Evaluation and Program Planning

Cardiovascular Health Assessments Among Unsheltered Adults: An Ethical Community-Based Framework for Screening Programs

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Abstract:	Background: Homeless and unsheltered individuals experience disproportionately high rates of cardiovascular disease (CVD) yet remain underrepresented in formal health screening programs. Nonprofit and community-based organizations often conduct outreach services, but few have established ethical, standardized, or replicable methods for assessing physiological risk factors in field settings. Objective: To describe the development and implementation of an ethical, field-based methodology for cardiovascular screening within homeless outreach programs, emphasizing participant safety, consent, and operational feasibility. Methods: The methodology was established as part of a Quality Improvement (QI) initiative by Valliant Foundation’s outreach program. Ethical oversight was provided by the Valliant Foundation’s Ethics Committee, which determined that the project to be Non-Human Subjects Research. The framework integrates volunteer training, capacity screening, verbal consent procedures, vital sign collection, and emergency action protocols for hypertensive crises and altered mental status. Additionally, self-reported screening was conducted for other health risk factors, such as nicotine use and diabetes. All data were collected anonymously and utilized exclusively to inform service prioritization and to develop health education strategies. Results: The methodology proved feasible and ethically sound for use in mobile outreach environments. The framework successfully identified elevated CVD risk among unsheltered adults while maintaining participant autonomy and safety. Key innovations include standardized exclusion criteria, integration of emergency response protocols, and independent ethical oversight. Conclusion: This paper presents a replicable, ethically grounded methodology for cardiovascular risk screening in homeless outreach settings. The framework supports other nonprofit and public health organizations seeking to integrate evidence-based vital sign assessment into humanitarian fieldwork.
Opposed Reviewers:	

Highlights

- Replicable, ethical methodology improves public health service quality.
- Mandatory capacity screening, informed consent, and emergency protocol used.
- Oversight by ethics committee to ensure compliance with relevant laws and consent.
- Consideration for direct and quasi-identifiers in data collection and storage.
- Framework integrates emergency protocols respecting autonomy to decline services.

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Declaration of Competing Interests

The Principal Investigator (S.J.V.) oversaw the conception and execution of this methodology paper. This work was supported by Valliant Foundation. The project underwent ethical review by the Valliant Foundation's Ethics Committee. Sarah Jean Valliant discloses her role as President of the Board of Directors of the Valliant Foundation, which supported this project. All authors declare no other financial or personal relationships with any other people or organizations that could inappropriately influence or bias the work.

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Title page with authors and affiliations redacted per journal requirements.

Abstract

Background: Homeless and unsheltered individuals experience disproportionately high rates of cardiovascular disease (CVD) yet remain underrepresented in formal health screening programs. Nonprofit and community-based organizations often conduct outreach services, but few have established ethical, standardized, or replicable methods for assessing physiological risk factors in field settings.

Objective: To describe the development and implementation of an ethical, field-based methodology for cardiovascular screening within homeless outreach programs, emphasizing participant safety, consent, and operational feasibility.

Methods: The methodology was established as part of a Quality Improvement (QI) initiative by Valliant Foundation's outreach program. Ethical oversight was provided by Valliant Foundation's Ethics Committee, which determined that the project to be Non-Human Subjects Research. The framework integrates volunteer training, capacity screening, verbal consent procedures, vital sign collection, and emergency action protocols for hypertensive crises and altered mental status. Additionally, self-reported screening was conducted for other health risk factors, such as nicotine use and diabetes. All data were collected anonymously and utilized exclusively to inform service prioritization and to develop health education strategies.

Results: The methodology proved feasible and ethically sound for use in mobile outreach environments. The framework successfully identified elevated CVD risk among unsheltered adults while maintaining participant autonomy and safety. Key innovations include standardized exclusion criteria, integration of emergency response protocols, and independent ethical oversight.

Conclusion: This paper presents a replicable, ethically grounded methodology for cardiovascular risk screening in homeless outreach settings. The framework supports other nonprofit and public health organizations seeking to integrate evidence-based vital sign assessment into humanitarian fieldwork.

Introduction

Homelessness is a growing public-health crisis in the United States [1], marked by disproportionate rates of chronic disease, premature mortality, and limited access to preventive care [1]. Homeless and unsheltered individuals experience disproportionately high rates of Cardiovascular disease (CVD) [2], yet unsheltered adults remain excluded mainly from routine screening and long-term management services. The barriers are multifactorial, ranging from fragmented healthcare access and mistrust of institutions to environmental stress [3], poor nutrition [4], and the physiological burden of living outdoors [5]. These factors collectively create a sustained state of cardiovascular strain [6], aligning with evidence from meta-analysis demonstrating higher rates of cardiovascular morbidity and mortality among homeless adults.

