Note: This protocol was submitted April 1, 2021 and approved April 5, 2021.

Not Human Subjects Research Determination

When complete, submit this form to the Research Determination Committee via email:
KPNC-RDO@kp.org

Please provide a response to each of the following questions. Indicate N/A where items are not applicable

In your response, please include any information sheets that will be distributed to the participants.

Name:	Tracy Lieu
Project Title:	Outreach to enhance COVID-19 vaccination among hesitant elderly
Principal Investigator: Tracy Lieu, MD, MPH Director, Division of Research Kaiser Permanente Northern California	
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Notes: Project suggested by Irene Chen, MD, TPMG Associate Executive Director	
Tracking number (To be filled in by the RDO): RDO KPNC 21 - 044	

1. Purpose, specific aims and/or objectives

   The purpose of this project is to gather information that helps The Permanente Medical Group increase rates of COVID vaccination among elderly patients, especially those who are African-American or Latinx.

   Specific Aim A: For African-American and Latinx patients who are 65 years and older and have not made a vaccine appointment after an initial outreach (usual care), we will address these questions:

   1. Compare culturally tailored extra outreach with usual care;
   2. Compare culturally tailored outreach with generic extra outreach;
   3. Compare generic extra outreach with usual care

   For patients of other racial/ethnic groups (white, Asian, and other) who are 65 years and older and have not made a vaccine appointment after an initial outreach, this project will compare generic extra outreach with usual care.

   Specific Aim B: Among a sub-group of patients who appear not to have booked a COVID-19 vaccine appointment subsequent to the extra outreach, we will evaluate the validity of the computerized data, and explore what additional information patients would welcome to inform their decisions about COVID-19 vaccination beyond the extra or culturally tailored outreach.

2. Target population:
   Include:
   Sample description (including estimated size and whether all, adult (18 and older) of adolescent:
   Sample location (e.g. list all facilities included or if region-wide state KPNC):
   Time Period (start and stop dates):

   Description: The eligible population is Kaiser Permanente Northern California patients 65 years and older at the 5 medical centers listed below. As part of usual care, these patients were sent initial outreach

messages via non-secure email (or letters if they had no email address on file) inviting them to schedule a COVID vaccine appointment at KP. All KPNC patients in this age range were sent initial outreach messages between late January and February 28, 2021.

Location: This project will include eligible patients at selected medical centers that have high proportions of patients who are African-American and/or Latinx. The subregions/medical centers to be included are the East Bay (Oakland, Richmond), South Sacramento, Central Valley (Modesto, Manteca, Stockton), Fresno, and San Jose. In Fresno, the Central Valley, patients of all race/ethnicities are included. In South Sacramento, only African-American and Latinx; in San Jose, only Latinx; and in the East Bay, only African-American. This provides a good representation of geographic locations and racial/ethnic groups. The numbers of patients being included are:

Service Area	**Race-Eth-Lang**	**No. of eligible patients**
FRS	African-American	639
	LatinX-English	2109
	LatinX-Spanish	727
	Asian	785
	White	7936
	Other/Unknown	833
	FRS TOTAL	*13,029*
CVL	African-American	1219
	LatinX-English	2037
	LatinX-Spanish	1158
	Asian	1676
	White	9795
	Other/Unknown	1591
	CVL TOTAL	*17,476*
SSC	African-American	1755
	LatinX-English	1002
	LatinX-Spanish	584
	SSC TOTAL	*3341*
SJO	LatinX-English	1501
	LatinX-Spanish	800
	SJO TOTAL	*2301*
East Bay	African-American	*Estimated 3,000*

Time Period: The extra outreach interventions are taking place between March 29, 2021 and April 30, 2021. The analysis of outcomes will include retrospective data analysis from January 1, 2021 through May 31, 2021.

For aim A the entire sample will be used. For aim B, we will identify subsamples of 400 African-American, 400 Latinx, and 400 white/Asian/other patients. These subsamples will be selected at random from among patients in the participating locations who appear neither to have yet received COVID-19 vaccine (from any KP or non-KP location in the state) no to have a pending appointment with KP, despite extra outreach. The data informing this aim will be collected by survey, with survey activities

scheduled to take place mid-May through mid-July 2021.

3. Procedures used to gather information
    a. Indicate if these procedures would be conducted as part of standard of care, regardless of the proposed activity.

The procedures to be used are all within the standard of care practice for immunizations. Some patients will receive additional outreach emails/letters. Such emails/letters are routinely used by TPMG's population health team for other preventive services, for example colorectal cancer screening, to tailor outreach activities to subpopulations that do not have the expected response rate to the initial usual care outreach procedures.

All patients will receive at least usual care outreach. Two patient subgroups will be assigned at random to receive additional outreach, as below. The decision to use random assignment was made by operational leaders for quality (Drs. Irene Chen and Deb Sawyer) in order to gain more valid information about the effectiveness of the different approaches to outreach and inform future operational decisions.

- **Group A -- Usual care**: This consisted of a generic non-secure email, or for those patients who did not have an email address, a letter. The content of the email and letter (**Appendix A**) informed the patient that they were eligible to receive COVID vaccination and invited them to schedule an appointment. The usual care intervention has already been made for all KP patients aged 65 and older. The last date this outreach was conducted was February 28, 2021.

