Title: Take 2 Pills and Go Help in the Morning: A Feasibility Study of Engaging Patients as Volunteers

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I. TAKE 2 PILLS AND VOLUNTEER IN THE MORNING: A FEASIBILITY STUDY OF ENGAGING PATIENTS AS VOLUNTEERS

II. IMPACT ON REDUCING HEALTH DISPARITIES

We propose to examine the feasibility and acceptability of a novel intervention in which primary care providers in safety net clinics "prescribe" volunteering to their uninsured patients. In a nutshell, we plan to develop a brand new intervention that envisions having providers recommend volunteering as part of a patient's treatment plan—alongside, for example, their recomendations for diet and exercise. The initial setting would be Loyola Medicine's Access to Care (ATC) Clinic, a program using attending physicians and residents to deliver primary care to approximately 1,000 low-income uninsured patients annually. Willing patients would be connected to volunteer opportunities within the Loyola University Health System (LUHS) or to a local nonprofit agency situated in their own communities. The purpose of this application is to support research activities that would 1) inform the development of an intervention that would be a) acceptable to the target population and b) feasible to administer in under-resourced clinical settings; and 2) determine whether (and what kind) of preliminary outcomes related to well-being, activation, self-esteem, new skills, connection to others, etc. might accrue to patients connected to volunteer activities in an initial test of the intervention.

Substantial evidence from randomized controlled trials and cohort studies, primarily involving older adults, suggests that volunteering contributes to improved mental health, greater longevity[1] and beneficial health behaviors.[2] Surprisingly little research exists on the experience of *patients* as volunteers.[3,4] We posit that multiple positive outcomes are likely to accrue from engaging patients, especially vulnerable patients, as active participants in helping others.

Moreover, volunteering has the potential to address multiple social determinants of health—education, economic stability, health care services, social integration, and community engagement—that could benefit the individual/patient, clinic, and community. Reaching beyond the health status of the patient and into the surrounding social structures and economic systems is a worthy investment since **socioeconomic factors**, such as education, employment, income, and social support, are estimated to **account for nearly half of health outcomes**. By contrast, the relative contributions of clinical care and insurance to health outcomes are estimated to be only 20%.[5] Thus, while changing our health system and increasing insurance coverage are necessary strategies to improve health outcomes of the uninsured, **advancing population health and achieving health equity will require new nonclinical approaches that more deliberately incorporate broader social determinants of health. This proposal fits squarely within that broader paradigm, which could also be termed "THE OTHER 80%."**

This project helps fill a gap in health equity research. We target the uninsured, who are often ignored by innovations designed to reduce health disparities (e.g., medical homes, accountable care organizations, coverage of preventive health services) as these innovations are typically tied to third-party payments. Nevertheless, the uninsured constitute a large, costly, and enduring vulnerable population that presents multiple challenges—but also untapped abilities. *Moreover, their less healthy profile means that they have all the more to gain from the potential benefits of the intervention*. Approximately 30 million people are projected to remain uninsured by 2027.[6] It is well documented that they are disproportionately poor, black and Hispanic, nonelderly adults. Moreover, health disparities are present across demographic groups like race/ethnicity, socioeconomic status, religion, disability, age, geography, gender, etc.—so an intervention that focuses on the uninsured rather than a single disparate population group (e.g., African Americans) has the advantage of impacting multiple population groups experiencing different kinds of disadvantages.

From a policy perspective, the lessons learned through this project may be directly applicable to contemporary Medicaid policy discussions. For instance, there is now substantial interest in requiring Medicaid beneficiaries to work as a condition of eligibility. To date, three states (AR, IN, and KY) have received federal approval to enact Medicaid work requirements, and applications are pending in an additional 7 states (AZ, KS, ME, MS, NH, UT, and WI). Policymakers, consumer advocates, and safety net providers in these affected states

(and any others that might follow suit) trying to preserve Medicaid for the low income (and disproportionately minority) beneficiaries subject to the new work requirements might be especially interested in an intervention that encourages volunteerism among vulnerable patients since volunteering/community service counts as work activities in all but three states' plans (NH, UT, and WI).

III. INTRODUCTION/BACKGROUND

Our health system does not assure affordable, accessible, and equitable care or produce the highest level of health for everyone who lives in the United States. Being uninsured is one reason why.

Negative Consequences of Being Uninsured. Having no insurance is associated with a host of health, social, and economic disparities: less access to health care,[7,8] poorer treatment,[9] worse health outcomes,[10] higher debt,[11,12] and greater social isolation.[13]

Beyond issues of inequity, the costs are enormous: the uninsured are estimated to account for $85 billion yearly in uncompensated care, which is borne by the individual, employer, health system and society [14,15]

Magnitude of the Uninsured Problem. In 2018, there are an estimated 30 million individuals, mostly adults 18-64, who are uninsured, and this number is expected to hold steady over the next decade [6]. While the Affordable Care Act (ACA) has reduced the number of uninsured by roughly 14 million, the average percentage of U.S. residents without insurance is still high: 10.3% across all states, 13.3% in non-Medicaid-expansion states (n=18 states), and 8.1% in Medicaid-expansion states (including Illinois). Put differently, that is 1 uninsured person out of every 12 people living in a Medicaid-expansion state. And that is arguably the best-case scenario after the ACA.

