MONOGRAPH

# Street Medicine: Creating a "Classroom Without Walls" for Teaching Population Health



Noemi C. Doohan<sup>1</sup> · Ranit Mishori<sup>2</sup>

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#### Abstract

"Street Medicine" programs provide medical care to homeless populations outside of traditional healthcare institutions, literally on the street and in transitional settings where unsheltered homeless people live. Such programs are emerging around the world often based at medical schools and primary care residency programs, and can provide ideal frameworks for twenty-first century "Classrooms Without Walls" aimed at improving Population Health. We provide a 12-step blueprint for creating a Street Medicine program in the context of a medical teaching institution.

Keywords Street medicine  $\cdot$  Homeless healthcare  $\cdot$  Population health  $\cdot$  Marginalized populations  $\cdot$  Medical education  $\cdot$  Complex care

# Introduction

# The evolution of Street Medicine

In 1992, Jim Withers, a faculty attending physician at the University of Pittsburgh Medical Center Mercy Hospital Internal Medicine Residency Program, dressed like a homeless person and, with a backpack filled with medicine, began clandestinely providing free healthcare on the streets at night for the unsheltered in his community [1]. What began as one doctor's mission to create a "Classroom of the Streets" to teach about caring for excluded people, has grown over the last 25 years into the Street Medicine Institute (SMI) and movement (www. streetmedicine.org). Through the Street Medicine Institute's annual international symposium, the movement has developed global reach. Based on information from the SMI website as well as anecdotal reports, Street Medicine colleagues on every continent are innovating and defining best practices, in partnership with a wide range of brick and

Ranit Mishori mishorir@georgetown.edu

mortar settings from academic centers to rural health clinics, all geared towards serving the unsheltered.

As the Street Medicine movement has grown, so has learner interest, as evidenced by the many clubs and programs that have popped up in affiliation with various medical institutions around the world. Despite the anecdotal growth in learner interest in homelessness and street medicine, its true extent has yet to be formally studied. It is important to distinguish between educational initiatives about homelessness (sometimes done via panels, didactics, speaker series, and electives) and the practice of street medicine—where medical care is provided on the street and in transitional settings where unsheltered homeless people live: under bridges and overpasses, in parks, alleys, and on street corners.

Street Medicine programs are often started by inspired learners who engage faculty sponsors, put on backpacks filled with medical supplies, and go out to homeless populations with the guidance of the SMI. Dr. Jim Withers describes these practices as "level one programs" or the "Robin Hood stage" in which there is minimal programmatic infrastructure, but a high level of commitment to the philosophy of social justice and health care as a human right.

While the impulse to respond rapidly to the health crisis of homelessness is laudable, creating a successful and sustainable Street Medicine program is challenging. Street Medicine practices involve many of the same challenges encountered with creating any new clinical service including accessibility, continuity, liability, continuous quality improvement,

<sup>&</sup>lt;sup>1</sup> Scripps Mercy Family Medicine Residency Program, - Chula Vista, Chula Vista, CA, USA

<sup>&</sup>lt;sup>2</sup> Global Health Initiatives, Georgetown University School of Medicine, 3900 Reservoir Rd. NW, GB-01D, Washington, DC 20007, USA

maintaining standards of care and avoiding negative unintended consequences. Furthermore, homeless populations are medically complex, transitory, and live in unpredictable and, sometimes, inaccessible, settings. Homelessness is tightly linked with barriers to care, co-morbidity with substance abuse and mental illness, as well as poor health outcomes overall, a shortened lifespan and increased mortality [2–6].

Street Medicine programs provide rich environments for teaching and studying health equity, and for exploring improvement in population health measures and practices [7]. These "Classrooms Without Walls" are clinically, philosophically, ethically, and pedagogically aligned with the depth and scope of primary care. We believe that Family Medicine, and other primary care clinical practices, are the ideal educational homes for such initiatives due to their broad scope which includes Behavioral Health, and their emphasis on Population Health and community oriented primary care [8].

#### Discussion

At the moment, there are no standardized, peer-reviewed published best-practices or approaches for starting a Street Medicine program.

Herein, we describe a model for developing a Street Medicine program that combines family medicine and population health concepts.