Community-based organizations increasingly attempt to fill this gap through outreach programs that provide health education, first aid, and basic clinical screening. However, few of these initiatives operate under a standardized, ethically reviewed, and replicable methodological framework. In many cases, volunteers collect vital signs or health data without clear procedural guidance regarding informed consent, capacity assessment, or emergency response. This lack of structure introduces ethical and practical risks, both for participants and for organizations seeking to act responsibly within the boundaries of non-research community service.

To address this need, the Valliant Foundation developed a structured Quality Improvement (QI) framework for ethical field screening of cardiovascular risk factors among unsheltered adults in San Francisco. The goal was not to produce generalizable research findings but to create a safe, transparent, and reproducible model that community organizations could adopt to inform outreach decisions, guide referrals, and improve service quality. This paper presents the methodology in detail, outlining the ethical oversight process, capacity and consent screening, data-collection procedures, and emergency-response protocols that together form a practical and ethically sound approach to community-based cardiovascular assessment.

Methodology

Ethical Oversight and Project Definition

This report summarizes data collected through a community needs assessment conducted by Valliant Foundation's outreach program. The activity was strictly defined as an Operational Needs Assessment, not a research project, with the sole purpose of gathering descriptive data to guide non-profit operational decisions regarding resource prioritization, referrals, educational materials, and services.

Before commencement, the project underwent review by Valliant Foundation’s *Ethics Committee*, an independent oversight body authorized under the Foundation’s bylaws to review, approve, and enforce ethical standards for operational and research activities. The Committee determined that this project constitutes Non-Human Subjects Research (NHSR) under 45 CFR 46.102, as it does not aim to contribute to generalizable knowledge and was conducted solely to inform nonprofit operations and outreach programming. Regular check-ins with the committee were performed to maintain ethical oversight and monitoring.

Inquiries regarding this determination may be directed to Valliant Foundation's Ethics Committee for further clarification, interest, or guidance at ethics@valliant.org

Study Setting and Participants

The assessment was conducted in San Francisco, California, from November 2024 to September 2025 as part of regular outreach activities targeting the unsheltered community. Specific San Francisco communities served included the Inner Mission District, Tenderloin, and the Embarcadero. Data were collected only during daylight hours and in good weather to ensure environmental factors did not impose an undue burden on cardiovascular status. A total of 72 responses were collected for demographic metrics and vital signs. Data on nicotine use and diabetes prevalence were compiled later, yielding 116 total responses.

Capacity Screening

Volunteers were instructed to proceed only if the individual was Alert and Oriented (A&O x4), able to state their name, location, approximate time/day, and explain the purpose of the assessment (e.g., "You're asking questions to help your organization").

Exclusion Criteria with a "Hard Stop" protocol was implemented to ensure participants provided explicit, voluntary, and informed consent and had the capacity to participate. The assessment was immediately discontinued if the individual appeared disoriented, confused, exhibited severely disorganized speech, appeared to be in a state of acute psychosis or severe paranoia, was under the acute influence of illicit drugs, or showed signs of severe intoxication that prevented understanding. Participants could withdraw consent at any time, for any reason, without penalty.

Eligibility Criteria

Strict eligibility criteria were applied to ensure the safety of all participants and to maintain the integrity and operational utility of the collected data. These criteria were designed to minimize potential risks, reduce variability introduced by confounding factors, and ensure that the study population was appropriately representative of the target group for which the findings are intended.

Inclusion criteria required participants to demonstrate sufficient capacity and orientation to engage meaningfully and provide informed consent in the survey. Participants were eligible for inclusion if they demonstrated alertness and orientation to person, place, time, and situation (A&O x4) with verbal consent obtained by the participant after any outstanding questions were answered.

Exclusion criteria implemented protect prospective participants and the volunteer team from potential harm and uphold ethical standards. Individuals lacking decision-making capacity were excluded, as were those who withdrew or refused to proceed at any point in the encounter. Individuals displaying alterations in mental status or under the apparent influence of drugs or alcohol were excluded due to a lack of capacity or inability to provide informed consent. Stably housed individuals were also not eligible for participation. Figure 1 illustrates the screening process for participant eligibility, detailing the inclusion and exclusion criteria, capacity assessment, and consent procedures. This flow clarifies how participants were systematically evaluated to ensure ethical engagement, safety, and reliable data collection.