The Uninsured at Loyola's Access to Care (ATC) Clinic. Closer to home (see Table 1), in ATC Clinic's catchment area, rates of uninsurance are much higher than in Illinois and comparable to or worse than uninsurance rates in neighboring Chicago, where residents are more than twice as likely to be uninsured than the rest of Illinois.

Table 1. Uninsurance in ATC Clinic's Catchment Area

Characteristic	Illinois	Chicago	Broadview	Berwyn	Cicero	Franklin Park	Maywood	Melrose Park
Population size	12.8 m	2.7 m	7,823	55,748	82,992	18,110	23,756	25,229
Persons <65 w/out health insurance (%)	7.4	16.3	16.2	14.8	23.9	16.1	18.0	21.0

Source: U.S. Census, Data as of July 1, 2016.

It is not coincidental that the ATC Clinic attracts patients from neighborhoods that have large percentages of low income and minority residents. Being a member of a racial/ethnic minority group, being low income, or being a non U.S. citizen are all risk factors for uninsurance.

Loyola's ATC program is a by-product of a partnership between Loyola and "Access to Care," a Cook County program (http://www.accesstocare.org/) sharing the same name. Loyola contracts with Access to Care to provide low-cost primary care ($5/visit), laboratory and radiology services ($5), and medications ($5 to $40) to low income (<300% of poverty) uninsured and underinsured residents in suburban Cook County. In return, the providers receive an annual nominal fee of about $70 per patient. Loyola's ATC program currently has 952 active adult patients and provides about 3,000 visits annually. A majority is female (roughly 60%) and ages range from 19 to 83. Hispanics comprise the largest racial/ethnic group (78%) followed by African Americans (18%). Reflecting their high chronic disease burden, the top diagnoses are diabetes, hypertension, obesity, depression, osteoarthritis and dyslipidemia. There is one attending physician, Dr. Fitz, a co-investigator on this proposal, who sees patients on Monday, Wednesday and Thursday afternoons and all day on Tuesday.
The clinic is open on Fridays for acute care visits, and the Loyola Immediate Care centers and Emergency Department are available to patients during off-hours or for more urgent needs. LUHS also provides tertiary care with consult and procedural support for ATC Clinic patients at the main hospital. The clinic is a residency training site, enabling residents to learn from and care for patients during their 3-year training program in a continuity care model. Dr. Fitz oversees 3-4 residents at a time who rotate through the clinic every 5 weeks for a total of approximately 20 different residents per year.

Ameliorating the Effects of Being Uninsured. In the absence of expanding health insurance coverage,[16] a policy option that is effective but not feasible in the current political climate, there are steps we can take to mitigate the harms of being uninsured. Lessons from the social determinants of health literature prompt us to focus our attention *outside* the health system—i.e., **"THE OTHER 80%."** The proposed "prescribing volunteerism" intervention is offered in this spirit: an incomplete fix on its own but a strategy that would likely garner political support from both sides of the aisle, and one that is arguably an improvement over the status quo.

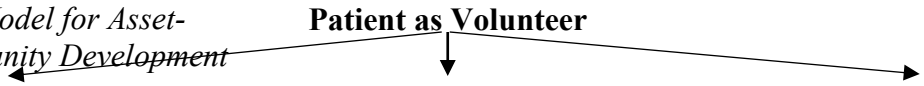
Extent of Volunteerism and Its Benefits. According to 2015 data from the U.S. Bureau of Labor Statistics, one in four Americans volunteers each year, with higher participation rates among Whites (26%) than African Americans (19%) or Hispanics (16%). Volunteers spend a median of 52 hours per year on volunteer activities. The United Nations and governments around the globe encourage volunteerism as a strategy to not only engage people in their communities and improve social capital but also to reduce health inequities.[1] The idea that volunteerism could be "prescribed" by doctors as a way to improve health reached the pages of *The Atlantic*, which suggests that it is not as far-fetched as it might first seem.[17] Adding to the large body of evidence suggesting a correlation between volunteering and numerous health benefits, the meta-analyses[1,18] plus randomized controlled trials (RCTs) involving older adults[19,20] and adolescents[21] showing sustained improvements in physical activity and lower cardiovascular risk, respectively, make a convincing case that volunteering contributes to better health.

Preliminary Work. Given the uncharted nature of the proposed study, we administered a three-question survey designed to gauge the general acceptability of and demand for volunteering among uninsured patients seeking care in the ATC Clinic. Front desk workers distributed the survey over a two-week period in April, 2018. Formatted two-sided in English and Spanish, the survey asked about past volunteering experiences, level of interest in volunteering, and the likelihood of their volunteering if recommended by their physician.