- **Group B – Generic Extra Outreach**: This will consist of usual care (the 1st outreach) plus a 2nd and 3rd outreach for those patients who have not yet booked vaccine appointments by 14 days after the prior outreach. The 2nd outreach will consist of a generic secure message sent by the regional department (TPMG Consulting Services) on behalf of the patient's primary care provider. Patients who do not have access to secure messages (i.e., not enrolled in kp.org) will be sent a generic letter (**Appendix B**). The 3rd outreach will consist of a generic postcard (**Appendix C**) that includes a QR code that links to the vaccine appointment booking website.

- **Group C – Culturally Tailored Extra Outreach**: This workflow will be the same as the generic extra outreach, except that for the 2nd and 3rd outreach messages, each patient will be sent content that is culturally tailored for African-American and Latinx patients (**Appendices B, C, and D**).

As noted above, it's important to note that the additional outreach being planned is not unusual or experimental. The outreach content is being created by experts with TPMG Health Engagement and Consulting Services and is based on well-tested templates from colorectal cancer screening outreach efforts. The secure message, letter, and postcard content is being adapted from these templates. The culturally tailored content also draws on culturally tailored messages used in colorectal cancer screening outreach.

For African-American and Latinx patients at the selected medical centers, 1/3 have been assigned to each of the above 3 groups (Usual Care, Generic Extra Outreach, or Culturally Tailored Extra Outreach).

For patients of other race/ethnic groups at selected medical centers (e.g. white, Asian, other), ½ will be assigned to Usual Care and ½ will be assigned to Generic Extra Outreach.

It is standard practice for our system to evaluate organizational effectiveness in patient care. Medical centers often initiate specific outreach to patients in addition to regionally-initiated outreach (which is what this project is). This regional evaluation will not preclude participating medical centers from making specific outreach that would have been part of their usual patient outreach for COVID vaccinations. However, we will ask them to refrain from copying the specific content of the extra outreach interventions during the 6 weeks of the project.

4. Description of the data/samples gathered about individuals including names of datasets, URL, etc.
    a. What data/samples will be collected, how and by whom the data will be analyzed
    b. How will/were the data/samples gathered from individuals? (e.g., obtained as part of an IRB approved protocol or as part of routine clinical care)
    c. Can the collected data/samples be directly or indirectly associated/linked with individual identifiers?
    d. Can others directly or indirectly associate/link the collected information with individual identifiers?

We will conduct an analysis using computerized data from KPNC sources. The primary outcome of this analysis will the receipt of a first dose of COVID-19 vaccination. A secondary outcome will be making an appointment to receive COVID-19 vaccination (which may be at some point in the future at the time this analysis is completed).

Aim A: The computerized data can be linked with individual identifiers in the source data by the programmer/analysts on the operational team who are participating in this project. Individual identifiers will be excluded from the final datasets created for this analysis.

Aim B: The survey will evaluate the validity of the computerized data (specifically, to see whether a patient has received COVID-19 vaccination at a location outside KP that was not captured in the data that KPNC receives from CA state), and explore what additional information patients would welcome to inform their decisions about COVID-19 vaccination; (specifically, whether African-American, Latinx, and white/Asian/other patients differ in their rates of self-reported (a) non-financial barriers to making vaccine appointments, (b) hesitancy about receiving COVID-19 vaccine, and (c) level of confidence about having the right information to make a good decision). Patients will be contacted first by email and letter (USPS), and subsequently by telephone; the survey will be administered via the internet (on the KP RedCap platform behind the KP firewall) or hard copy, and subsequently by telephone. Our timeline is summarized as follows:

Wave 1: Field email & mailed survey	Final Outreach (touch 3) + 28 days
Wave 2: Non-responders: repeat email survey to Wave 1	Wave 1 + 14 days
Wave 3: Non-responders: repeat mailed surveys and begin calls	Wave 2 + 7 days
Close survey	Wave 3 + 28 days
Data analysis and manuscript writing	Close survey + 28 days

The survey, cover letter and telephone script comprise **Appendices E, F, and G**.

5. Generalizability of project findings, or value of project findings

These findings will be primarily applicable to TPMG. The primary purpose of this project is to inform decisions about how to conduct outreach to enhance COVID vaccination rates within the KPNC population in the future. The findings will be described in presentations and reports and disseminated via the Adult and Family Medicine chiefs' group of TPMG.

We hope that at least some of the findings will be generalizable to other health care systems that are attempting to enhance COVID vaccine acceptance provide care via video visits to diverse populations. We plan to submit a manuscript based on the findings to a peer-reviewed journal.

Addendum

Statistical Analysis Plan

The primary analysis will use intention-to-treat assignment and will compare time to vaccination between each outreach arm with usual care. Descriptive statistics will include the percent vaccinated at 8 weeks after the intervention start.

For the primary analysis, we will create Cox proportional hazards regression models that include a fixed effect for study arm and will adjust for variables used in stratification, i.e. race-ethnicity-language group and geographic area. Subgroup analyses will be conducted to evaluate the association of study arm with time to vaccination in each of the four race-ethnicity-language groups (African American or Black, Latino-English preferred, Latino-Spanish preferred, and Asian/White/Other/Unknown).

To evaluate other predictors of vaccination, we will create a Cox proportional hazards model that includes all patient characteristics as well as study arm. Tests of significance will be two-tailed with an alpha of .05. No Bonferroni or other formal correction for multiple comparisons will be used.

The sample size will be determined by including all eligible patients in the population. Because this number cannot be known prior to the study, power will be estimated on a post-hoc basis.