Inclusion	Exclusion

Capacity and Orientation: The individual is Alert and Oriented (A&O x4), meaning they can state their name, location, approximate time/day, and can explain the purpose of the assessment back to the volunteer (e.g., "You're asking questions to help your organization")	Lack of capacity
Voluntary and Informed Consent: The individual is informed about the survey and explicitly provides verbal consent to participate	Refusal/Withdrawal: The individual does not consent to start or wishes to stop at any time.
Stability (Implied): The person is stable and, if previously identified with a medical concern, gives explicit consent to continue after services were offered and declined.	Severe Intoxication/Psychosis: Presenting with severe intoxication, under the acute influence of illicit drugs, or showing signs of acute psychosis, severe paranoia, or severely disorganized speech that prevents understanding.
Experiencing homelessness (as defined by lack of fixed, regular, and adequate nighttime residence)	Stably Housed

Figure 1. Flow of Participant Screening, Inclusion, and Exclusion Based on Eligibility Criteria.

Verbal Consent

Before data collection, volunteers received in-person training from outreach officers during outreach missions. The outreach officers covered essential elements, including introducing themselves and the organization, offering resources to the unhoused community, and maintaining participant confidentiality. Following the training, the next step was to request voluntary participation in the public health questionnaire survey, emphasizing that participation was entirely voluntary and could be discontinued at any time. Regardless of participation, all individuals were provided with resources to help them access essential items. Crucially, verbal consent is required before proceeding with any questionnaire or physical screening. If participants did not grant consent, volunteers did not continue the procedure, thereby ensuring that all interactions respected participant autonomy and ethical standards.

Data Collection

The questionnaire collected demographic data (age, gender, race/ethnicity), diabetes and nicotine use data, two physiological metrics, and one subjective metric: blood pressure, heart rate, and pain score, respectively.

Data was collected across the Inner Mission, Tenderloin, and Embarcadero neighborhoods of San Francisco, California. Outreach team members then approached participants and obtained informed consent, ensuring that participants appeared alert and oriented and had capacity.

Physiological measures were collected using Food and Drug Administration (FDA)-cleared medical devices, including automated wrist sphygmomanometers and finger pulse oximeters. BP monitoring devices used include the G.Lab automatic blood pressure cuff and the Omron digital blood pressure cuff. The finger pulse oximeter devices used are Consumer Value Store (CVS) - brand devices. All devices were inspected for functionality to ensure the accuracy of vital signs measured and the safety of participants. Data were collected under the supervision of licensed medical professionals who oversaw the use of these devices and ensured proper use throughout the study. To minimize literacy bias, surveys were administered orally to participants by members of the health team.

In addition to physiological measures, subjective pain reporting was collected using the Numeric Pain Rating Scale (NPRS)[9]. The NPRS is utilized as a standardized tool to assess pain intensity. Participants were asked to rank their current pain levels on a scale of 1 to 10. Although standard practices used in clinical healthcare settings do include the ranking of “0” and participants may state a number greater than “10”, any rate provided as “0” will be transformed to “1” and any numerical value reported by a participant greater than 10 will be transformed to “10” for data analysis purposes.

All data were collected anonymously in the field, with each participant assigned a random string of letters and numbers as an identifier; no direct identifiers[8], including but not limited to names, telephone numbers, email addresses, or Social Security numbers, were ever collected. Furthermore, a comprehensive effort was made to avoid groups of indirect identifiers that could risk re-identification, including all elements of dates related to the individual (except the year), precise neighborhood location (although the methodology was conducted in the Inner Mission District, Tenderloin, and the Embarcadero of San Francisco), and photographs or biometric data. Data analysis for reports also clustered sensitive information: for example, all diabetes types were grouped to reduce the likelihood of identifying an individual with a rarer type, such as Type 1.

To maintain security, data files are stored in password-protected files, accessible only by the Principal Investigator and a select few authorized project managers. Regular monitoring of collected data immediately after each collection event must be performed to screen for direct or quasi-identifiers to reduce the likelihood of possible re-identification. Should it be discovered that a direct identifier or quasi-identifier was collected by mistake, the entire data item for that participant must be immediately deleted. In line with institutional best practices, once data collection is complete, these files must be encrypted. The documents will be held for a maximum of five years before mandatory deletion from institutional servers, thereby ensuring the long-term protection of participants while supporting the project's aim to provide a safe, transparent, and reproducible model for other organizations.