In all, we collected 24 completed surveys (50% Spanish; 50% English). A substantial minority (42%) of patients have done volunteer work in the past or are currently doing volunteer work, but past volunteering was higher among English-speaking (ES) patients (67%) than Spanish-speaking (SS) patients (17%). Fully two-thirds of patients (67%) said that they are "somewhat interested" to "very interested" in learning about possible volunteer jobs, with some differences between ES (75%) and SS (59%) patients. Reassuringly, very few reported being *not* likely (8% ES; 17% SS) while half of the patients said they are "likely" or "very likely" to engage in volunteer work if recommended by their doctor. See Appendix B for details.

Conceptual Framework. Our study is guided by a conceptual model (Figure 1, below) that advances volunteering as an intervention that can improve well-being at the patient-, clinic-, and community-level. It does so by increasing patients' capacity to build communities by way of addressing the social determinants of health. In this proposal, we focus on measuring the benefits that may accrue to the patient, reserving the

Figure 1. A Model for Asset-Based Community Development



Patient	Clinic	Community
INCREASED WELL-BEING Increased life skills Increased self esteem Increased emotional gratification Increased dignity, power, prestige Improved health status Increased self-efficacy/activation Increased networks	ENHANCED PATIENT-CENTEREDNESS Increased respect for patient Increased equality between provider-patient Mutually reinforcing	IMPROVED WELL-BEING Increased social capital Increased civic engagement
Focus on the Social Determinants of Health		
Education Economic Stability	Health & Health Care	Social & Community Context Neighborhood

assessment of additional benefits to the clinic and community for future studies.

Our research adopts an asset-based approach. We intentionally leverage (and seek to bolster) the abilities of vulnerable patients rather than focus on their needs. If we determine that patients can serve as volunteers, our research would suggest new, empowering roles that they can play in an era of patient-centered care, and new ways that patients can become healthier, more skilled, more connected, and more civic-minded.

IV. SPECIFIC AIMS

The overall objectives of this feasibility study are to evaluate the acceptability and feasibility of promoting volunteerism in safety net settings, and to gather preliminary evidence that will inform a larger study. Toward these ends, we propose a sequential mixed-methods research design in which information from earlier aims will inform the implementation of subsequent aims. We propose the following aims and methods:

1. **Assess the acceptability and feasibility of the "prescribing volunteerism" intervention among uninsured patients, providers, and executives in diverse ambulatory care safety net settings.**
   - Safety net settings will include an academic medical center ambulatory clinic, free medical clinic, and federally qualified health center. These settings disproportionately serve patients at risk for experiencing health disparities: low income, uninsured, immigrants, and members of racial/ethnic minority groups.
   - We will carry out focus groups with patients, and key informant interviews with clinical staff and clinic executives to help inform Aims 2 and 3, see below.
2. **Establish linkages between the intervention setting and other community-based, nonprofit organizations offering volunteer opportunities in Loyola's catchment area.**
   - Loyola Medicine's ATC Clinic will be the initial intervention setting.
   - We will establish formal linkages between the intervention site and the following: Loyola University Medical Center in Maywood, Gottlieb Memorial Hospital in Melrose Park, MacNeal Hospital in Berwyn, and other community-based, nonprofit organizations that could offer volunteer opportunities in Loyola's catchment area. [See Appendix C for letters of support from example community partners, Maywood Fine Arts, Quinn Community Center in Maywood, and the Illinois Coalition of Immigrant and Refugee Rights, which has numerous affiliated partners in the ATC Clinic's service area.] Feedback from patient focus groups will inform our outreach to community organizations as we will seek to find opportunities that match patients' interests and preferences.
3. **Gather preliminary data about the potential effectiveness of a volunteer program in a safety net setting.**
   - We will implement a small pilot of the intervention in the ATC Clinic to learn if it will be feasible and effective on a broad scale.
   - We will recruit 50 uninsured patients, with 25 in the intervention group and 25 in the control group. For the 25 uninsured patients who initiate volunteering at one of the designated sites, we will collect data on the nature and intensity of their volunteering (e.g., role/position, hours, and # of times) as well as outcome measures such as activation, self-esteem, and well-being. We will compare outcomes between the intervention group and an uninsured comparison group, which will be comprised of ATC Clinic patients who expressed an interest in volunteering on a screening form but were not assigned a volunteer job.
   - We hypothesize that volunteering will be associated with improved outcomes.

V. PROJECT OUTLINE

We propose a sequential mixed-methods research design that involves three stages, which align with the 3 aims. Stage 1 involves collecting qualitative data and developing intervention-related materials and procedures. Stage 2 involves establishing linkages with the nonprofits offering volunteering opportunities. Stage 3 is the initial test of the intervention. Stage 1 informs Stages 2 and 3, and Stage 2 informs Stage 3. By the end of the study, we expect to have enlisted approximately 130 research subjects to help us achieve the aims of the study, including: 110 uninsured patients, who will participate in focus groups (n=60) or the intervention (n=25 intervention, n=25 control); 9 clinicians from the ATC Clinic, free clinic, and FQHC; 3 clinic executives representing the aforementioned safety net settings; and 7 nonprofit organizations that offer volunteer jobs.

Aim 1. Assess the acceptability and feasibility of the "prescribing volunteerism" intervention among uninsured patients, providers, and executives in diverse ambulatory care safety net settings.

