared to women with comorbid DM plus obesity or hypertension vs. none of these comorbidities had an aOR 1.15, 95% CI: 0.77–1.13, p = 0.18 and an aOR 1.21, 95% CI: 0.11– 1.41, p = 0.004, respectively. Men compared to women with comorbid DM plus obesity or hypertension vs. only comorbid DM had an aOR 1.19, 95% CI: 1.13–1.47, p < 0.001 and an aOR 1.26, 95% CI: 0.1.17–1.35, p = 0.002, respectively. Women compared to men with comorbid DM plus renal failure vs. none of these comorbidities had an aOR 1.09, 95% CI: 0.97–1.22, p = 0.27 (not significant).

In contrast, women compared to men with comorbid DM plus renal failure vs. only comorbid DM had an aOR 1.08, 95% CI: 1.02–1.18, p = 0.01.

3.4. Sepsis

Sepsis during hospitalization in the cohort of patients with comorbid DM, who were admitted for AP, was observed in 1.86% of admissions vs. 1.13% in the cohort who did not have comorbid DM. In an

unadjusted analysis comorbid DM was associated with a 132% increased risk of developing sepsis (OR: 2.32; 95% CI: 2.11–2.83; p = 0.005). Upon multivariable analysis, comorbid DM was associated with a 53% increased risk of developing sepsis (aOR: 1.53; 95% CI: 1.09–1.55; p = 0.002).

3.5. Healthcare utilization outcomes

The cohort of patients admitted for AP who had comorbid DM, had significantly increased hospital LOS (4.5 days vs. 3.7 days; p < 0.001, hospital costs ($9934 vs. $8486; p < 0.001), and decreased odds of discharge to home (81.7% vs. 87.4%, p < 0.001) as compared to the cohort who did not have comorbid DM. Upon multivariable analysis, comorbid DM was associated with 18% lower odds of being discharged to home (aOR: 0.82; 95% CI: 0.73–0.94; p = 0.002).

4. Discussion

This is a first large retrospective case-control study of adult patients with AP to report that comorbid diabetes mellitus is associated with a 31% increased risk of inpatient mortality, a 53% increased risk of developing sepsis, increased hospital length of stay, and hospital costs. A total of 37 different comorbidities were reported in this patient population but we found only 8 of those comorbidities were associated significantly with DM in AP. Overall, men compared with women with AP and comorbid DM, obesity and/or hypertension had worse outcomes and increased mortality. In contrast, women compared with men with AP and comorbid renal failure had worse outcomes and increased mortality. Differences in ethnicity and race were also noted. While several risk factors are shared between men and women for AP, our data suggests that diabetes, obesity, and hypertension render men more susceptible to worse outcomes for AP, whereas renal failure makes women more susceptible to worse outcomes for AP. In men worldwide, factors such as smoking, alcohol, abdominal obesity, and diabetes account for the overall increased risk of developing AP. Women on the other hand, show a greater risk of biliary pancreatitis and postendoscopic retrograde cholangiopancreatography pancreatitis [10,11].

Sex differences in AP may arise due to anatomical differences in pancreas size between men and women.Another retrospective study revealed that women compared to men with AP were less likely to die, had lower incidence of sepsis, shock, acute kidney injury, and pancreatic drainage than men with AP [12]. While ICU admissions incidence were lower women with AP than men, the mean length of stay and hospital charges and cost did not differ by sex [12].

Increased risk of severe acute pancreatitis is associated with intra-abdominal, omental fat and intra-pancreatic fat distribution [13,14]. While men compared to women have a greater propensity for developing intra-abdominal fat, other studies report that risk for severe AP is similar in men and women with similar intra-abdominal fat content [15]. Our data suggests that men compared to women with comorbid obesity have worse AP outcomes and have a higher mortality rate. Higher intra-pancreatic fat mass increases the risk for severe acute pancreatitis, [13] but sex differences have not been studied in the

context of intra-abdominal versus intra-pancreatic fat mass distributions; mechanisms remain largely unexplored [14].

5. Conclusions

In conclusion, we report that comorbid diabetes, obesity, hypertension, and renal failure increases the risk of mortality and worse outcomes for patients with acute pancreatitis; only 8 out of 30 comorbid conditions worsen AP outcomes. Comorbid diabetes, obesity, and hypertension have worse outcomes for men, whereas comorbid renal failure has worse outcomes for women. When evaluating treatment regimens, these comorbid conditions and outcomes should be taken into account.

Conflict of interest

The authors declare no conflict of interest.

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"Mind the Gap" - An overview of the role of the Extensions Community Healthcare Outcomes (ECHO) model in enhancing value

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ABSTRACT

The ECHO (Extensions Community Healthcare Outcomes) model of healthcare delivery has grown rapidly since its establishment and increased in popularity in recent years. This expansion has developed alongside the growing incidence of chronic diseases and the need to better manage them. The increasing uptake in ECHO has presented a requirement to assess its true value as healthcare costs are increasing globally, resulting in a growing demand by governments and policy makers to ensure chronic disease management strategies provide true value. Therefore, the aim of this review is to examine the impact that ECHO has on clinical practice and how such impacts are measured or evaluated. A narrative literature review is carried out to examine the outcomes assessed in ECHO related studies. Three key academic databases were utilised for the literature search: Web of Science, PubMed, and Medline. Keywords relating to the review were chosen and searched for. Papers were screened using specified inclusion and exclusion criteria relating to years of publication (2000–2020), type of publication (original research, review papers and meta-analyses) and language requirements (English language only). This review found that while the ECHO model is expanding, and improving the so-called "knowledge gap" between specialists and primary care physicians, there is also a gap in the ways value is examined within ECHO. Most studies on ECHO lack an examination of patient reported health outcomes and appropriate, comparative costing methods. Current ECHO-related studies lack vital components that demonstrate the value of the model. Such components include patient reported health outcomes and detailed costing comparisons between the ECHO model and the traditional care pathway it is replacing.

Keywords: ECHO; patient reported outcomes measures; healthcare management;telemedicine; e-health; digital healthcare

1. Introduction

Chronic disease incidence rates are at unprecedented levels. In 2020 chronic disease contributed to some 73% of global deaths [1]. The increasing complexities associated with chronic conditions require more specialised, multidisciplinary medical teams and a more integrated approach to care [2]. Alongside the growing burden of chronic disease, multimorbidity is becoming an increasing issue as life-expectancy also continues to increase. Multimorbidity is defined as being "the coexistence of two or more chronic conditions" [3]. Most people living with one chronic condition, will often have associated co-morbidities [4]. As non-communicable diseases reach epidemic proportions [5] so too does the associated cost and the pressure they put on healthcare infrastructure worldwide. Both spending on chronic conditions and their overall costs are increasing [6]. Multiple morbid conditions often result in

patients availing of more hospital resources, pharmacological interventions and even admissions [7]. Rapoport et al. [8] found that appointments with doctors increase by a half per each chronic condition experienced by a patient.

The World Economic Forum [9] predicts that chronic disease may cost as much as USD 47 trillion by 2030 and as such there is an increasing need to better manage chronic disease. While most people in the developed world have access to a general practitioner in a primary care setting, specialty care is not as widely accessible [10]. It has been well-discussed and documented in the literature that rural areas lack the same healthcare resources that their urban counterparts [11]. Medical diversity is another issue faced in rural medicine. In 2004, 41% of physicians in rural areas of 10,000 people or less were family physicians [12]. These factors have acted as motivating drivers for the formation of the ECHO (Extension in community healthcare outcomes) project and hence the ECHO model was born out of these necessities in the early 2000s.

The concept of the ECHO model is a simple one. The model centres around an expert or a team of experts such as a consultant or multidisciplinary team. This expert or team of experts conduct regular telehealth meetings on an online video platform which non-expert physicians can join to learn more about a particular disease, ask questions or even present patient case-studies for expert input [13].

Due to the challenges faced by rural medicine, the ECHO model was initially established by Dr Arora to better manage the growing prominence of the Hepatitis C Virus (HCV) in New Mexico amongst underserved and rural communities. New Mexico is a largely rural state [13] and as such, patients in remote areas often did not have access to specialist healthcare. The HCV epidemic originated from mass infection in the 1970s and 1980s [14]. By the early 2000s numerous people were left without specialist care due to their rural location. Before the commencement of ECHO, approximately 1,600 patients received care for HCV despite around 34,000 patients suffering with the virus [15]. The ECHO project began with specialist care teams holding weekly tele-ECHO meetings in which the specialist and community providers use video technology to communicate via a hub and spoke platform (Figure 1). Physicians can join from remote locations to learn from both each other and the specialists present. The tele-meeting was the first of its kind to provide an opportunity for rural physicians to troubleshoot and present complex medical cases. It enabled primary care physicians to treat patients they would have otherwise referred elsewhere [16]. The concept enabled thousands to receive specialist care from their own physician. The aim of ECHO was to deliver specialist care to those remote, underserved geographical areas that would otherwise be overlooked.