Emergency Response Protocol

The protocol prioritized participant well-being. Specific medical “red flags” were defined as abnormal vital sign readings that could indicate urgent or emergent clinical concern. This included elevated blood pressure (systolic pressure >180 or diastolic pressure >120) and other metrics for abnormal heart rate, respiratory rate, and blood glucose readings. If a red flag was identified, the assessment was paused, and the participant was calmly informed of the potential danger. Immediate help was offered, such as calling 911. Volunteers documented vital signs and the actions taken (e.g., "BP 210/137. Offered to call 911; person declined"), and participants' autonomy to decline services was respected.

If participants disclosed suicidal or homicidal ideation at any point during the survey, volunteers were trained to evaluate the level of risk and to dial 911 if the person was deemed to be an imminent risk to themselves or others within the next 24h. If a person is considered to have an A&O status of less than 4, volunteers are directed to activate the emergency response system by dialing 911.

Additionally, all unhoused persons under 18 who are not accompanied by an adult deemed to have capacity will automatically trigger the Emergency Response Protocol. Additionally, unhoused children who are accompanied by an adult who meets the aforementioned capacity criteria, but outreach members suspect may be experiencing abuse or neglect (e.g., inadequate meals or hygiene, physical abuse) will also trigger the Emergency Response Protocol. Deciding whether to activate 911 or the non-emergency line will be determined on a case-by-case basis, with the child's well-being paramount and the avoidance of abuse of emergency lines.

Implementation outcomes

The Mobile Outreach Initiative (MOI) was implemented to provide a respectful, consent-based health service and to connect unhoused individuals experiencing homelessness with vital and other essential resources, including free clinics, mental health/substance abuse therapy, city-provided shelters, and the Homeless Heartline from Valliant foundation. Beyond the provision of basic medical screening services, the initiative's success is defined by personal connection, empathetic listening, and affirmation of dignity fostered during interaction. This tangible impact of this approach illustrates improvement in our visit.

During an outreach mission in the Mission District, a group of three volunteers encountered an individual who provided verbal consent for a free basic medical screening, including blood pressure, blood glucose, temperature, oxygen saturation, heart rate, and respiratory rate, as well as a public health questionnaire. This interaction was conducted through open dialogue and empathetic listening, ensuring the participant felt heard and respected. The team also provided a sheet detailing our foundation’s Homeless Heartline, free healthcare clinics for check-ups, and other community resources for the participant if they decide to use them. Through this initial interaction it demonstrates a high level of acceptability of the services offered by the MOI. A real-world demonstration of our person-centered approach was evident during a key moment of the encounter. The participant requested to use a team member’s phone to call his mother, expressing a basic human need for connection. Facilitating this request in a public health setting shows a simple gesture and a foundational principle that humans have a right to a standard of living adequate for health, which includes social connection and care [7]. The conversation that followed was private, but afterward, the participant expressed feeling a sense of restored connection and dignity. The participant thanked the team, validating the power of our human-centered approach.

About ten days later, the MOI team reencountered the participant, this time on a different street in Union Square during another outreach mission. The participant shared an update on their well-being, reporting that since the initial encounter, they have started reducing their smoking and are feeling better, with a sense of starting strong. Additionally, the participant said they are actively taking small steps to make changes and hope to see the MOI team again

During another outreach mission in the Tenderloin, a large group of unhoused individuals shared their concerns with multiple volunteers about high blood pressure readings and experiences with hypertension. The screener included a section to report difficulty finding outreach programs or primary care resources to help manage their condition. It was found that a majority of unhoused persons experienced difficulty gaining access to and in continuity of care. Following MOI protocol, volunteers consulted with supervising medical professionals, listened attentively to the participants' concerns, and reassured them that the free clinics listed on the foundation’s resource sheet provide access to healthcare services. In the lower part of the Tenderloin, volunteers offered extra food, water, and emergency blankets to unhoused individuals who declined the full screening but wanted a brief physical check-up and a conversation. Some participants told others about the volunteers' presence to help the community, creating a safe environment for others to seek check-ins. Several provided verbal consent to complete both the physical screening and the questionnaire.

Volunteers conducted these interactions with care, aligned with program procedures, and made participants feel supported and cared for. As a result, many expressed gratitude for the team’s efforts, verbalizing that they felt treated with dignity and not overlooked. This feedback articulates the value of our outreach in supporting the unhoused community, who are often unheard.