Study Design and Methods, Setting, and Subjects. We will use a grounded theory qualitative approach to gather information about the project's acceptability and feasibility from the perspective of patients, clinicians, and clinic executives. We plan to use 90-minute focus groups to collect information from patients (n=60) and 30- to 45-minute key informant interviews for clinicians (n=9) and clinic executives (n=3). Focus groups and interviews will be audio-recorded. To increase generalizability of the intervention, the focus groups and interviews will be carried out in three safety net settings: ATC Clinic, CommunityHealth free clinic (see Appendix C for letter of support), and a FQHC to be determined. Volunteer-based free clinics, which are estimated to serve 2 million uninsured adults annually,[22] have a well-developed volunteer infrastructure, and may be especially apt for enhancing patient centeredness in this intervention as they are well-equipped to offer volunteer activities *inside* their clinics. By contrast, FQHCs use a staff model but are significant providers of comprehensive primary care to the uninsured, serving some 5 million uninsured adults annually.[23] Potential future replication of the intervention in FQHCs would greatly expand reach, so activities in this project help prepare us for this opportunity.

In the focus groups, we will seek input from patients about their past volunteer experiences and the motivations for volunteering, perceived benefits of volunteering, reasons for not volunteering, opinions about the idea of having a doctor recommend volunteering, reactions to draft marketing materials, perceived likelihood of volunteering if recommended by a doctor, and volunteer interests.

To explore the intervention's acceptability as well as its practicality and compatibility with the practice setting, we will interview clinicians who would play a key role in recommending volunteerism to their patients as well as clinic executives who would be responsible for implementation. Where applicable (e.g., free clinic), we will explore best practices for recruiting patients into volunteer roles.

Data Analysis. We will use a combination of professional transcription services and student research assistants to transcribe the focus groups and interviews. To facilitate rapid learning, we will code each transcript only once and then enter them into NVivo. Team members will meet to discuss learnings, identify themes, and come to consensus on the meaning of any ambiguous content. Lessons learned will inform Aims 2 and 3.

Deliverables. We will:

- develop marketing materials based on messaging that seems to resonate with patients, and from feedback we received on sample posters and flyers during the focus groups.
- establish procedures for raising awareness about the intervention (who says what and when), ensuring that there is a "warm hand-off" from the provider to an ATC Clinic staff person.
- develop a screening tool (modeled after the 3-question survey about volunteering that we distributed to patients) to identify patients who would be interested in volunteering, though we plan to add items about demographic and clinical characteristics to aid our matching intervention and control subjects under Aim 3.
- develop a one-page information sheet about the intervention and its value to educate ATC Clinic medical residents about the intervention. Education contacts will commence at the start of each rotation.

The materials we develop and processes we establish during Aim 1 will be implemented in Aim 3.

Aim 2. Establish linkages between the intervention setting and other community-based, nonprofit organizations offering volunteer opportunities in Loyola's catchment area.

Study Design and Methods, Setting, and Subjects. As with Aim 1, we will use a qualitative approach, relying on key informant interviews to gather information from community nonprofits offering volunteer opportunities and organizations that link individuals to volunteer jobs. We will conduct key informant interviews with 5 nonprofit organizations offering volunteer activities to learn about their volunteer offerings and solicit their input on how to set up effective, two-way communication channels, ensuring that the ATC Clinic receives regular reports about volunteer hours completed by patients at the community sites. To learn about best practices linking individuals to nonprofit volunteering activities, we will conduct 2 key informant interviews with volunteer referral centers at the University of Chicago (https://ucsc.uchicago.edu/) and in New York City (https://www.nycservice.org/). Additionally, we expect that repeated communication would be

beneficial with our most active nonprofit partners and will establish a learning collaborative with 5 nonprofits that can provide regular feedback to the research team through monthly calls.

Data Analysis: Following the approach from Aim 1, we will have only one coder for each transcript but devote ample time for discussion of findings among team members. The findings will be used to develop a referral form as well as inform the execution of Aim 3.

Deliverables. We will develop a referral form that ATC Clinic staff will use to link patients to volunteer opportunities.

Aim 3. Gather preliminary data about the potential effectiveness of a volunteer program in a safety net setting. As noted, information from the earlier aims will inform some of the details for the final aim. Nonetheless, the general framework for the implementation of the pilot intervention is outlined below.

Study Design, Setting, and Subjects. For this pilot phase, we will use a quasi-experimental difference in differences study design that compares two groups, one that volunteers and one that does not. We will recruit patients from the ATC Clinic. Patients will be eligible to participate if they: 1) are adults 18+; 2) received care at the clinic at least twice in the past year; 3) are not currently volunteering; 4) speak Spanish or English, and 5) deemed fit to participate by their provider.