#### Define educational competencies

Inherent in its mission, identity, and name, Street Medicine requires skills that go beyond what is routinely taught in undergraduate or graduate medical education. With its atypical clinical setting and complex patient population, the skills and competencies most aligned with Street Medicine could be borrowed from other fields where medicine is delivered in low resource settings, with underserved or marginalized patient populations and in the field or under harsh conditions. For example, educators may review and adapt the skills and competencies most commonly suggested for Global Health education [9, 10].

Furthermore, learners must possess knowledge anchored in a deep appreciation for the impact of the social determinants of health [11] and the political determinants of health [12, 13] on the lives of homeless patients, and an understanding of the enormous disease burden [3] experienced by this population. Attitudes should be tied to exploration of themes related to health equity [14] and social justice [15]. Clinical skills can be linked with existing undergraduate and graduate recommendations, involving communication and interpersonal skills, professionalism and ethics, system-based issues (including healthcare financing and utilization), among others. Some programs have been working on developing general guidelines and resources [16–19], especially related to homelessness in general. Related competencies include Adverse Childhood Experiences [20], trauma informed care [21], harm reduction, principles of homeless outreach [16], and deescalation techniques [22]. In addition, skill development should focus on substance abuse, and mental and behavioral health, as these issues are interlinked with each other and with homelessness both as risk factors and as chronic health problems. Methods for ensuring competency in continuous quality improvement should be integrated throughout the curriculum.

#### **Develop a Curriculum**

Once competencies have been defined, the curriculum can be designed to meet these requirements. Street Medicine provides a "Classroom Without Walls" and as such the goal is to offer experiential learning to health profession students and residents, out on the streets working directly with individuals who are unsheltered. However, any curriculum must involve preparation before going out to the streets and include didactic teaching to provide learners with contextual background. Pedagogically, didactics can be delivered via small group discussions and case-studies [18] and with "bedside teaching" during street rounds.

Ultimately, Street Medicine is about engaging with this population where it lives. Various experiential electives for the provision of health care for homeless populations have been described in the literature, in various settings, primarily at fixed location homeless shelters and specialized clinics [23], but not necessarily on the street or in transitory settings. A program for medical and pharmacy students in New Mexico where learners provided care to homeless individuals in shelters as well as conducted street outreach was perceived by the learners "uniformly" as "transformative" [16]. One leader, Dr. Aurinés Torres-Sánchez, describes the Street Classroom as an ideal environment for training medical learners in the values and practices of social justice and equity [24].

#### Create evaluation and assessment protocols

Measurement and reporting outcomes will be important for population health data, epidemiology, and continuous quality improvement as well as for medical education scholarship. For learners, we can assess knowledge acquisition via exams and surveys as well as from direct observation of clinical encounters. Attitudinal changes can be assessed via surveys [25, 26] or via instruments such as the Health Professional Attitudes Toward the Homeless Inventory (HPATHI) [27]. Some have looked for associations between homeless medicine programs and various professionalism measures, showing improvements in empathy and decreases in negative stereotypes [19, 28]. Additional learner-associated measurements can include changes in wellness metrics and burnout scores, an emerging field of research in medical education and in primary care. Previous studies have demonstrated that feeling engaged leads to increased satisfaction at work [29–31]. We can hypothesize that Street Medicine may improve learner engagement, and thus wellness, but needs further study. Table 1 includes some suggestions for learner evaluation and assessment modalities.

Patient-oriented outcomes must be included so that we can learn what interventions work best for this population [32]. One study assessing the quality and "best practices" of several Street Medicine programs recommended two patient-centered outcome measures: patient engagement and patients' subjective assessment of their well-being [33].

Other metrics can assess the population health and downstream benefits of Street Medicine, including changes in acute care vs. primary care utilization; hospital Length of Stay; housing status; morbidity and mortality; and improvements in social and political determinants of health.