While the majority of interactions with participants do not result in an emergent need for medical attention, there have been incidents in which participants and volunteers encounter emotionally complex situations that highlight the importance of empathy, emotional validation, and respect for autonomy during crises and health emergencies. During an encounter with an unhoused individual, the conversation began when the participant noticed a cross necklace a volunteer was wearing. The participant, a native Spanish speaker, was able to communicate comfortably as volunteers proficient in Spanish engaged in conversation using the participant’s preferred language. Volunteers intentionally positioned themselves at eye level, adopted open, welcoming body language, and maintained a warm, attentive demeanor. This approach facilitated an atmosphere of respect and trust as the vital sign screening began. The participant shared that they had experienced homelessness for approximately seventeen years, describing a profound faith that divine intervention had sustained and protected them throughout their time without shelter. The participant expressed a belief that God had safeguarded them throughout their experience of being unsheltered.

As dialogue between the volunteers and the participant continued, the conversation took an abrupt turn as the participant became tearful and expressed that they had been experiencing increasing suicidal ideation over the past year. During the interaction, volunteers adhered to the organization’s Emergency Response Protocol, systematically progressing through de-escalation measures while prioritizing the participant’s safety and autonomy. When the participant expressed a desire for professional assistance, volunteers facilitated activation of emergency medical services and coordinated ambulance transport in accordance with the participant’s request. Throughout this process, the volunteers maintained continuous engagement, provided reassurance, and monitored the participant’s emotional and physiological status to prevent escalation and ensure comfort. This experience highlights the importance of culturally and linguistically responsive care, which not only supports effective crisis management but also promotes trust, emotional security, and respect for participants’ self-determination.

Regarding other incidents in which the Emergency Response Protocol was utilized in MOI, EMS activation was warranted; however, the autonomy of participants was respected as they declined 911 transport. On two separate occasions during blood glucose checks using glucometers, participants had hypoglycemia. In both circumstances, the participants were A&Ox4 and informed that they had a blood glucose level that was potentially dangerous if a medical professional did not intervene.

On each occasion, both participants declined EMS activation for different reasons. One participant expressed concerns about the cost of an ambulance, fearing it would result in an unaffordable medical bill in addition to being seen at an emergency department, where complex levels of patient care are provided and can lead to expensive bills. The other participant also politely declined, expressing uncertainty and unease about going to the emergency room for undisclosed reasons. In both instances, the outreach volunteers respected participants' wishes while ensuring they were informed of potential risks. Such interactions underscore the ethical balance between protocol obligations and honoring autonomy.

Program Development and Training:

Valliant Foundation requires all outreach volunteers to complete training led by outreach officers who supervise the missions. Each outreach team includes at least two medically trained officers to ensure the safe measurement of vital signs, such as blood pressure and heart rate, using FDA-cleared equipment. All training materials are developed by licensed medical professionals affiliated with Valliant Foundation and reviewed by the Ethics Committee to ensure accuracy and compliance.

Training sessions are conducted during outreach missions, during which volunteers observe experienced outreach officers performing vital sign assessments and administering public health questionnaires. Additionally, the Foundation offers classroom-based training sessions led by the Research Director. Before participating in field missions, volunteers must demonstrate proficiency in conducting vital screenings under the supervision or guidance of an outreach officer.

Field Implementation:

The screening program operated from November 2024 through October 2025, with biweekly outreach missions across San Francisco's inner Mission District, the Tenderloin, and the Embarcadero. Over these 12 months (approximately 52 weeks), conducting two missions every two weeks resulted in an effective frequency of about one outreach mission per week. Teams of 4–6 volunteers conducted assessments during daylight hours in public areas where unsheltered individuals frequently congregated. The workflow followed a standardized sequence: participant greeting, capacity screening (A&O×4), verbal consent, physiological data collection, health education, and, when indicated, referral to local free or low-cost clinics. As part of the greetings, volunteers consistently offered immediate supplies and support, such as food, water, and focused check-ins to establish engagement in the subsequent steps.

To reduce the potential for coercion and ensure ethical engagement, volunteers first provide access to food and essential resources before discussing opportunities to participate in surveys. This approach prioritizes participants' immediate well-being and mitigates undue influence in populations experiencing resource scarcity. Before conducting any physiological assessment, volunteers perform a cognitive capacity screening to confirm participants' ability to provide informed consent and proceed only after obtaining verbal consent. All volunteers receive structured training in standardized physiological data collection procedures and culturally responsive health education, aligned with program standards and ethical best practices.