Recruitment. To meet our recruitment target of 50 patients (n=25 in intervention arm, n=25 in control arm), we will use a multi-pronged approach that involves marketing materials (e.g., posters, flyers), repeat messaging about the volunteer program, provider education to reinforce messaging, and direct recruitment at the clinic visit. All eligible patients will be invited to participate in the study. We will continue to recruit patients into the intervention group until 25 participants consent to being referred to one of the volunteer activities that were established under Aim 2 during Stage 2. Once the cohort is filled, we will review the completed screening forms to identify patients who share similar characteristics with the intervention group and invite them to participate in the study as controls. Though our preliminary data would suggest that nearly half of the ATC Clinic patients would be interested in the intervention, we conservatively estimate that it will take 4 weeks to recruit and consent 25 subjects into the intervention. This estimate is based on the assumption that we can recruit just 10% (n=6) of each week's total patient caseload, which is about 60 per week. Moreover, the 10% estimate takes account of the roughly 8% of patients who would be expected to be in current volunteer jobs and ineligible for the intervention. We will take an additional three weeks to recruit and consent the control patients.

Intervention. We will link the intervention subjects to volunteer opportunities at Loyola or in their communities and track their "referral completion" and volunteer activities through agreed upon communication channels devised under Aim 2. Subjects will be engaged in volunteer tasks for at least four months.

Data Collection/Measures. Data will be collected for all eligible patients (intervention and controls) who consent to be part of the study. (See Appendix D for complete details.) We will collect data at two time points, at baseline and at the end of the study. At baseline, we will collect demographic and outcome information. Upon completion of the study period, we will gather information on outcomes and volunteer job satisfaction (for those who volunteered). Additionally, for those who volunteered, we will collect data about the site, nature, and intensity of their volunteering activities. All surveys will be interview-administered by the study team. Several (previously validated in English and Spanish) instruments will be used to assess outcomes. All subjects, regardless of arm, will be assessed on well-being (using word and visual methods), self-esteem, and activation/efficacy. Volunteers referred to volunteer jobs will be asked to report on motivation for volunteering, satisfaction with volunteer experience, benefits of volunteering (e.g., life skills, networking), and barriers to volunteering. To reduce respondent burden and fatigue, the series of baseline and follow-up surveys is each expected to take about 30 minutes.

To compensate patients for their time and contribution to the study, to help address barriers to participation, and as a sign of respect, we will provide a $20 Target gift card to all patients who complete the baseline assessment and another $20 Target gift card at the study's completion.

Data Analysis. We will carry out several analyses. First, we will compare baseline data between those who participated in the volunteer program with those who did not. The comparison group will be derived from patients who indicated an interest in volunteering but were not assigned a volunteer job. We will select 25 patients who are "frequency matched" on severity of chronic disease, race/ethnicity, age group, gender, highest

level of education, and work status. Second, we will carry out a simple difference in difference estimation approach in which we will examine differences in outcomes between baseline and the end of the study between the two comparison groups. The idea is that the simple "pre-post" design may be biased because of unobserved factors that affect outcomes and that changed along with the intervention. If these unobserved factors also affected the control group, then double differencing can remove the bias and isolate the intervention effect. We will use basic descriptive statistics and chi-square tests to compare differences in proportions and the t-test or the Kruskal-Wallis test to compare means. If the sample size allows it, we will explore regression methods.

Human Subjects Concerns/Risks. The study presents minimal risks with potential health benefits to subjects willing to initiate volunteer activities. While participation is completely voluntary, there is a risk that patients might feel coerced to participate in the intervention. To address this concern, staff will reassure patients that failure to participate will in no way affect their care at the ATC Clinic. The protocol and all study materials will be submitted to the Stritch School of Medicine (SSOM) Institutional Review Board. Interested eligible individuals will be guided through standard informed consent processes. All forms, except the consent form, will exclude participants' names and contact information; a participant will only be identifiable via 6-digit participant identification code. That code will be attached to the name and contact information in a password-protected file. This file will be kept in a separate space and will be accessible only to the study team. Nobody outside the research team will use or disclose data. Data will be presented or published only in aggregate form.

Timeline. We propose our timeline as follows.

Task/Month	7/18	8/18	9/18	10/18	11/18	12/18	1/19	2/19	3/19	4/19	5/19	6/19
Preparation												
Finalize focus groups/interviews	■											
Obtain IRB approval for Stage 1 qualitative inquiry	■	■										
Stage 1: Qualitative Work and Development of Intervention-Related Materials and Procedures												
Conduct focus groups/interviews		■	■									
Analyze qualitative data			■									
Develop marketing materials			■									
Develop protocol/clinic procedures for recommending volunteerism			■									
Develop 1-page information sheet for medical residents/providers			■	■								
Develop screening tool to gauge interest in volunteering/match arms			■	■								
Establish ATC procedures for referring patients to volunteer jobs			■	■								
Obtain IRB approval for Stages 2 and 3 (amendment)					■	■						
Stage 2: Establishing Linkages with LUHS and Community Nonprofits Offering Volunteer Opportunities												
Establish formal linkages			■	■	■	■	■					
Conduct key informant interviews				■	■							
Analyze interview data				■	■							
Develop referral form					■							
Stage 3: Conduct pilot at ATC Clinic												
Recruit and consent subjects						■	■					
Educate providers/residents							■					
Implement intervention							■	■	■	■	■	
Analyze pilot data, generate results												■
Submission of manuscripts and presenting findings at conferences will occur after the funding period.												