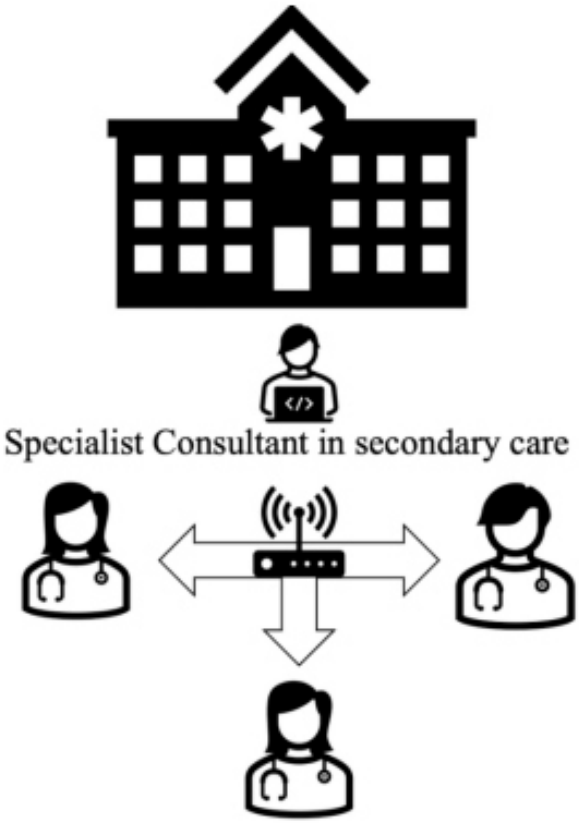

Figure 1. A configuration of the ECHO model (Concept illustration by authors).

ECHO has since grown [17] and now spans over 4600 different programs and over 191 countries [18].

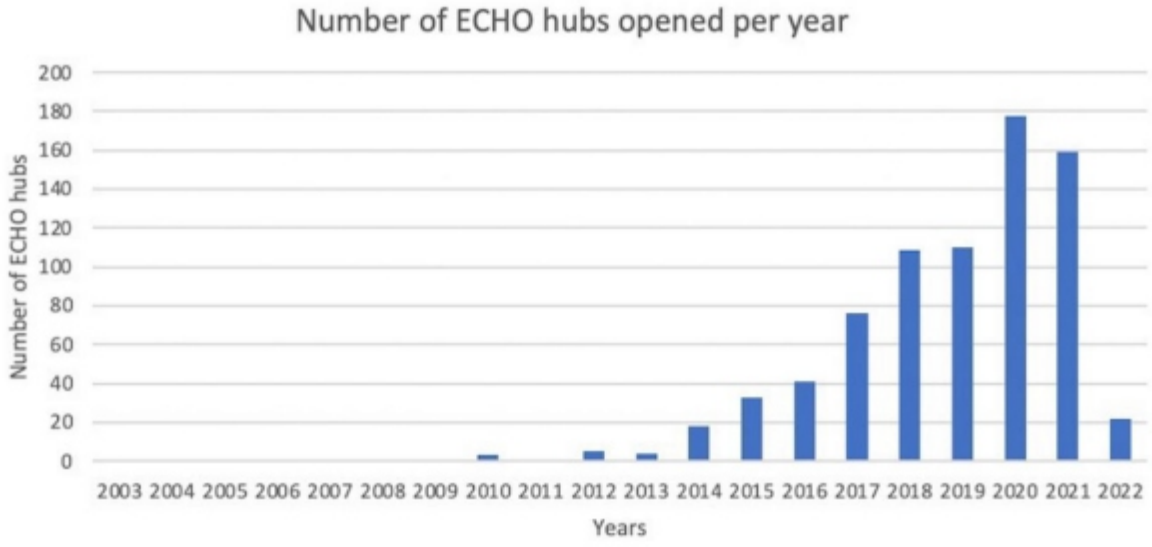

Figure 2. ECHO Hub launches in the US by year [18].

This growth warrants an in-depth analysis of the true impact of ECHO. This growth warrants an in-depth analysis of the true impact of ECHO. Therefore, the overall aim of this review is to examine common clinical outputs such as: healthcare outcomes, healthcare professional competencies and cost. In order to properly assess the true value provided by ECHO healthcare outcomes and compare it to other healthcare interventions, the cost of the intervention must be analysed.

2. Methodology

Papers for the review were searched on a range of reputable, academic databases (Figure 3) including Web of Science, PubMed and Medline using the following search terms: "ECHO model", "Project ECHO", "Extensions in Community Healthcare Outcomes", "Extensions in CommunityHealthcare Outcomes project", "telehealth" and "telemedicine". Suitable papers were those relevant to the topic that met the inclusion criteria. Following the initial search, papers were hand-selected on reading the abstracts of papers. Inclusion criteria for this paper included: publication date between 2000–2020, full-text papers available in English and categorised as any of the following: original research, review papers and meta-analyses. If a paper met all of the inclusion criteria it was read in full by the author. Similarly, if there was any ambiguity surrounding a paper's suitability, it was also read in full. If the full text revealed that not all the inclusion requirements were present, the paper was excluded. Suitable papers were read in full and then categorised into their relevance to the review.

Additional literature was then acquired using the snowball method in which already-included literature led to more relevant papers. A framework with two broad categories was predefined: clinical disease applications and the impact of ECHO, which included the previously defined outcomes of the model - the clinical outcomes of the patient, the impact ECHO has on professional competency and ECHO's potential for cost-saving. An individual paper could be categorised into more than one field. The review was further expounded by reading each category separately and regrouping papers where appropriate. Data obtained for certain statistical information were gathered by directly targeting appropriate websites [1,5].3. ResultsECHO has been used in a wide range of chronic diseases across numerous clinical areas. Some of its applications are:

3.1. A tool in chronic disease management

Using Hepatitis C as a model [15] ECHO branched into other disease areas, including chronic disease. Due to the complex, wide-ranging and highly specialised nature of chronic disease, ECHO provides clinicians in primary care with the expertise and education to treat patients without referral elsewhere.

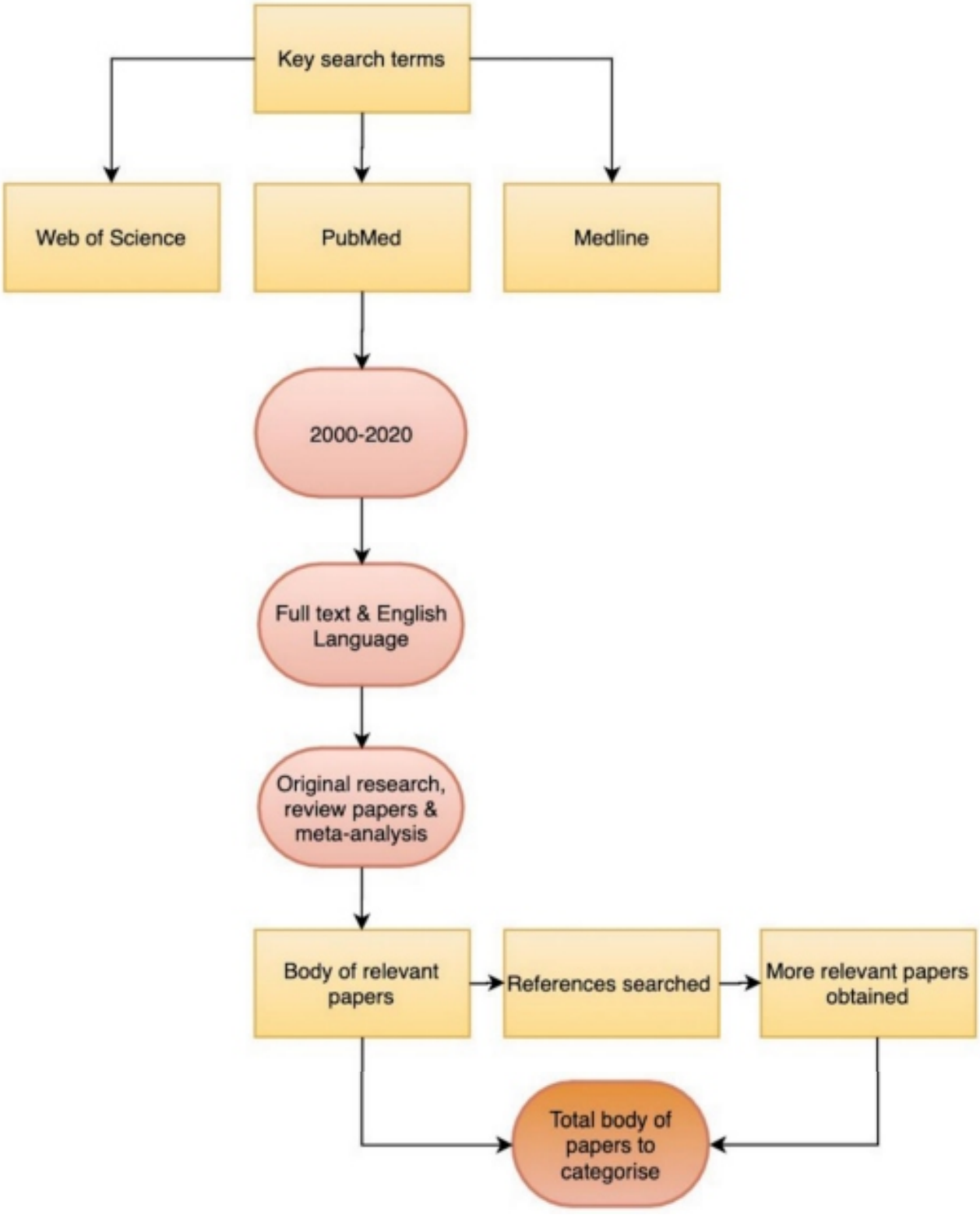

Figure 3. Search strategy (2000–2020) used within this review.