Operational Challenges and Adaptations:

Initial missions encountered difficulties maintaining device calibration and ensuring privacy in busy public spaces. To address this, teams added a second blood pressure monitor for cross-verification and implemented a "quiet zone" policy during assessments. The Ethics Committee reviewed interim reports annually to monitor compliance with and adherence to ethical standards as needed.

An additional challenge arose during data analysis due to missing or unknown data. Upon review, there were 72 total entries used for vital sign data analysis, with 13 blood pressure readings omitted and six heart rate readings omitted due to missing or unknown data or if a recording was outside physiologically plausible limits (e.g., BP readings of 120/172, 135/32; HR reading 825). These data points revealed logistical barriers that demanded a pragmatic approach to future data collection to ensure complete survey reporting and underscored the importance of preserving the analytical integrity of the data.

Discussion

Valliant Foundation developed the methodology presented here as a structured QI initiative to address a critical gap in community health services for unsheltered populations. Unsheltered adults experience disproportionately high rates of cardiovascular disease (CVD) but are routinely excluded from traditional screening and long-term management services. While community organizations frequently conduct outreach, many efforts lack a standardized, ethically reviewed, and replicable methodological framework, which creates significant ethical and practical risks for both participants and organizations. This framework provides a transparent, safe, and reproducible model explicitly designed to overcome these systemic barriers and inform organizational decisions on resource prioritization and referrals.

This model advances current outreach practices by integrating rigorous ethical and safety standards directly into field operations. Key innovations include standardized exclusion criteria, mandatory use of capacity screening (A&O x4 verification), and comprehensive emergency action protocols. These elements ensure participant autonomy is maintained, particularly through strict adherence to verbal consent procedures and the ability for participants to withdraw without penalty. Compared to non-standardized outreach efforts, where volunteers may collect vital signs without clear procedural guidance, this framework mandates the use of FDA-cleared medical supplies and supervision by licensed medical professionals to ensure accuracy and proper device use.

Implementation of this methodology revealed how these standards shaped the participant behaviors and responses. For instance, the use of rapport-building techniques created an environment of emotional safety and trust between volunteers and the participant with suicidal ideation. As volunteers followed the Emergency Response Protocol and honored the participant's request for EMS transport, this demonstrated clear methodological consistency while empowering the participant to self-direct the next steps to their mental health care.

The methodology proved feasible and ethically sound for use across diverse, mobile outreach environments in San Francisco. Safety and ethical integrity were prioritized through the "Hard Stop" protocol, which immediately discontinues the assessment if a lack of capacity or refusal is encountered. Furthermore, the emergency response protocol clearly defines medical "red flags" (e.g., systolic pressure >180 or diastolic pressure >120). It mandates that immediate help, such as calling 911, must be offered while simultaneously respecting the participant's autonomy to decline services.

Ethical oversight was managed by Valliant Foundation's Ethics Committee, as empowered under the foundation's bylaws, which is vested with the authority to monitor, review, approve, deny, or recommend modifications to all research, programs, and quality improvement initiatives conducted under the foundation's purview. The committee operates with adequate institutional support and resources to effectively exercise its oversight responsibilities. The committee is free of undue influence from Valliant Foundation members and abides by the principles of the Declaration of Helsinki. The committee is composed of qualified members, both affiliated and unaffiliated with the Foundation, who possess essential training and demonstrate competence in research ethics and regulatory compliance, and at least one member holds a legal degree (JD). In accordance with its governing authority, the Ethics Committee formally determined that the present project constitutes Non-Human Subjects Research (NHSR) under 45 CFR 46.102, thereby affirming its designation as an operational assessment rather than research intended to produce generalizable knowledge. After initial approval, the committee must meet with the principal investigator every 12 months to provide continued ethical oversight and project monitoring.

The methodology possesses specific limitations inherent to its design as a needs assessment. The activity was restricted to a single-city implementation (San Francisco, CA) and collected data only in three specific neighborhoods (Inner Mission District, Tenderloin, and the Embarcadero) during daylight hours and good weather. Although conducted under medical professional supervision, the data collection relied heavily on the careful training and execution of protocols by the outreach team members and volunteers.

During one outreach visit, a volunteer initially recorded an unusually low blood glucose reading. As emphasized in the methodology, the volunteer immediately consulted their supervising medical professional. Together, they expressed genuine concern for the participant's health and asked additional questions to ensure the individual had access to a primary care provider and felt safe visiting them. The participant was alert and oriented to person, place, time, and situation (A&Ox4). They were able to maintain their airway and accepted food from the volunteer, eating without difficulty. The participant was also encouraged to visit a free clinic listed on the foundation's resource sheet for further evaluation of possible hypoglycemia. They agreed and asked follow-up questions about the clinic locations and how to get there, demonstrating high acceptability of the services offered.