#### Acquire sustainable sources of funding

 
 Table 1 Suggestions for evaluation and assessment

As with any new educational program, the business case must be made to the sponsoring institution so that the program can be sustainably funded. International data show that complex populations, including the homeless, comprise approximately 5% of the overall population and incur 50% of health care costs [34]. Homeless populations tend to be super-utilizers of acute systems of care [35-37], so a Street Medicine program, providing "hotspotting", (medical outreach to superutilizers), such as described by the Camden Coalition Hotspotting Curriculum (www.camdenhealth.org/curriculumum, www.camdenhealth.org/curriculum), may be cost-saving, especially if linked with primary care. Some talking points may include that Street Medicine (a) may improve access to primary care, thus avoiding unnecessary utilization of acute care services (b) may overlap with Disaster medicine, thus improving the effectiveness and reach of disaster preparedness and response. Planners should use data from annual homeless surveys such as the, federally mandated Point in Time counts. Tracking of homeless populations is challenging and is done differently in different settings. There are several grant funded Street Medicine programs across the USA which the authors have learned about anecdotally. It would be beneficial to develop a tracking system of successful grants for Street Medicine programs in order to help guide future grant writing efforts. For example, in September 2019, a \$ 1-million HRSA RCORP (Health Resources and Services Administration Rural Communities Opioid Response Program) grant written by one of the authors (Doohan) was awarded to Adventist Health Ukiah Valley hospital for a "Safe Haven Clinic" that includes Street Medicine, sobering, medical respite, and a pharmacy in one facility located proximal to the Emergency department.

#### **Conduct needs assessment**

A needs assessment determines best locations and times for street rounds, identifies interested stakeholders such as law enforcement and first responders, and seeks collaboration from partner agencies, including churches, inclement weather shelters, and sobering centers. The goal is to provide Street Medicine rounds on the same day of week and at the same time, to enhance reliability. It may be preferable to conduct street medicine rounds at night when volunteer clinicians are available and homeless populations have settled and may be more open for "house calls".

One key concept is to "follow the food" and set up a mobile clinic alongside a program that provides free meals. Such places can serve as a starting point for street rounds, and then expand to a route leading to/from that spot that includes places like sobering centers [38].

Programs should conduct a safety assessment of the area where rounds take place so that every precaution is taken to ensure that faculty, learners, and the people served are kept safe. This can be achieved by coordinating with local law enforcement, avoiding areas where criminal behavior has been known to occur, and meeting in well-lit and populated area. According to anecdotal reports from the Street Medicine Institute website, Street Medicine is a relatively safe practice, such that "thousands of street rounds have been conducted throughout the world without incident".

nt	Who	What	Examples
	Learner	Knowledge acquisition	Exams, surveys, direct observation
		Clinical skills	Direct observation
		Attitudinal changes	Surveys [25, 26], such as the Health Professional Attitudes Toward the Homeless Inventory (HPATHI) [27]
		Professionalism	Empathy instruments [19, 28]; professionalism scales; professional identity formation scales.
		Wellness metrics	Burnout instruments; levels of satisfaction [29–31].

# Define organizational structure

Because Street Medicine programs are complex systems of healthcare delivery in atypical clinical settings, it is important to have clear organizational structures and chains of command. It can be very helpful to use a system such as the Incident Command Structure (https://www.fema.gov/incident-commandsystem-resources) developed by the US government for disaster preparedness and response. A typical team may include an Incident Commander (the lead faculty physician/medical director) and 4 team leaders: Finance; Logistics (medical packs, transportation, volunteer coordination); Operations; and Planning. Not all individuals in the program are involved in the operations on the street. In fact most of the work is actually done behind the scenes and not on the front lines of care provision.

# Partner with local agencies

In addition to getting buy-in from a medical education institution, teaching hospital, or residency program, it is crucial to develop partnerships with local organizations or healthcare institutions that serve the homeless population, have insight about their needs and behaviors, and could contribute to the provision of social services and self-care capacity. Partners can include the local police, department of health, Emergency Medical Systems, local emergency departments, homeless shelters, food pantries, substance use disorder treatment a services, and housing authorities. These partnerships can foster and enhance care coordination and provision of multiple other services via regularly scheduled meetings. Having an MOU (Memorandum of Understanding) between the partner agencies and the Street Medicine program is advisable and typically requires institutional legal review.

# Create policies, procedures, and protocols

Commonly, Street Medicine programs are quick to respond to the call to service without creating policies and procedures first. Indeed, many policies and procedures will develop and be finetuned over time, but basic policies and procedures must be established from the start and reviewed by legal counsel and/or risk management according to the standards of the institutions involved. Suggested protocols include: principles of homeless outreach, response to violence, interacting with the media, and "follow-ups". Referral procedures must be established related to calling an ambulance, sending a patient by non-urgent transport to the hospital Emergency Department, facilitating timely access to continuity primary care, and communicating referrals and "warm hand offs" to partners or other agencies [39].