ECHO has been widely utilised in the treatment of chronic pain. Chronic pain is defined as pain that lasts longer than six months [19]. Furlan et al [20] evaluated the effect ECHO had on primary physician's ability to manage chronic pain in patients within their rural areas. The ECHO hub was operated by a multidisciplinary team of physicians from various clinical backgrounds including pain medicine, family

practice, neurology, psychiatry, and addiction. This panel of experts is typically the same across the discipline of chronic pain. The weekly clinic was two hours long in which an expert presented or participating rural healthcare professionals could present their own case-study. The outcome measures for this study included self-efficacy and utilised pre and post comparisons. The study demonstrated a significant improvement in both knowledge and self-efficacy.

These differences in outcomes in the utilisation of ECHO for chronic pain might be attributed to a number of factors. Firstly, the length of the intervention or ECHO training might affect how successful it is in improving professional competency and efficacy. Some studies here have spanned several years while others have been less than a year. Similarly, as methods to improve the management of chronic pain globally have been increased [21] it is hard to suggest that ECHO is solely responsible for the improvement in management capabilities, but it has aimed to improve the chronic pain epidemic alongside other management strategies and policies [22]. Most of the ECHO programs targeting chronic disease are made up of a diverse multi-disciplinary team. As most cases of chronic disease are complex and comorbid in nature, an expert in the disease alone would not be sufficient to provide the necessary expertise to ensure thorough expertise on all that the disease presents [13]. There are now a wide range of ECHO programs targeting other chronic diseases not discussed in-depth in this review, these programs span the globe. As ECHO is being so widely employed within chronic disease management an in-depth understanding of its true impact in terms of delivering value is more important than ever.

3.2. Professional knowledge, efficacy, and the dissemination of information

The original aim of the ECHO model was to remove the barriers to specialist care for patients by educating and empowering primary care clinicians [13]. The removal of these barriers allows for knowledge dissemination, to educate primary care physicians, thus improving their overall self confidence in their practice and thus, their efficacy. Almost every study examining the utility of ECHO examines some form of efficacy, knowledge, or confidence. While almost all studies employ these outcome measures, the methods used to examine them can differ widely. Self-efficacy tests are very commonly employed [23]. These surveys are often carried out pre and post-test for comparison. In other cases, a more objective form of pre- and post- assessment was carried out [24]. Self-reported confidence is also explored using surveys [25]. Not all tests are “self-reported” with some studies opting for more objective measures such as the KnowPain-12 scale. This survey is an adaptation of the knowPain-50 in which the test correlates with clinical behaviours and distinguishes between physicians with different levels of pain management expertise [26]. Some methods of outcome measurement are more objective than others. It is widely known that self-reported data is subject to bias [27] and as such, between the self-reported data and non-self-reported data, there are varying degrees of reliability, validity, and

as such, between the self-reported data and non-self-reported data, there are varying degrees of reliability, validity, and objectivity. While some act as an objective measurement of knowledge gained from the ECHO intervention [28], others are more self-reliant and subjective [20]. Although self-efficacy demonstrates improved self-confidence and self-belief in healthcare professionals, it has been demonstrated that physicians have a limited ability to self-evaluate [29] and as such, while this is an improvement, it may not necessarily translate into clinical relevance.

3.3. Patient clinical outcomes

ECHO allows for the breaking of barriers between primary and specialist care, the dissemination of information allows clinicians to become more educated in previously inaccessible expert care. As a result, patients too have improved access to previously untapped specialist care. This diffusion of knowledge and communication allows the closing of the treatment gap in many healthcare settings.

In general, studies have demonstrated that healthcare professionals engaging in the ECHO project feel more efficacious and confident and thus, this should translate into patient outcomes [30,31]. However, very few studies have examined patient outcomes [32]. Most discuss how improved education should, in theory, translate to better outcomes but few directly demonstrate this.

Some studies do exhibit how they directly affect patients. When Katzman et al. [33] used ECHO as an educational tool for opioid prescribing, the study looked at specific metrics relating to the numbers of patients being prescribed opioid analgesics and co-prescribing of opioids per patient per year when compared to a comparison group. The number of patients benefitting from this can be seen by the sheer volume of patient cases being presented at each ECHO meeting. This demonstrated a clear, direct effect on patients. Similarly, some other studies have demonstrated the effect ECHO has had on mortality rates within certain complex, chronic disease. Viral response of patients with HCV has been compared in patients being treated by specialists and a group being treated by project ECHO healthcare professionals, both groups had similar outcomes [15].

3.4. A potential for cost-saving

ECHO could deliver expertise in a short space of time, quickly educating healthcare professionals on how to better manage and treat their patients. By being able to access care faster, it can eliminate the need for costly and time-consuming referrals elsewhere. While numerous studies imply that there are cost-savings, few analyse the cost-effectiveness of the ECHO intervention [34]. Many interventions don't directly discuss cot-effectiveness or cost-saving but do utilise other metrics that would imply downstream cost-savings. While in theory, ECHO should demonstrate a cost-saving, in some cases, the value of ECHO can be seen in other valuable ways. Generally, most studies that do explore the cost-saving potential of ECHO either demonstrate a clear saving or at least a saving in another, non

economical way [20,31]. While this is typically the case, one study by Rattay et al [34] revealed that when the ECHO intervention was implemented in chronic HCV, it was more expensive than traditional care. The study discusses that this could be due to ECHO allowing for more targeted screening, higher adherence or improved access to treatment but were unable to confirm that this was the case.

3.5. The challenges of the ECHO model

While the ECHO model has allowed for the expansion of specialist care to otherwise deprived rural areas, it is not without its own challenges and limitations. ECHO faces barriers to its implementation which make uptake of the model limited to healthcare settings that can overcome these barriers. ECHO requires high-speed internet in order to operate. While this is not an issue for most of the developed world, it remains a problem for healthcare providers working in deeply rural communities around the world [35]. Similarly, ECHO faces logistical challenges. As ECHO relies on the input from a large multidisciplinary team of experts there may, at times be confusion over which care provider oversees certain patients [36] leading to disjointed patient care. Another potential challenge facing the future of the ECHO model is the onset of artificial intelligence in the management of chronic disease. Healthcare is moving towards more input from artificial intelligence sources which are becoming more readily available all over the globe making care more patient-focused and less centered around hospital care [37]. If the ECHO model does not integrate these changes into its future model, then it may fast become an outdated approach to chronic care management.

4. Discussion

This review examined the current applications of the ECHO model and how those applications might change in the future. It is clear from this review that ECHO, since it was first established has grown considerably in terms of clinical disease areas and also the impact it actually has on each of those clinical areas. As ECHO continues to expand and grow into more geographical areas and more clinical disease areas, it can be expected that more longitudinal studies will be available. As digital healthcare undergoes constant growth and investment as well as improved regulatory structures, all of which have been fast-tracked by the COVID-19 pandemic it can be expected that it too, will encourage the growth and dissemination of the ECHO model.

ECHO is working on closing the knowledge gap between rural and specialist care teams. The studies included in this review generally demonstrate improved clinician knowledge in terms of understanding symptoms, diagnosis and treatment within a particular disease area which leads t o improved confidence and more efficacious work. However, it should also be noted that studies employ different metrics and means of measuring these outcomes and some are more objective than others, therefore comparing them might be inappropriate.

It is implied that by improving the standard of care provided to patients that, they too, will benefit from this. However, most studies do not actually explore the direct effect ECHO has on patients, their potential benefits are merely implied. This, therefore, cannot be used as definitive evidence that ECHO truly benefits patients in terms of improved clinical outcomes. One study [32] examined the impact ECHO had on patient outcomes and found it to be effective but needed more data to determine how efficacious it is. This study only included six papers that discussed patient outcomes and as such the data was limited. While ECHO is improving clinician's self-assessed outcomes, there isn't enough data to examine how patients are directly impacted, the inclusion of how ECHO impacts the health outcomes for any given disease within the standard sets prescribed by the International Consortium for Health Outcomes Measurement (ICHOM) should also be examined. More patient-centric studies are needed in order to obtain a holistic view of ECHO's value. Further clinical outcome measures should be employed including disease severity, impact on quality of life and impact on quality of life adjust years (QALY). Similarly, longitudinal qualitative studies are needed in order to assess the effects of ECHO, years after its first intervention in order to establish if the effects and adherence to its use is short-lived or sustainable long-term. Most of the studies included here don't contain any form of cost-analysis or cost comparison between ECHO and the previous care pathway. Without a clear cost-analysis of any kind, it is difficult to calculate or examine ECHO's true value. It has been demonstrated that ECHO can be expensive to implement [34] but the exact reasons for this are unclear. Henceforth, future studies should include some analysis of cost-effectiveness.

5. Strengths and limitations of this review

This review provided a summary of current ECHO interventions being applied within chronic disease management as well their advantages and disadvantages. It also helped identify current gaps that exist within the literature examining the true impact of the ECHO model allowing for a more critical approach to interpreting and conducting future ECHO studies.

Alongside these strengths, this review also had its limitations. Firstly, this review was limited by its chosen time period. Due to 2020 being the cut-off point for studies, it excludes many newer studies that explored the ECHO model during the Covid-19 pandemic. As such studies were not included it cannot determine whether ECHO studies are employing some of the aforementioned outcome measures that were excluded in historical studies. This review also only included articles available in English and therefore may not be exhaustive.

6. Conclusions and future recommendations

ECHO has been successfully closing the knowledge gap between specialist and primary care, but it is undeniable that studies attempting to demonstrate the positive effects of ECHO contain their own gaps.