VI. OUTCOMES/SUSTAINABILITY

We have conceived of our entire research endeavor in 4 distinct phases: Phase 1 – feasibility, *the focus of this application*; Phase 2 – exploratory; Phase 3 – efficacy; and Phase 4 – dissemination and implementation.[24] Our long-range goal is to secure a R01 grant to 1) test the efficacy of the Engaging Patients

as Volunteers intervention in a randomized, controlled trial; and 2) replicate the intervention broadly.

To prepare a successful R01 application, we plan (Phase 1) to first demonstrate the intervention's feasibility and acceptability by the proposed activities. Then, in Phase 2, we will seek additional extramural support to further explore the intervention. We will carry out the definitive randomized controlled trial in Phase 3. And during Phase 4, our focus would shift to replication and broad dissemination. We would anticipate that a R01 grant would encompass Phase 3 and (at least some aspects of) Phase 4.

The results generated from this Phase 1 feasibility project will be used in a National Institutes of Health (NIH) National Institute of Minority Health and Health Disparities (NIMHHD) R21 (Phase 2) application, which allows direct costs up to $275,000 over two years. NIMHHD is inviting applications on systems-wide health services research that test "strategies to organize, manage, finance and deliver health care to improve minority health or reduce health disparities." In particular, the agency is encouraging applications that are highly innovative and address larger systemic factors outside the health system (i.e., exactly what we describe above as "the other 80%" of what determines health outcomes). The longer duration and larger budget of the NIH would allow for scaling up and refining the intervention in the main site, Loyola's ATC Clinic, as well as spreading the intervention to additional safety net sites. The planned qualitative research activities with providers, staff, and patients in other clinic settings during Phase 1 will set the stage for expanding the intervention to additional settings (Phase 2).

The Evidence for Action: Investigator-Initiated Research to Build a Culture of Health funding opportunity sponsored by the Robert Wood Johnson Foundation would be another potential source of funding to consider, either as a substitute for or complement to the NIH R21 application. Similar to the R21 mechanism, the Culture of Health grants are typically in the range of $100K to $300K over a period of one to three years. Thus, the budget size and duration would be adequate to further test the intervention.

Besides the above funding opportunities, our team will strive to elevate the profile of this highly innovative research and hopefully attract the attention of funders by seeking to disseminate early study findings at the American Public Health Association as well as at national and state conferences targeted to free clinics.

Ongoing student involvement also can help us sustain our connection to the ATC Clinic when grant funds from Health EQ are exhausted. For instance, we plan to encourage students in the Master of Public Health (MPH) program to pursue their practicum and capstone experiences at the ATC Clinic. Ideally, their experiences would include components that would advance this project's goals.

VII. TEAM

The team of key investigators is highly diverse, representing backgrounds in health policy and social work (Julie Darnell-PI), medicine (Matt Fitz, Nallely Mora), and epidemiology (Abigail Silva, Mora), with English/Spanish bilingual proficiency (Fitz, Silva, Mora). Combining expertise in health disparities research, patient care, and collaborations with community-based providers, the team is well qualified to carry out the study. The team has formal training in and substantial experience with the proposed quantitative and qualitative methods. Faculty are housed in the SSOM Department of Public Health Sciences and in the LUHS Department of Internal Medicine. Additionally, the application includes meaningful opportunities for ATC-affiliated residents as well as students to become involved in research activities. We anticipate that our community partners, which include the safety net providers as well as nonprofits offering volunteer opportunities, will play active roles as key informants and advisers throughout the study period. The letters of support demonstrate their enthusiasm about our application. Two team members have worked together previously on funded research (Darnell and Mora) and Dr. Fitz is a mentor to Dr. Darnell. This application is bringing together two investigators (Darnell, Silva) for the first time, though they share an interest in working with safety net institutions to address health disparities. The team includes a key staff person (Yvette Lugo) at the ATC clinic, who will serve as liaison with the ATC Clinic patients. The roles/responsibilities of each team member is provided in the budget justification, which is included in Appendix E.

VIII. BUDGET/FUNDING

We request funding in the amount of $49,738 to initiate a new and highly promising frontier of research activity that advances the work of several early- and mid-career investigators. Seed funding from the Health-EQ

will allow our team to produce preliminary data that will make future extramural applications more competitive. We provide details about the budget in Appendix E.

IX. PROTECTION OF HUMAN SUBJECTS

Please note that we have spelled out our methods for protecting human subjects for only the **patient focus groups, the first activity in our qualitative study**. We will append this section with additional details about the key informant interviews as well as the intervention in subsequent amendments.

The qualitative portion of our study involves focus groups with clinic patients and key informant interviews with healthcare professionals. We have taken steps to protect the human subjects involved in these activities. In general, we propose to use research information sheets (Research Info Sheet for Patient Focus Groups is attached in this application; the Research Info Sheet for Key Informant Interviews is under development) in lieu of obtaining written informed consent.

Participation in the qualitative study is voluntary. Patients will be recruited with flyers displayed and distributed in the clinic. Healthcare professionals for key informant interviews will be recruited directly by email and/or by phone.