From the medico-legal and ethics perspective it is important to have written policies about the different roles and responsibilities of the various team members, especially the learners, to avoid anyone working beyond their scope of practice or above their level of education or expertise. It is essential to confirm how medical malpractice insurance will be provided to the team or to volunteer faculty from organizations outside the teaching institution.

# Establish electronic medical record and data tracking system

A Street Medicine program must be held to the same standards as any medical clinic, and that includes record keeping and maintaining HIPPA compliance despite the public environment where Street Medicine clinics occur. There are affordable, cloud based mobile Electronic Health Records that can be customized such as OpenMRS. Data can be integrated with the home-institution to improve care coordination, for Quality Improvement projects and outcome reporting. Strategies should be explored for ethical data sharing with partner agencies to improve the health of the population served [40].

# Determine medication formulary and stock medical packs

In the model described herein, the scope of practice is urgent care. All drugs, tools, and supplies are carried by team members in backpacks. Three packs are typically needed: a clinician ("prescriber") pack, a nursing pack, and a wound care pack. Table 2 includes a description of tools, equipment, and medications included in the packs. Consider conducting periodic vaccine clinics and health screenings for chronic and communicable diseases such as HIV, Tuberculosis, Hepatitis C, and diabetes and adjust the supplies accordingly. Collaborate with the pharmacy department of the sponsoring institution to determine protocols and mechanisms for dispensing free medications, storage, tracking, and removal of expired drugs. Do not carry "high street value" medications in the packs such as narcotics and benzodiazepines.

# Form Street Medicine Teams

In this model, teams are led by a faculty primary care physician, consist of learners (health profession students, residents) and are supported by clinicians and volunteers from other disciplines.

Team staffing is an ongoing process. All members are expected to contribute to patient care as well as to teaching. The model suggested here includes 8 team roles: Clinicians (MD, NP or PA), nurse, behaviorist, case manager/social worker, scribe, pack logistician, peacekeeper, and street ambassador (person with "lived experience" of homelessness). Roles can be doubled up such as behaviorist/case manager, peacekeeper/street ambassador, scribe/pack logistician. Medical learners assume different roles depending on their experience, interest, and skill. Table 3 describes the roles of each member of the team, according to the model presented in this paper, and their unique responsibilities.

Table 2	Street medicine pack supplies and suggested m	nedications
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Pack	Clinician	Nurse	Wound care
Supplies	<ul> <li>Stethoscope</li> <li>Otoscope</li> <li>Ophthalmoscope</li> <li>Handheld ultrasound machine</li> <li>Medications</li> </ul>	<ul> <li>Blood pressure cuff</li> <li>Pulse oximeter</li> <li>Glucometer, lancets, and strips</li> <li>Basic blood and urine collection supplies and testing kits</li> </ul>	<ul> <li>Staple and suture removal kits</li> <li>Sterile saline</li> <li>I and D supplies</li> <li>Dressings and wound treatment supplies</li> </ul>
Suggested medications (prescription drugs are dispensed from the Clinician pack under the supervision of the team clinician and per pharmacy protocols for the health care system)	<ul> <li>int/iris/bitstream/han</li> <li>Examples include me antifungals, NSAIDS</li> <li>Dispensing medication</li> </ul>	• Sharps and biohazard containers elected from the WHO list of essential medi- dle/10665/273826/EML-20-eng.pdf?ua=1 dications for constipation and diarrhea, anti- S, naloxone, albuterol inhalers, antihistamine ns with high "street value" such as narcotic he risk to the team of keeping these medicat	emesis, antibiotics and es, etc. s and benzodiazepines is

Front line Street Medicine may be challenging to some learners. While some exposure is good to give all learners, some learners find the high level of suffering and implicit chaos of the "Classroom Without Walls" uncomfortable or upsetting. A mechanism for screening volunteers and learners and assigning appropriate roles should be part of the initial and ongoing training. Learners who may not be well suited for participation in street outreach can have valuable roles on the logistics, planning, or finance sides.

One option is to start the Street Medicine program gradually, initially with a nursing clinic based on a public health nursing model [41], and then scale up. This model, where nurses monitor vital signs, conduct health screening, wound care, and care coordination, requires physician oversight.

#### Dedicate time for reflection and advocacy

Individuals who work with medically complex and marginalized individuals, such as unsheltered homeless populations, should have opportunities to process what they may be exposed to [42], including injustice, discrimination, neglect, abuse, and preventable death.