Given the projected growth of digital healthcare it is expected that the ECHO model will continue to expand in its dissemination. While ECHO somewhat validates its improvements at improving confidence and knowledge with clinicians, there is a need for more patient centric-outcome measures to explore the offset effect ECHO has on specific, clinically relevant outcome measurements as well as in-depth cost comparators. Therefore, future recommendations include the need for more empirical and robust assessments of value within ECHO studies. The use of platforms like ECHO are more valued than ever before due to the consequences of the covid-19 pandemic. The pandemic highlighted the need for more digital and remote healthcare solutions. Henceforth, it is even more important that these solutions are appropriately assessed in terms of cost-effectiveness and that their impact to clinical outcomes are examined as they become more routine in chronic disease management.

Conflict of interest

The authors declare no competing interests.

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The effect of guardians' health literacy on the child's spending time at home: A cross-sectional study among Japanese schoolchildren

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ABSTRACT

Background: The contents of children's daily activities and the amount of time spent on them has been directly linked to their health and development. Parental health behavior has also been considered a key factor, and the aim of this study was to determine the relationship between parent/guardian health literacy (HL) and their child's time spent at home by behavioral types.The study was conducted in elementary schools in Japan. Method: The target subjects for this study were elementary schoolchildren (all grades, aged 6 to 12 years) and their parents/guardians, and almost 3000 schoolchildren and their parents/guardians in the Northern and Southern districts in Japan participated.The questionnaire for parents/guardians included amount of time spent per day on the seven major behavioral contents of their child's time at home, on weekdays and weekends, respectively, and a shortened five-item health literacy (HL) scale. Parent/guardian HL results were categorized into two groups (low HL group and high HL group), and we analyzed the association between the HL and child's time spent at home by behavioral contents. Results:Children in the high HL parent/guardian group spent significantly less time watching TV and playing games than those in the low HL group, both on weekdays and weekends. Time spent playing outside on weekdays and on hobbies on weekdays and weekends was significantly longer for children in the high HL parent/guardian group than in the low HL group. Results of logistic regression analyses adjusted for confounders showed that higher parental/guardian HL reduced children's spending more than 30 minutes watching TV or playing games and increased children's spending more than 30 minutes on outside playing and doing hobbies. Conclusions: Parental/guardian HL affected the child's time spent at home. The results could suggest that increasing parental/guardian HL has strong potential to improve children's major lifestyle behaviors

Keywords: health literacy; guardian;schoolchildren; time spent at home; Japanese

1. Introduction

There are still many issues related to children's health, such as lack of time for physical activity, increased time with screens, sedentary time and unbalanced diets [1–3]. It has been reported that a healthy lifestyle in childhood is associated with disease risk and mental risk in adulthood [4], and many

studies have been conducted on how to promote and acquire healthy lifestyles from childhood [5]. Children's healthy lifestyles and health behaviors have been known to be affected by various factors [6,7]. Family environment and parents/guardians are influential on children's lifestyles [5,8], of which parental health literacy is likely to be a strongly relevant key factor [6,9,10]. Because children depend on their parents and guardians to prevent and deal with health problems, this suggests that children may be disadvantaged if their parents' and guardians' knowledge and skills, that is, their health literacy, are inadequate [6]. Although there are previous reports on parents'/guardians' health literacy and children's physical activity, nutrient status and screen time, it seems that reports on other patterns of behaviors and the amount of time children spend at home are limited. Therefore, this study examined the association between children's typical lifestyle behaviors, spending time at home and health literacy of their parent/guardian by a cross-sectional study.2. Materials and methods

2.1. Study design and subjects

We conducted a cross-sectional questionnaire survey on the lifestyle of schoolchildren and their guardians between November 2015 and March 2016. Nine public elementary schools covering all grades of children (grades 1st to 6th, aged 6–12) in regional central cities in Northern and Southern districts in Japan participated, with a total of 3327 guardians among 4263 enrollees (cooperation rate: 78.0%).

2.2. Questionnaires

The question about time spent at home by the child asked for average times(in minutes) per day on a usual day and noted separately weekends and weekdays. The following 7 items were included: watching television, including DVDs and/or another video; playing video games (including handytype); studying, including homework; reading books (including comic book reading, except for homework); help with family and housework; outside playing; and time doing hobbies.

To estimate health literacy (HL), we used a validated questionnaire with five items, which was short and adapted to the Japanese population [11]. The questions asked about the degree to which a person (i) can gather information about one's own illness and health from various sources, such as newspapers, books, television and the internet; (ii) can pick out the information one needs from lots of information; (iii) can understand the information and communicate it to others; (iv) can judge the credibility of the information; and (v) can decide on plans and actions to improve one's own health based on the information. The structures of these questions are based on communicative HL for the first three questions (items i–iii) and critical HL for the latter two (items iv–v). Each item was rated on a 5-point Likert scale ranging from 1 ("strongly disagree / not at all") to 5 ("strongly agree"), where high points mean high literacy. The points were summed, and the total scores ranged from a minimum of 5 to a

maximum of 25 points.

The questionnaire also contained basic characteristics of the parent/guardian (position from child'sside, age, type of employment) and family environment (number of family, number of children, source of household income, feeling of financial leeway). As school policy limited detailed questions such as child's age, school grade, sex/gender and parents'/guardians' personal status, such as marital status, educational background, home economics and other social indicators, alternative minimum questions were adopted in this study.

2.3. Statistical analysis

We excluded imperfect responses for child's time spent and items of health literacy, and 3188 individual data were used in analyses (4.2% of the participants excluded). Variables are presented as mean ± standard deviation for continuous variables or prevalence (%) for categorical variables. The total HL score was classified into two categories based on the median or average score. This classification has been adopted in similar previous studies for Japanese people [12–14]. In this study, the cut-off score was 18, with less than 18 as the low group (low HL) and 18 or more as the high group (high HL).

We used the chi-square test for comparisons of proportions and Welch's t-test for continuous variables between two groups (low HL, high HL). The distribution of the data showed that a 30-minute interval was appropriate.We also calculated the odds ratio (OR) and the 95% confidence intervals (95% CI) using logistic regression analysis for each category of child time spent in the high HL group at 30 minutes or more with less than 30 minutes as a reference. Adjusting variables included the following: position of parent/guardian from the child'sside, age group of parent/guardian, type of employment of parent/guardian, number of family members, number of children, major source of household income, feeling of financial leeway.

All statistical analyses were performed using SPSS version 25 for Windows (IBM Corp., Chicago, IL, USA). The level of statistical significance for each analysis was set at $P < 0.05$.

2.4. Ethics

This survey was conducted according to the Ethical Guidelines for Epidemiological Studies established by the Ministry of Health, Labor and Welfare & Ministry of Education, Culture, Sports, Science and Technology in Japan. The Ethics Committee Tohoku University Graduate School of Medicine approved the research protocol (No. 2015–1–810, 2019–1–482). The survey was anonymous, and the submission of the questionnaire was regarded as consent to participate.

3. Results

Table 1 shows the background characteristics of parents/guardians and family environments. The

overall characteristics of the parents/guardians who participated in this study were the following: Most were mothers (95.2%), and most were in their 30s–40s (47.4%). The most common type of employment was part-time (46.6%), and the next most common was housewife (23.1%). The most common number of family members was 3–5 (83.1%), with two children (49.9%)being the most common. The main source of household income was a full-time work-based company salary (71.1%), and almost half (49.5%) of the respondents answered that they felt they did not have enough financial leeway. Comparing the characteristics of the HL groups, significant differences were found in the dispersion trends for position from the child's side, number of family members, major source of household income and feeling of financial leeway.

Table 2 shows the results of comparison of child time spent in minutes (min) for the seven behavioral categories by parent/guardian HL group. The child's time spent on watching television was longer in the group with low HL on both weekdays and weekends, with statistically significant differences between the two groups (weekday: low HL group 90.3 min, high HL group 83.2 min, difference 7.07 min, $P < 0.001$; similarly, weekend: 146.9 min, 136.3 min, difference 10.67 min, $P = 0.001$). The child's time spent on playing video games was also longer in the group with low HL on both weekdays and weekends, with statistically significant differences between the two groups (weekday: low HL group 34.7 min, high HL group 30.1 min, difference 4.62 min, $P < 0.001$; similarly, weekend: 70.5 min, 62.0 min, difference 8.51 min, $P = 0.001$). There were no significant differences between HL groups for time spent studying, reading books or helping with family/housework. The tendency was for time of studying and helping family/housework to be slightly longer in the higher HL group and time of reading books to be slightly longer in the lower HL group. The child's time spent on playing outside was greater in the high HL group both on weekdays and on weekends. A statistically significant difference was shown only on weekdays (low HL group 28.8 min, high HL group 32.3 min, difference 3.50 min, $P < 0.001$). The child's time spent on doing hobbies was greater in the high HL group on both weekdays and weekends, with statistically significant difference (weekday: low HL group 8.4 min, high HL group 10.0 min group, difference 1.64 min, $P < 0.038$; similarly, weekend:17.8 min, 21.6 min, difference 3.74 min, $P = 0.014$).

Table 1. Demographic characteristics among parents/guardians according to HL groups.