These moments demonstrated the program's compassion and methodological consistency in real-world settings. Since the project was defined strictly as an Operational Needs Assessment to guide nonprofit operations, the data collected and the methodology were primarily intended for service prioritization and quality improvement, rather than contributing to generalizable research findings.

Despite these limitations, the framework is highly replicable and supports adoption or adaptation by other nonprofits and public health organizations. The model offers a practical template for organizations seeking to integrate evidence-based vital sign assessment into humanitarian fieldwork. By detailing the procedures for capacity screening, consent, data collection (including demographic data, blood pressure, heart rate, and pain score), and emergency response, this methodology enables other agencies to safely and ethically assess chronic disease burden, such as high blood pressure, diabetes, and nicotine use prevalence, within their own specific outreach contexts. The framework strengthens accountability for outreach and ensures that organizational activities are ethically grounded, regardless of whether they are defined as QI or NHSR.

Lessons Learned

As mentioned previously, some operational challenges and adaptations helped improve future MOI missions and the overall quality of data collection. It was important for the team to understand that the Emergency Response Protocol would become a living document as emergencies or unanticipated events occurred during field operations. As a result, the protocol guidelines were consistently reviewed and updated, and volunteers were informed of any changes or new protocols to follow to adhere to the organization's values and standards of conduct, ensuring this project remained ethical and maintained the integrity of all interactions between volunteers and participants. Healthcare professionals developed supplemental education and training materials to train new volunteers and refresh the education of experienced volunteers. Following training, volunteers received educational materials and quizzes to reinforce learning and strengthen knowledge retention..

Additionally, many volunteers had their first exposures to real-world public health service, which employed their verbal communication skills and abilities to record data. This demanded soft skill development from all volunteers towards participants. This included soft skills such as patience, empathy, cultural humility, active listening, and de-escalation to uphold ethical boundaries and support participant autonomy. The development of these interpersonal skills is vital for future MOI missions, as a balance between professionalism and human connection has been learned.

Documentation practices improved throughout the project, as the team began with several instances of incomplete, missing, or erroneous data that challenged the integrity of the reported data points. Training volunteers to accurately record data increased the reliability of data points and improved their ability to recognize abnormal vital sign readings by increasing familiarity with normal physiological ranges introduced during training. This practice also reinforced volunteers’ abilities to identify red flags during vital sign screenings and to follow Emergency Response Protocols when screenings were abnormal, which could ultimately be life-saving for participants being screened and surveyed.

Conclusion

This paper presents the development and implementation of a standardized, ethically grounded field methodology for cardiovascular risk factor screening within homeless outreach programs. Central to this framework is the integration of rigorous ethical safeguards—including A&O x4 cognitive capacity screening, an explicit Hard Stop protocol, and clearly delineated emergency action procedures for high-risk findings such as hypertensive crises. The methodology demonstrated both feasibility and ethical integrity in mobile outreach settings, successfully balancing accurate cardiovascular risk assessment with the preservation of participant autonomy, safety, and dignity.

By uniting ethical rigor with operational practicality, this framework establishes a replicable and scalable model that enhances accountability and supports high-quality care delivery within outreach initiatives. Moreover, its emphasis on culturally and contextually responsive engagement underscores the potential of mobile, ethically governed health interventions to reduce inequities in cardiovascular disease prevention. The model provides a foundation for nonprofit and public health organizations seeking to extend evidence-based screening, strengthen ethical standards, and promote equitable access to preventive health services among unsheltered and underserved populations.

Other Information

Ethics Statement

This project was reviewed by Valliant Foundation Ethics Committee and determined to constitute Non-Human Subjects Research under 45 CFR 46.102.

Funding & Conflicts of Interest

This work was supported by Valliant Foundation. No specific grants or awards were given to this project. Health supplies and volunteers were provided through Valliant Foundation. This project did not accept federal or state funding.

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

During the preparation of this work, the authors used NotebookLM to improve grammatical, spelling, and organizational clarity. After using this service, the authors reviewed and edited the content as needed and took full responsibility for the published article.

Author Contributions

Redacted per journal requirements

Appendix

Capacity Screening (A&O x4)- a medically merited screening that assesses the alertness and orientation of an individual- person, time, place, and event.