Program leaders should continuously assess the learners' wellness, burnout and vicarious trauma risk by using validated instruments [43]. Team wellness can be promoted through regular team debriefs, reflective practices (oral or written), as well as self-care activities.

Work with homeless populations may also lead learners to seek opportunities to engage in advocacy on behalf of this population and in efforts to promote policies and practices to

Table 3 Team members and their unique roles and responsibilities

Roles	Duties
Pack logistician	Keeping the Street Medicine packs stocked and assisting with distribution of supplies from the packs as directed during Street Medicine rounds
Peacekeeper	Assessing and maintaining scene safety during street rounds; using de-escalation techniques as warranted
Clinician (MD or PA or NP with supervision as appropriate)	Lead the medical team ("team leader")
Nurse (or MA or LVN)	Assist Team leader in provision of medical care and provisior of nursing care including wound care, vital signs, vaccinations, and nursing education
Behaviorist (and addiction specialist)	Provide behavioral health support for the team including supportive care for substance use disorder
Street ambassador	Ideally a person with lived experience of homelessness who can build and maintain trusting relationships between street community and team
Scribe	Assist with documentation in the medical record
Case manager/social worker	Assist with care coordination and making connections to systems of care

Table 4	Table 4         Educational and other resources	
Organizatio	tion	Website
Street Med	Street Medicine Institute	https://www.streetmedicine.org/

AAMC news AMA news

(IMI)

https://sbdww.org/

Doctors Without Walls-Santa Barbara Street Medicine

Family Medicine Residency Program Adventist Health Ukiah Valley

Street Medicine Detroit

University of Buffalo (UB) HEALS team

nttps://medicine.buffalo.edu/news and

http://streetmedicinedetroit.org/

https://AHfamilyresidency.org

JPS Fort Worth Texas Street Medicine

Loma Linda University (LLU) Street Medicine University of Illinois at Chicago (UIC) Street Medicine

https://news.wttw.com/2018/10/30/uic-medical-students-

seek-fill-void-health-care

https://www.camdenhealth.org/curriculum/

stateline/2018/09/18/the-homeless-get%2D%2Dsick-

org/en/research-and-analysis/blogs/ street-medicine-is-there-for-them

https://www.pewtrusts

nttps://caps.llu.edu/volunteer-now/street-medicine

Camden Coalition Hot-spotting Curriculum

Point in Time Count guidelines

Incident Command System (ICS)

https://www.fema.gov/incident-commandsystem-resources

https://www.hudexchange.info/programs/hdx/guides/

pit-hic/#general-pit-guides-and-tools

care to the unsheltered homeless where they live and SMI facilitates and enhances direct provision of health Description

assists new Street Medicine programs in start-up. Article highlighting programs that engage medical students in treating the homeless

as an example of the AMA Accelerating Change Integrating Street Medicine into Medical Education

Street Medicine program founded in 2005 by the author in Medical Education Consortium

ND in Santa Barbara CA which primarily incorporates undergraduate learners and utilizes the care delivery model described in this article

incorporates undergraduate and graduate medical learners founded in 2015 by the author ND in Ukiah CA which Sponsoring Institution of the Street Medicine program

and utilizes the care delivery model described in this article "In December 2011, program founder Jonathan Wong, then a first year medical student, caught wind of the growing

'Medical Students take to the Streets to help Buffalo's practice of street medicine" homeless population"

JPS sponsors twelve medical residency training programs affiliated with 2 academic centers: Baylor and University Sponsored by JPS Health Network-Care Connections. of Texas Southwestern

student-run outreach group aimed at serving the homeless oma Linda University Street Medicine is a volunteer populations of the city of San Bernardino, CA.

UIC medical students created Chicago Street Medicine with the goal of improving the health of the city's homeless through outreach, education, research, and advocacy

and Clese Erickson (AAMC) identified need to equip providers Hotspotting: an effort to train the next generation of providers with tools to better care for patients with complex health and Jeffrey Brenner (Camden Coalition of Healthcare Providers), social needs earlier in their careers. The result was Student to deliver integrated, person-centered care for patients with In 2013, Andrew Morris-Singer (Primary Care Progress),

unsheltered homeless persons on a single night in January The Point-in-Time (PIT) count is a count of sheltered and by the US federal government department of Housing complex needs.