		Parent/guardian HL score		
	Total (n = 3188)	Low group (n = 1689)	High group (n = 1499)	*P**
Position from child's side				
Mother	95.2	94.6	95.8	0.035
Father	3.5	3.8	3.2	
Others	0.8	1.2	0.4	
Age group, years old				
<30	2.4	2.1	2.7	0.351

30–39	47.4	47.0	47.8	
40–49	47.2	47.7	46.7	
>49	2.5	2.8	2.2	
Type of employment				
Full time job	22.0	23.1	22.5	0.114
Part time job	46.6	43.4	45.1	
Self-employed	4.0	4.9	4.4	
Housewife	23.1	24.5	23.8	
On leave of absence/parental leave	0.9	1.4	1.2	
Seeking employment	0.4	0.4	0.4	
Others	2.4	1.3	1.9	
Number of family members				
<3 persons	2.4	2.8	1.8	0.003
3–5 persons	83.1	81.1	85.5	
>5 persons	14.1	15.7	12.1	
Unknown	0.5	0.4	0.6	
Number of children				
1 child	15.0	14.8	15.3	0.896
2 children	49.9	49.8	50.0	
>2 children	35.1	35.4	34.8	
Major source of household income				
Self-employed (including agriculture, forestry, and fisheries)	7.6	7.7	7.4	0.045
Company employee, full-time salary	71.1	72.2	70.0	
Company employee, part-time salary	12.6	11.1	14.2	
Public servant salary	5.1	4.9	5.3	
Others	0.4	0.5	0.3	
Feeling of financial leeway				
Enough	26.6	22.9	30.9	<0.001
Not enough	49.5	51.5	47.4	
Neither	22.8	24.3	21.1	

Table 2. Contents and minutes of child'stime spent at home compared by HL groups.

	Parent/guardian HL score			
	Low group	High group	Difference*	*P*#
Contents of daily spending time				
Watching television				
Weekday	90.3±57.4	83.2±54.3	7.07	<0.001
Weekend	146.9±94.5	136.3±90.2	10.67	0.001
Playing video games				
Weekday	34.7±39.6	30.1±34.4	4.62	<0.001
Weekend	70.5±72.1	62.0±68.0	8.51	0.001
Studying				
Weekday	49.2±25.7	49.3±25.4	−0.11	0.902
Weekend	42.1±39.0	43.3±35.5	−1.22	0.353

Reading books					
	Weekday	18.2±22.6	17.6±19.4	0.64	0.389
	Weekend	26.9±32.9	26.1±30.8	0.83	0.463
Helping with family/housework					
	Weekday	10.5±12.6	11.0±12.2	−0.47	0.280
	Weekend	15.6±20.8	15.8±17.6	−0.19	0.781
Playing outside					
	Weekday	28.8±35.5	32.3±36.6	−3.50	0.006
	Weekend	73.4±85.9	78.0±89.7	−4.65	0.136
Doing hobbies					
	Weekday	8.4±22.6	10.0±22.0	−1.64	0.038
	Weekend	17.8±40.7	21.6±44.7	−3.74	0.014

*Note: Values in table: mean ± standard deviation, values in minutes; *Difference of the mean of the low-scoring group minus the mean of the high-scoring group;#Welch t-test.

Table 3. Results of odds ratios of time spent by children with high HL group parents/guardians.

		No. in HL group		Crude OR (95%CI)	*P*	Adjusted OR (95%CI)	*P*
		Low	High				
Watching television							
Weekday	<30 min	87	107	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1602	1392	0.71 (0.53–0.95)	0.020	0.71 (0.53–0.95)	0.022
Weekend	<30 min	104	108	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1585	1391	0.85 (0.64–1.12)	0.237	0.86 (0.65–1.14)	0.304
Playing video games							
Weekday	<30 min	729	701	1.00 (ref.)		1.00 (ref.)	
	≥30 min	960	798	0.86 (0.75–0.99)	0.041	0.86 (0.75–0.99)	0.038
Weekend	<30 min	413	440	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1276	1059	0.78 (0.67–0.91)	0.002	0.78 (0.66–0.91)	0.002
Studying							
Weekday	<30 min	165	133	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1520	1362	1.11 (0.87–1.41)	0.387	1.11 (0.87–1.41)	0.396
Weekend	<30 min	474	378	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1214	1121	1.16 (0.99–1.36)	0.068	1.16 (0.99–1.36)	0.064
Reading books							
Weekday	<30 min	1111	988	1.00 (ref.)		1.00 (ref.)	
	≥30 min	576	511	1.00 (0.86–1.16)	0.974	0.99 (0.86–1.15)	0.904
Weekend	<30 min	903	779	1.00 (ref.)		1.00 (ref.)	
	≥30 min	786	720	1.06 (0.92–1.22)	0.399	1.05 (0.91–1.21)	0.482

Helping with family/housework							
Weekday	<30 min	1465	1296	1.00 (ref.)		1.00 (ref.)	
	≥30 min	223	203	1.03 (0.84–1.26)	0.784	1.05 (0.86–1.29)	0.632
Weekend	<30 min	1280	1124	1.00 (ref.)		1.00 (ref.)	
	≥30 min	409	375	1.04 (0.89–1.23)	0.600	1.06 (0.90–1.25)	0.486
Playing outside							
Weekday	<30 min	864	683	1.00 (ref.)		1.00 (ref.)	
	≥30 min	825	816	1.25 (1.09–1.44)	0.002	1.24 (1.08–1.43)	0.003
Weekend	<30 min	524	425	1.00 (ref.)		1.00 (ref.)	
	≥30 min	1165	1074	1.14 (0.98–1.32)	0.100	1.14 (0.97–1.33)	0.105
Doing hobbies							
Weekday	<30 min	1445	1208	1.00 (ref.)		1.00 (ref.)	
	≥30 min	244	291	1.43 (1.18–1.72)	<0.001	1.39 (1.15–1.68)	0.001
Weekend	<30 min	1270	1049	1.00 (ref.)		1.00 (ref.)	
	≥30 min	419	450	1.30 (1.11–1.52)	0.001	1.27(1.09–1.49)	0.003

*Note: Abbreviations in the table: OR = odds ratio, CI = confidence interval, ref. = reference; Adjustment variables as follows: position of parent/guardian from child'sside, age group of parent/guardian, type of employment of parent/guardian, number of family members, number of children, major source of household income, feeling of financial leeway.

Table 3 shows the odds ratios for child time spent for more than 30 minutes compared to less than 30 minutes in the group with high parental/guardian HL. The ORs of spending more than 30 minutes for watching television and video game playing were lower in the higher HL group. The adjusted Ors were 0.71 (95% CI = 0.53–0.95, P = 0.002) for weekday television watching, 0.86 (95% CI = 0.75–0.99, P = 0.038) for weekday video game playing and 0.78 (95% CI = 0.66–0.91, P = 0.002) for weekend video game playing. The ORs were close to 1.00 for study time, reading time and helping with family/housework either on weekdays or weekends. The ORs of spending more than 30 minutes playing outside and doing hobbies were higher in the higher HL group. The adjusted ORs were 1.24 (95% CI = 1.08–1.43, P = 0.003) for weekday playing outside, 1.39 (95% CI = 1.15–1.68, P = 0.001) for weekday hobby time and 1.27 (95% CI = 1.09–1.49, P = 0.003) for weekend hobby time. In a detailed analysis, significant differences in weekday television watching, weekday playing video games, weekend playing video games and weekday outside playing were even more noticeable for the more than 120 minutes time (not shown in the result table). The adjusted ORs were 0.65 (95% CI = 0.46–0.92, P = 0.041) for weekday television watching, 0.64 (95% CI = 0.47–0.88, P = 0.006) for weekday playing video games, 0.67 (95% CI = 0.55–0.82, P < 0.001) for weekend playing video games and 1.46 (95% CI = 1.05–2.04, P = 0.026) for weekday outside playing.

4. Discussion

We examined the association between parental/guardian health literacy and child's time spent at home, based on data of approximately 3000 Japanese schoolchildren. Overall, parental/guardian HL was strongly associated with the following four behavioral categories of time spent by children: watching television, playing video games, playing outside and doing hobbies. Our results for TV time and game time are consistent with previous studies, and regarding outdoor play as a physical activity, the direction of the results of the present study agrees with other previous studies [1,3,6–8].The largest difference in terms of number of hours was found for weekend watching television, which was approximately 10.6 minutes/day longer in the low parent/guardian HL group. The second largest time difference was found for weekend time playing video games, which was about 8.5 minutes/day longer in the low parent/guardian HL group. Children in the high parent/guardian HL group spent approximately 4.6 minutes more time playing outside on weekends and 3.7 minutes more time doing hobbies on weekends than children in the low parent/guardian HL group. The differences were measured in minutes and appeared small; however, this difference would be larger with longterm cumulation. Elementary schools in Japan have roughly 200 school days in a year. It is estimated that a difference of 7 min/day in children's weekday TV watching amounts to a difference of 1400 min/year, that is, about 23 hours.The results of the logistic analysis indicated that higher parental/guardian HL may reduce the probability of children spending more than 30 minutes watching TV on weekdays and playing on weekdays and weekends. Higher parent/guardian HL indicated that the probability of children spending more than 30 minutes outside on weekdays and on weekday and weekend hobbies increased. Sub-analyses also suggested that higher parental/guardian HL, less likely for children to spend more than 2 hours watching TV on weekdays and playing games on weekdays and weekends while more likely for children to spend more than 2 hours playing outside. These results suggest that if parents/guardians have a high level of HL, it might be possible to reduce the amount of time children spend watching TV and playing games to less than 30 minutes or less than 120 minutes and to increase the amount of time they spend playing outside and enjoying their hobbies to more than 30 minutes or more than 120 minutes.