We will be asking patients to participate in focus groups lasting approximately two hours, and healthcare professionals to participate in key informant interviews lasting approximately 30 to 45 minutes. The focus groups will be conducted in person while the key informant interviews will be conducted both in person and by phone.

Immediately before the focus groups and in advance of the key informant interviews, patients and healthcare professionals will be given a copy of the corresponding research information sheet, which is being used in place of obtaining written consent, a noted above. We anticipate that we will send the research information sheet to key informants as an attachment in an email. Regardless of participant type, all participants will also be verbally reminded of their rights and the risk of the study immediately prior to their participation. Starting from recruitment, all participants will be regularly encouraged and given the opportunity to ask questions via email, phone, and in-person.

At the start of the focus group or key informant interview, participants will be asked to fill out a background survey. (Survey for Focus Groups is attached & Survey for Key Informant Interviews is under development). No identifying information will be recorded on the surveys, and all results of this survey will be kept anonymous and de-identified.

The focus groups and key informant interviews will be audio recorded. We will record only the participant's first name plus his/her first initial of his/her last name (e.g., Maria B.) in all handwritten notes and transcriptions. Members of the research team will be keeping the handwritten notes, audio recordings, and computer files. All research materials will be kept on password-protected computers. All audio recordings will be destroyed once the key informant interviews have been transcribed. There are no plans to destroy the handwritten notes, transcribed notes, and computer files, as these materials may be useful for future grant applications.

We assure all our participants that no information identifying them will be used in any reports or presentations at scientific meetings. Eventually, we may publish what we learn from the focus groups and key informant interviews. Again, all written reports/articles will not include any information that identifies any specific person. A participant's individual privacy will be maintained in all published and written data resulting from the study. Furthermore, no information about the participants during the research will be disclosed to others

(besides members of the research team) without their written permission, except if necessary to protect their rights or welfare.

The risk associated with this study for both clinic patients and healthcare professionals is the potential loss of confidentiality. Furthermore, the risk of losing confidentiality is potentially greater for the focus group participants since other participants may repeat what they heard during the focus group. We cannot and do not guarantee or promise that participants will receive any benefits from this study.

Non-Loyola-affiliated professionals involved in the key informant interviews will be offered $50 Target gift card for their participation. Clinic patients will be compensated with a $30 Target gift card for participating in the two-hour focus groups.

All of the researchers involved in the study have completed the CITI training.

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APPENDIX B. PRELIMINARY WORK - VOLUNTEERING SURVEY

Table 2. Survey of ATC Clinic Patients about Volunteering, April 2018

Item	Response	All n=24	English n=12	Spanish n=12
Past Experiences Volunteering	Currently volunteering	8%	8%	8%
	Volunteered in past 12 months	17%	25%	8%
	Volunteered more than 12 month ago	17%	33%	0%
	Never Volunteered	58%	33%	83%
Interest in Volunteering	Not Interested	33%	25%	42%
	Somewhat Interested	21%	42%	0%
	Moderately Interested	38%	33%	42%
	Very Interested	8%	0%	17%
Likelihood of Volunteering if Recommended by MD	Very Unlikely	0%	0%	0%
	Not Likely	17%	8%	17%
	Neutral	33%	42%	33%
	Likely	33%	50%	33%
	Very Likely	17%	0%	17%

English Survey

1. **Have you ever done volunteer work for an organization (example: school, church, or hospital)?**
    1) Yes, I am currently doing volunteer work
    2) Yes, I have done volunteer work in the past 12 months
    3) Yes, I have done volunteer work, but it was longer than 12 months ago
    4) No, I have never done volunteer work
2. **Would you be interested in learning about possible volunteer jobs?**
    1) Not at all Interested
    2) Somewhat Interested
    3) Moderately Interested
    4) Very Interested
3. **If your doctor advised you to do volunteer work as part of your treatment plan, how likely is it that you would volunteer?**
    1) Very Unlikely
    2) Not Likely
    3) Neutral
    4) Likely

Spanish Survey

1. **¿Alguna vez ha hecho trabajo voluntario para una organización (por ejemplo: escuela, iglesia, hospital)?**
    a. Sí, actualmente estoy haciendo trabajo voluntario
    b. Sí, he hecho trabajo voluntario en los últimos 12 meses
    c. Sí, he hecho trabajo voluntario, pero fue hace más de 12 meses
    d. No, nunca he hecho trabajo voluntario
2. **¿Le interesaría aprender más sobre posibles trabajos voluntarios?**
    a. Nada Interesado(a)
    b. Poco Interesado(a)
    c. Moderadamente Interesado(a)
    d. Muy Interesado(a)
3. **Si su médico le aconseja que haga trabajo voluntario como parte de su plan de tratamiento, ¿qué tan probable es que usted haga trabajo voluntario?**
    a. Muy Improbable
    b. No Probable
    c. Neutral
    d. Bastante Probable
    e. Muy Probable

APPENDIX C: LETTER OF SUPPORT-MAYWOOD FINE ARTS

APPENDIX C: LETTER OF SUPPORT-QUINN COMMUNITY CENTER

APPENDIX C: LETTER OF SUPPORT-ILLINOIS COALITION OF IMMIGRANT & REFUGEE RIGHTS (ICIRR)

APPENDIX C: LETTER OF SUPPORT-COMMUNITYHEALTH (FREE CLINIC)

PLEASE NOTE: THE LETTERS OF SUPPORT (FORMATTED AS SEPARATE PDFS) ARE OMITTED FROM THIS VERSION OF THE PROTOCOL.