ICS is a management system designed to enable effective and efficient domestic incident management by integrating a and Urban Development (HUD)

combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure

Organization         Website           Patient Safety Network of the Agency for Healthcare Research and Quality (PSN AHRQ)         https://psn (psn AHRQ)           Open MRS         https://open/psn		
ty Network of the Agency heare Research and Quality IRQ)	site	Description
	https://psnet.ahrq.gov/ https://opennrs.org/	AHRQ Patient Safety Network (PSNet) is a national web-based resource featuring the latest news and essential resources on patient safety. Open Medical Record System (OpenMRS®) was created
		in 2004 as an open source medical record system plationm for developing countries. OpenMRS is a multi-institution, non-profit collaborative led by Regenstrief Institute, a world-renowned leader in medical informatics research, and Partners In Health, a Boston-based philanthropic organization with a focus on improving the lives of underprivileged people worldwide through health care service and advocacy.
Vertical Change https://w	https://verticalchange.com/	Subvertical LLC, a California company, was formed in 2012 to bring affordable modern software technology to bear on the data management and analysis problems that face the social service and public health sectors. This software is used as a platform for a mobile Electronic Health Record for the Adventist Health Ukiah Valley Street Medicine program founded by author ND
cless	http://dashconnect.org/wp-content/uploads/2018/05/ DASH-Bright-Spot_Chicago.pdf https://www.cbsnews. com/news/boston-doctor-jim-oconnell-house- calls-to-the-homeless/	A legal approach to sharing health and education data: this resource highlights a bright spot in Chicago Illinois as an example The integrated care model at BHCHP unites physicians, physician assistants, nurse practitioners, nurses, case managers, and behavioral health professionals in close collaboration in a variety of settings - on the streets, at the Barbara McInnis House, in our shelter-based clinics, in the hospitals, and in housing .
2nd International Symposium on Homelessness, Health and Inclusion 2014	https://www.pathway.org.uk/wp-content/uploads/ 2014/05/2014-conference-report.pdf	Homelessness, Social Exclusion and Health Inequalities: Long-term impacts conference report
Medical Reserve Corps (MRC) https://rr	https://mrc.hhs.gov/pageviewfldr/About	The MRC is a national network of volunteers, organized locally to improve the health and safety of their communities. The MRC network comprises approximately 190,000 volunteers in 900 community-based units located throughout the United States and its territories. Street Medicine teams readily integrate into MRC disaster training and doubnearce.
Our World in Data. https://o	https://ourworldindata.org/homelessness	Provide data and empirications provide data and empirication of the providence on homelessness, focusing specifically on how it affects people in high-income countries.

end homelessness and address co-occurring conditions, including innovations for treating substance use disorder (SUD) and mental health issues ("dual diagnosis"). Advocacy training may be a powerful tool for professional development and identity formation and to assist learners in developing their leadership skills [44]. Table 4 includes educational and other resources that can help guide advocacy, innovation, and reflection.

# Conclusion

Street Medicine programs are emerging, led by physicians and learners who want to practice humanistic medicine. With this increasing demand, there is a growing need to create blueprints for educators considering starting a program in their institution. Street Medicine programs comprise ideal "Classrooms Without Walls" for Population Health education, where clinical care, education, and research co-occur, and where learners can experience health care delivery for complex populations.

The heart of the model described in this article is the Street Medicine rounds: a mobile backpack based urgent care provided where people experiencing homelessness hang out, reside, dwell, or sleep. The goal of this model is to "go to the people", with multidisciplinary primary care teams, to establish trusting relationships and provide urgent medical and social care in its broadest context.

As Street Medicine programs mature, the focus should ideally shift to include supporting homeless populations through transitions of care, expansion of care across the spectrum into teaching clinics and hospitals, and enhancing integrated systems to avoid further marginalizing unsheltered homeless populations into silos. Hospital based leadership roles, such as the Chief Primary Care Medical Officer can help with this integration [45].

Ultimately, programs must promote Housing First models and permanent supportive housing [46] as sustainable solutions to end homelessness [47].

Street Medicine provides a learning environment rich with opportunities to incorporate social justice and humanism into medical education. It forms a powerful longitudinal curriculum in community health, health systems management, and population health where learners can be of great service to their communities and the most vulnerable and marginalized in society. As such programs proliferate, those involved must also engage in program monitoring and evaluation to establish an evidence-base and assess the impact of such programs on learners and on the population being served.

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#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

Ethical approval N/A

Informed consent N/A

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