In recent years, reports have also accumulated on children's screen time, sedentary time and their health disadvantages [3,5,15,16]. The TV watching and video gaming time collected in this study could be substituted as total screen time or sitting time, although use of computers, mobile phones and smartphones was not included. Hence, screen time and sitting time were not estimated in this study. Our study also has some limitations. First, the data on children's time spent at home was based on questionnaire responses by parents/guardians and not actual measurement data, so some response errors were unavoidable. There may also be differences in content-specific time by child age and by sex. Our present study has not fully examined the variables. The information such as the child's sex/gender, year of age and class could not be added to the questionnaire due to concerns about the possibility of

identifying the child. In particular, the time spent playing outside may differ by gender and age group. This remains an issue for future surveys. It has been also reported that parenting style could be significantly related to children's daily life and health behaviors [17–20]. The present study may not have adequately adjusted for parental parenting attitudes. It may also be insufficient for SES indicators, but the impact of SES as a predictor of health literacy appears to be limited [21].The present study focused on the relationship between parental/guardian HL and seven behavioral categories of child'stime spent at home. There are few reports investigating the time spent by Japanese schoolchildren and the parents' HL, so the results of this study are very meaningful. Many factors, including the parental/guardian HL focused on in this study, have direct and indirect or combinatory influences on children's health behaviors and health outcomes. Further findings are expected from comprehensive and continuing epidemiological study.

5. Conclusions

Our study conducted in Japanese schoolchildren showed that parental/guardian HL was associated with some contents of child's time spent at home. High parental/guardian HL was negatively associated with children's time spent watching TV and playing games, while times spent playing outside and doing hobbies were positively associated.

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Conflict of interest

All authors declare no conflicts of interest in this paper.

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Public beliefs and willingness to accept COVID-19 vaccines among adults in South-Western Nigeria: A cross-sectional study

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ABSTRACT

Background: Despite the government's and development partners' unmatched efforts to ensure that every eligible person receives vaccinations, there have been concerns about vaccine fear, government mistrust, vaccine hesitancy and rejection expressed by the public, as well as various conspiracy theories involving the COVID-19 vaccines. This study assessed the public beliefs and willingness to accept COVID-19 vaccines and related factors among residents of Ondo State, Nigeria. Methods: Using a convenience sample technique, a cross-sectional survey of the adult population was carried out in the months of February and March of 2022. Factors influencing beliefs and willingness to accept COVID-19 vaccines were found by using univariate and multivariate statistical analysis. Results: 306 out of 323 respondents completed the survey and were included in the final analysis. The respondents mean age was 28.16 ± 16.2 years. Although n = 223, 72.9% of respondents reported to have received at least one dose of COVID-19 vaccines, (n = 205) 67.0% believed COVID-19 vaccines to be effective. Among the individuals who had not yet had any COVID-19 vaccinations, 2.6% (n = 8) of respondents were willing to accept the vaccines, whereas 14.1% (n = 43) were unwilling. Respondents' beliefs about the efficacy of COVID-19 vaccines were influenced by their gender, occupation, religion and educational attainment ($p < 0.005$). Conclusion: The study revealed a good level of positive beliefs about the vaccine, which was mirrored in vaccination history. However, those who had not yet received the vaccine were unwilling to do so, opening the door for more aggressive risk communication to be able to alter the course of events. In addition to addressing additional COVID-19 vaccination myths, we advise policy-makers to develop communication strategies that emphasise the safety of the COVID-19 vaccine. It is advised that all relevant stakeholders be included in government COVID-19 vaccination programmes by sharing timely, transparent information that fosters accountability.

Keywords: COVID-19; vaccines; beliefs; willingness; vaccination hesitancy; Nigeria

1. Introduction

The novel coronavirus disease 2019 (COVID-19), which was first discovered in Wuhan, China in December 2019, was described as a global public health pandemic by the World Health Organization (WHO) on the 11th of March 2020 [1]. Since the onset of the COVID-19 pandemic, the disease has

spread to over 215 countries [2]. Globally, the pandemic has continued to pose a threat to socioeconomic stability, food security, trade, health systems, education systems and infrastructure in both high- and low-income countries. As of the 1st of July 2022, there have been 545,226,550 confirmed cases of COVID-19, including 6,334,728 deaths reported to the WHO [3]. In Ondo State, Nigeria, there have been 104,396 cases tested for COVID-19, 5173 confirmed cases, 109 deaths, 4749 cases discharged and 315 cases on admission as of the 1st of July 2022 [4].COVID-19 vaccines were introduced to combat the ongoing COVID-19 pandemic. On 8 December 2020, the first COVID-19 vaccination was administered outside of a clinical research environment [5]. By 8 December 2021, 55.9% of the global population was estimated to have received at least one dose of a COVID-19 vaccine [6]. Only 57% of nations, almost all of which are high-income nations, had vaccinated 70% of their total population as of May 2022, as compared to almost a billion individuals in low-income nations who are still unvaccinated [3]. In March 2021, Nigeria received about 4 million doses of AstraZeneca/Oxford vaccines through the COVID-19 Vaccines Global Access facility, i.e., a partnership between the Coalition for Epidemic Preparedness Innovations, Global Alliance for Vaccines and Immunizations (GAVI), United Nation Children's Fund (UNICEF) and WHO [7]. Priority groups such as frontline healthcare workers, security personnel, strategic leaders and other public personnel identified as eligible for the first phase of the COVID-19 vaccination were first vaccinated in March 2021, as coordinated by the National Primary Health Care Development Agency, through the State's Primary Health Care Development Agency, and in partnership with development partners [8,9]. However, there has been implementation of other phases of the vaccination programme: Phase 2 (16 August 2021 to 16 November 2021) and Phase 3 (17 November 2021 to date), giving wider access to other COVID-19 vaccines such as Moderna and Pfizer to the general public [9].As of the 1st of July 2022, 20.8% of the total eligible population have been fully with the COVID-19 vaccine, and only 10.7% of the population have been partially vaccinated with one dose of COVID-19 vaccine [9]. Specifically, in Ondo State, only 9.5% of the target population have been fully vaccinated against COVID-19, and 16% partially vaccinated [9]. A high vaccination coverage is typically required for the immunisation campaign to be successful.

However, despite the government's and development partners' unmatched efforts to ensure that every eligible person receives vaccinations, there have been concerns about vaccine fear, government mistrust, vaccine hesitancy and rejection expressed by the public, as well as various conspiracy theories surrounding the origin of COVID-19 and the speculated motives behind the vaccines in Nigeria [10].

There have been few studies in Nigeria among health workers and the general public that assessed the level of awareness, perceptions and willingness to accept COVID-19 vaccines [11–13]. Adedeji-Adenola and colleagues [13], who explored the factors influencing COVID-19 vaccine uptake among adults in Nigeria, found sociodemographic factors such as occupation, religion and education to be predictors of COVID-19 vaccination awareness. They also found health workers to have more of a

positive perception towards COVID-19 vaccination than non-health workers. A study [12] conducted prior to the introduction of COVID-19 vaccines in Nigeria found that older age, males, trust in government, trust in public health authorities and confidence in vaccine developers were significantly associated with COVID-19 vaccine acceptance. A similar study [11] was conducted among health workers in Ondo State, Nigeria prior to the availability of the COVID-19 vaccine in the country and state [11]. They found that only 53.5% of the health workers had positive perceptions of the COVID-19 vaccine, and only slightly more than half (55.5%) were willing to receive vaccination. Predictors of willingness to receive the COVID19 vaccine included having a positive perception of the vaccine and a higher perceived risk of contracting COVID-19.

There has been no study in Ondo State evaluating public's perceptions, beliefs and willingness to receive COVID-19 vaccines post-introduction of the vaccines in the state. Nigeria is a country that is multi-ethnic, multi-cultural and multi-religious [14]. Experiences from the government's expanded immunisation programme indicate that different parts of the country have varying levels of vaccination coverage [15]. When compared to the northern states, higher vaccination coverage rates have been seen in the southern states [16]. Additionally, intra-state coverages reveal that urban areas have higher coverage than rural areas. Inequalities in socioeconomic status and literacy levels are also present [16]. Given these facts, it is clear that it is important to understand the context-specific variables that can affect the uptake of COVID-19 vaccines in Ondo State, South-West Nigeria. Moreover, the low vaccination rates in Ondo State necessitate an understanding of the beliefs and willingness to accept the COVID-19 vaccine. Findings from this study will be very useful in guiding the ongoing implementation of the vaccination programme and the subsequent phases of the programme. Therefore, this study aimed to assess the beliefs and willingness to receive COVID-19 vaccines among the public in Ondo State, Nigeria.

2. Materials and methods

2.1. Study setting

The study area was Ondo State in the southwestern part of Nigeria. It has a land area of approximately 14,789 km2 and a projected population of 5.3 million people, as based on the 2006 national census population in Nigeria, which projected a growth rate of 3.0% [17]. The state is divided into 18 local government areas (LGAs) and 203 political wards. This study was conducted in two LGAs in the state, i.e., Akure South, which is considered an urban LGA, and Ondo East, a rural LGA (Figure 1). The Akure South LGA is the headquarters of Ondo State. It has 11 wards and a total population of 610,727 as the projected population. The Ondo East LGA has 10 wards and a projected total population of 129,262.

Figure 1. Map of Ondo State, Nigeria showing selected LGAs.

2.2. Study design, study participants and sampling

This was a cross-sectional study conducted from February to March 2022 in the Akure and Ondo East LGAs of Ondo State. Selection of the LGAs was based on convenience sampling. Study participants were Nigerian residents who were 18 years or older living in Ondo state. A sample size of 323 was estimated by applying an online sample size calculator [18] to a total population of 5,361,003 for Ondo State at a 95% confidence interval, a 5% margin of error and an 80% response rate.