APPENDIX D: MEASURES FOR PILOT INTERVENTION SUBJECTS

Table1. Proposed Measures for Pilot Intervention Subjects

Instruments	Measures	Respondent	Time estimate	
			Baseline	Follow up
Informed Consent	IRB-approved versions in English and Spanish to be developed for this project.	Intervention & Controls	10-12 min	NA
Demographics	Name, city residence, date of birth, gender, marital status, number of children, highest level of education, work status, occupation, annual income	Intervention & Controls	3 min	NA
Patient Activate Measure (PAM)[25,26]	Assesses a consumer's knowledge, skills and confidence for self-management. PAM segments people into one of four progressively higher levels of activation. *A validated Spanish version is available.*	Intervention & Controls	5 min	5 min
Patient-Reported Outcome Measurement Information System (PROMIS)[27 28]	Ten self-reported global health items, which are part of the Patient-Reported Outcome Measurement Information System (PROMIS) project. Items measure physical, mental, and social well-being. *A validated Spanish version is available.*	Intervention & Controls	5 min	5 min
Rosenberg Self-Esteem Scale [29]	Ten statements are included in the self-report measure that pertain to self-worth and self-acceptance. A four-point scale ranging from "strongly agree" to "strongly disagree." The items were selected as a Guttman scale with 7 "contrived items." *A validated Spanish version is available.*	Intervention & Controls	5 min	5 min
Arizona Integrative Outcomes Scale (AIOS)[30 31]	A global well-being scale, is a one-item, 100-mm visual analogue scale. As a purely visual tool, *Spanish validation is not applicable.*	Intervention & Controls	2 min	2 min
Volunteer Participation[32]	We will extract 36 items from a survey from Statistics Canada on Giving, Volunteering, and Participating. We will use items measuring: Motivation to Volunteer, Benefits of Volunteering, Satisfaction with Volunteer Experience, Skills Used, and Barriers to Volunteering. *Items will be translated by team member who is a native Spanish speaker.*	Intervention	NA	10-15 min
Total estimated time of survey administration			30 min	27-32 min

Demographics. Demographic data will include: name, city residence, date of birth, gender, marital status, number and ages of children, highest level of education, work status, occupation, and annual income.

Patient Activation Measure (PAM). The PAM 10 measurement instrument assesses a consumer's knowledge, skills and confidence for self-management. PAM segments people into one of four progressively higher levels of activation. The measure was developed using Rasch analyses and is an interval level, unidimensional, Guttman-like measure.[25,33]

Patient-Reported Outcomes Measurement Information System (PROMIS®). A 10 self-reported global health items obtained from an internet survey as part of the Patient- Reported Outcome Measurement Information System (PROMIS) project. Two dimensions representing physical and mental health underlie the global health items in PROMIS. These global health scales can be used to efficiently summarize physical and mental health in patient-reported outcome studies. PROMIS is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. It can be used with the general population and with individuals living with chronic conditions. The Patient-Reported Outcomes Measurement Information System (PROMIS) provides item banks that offer the potential for efficient (minimizes item number without compromising reliability), flexible (enables optional use of interchangeable items), and precise (has minimal error in estimate) measurement of commonly studied patient-reported outcomes.[34]

Rosenberg Self-Esteem Scale. The RSE Scale is a 10-item Likert-type scale designed to measure global self-esteem (Rosenberg, 1965). The items are rated on a 4-point scale from "strongly disagree" to "strongly agree." The RSE Scale contains an equal number of positively and negatively worded items. Positive items in the measure include: "I feel that I'm a person of worth, at least on an equal basis with others." Negative items include: "At times I think I am no good at all." A total score is derived by reversing the ratings of the five negative items and summing them with the ratings for the five positive items. The higher the score, the higher the self-esteem. Convergent, discriminant, and predictive validity have been supported in numerous studies.[35]

Arizona Integrative Outcomes Scale (AIOS) (24 h = 24-hour form, 1 m: 1-month form). AIOS is a global well-being scale is a one-item, 100-mm visual analogue scale (range, 0-100, with higher scores indicating greater sense of well-being). Subjects self-rate their combined physical, mental, emotional, social, and spiritual sense of well-being in the present moment. Arizona Integrative Outcomes Scale was specifically developed for use in complexity theory–driven research in Whole systems of complementary and alternative medicine, and has demonstrated that it will distinguish healthy from unhealthy populations as measured by physical health, and is inversely related to psychological distress.[30,36]

Volunteering Survey. A 36 item survey assessing the following aspects regarding volunteering: Motivation to Volunteer, Benefits of Volunteering, and Satisfaction with Volunteer Experience, Skills Used, and Barriers to Volunteering. Questions originate from a Canadian General social survey-giving, volunteering and participating, 2018. Survey was designed by the Bureau of Statistics Canada.