Emergency Response Protocol- a stepwise procedure outlining actions for volunteers to take when encountering participants with urgent or life-threatening vital signs or physiological abnormalities.

Hard Stop Protocol- a procedural rule mandating the immediate discontinuation of data collection when a participant lacks capacity, withdraws consent, or exhibits signs of severe intoxication, psychosis, or disorientation.

Hypertensive Crisis- a critically elevated blood pressure reading that is greater than or equal to 180mmHg systolic and greater than 120mmHg diastolic values.

Numeric Pain Scale Rating (NPSR) - a standardized 1-10 scale used in medical settings to quantify subjective reporting of pain. “1” serves as the benchmark for “no pain at all” and “10” serves as “the worst pain ever experienced.”

Operational Needs Assessment- a data collection activity performed solely to inform and improve the outreach efforts of a nonprofit organization (i.e., Valliant Foundation) or community-based outreach operations, distinct from formal research seeking a hypothesis-based conclusion.

Red Flag Criteria- thresholds for physiological metrics that trigger initiation of the Emergency Response Protocol, requiring immediate attention and offering of emergency services.

Regular Check ins-are scheduled meetings between the research team and the ethics committee to monitor study progress, ensure ongoing ethical compliance, address emerging issues, and maintain accountability throughout the research process.

Unsheltered population- any individual lacking a stable, regular, and adequate residence. Includes any individual living on streets, in vehicles, tents, temporary encampments, or shelter not belonging to them and not used for social purposes (i.e., government-funded hotel room)

Verbal Consent- confirmation of voluntary participation after the purpose, procedures, and rights of the participant were explained and any questions a participant had were answered, given the participant had full capacity (A&Ox4) and was over the age of 18, required before initiation of vital sign screening and questionnaire.

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Author Biographies

Dr. Carole Kulik, DNP, ACNP, RN, HCIC is a nursing professor at San Francisco State University with over 35 years of experience in clinical nursing, education, leadership and research. She has extensive expertise in teaching nursing research, scholarly writing, and public health issues, mentoring students to advance evidence-based practice. Her work integrates clinical insight with academic scholarship to improve patient care and health outcomes.

Sarah Jean Valliant, NREMT, has served San Francisco as an EMT at American Medical Response and has experience working at the National Suicide Hotline 988 managing suicidal crises. Furthermore, she has served as principal investigator on multiple systematic reviews and meta analyses, and has been a consultant on mixed methodology research study at another institution. She founded and led a large equestrian business and sold it prior to founding Valliant Foundation where she serves as President of the Board of Directors, and PI on multiple projects.

Ileana Jade Rodriguez is a first-generation Latina scholar and aspiring physician dedicated to advancing equitable healthcare. She has extensive clinical experience from an emergency medicine setting complemented by her education in biology and pre-medical sciences. Through her work as a project manager for Valliant Foundation she combines clinical skill, public health insight, and compassion to serve marginalized populations. Ileana aspires to bridge medicine and research through her work in healthcare and as a budding scientist, advocating for culturally responsive care and mentorship for underrepresented students in the biomedical sciences.

Rianna Rose Punzalan graduated from San Francisco State University with a Bachelor of Science in biology and double minors in chemistry and education. She is currently attending Skyline College for an Associate of Science in public health and psychology. She intends to continue her passion of creating significant contributions to academia and promoting conversation in science education.

Yacoob Modan NREMT is a nonprofit executive dedicated to advancing public health and community care. Yacoob is a senior biology student at San Francisco State University. In addition to his work as an EMT, he serves as CEO of Valliant Foundation, an organization dedicated to making change beyond San Francisco through high-quality, generalizable public health systematic reviews and outreach missions to help the unhoused population. He also volunteers with the Physicians Organizing Committee, supporting healthcare equity and community advocacy initiatives.

Angelina Ka Lee is Deputy Director of the Valliant Foundation, passionate about behavioral science and how the brain influences thoughts and actions. Her interest began while managing emotions and behaviors as a Recreation Leader, supervising 720–1,188 children over three summers. This experience inspired her to connect with underserved communities in San Francisco. Through volunteering with the unhoused, she strengthened her active listening and community engagement skills. In her current role, Angelina ensures equitable resource distribution, provides emotional support, and oversees foundation programs that help students secure funding and create lasting impact in the community.

Logan Holbrook is a biology student at San Francisco State University graduating in fall of 2025. He has undergraduate research experience working with fission yeast at the Pasion laboratory and has experience presenting one poster at the annual CIRM trainee networking conference. He is currently working with Valliant Foundation on multiple projects.