2.3. Data collection and analysis

A questionnaire was designed and incorporated into the Google survey form and interview-administered to respondents by trained research assistants. The study questionnaire contained questions on sociodemographic information such as age, gender, occupation,religion, level of education, history of COVID-19 testing and history of COVID-19 vaccination. The belief in COVID-19 vaccines and participants' willingness to receive the vaccine was assessed by using single-item questions, each with "yes", "no" and "maybe" answer options and multiple-choice follow-up responses for reasons that were established based on previous literature [19]. The study questionnaire was piloted among 10% of the intended sample size in communities outside of the LGAs selected for the study. Pretesting was carried

out to ensure internal consistency and eliminate ambiguities. Test-retest reliability for single items was established by using intraclass correlation, which was 0.8. Face and content validity was done by the main author and the researchers.

All completed questionnaires were analysed by using IBM's Statistical Package for the Social Sciences (SPSS) version 27. Descriptive statistics were computed to generate frequencies, means and standard deviations. Chi-square analysis was performed to explore associations between participants' sociodemographic characteristics and beliefs on COVID-19 vaccines and vaccination history. A significance level of $p < 0.05$ was considered statistically significant.

2.4. Ethical consideration

Ethical approval was sought and granted by the Health Research and Ethics committee of the Ondo State Ministry of Health with protocol number OSHREC 22/03/2022/429. Written consent was obtained from all participants before partaking in the study. Confidentiality was assured and the data collected were anonymized.

3. Results

A total of 306 of 323 respondents completed the survey forms and were included in the final statistical analysis of this study, giving a response rate of 94.7%.

3.1. Sociodemographic characteristics of respondents

Sixty percent (n = 185) of the responders were females, while 39.5% (n = 121) were males. About 50.7% (n = 155) of the respondents were in the 34–49 age range. Only 1.6% (n = 5) of the population was over 65 years (Table 1). The average age was 28.16 ±16.2 years. The participants worked in a range of occupations: 15.4% (n = 47) were students, 22% (n = 69) were civil/public servants and 39.2% (n = 120) were involved in commerce or trading. Health professionals made up 9% (n = 28), retired employees made up 4.9% (n = 14) and unemployed respondents made up 9.5% (n = 28). Fewer respondents (n = 13) had no education, as compared to 60.5% (n = 185) with tertiary education, 29.4% (n = 90) with secondary education and 4.3% (n = 13) with no education. The majority of respondents (91.8%; n = 281) identified as Christian (Table 1).

Table 1. Respondents' sociodemographic characteristics.

Characteristics	Frequency	Percent
Age group		
18 to 33 years	110	35.9
34 to 49 years	155	50.7
50 to 65 years	36	11.8
>65 years	5	1.6
Mean age ± SD	28 ± 16.2	
Gender		
Male	121	39.5
Female	185	60.5
Occupation		
Business/trader	120	39.2
Civil/public servant	69	22.5
Health worker	28	9.2
Housewife	15	4.9
Retired	14	4.6
Student	47	15.4
Unemployed	13	4.2
Religion		
Christian	281	91.8
Islam	25	8.2
Education		
None	13	4.2
Primary	18	5.9
Secondary	90	29.4
Tertiary	185	60.5

3.2. Respondent's beliefs and willingness regarding COVID-19 vaccines

Most respondents 67.0% (n = 205) believed in the effectiveness of COVID-19 vaccines. Twenty-one percent (n = 65) were indifferent on the effectiveness of COVID-19 vaccines, while 11.8% (n = 36) did not believe in the vaccine effectiveness (Table 2). There were more respondents 72.9% (n = 223) who had received at least one dose of COVID-19 vaccine than those who had not 27.1% (n = 83). Among those who had not received a single dose of any COVID-19 vaccine, we explored their willingness to be vaccinated. A very low proportion of respondents (2.6%; n = 8) indicated their willingness to receive COVID-19 vaccines; others (14.1%; n = 43) were not willing to take the vaccines, while 10.5% (n = 32) were hesitant on taking the COVID-19 vaccine. Regarding the reasons for the unwillingness or indecision expressed by respondents' beliefs about the vaccines, the majority (53.3%; n = 40) expressed concerns about the side effects and safety of the COVID-19 vaccines, 26.7% (n = 20) were not sure of its

efficacy and 12.0% (n = 9) did not trust the vaccination programme and also did not believe in the existence of the COVID-19 virus. Other reasons included the fact that the vaccines were produced outside of Nigeria (n = 3; 4%) and religious beliefs (n = 4; 5.3%) (Table 2).

Table 2. Respondents' beliefs, willingness, COVID-19 vaccination status and COVID-19 test history.

Characteristics	Frequency	Percent
Belief in COVID-19 vaccine		
Yes	205	67
No	36	11.8
Maybe	65	21.2
COVID-19 vaccination history (at least one dose)		
Yes	223	72.9
No	83	27.1
Willingness to take COVID-19 vaccine (*n* = 83)		
Yes	8	2.6
No	43	14.1
Maybe	32	10.5
Reasons for non-willingness to take COVID-19 vaccine (*n* = 75)**		
COVID-19 does not exist	9	12.0
COVID-19 is going away	1	1.3
I am not sure of its efficacy	20	26.7
The vaccine was made outside of Nigeria	3	4.0
I do not trust the vaccination programme	9	12.0
I am too young and do not need it	6	8.0
I am worried about its side effects and safety	40	53.3
It is against my religion	4	5.3
No reason	1	1.3
Others	5	6.7
History of COVID-19 testing		
Yes	33	10.8
No	273	89.2

*Note: ** multiple responses allowed.

3.3. Association between sociodemographic characteristics and belief in COVID-19 vaccines

Sociodemographic factors such as respondents' age group, gender, occupation, religion and level of education were all statistically significant with belief in COVID-19 vaccines ($p < 0.005$).

Respondents' history of COVID-19 vaccination and testing were also statistically significant with belief in COVID-19 vaccines ($p < 0.005$) (Table 3). Respondents between the age of 34 to 49 years more likely to believe in COVID-19 vaccine efficacy than those older than 65 years. A higher proportion of males believed in the vaccine effectiveness than females. As anticipated, health workers had better perception, whereas respondents who were unemployed had poor perceptions about the vaccines. Christians had better perceptions about the COVID-19 vaccines than Muslims. Those with no or only primary school education had poor perceptions than those with a tertiary education (Table 3). Respondents without a history of COVID-19 testing and vaccination had poor perceptions about COVID-19 vaccines than those who had previously been tested for COVID-19 and had received at least one dose of a COVID-19 vaccine.

Table 3. Association between respondents' characteristics and beliefs about COVID-19 vaccines.

Characteristics	**Belief in COVID-19 vaccine**			**Chi-square (X^2)**	**df**	**p-value**
	Yes *n* = 205 (%)	**No** *n* = 26 (%)	**Maybe** *n* = 65 (%)			
Age group				19.948	6	0.003*
18 to 33 years	69(62.7)	11(10.0)	30(27.3)			
34 to 49 years	112(72.3)	14(9.0)	29(18.7)			
50 to 65 years	22(61.1)	8(22.2)	6(16.7)			
>65 years	2(40.0)	3(60.0)	0(0.0)			
Gender				7.899	2	0.019*
Male	90 (74.4)	7(5.8)	24(19.8)			
Female	115(62.2)	29(15.7)	41(22.2)			
Occupation				74.451	12	<0.001*
Business/trader	69(57.5)	19(15.8)	32(26.7)			
Civil/public servant	60(87.0)	4(5.8)	5(7.2)			
Health worker	28(100)	0(0)	0(0)			
Housewife	2(13.3)	4(26.7)	9(60.0)			
Retired	12(85.7)	2(14.3)	0(0.0)			
Student	32(68.1)	5(10.6)	10(21.3)			
Unemployed	2(15.4)	2(15.4)	9(69.2)			
Religion				15.585	2	<0.001*
Christian	197(70.1)	29(10.3)	55(19.6)			
Islam	8(32.0)	7(28.0)	10(40.0)			
Level of education				114.017	6	<0.001*
None	1(7.7)	7(53.8)	5(38.5)			
Primary	3(16.7)	8(44.4)	7(38.9)			
Secondary	39(43.3)	15(16.7)	36(40.0)			

Tertiary	162(87.6)	6(3.2)	17(9.2)			
History of COVID-19 testing				12.374	2	0.002*
Yes	31(93.9)	0(0.0)	2(6.1)			
no	174(63.7)	36(13.2)	63(23.1)			
COVID-19 vaccination history				155.283	2	<0.001*
Yes	194(86.6)	4(1.8)	26(11.6)			
no	11(13.4)	32(39)	39(47.6)			

*Note: degree of freedom (df), *Significance level (P) ≤ 0.05.

3.4. Association between sociodemographic characteristics and COVID-19 vaccination history

Sociodemographic factors, which included age group, occupation, religion and level of education were significantly associated with COVID-19 vaccination history ($p < 0.005$). Only gender was not significantly associated with COVID-19 vaccination history (Table 4). Similar to the belief in COVID-19 vaccines, those who were between 34 to 49 years old were more likely to be vaccinated, while those who were above 65 years were less likely to be vaccinated. Health workers were more likely to receive COVID-19 vaccines than those who were unemployed. In the same vein, Christians and those with a tertiary level of education showed a higher likelihood of being vaccinated than those who were Muslims and with no education, respectively. History of COVID-19 testing was also significantly associated with COVID-19 vaccination history ($p < 0.005$). Those who had previously been tested for COVID-19 were more likely to receive a COVID-19 vaccination (Table 4).

Table 4. Association between respondents' characteristics and COVID-19 vaccination history.

Characteristics	**COVID-19 vaccination history**		**Chi-square (X^2)**	**df**	**p-value**
	Yes	**No**			
	n = 224 (%)	*n* = 82 (%)			
Age group			15.675	3	0.001*
18 to 33 years	70(63.6)	40(36.4)			
34 to 49 years	128(82.6)	27(17.4)			
50 to 65 years	24(66.7)	12(33.3)			
>65 years	2(40.0)	3(60.0)			
Gender			0.410	1	0.522
Male	91(75.2)	30(24.8)			
Female	133(71.9)	52(28.1)			
Occupation			65.934	6	<0.001*
Business/trader	83(69.2)	37(30.8)			
Civil/public servant	62(89.9)	7(10.1)			

Health worker	28(100.0)	0(0.0)			
Housewife	3(20.0)	12(80.0)			
Retired	12(85.7)	2(14.3)			
Student	34(72.3)	13(27.7)			
Unemployed	2(15.4)	11(84.6)			
Religion			19.208	1	<0.001*
Christian	215(76.5)	66(23.5)			
Islam	9(36.0)	16(64.0)			
Level of education			104.612	3	<0.001*
None	1(7.7)	12(92.3)			
Primary	1(5.6)	17(94.4)			
Secondary	55(61.1)	35(38.9)			
Tertiary	167(90.3)	18(9.7)			
History of COVID-19 testing			10.651	1	0.001*
Yes	32(97.0)	1(3.0)			
No	192(70.3)	81(29.7)			

*Note: degree of freedom (df), *Significance level (P) ≤ 0.05.

4. Discussion

The aim of the present study was to investigate the beliefs of the public and willingness of adults to accept COVID-19 vaccination in Ondo State, South-West Nigeria. Findings fromthis study revealed two-thirds of the respondents to have a positive belief in the effectiveness of COVID-19 vaccines. This agrees with a previous study of COVID-19 vaccine acceptance in Nigeria that also found an acceptance level of two-thirds [20], but lower than the findings by Olomofe and colleagues [21], who looked into predictors of COVID-19 uptake. Belief in a health intervention has been found to correlate with ensuing health behaviour and acceptance of interventions [22,23]. Interestingly, the percentage of respondents who reported to have had at least one dose of a COVID-19 vaccine exceeded the percentage of those who believed in the effectiveness of COVID-19 vaccines by 5.9%. Given that a person's perception that a vaccine is beneficial is reported to influence vaccination action from the health-belief model of illness behaviour [23,24], this disparity may imply that there were individuals who claimed indifference to—or expressed disbelief in the effectiveness of COVID-19 vaccines—but got vaccinated nonetheless. Moreover, the population who reported indifference to the effectiveness of COVID-19 vaccines was larger in number than those who were indecisive on taking a COVID-19 vaccine. Conversely, respondents who did not believe in the effectiveness of COVID-19 vaccines were fewer in number than those who responded that they were not willing to get a COVID-19 vaccine. These findings further suggest that expressed beliefs/attitudes sometimes differ from actual intentions and subsequent actions [25]. The intention-behaviour gap, which defines the inability to turn intentions into action, is also consistent with this study's findings. Although people wish to engage in recommended behaviour(s), many fail to do so [26].

Additionally, for those yet to receive any dose of a COVID-19 vaccine, safety issues remain a top concern, as more than half of the respondents expressed their unwillingness to be vaccinated due to safety reasons. This may not be surprising considering the various myths and misconceptions surrounding the development and deployment of COVID-19 vaccines during the early days of the pandemic—most of which still linger [24,27–29]. Several authors also found that safety was a top concern about the willingness to be vaccinated with COVID-19 vaccines [23,24,27,29]. Likewise, more than a quarter of respondents (26%) were not sure of the efficacy of COVID-19 vaccines. Similarly, 12% of the respondents expressed distrust with government vaccination programmes on COVID-19. This lack of confidence in the efficacy of the vaccine may be explained by the misconceptions that the development of COVID-19 vaccines was rushed, and that proper checks and balances were not done [30–32]. Transparency and prompt information are crucial for promoting beliefs since they can positively influence trust. The lack of trust in a government vaccination programme to deliver COVID-19 vaccination could be linked to the persistent belief by some people that COVID-19 does not exist and may just be a hoax to siphon money by the government and its agents. These efficacy and trust issues have also been reported by other researchers regarding their studies on the acceptance of COVID-19 vaccines [28,29,33]. Governments should aim to win the confidence and trust of the populace. We can approach this problem by using the lessons we have learned from the past belief-induced misrepresentation of poliomyelitis immunisation in Nigeria. Political and religious divisions, a lack of community involvement and widespread suspicion of government intentions and those of the international community were all contributing factors to the disruption of the vaccination campaign, which was designed to benefit the public [34].

Our study found a respondent's age, gender, occupation, religion, educational level to be factors that influence individual beliefs regarding the effectiveness of COVID-19 vaccines, and this is also reflected in their vaccination history; individuals who had gotten the COVID-19 vaccine were more likely to have a positive belief about the vaccines. This is congruent with findings from similar studies that showed that these variables positively correlate with the likelihood of getting vaccinated with a COVID-19 vaccine [13,29]. However, we found that young adults (34 to 49 years old) were more likely to be vaccinated than older ones. This refutes findings from previous authors who reported that much older people were more likely to be vaccinated with a COVID-19 vaccine [20,35]. Though more males (75.2%) than females (71.9%) had been vaccinated, the association between gender and the belief in the effectiveness of COVID-19 vaccines differed from vaccination history, as there was no association between the gender and vaccination statuses of respondents. This differs from the findings by other authors, who found that the male sex positively correlates with COVID-19 vaccination [13,21]. According to COVID-19 epidemiological statistics [3,4,12], men are more impacted than women. However, these findings may be because multiple factors relating to the individuals may have been responsible for the association in

the first instance.

The present study's findings on how religion affects people's willingness to get COVID 19 vaccines is not entirely surprising. This was similar to how the poliomyelitis vaccine was received in Nigeria [34]. Nigeria is renowned for being a strongly religious nation with respect for religious authorities who shape attitudes and beliefs [36]. The importance of religious leaders' direct participation in the spread of accurate information about vaccines, as well as in the resolution of difficulties relating to non-compliance with COVID-19 vaccination, is highlighted by their extremely strong influence. Education level was a significant factor in beliefs regarding the COVID-19 vaccine and the history of vaccination. People and geographic areas in Nigeria with low literacy rates have been reported to have mistrust or negative beliefs regarding vaccines [34].

In our study, we discovered that respondents' occupation had an impact on their immunisation and beliefs regarding the COVID-19 vaccine. People who were gainfully employed showed more positive beliefs about COVID-19 vaccines. As anticipated, every healthcare professional in this study had received at least one dose of the COVID-19 vaccination and displayed more favourable beliefs about the vaccine. This result is consistent with research from Ethiopia and Nigeria [13,37]. Due to their frequent contact with sick people, health workers are at a high risk of contracting COVID-19; hence, they should continue to be prioritized for COVID-19 vaccinations. They are crucial to the immunisation programme's success as well. According to Qattan and colleagues [38] their knowledge and views determine their recommendation to other non-health professionals, so all cadres of health workers should actively participate in assuring health education.

5. Study limitations implications for practice

This study adds a better understanding to the beliefs and willingness to receive COVID 19 vaccines among the public in Ondo State of South-West Nigeria, and it allows us to compare practices between regions of the country. It also provides current scenarios of public beliefs and willingness with regards to COVID-19 vaccination.

Our study revealed a disparity between what people profess and their actual action. This gives room for risk communication to be able to change the course of action, and this should be aggressively explored by policy-makers. Additionally, policy-makers should design communication activities that speak to the safety of COVID-19 vaccines, while not neglecting other aspects of misconceptions around COVID-19 vaccines. Strategies targeted at using males to influence their female relatives to get vaccinated should be actively encouraged, as demonstrated in the lower level of belief and vaccination history of females in this study's findings. While this study showed that gender influenced belief in vaccine effectiveness and not actual vaccination status, there is a good relationship that indicates that people follow a course of health action in which they believe [22,24]. Besides, concerns of females around the effects of vaccines

on their future reproductive capability [34] must be addressed through special women-only community fora and discussion sessions. Policy-makers should also engage with stakeholders by sharing transparent, timely and financial information when needed, especially with community leaders, to promote accountability and trust in government COVID19 vaccination programmes.

6. Study limitations

This research has several limitations. First of all, the convenient sampling method employed to select the study site is inherently biased [39], and our study was limited to two LGAs; as a result, it might not be representative of the population of Ondo State. Future studies with a larger sample size and more participants with lower literacy levels are needed to allow for more analysis and understanding of these demographic factors. Second, respondents self reported their COVID-19 vaccination history; interviewers did not look for COVID-19 vaccination cards. As a result, social desirability biases may have led to an overreporting of the study's findings regarding vaccination history. Third, we do not assert a causal relationship between sociodemographic characteristics and COVID-19 beliefs and vaccination history due to the cross-sectional design of the study. Despite the aforementioned drawbacks, this study is a novel attempt to close a gap in the literature on COVID-19 vaccine beliefs and can be used to inform future COVID-19 planning and policy in Ondo State, Nigeria. To the best of our knowledge, this is the first study to inquire about the acceptability of COVID-19 vaccines among the Ondo people.

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Conflict of interest

All authors declare no conflict of interest regarding the publication of this paper.

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