

Reach and effectiveness of a HEARTS hypertension pilot project in Guatemala

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ABSTRACT The World Health Organization Global Hearts initiative (HEARTS) and technical package aim to improve the primary health care management of hypertension and other risk factors for cardiovascular disease at the population level. This study describes the first HEARTS implementation pilot project in Guatemala's Ministry of Health (MOH) primary health care system. This pilot began in April 2022 in six primary health care facilities in three rural indigenous municipalities. The project consisted of HEARTS-aligned strategies adapted to enhance program sustainability in Guatemala. Outcomes were defined using the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework. The primary reach outcome was treatment count, defined as the absolute number of patients per month receiving medication treatment for hypertension. The primary effectiveness outcomes were mean systolic blood pressure (BP), mean diastolic BP, and proportion of patients with BP control (<130/80 mmHg). In the first month of the post-implementation period, there was a statistically significant increase of 25 patients treated per month above the baseline of 20 to 25 patients (P = .002), followed by a significant increase of 2.4 additional patients treated each month (P = .005) thereafter. The mean change in systolic BP was -4.4 (95% Cl, -8.2 to -0.5; P = 0.028) mmHg, and the mean change in diastolic BP was -0.9 (95% CI, -2.8 to 1.1; P = .376) mmHg. The proportion of the cohort with BP control increased from 33.4% at baseline to 47.1% at 6 months (adjusted change, 13.7%; 95% Cl, 2.2% to 25.2%; P = .027). These findings support the feasibility of implementing the HEARTS model for BP control throughout the MOH primary health care system, which is where most Guatemalans with hypertension seek care.

Keywords

Hypertension; implementation science; global health; health policy; Guatemala.

The World Health Organization (WHO) and the Pan American Health Organization (PAHO) HEARTS initiative is the most important global effort to improve the primary care management of hypertension and other cardiovascular disease (CVD) risk factors in health systems around the world. The WHO/PAHO HEARTS model focuses on the population-level management of CVD risk factors through six evidence-based, cost-effective components. The HEARTS acronym comprises *H*ealthy lifestyle counseling, *E*vidence-based protocols, *Access* to medicines, *R*isk-based management, *T*eam care and task sharing, and *S*ystems monitoring (1). Since HEARTS was launched in 2016, health systems in 33 countries in the Region of the Americas

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have signed on to implement it as part of PAHO's "Hearts in the Americas" initiative (2). Despite nearly all countries in the Region having committed to implement HEARTS, there is a lack of rigorous evaluation of HEARTS implementation projects. This study describes the first HEARTS implementation pilot project in Guatemala. Guatemala is a lower middle-income country and the most populous nation in Central America. Approximately 80% of the population is uninsured and dependent on the Ministry of Health (MOH) for primary health care (3). The objective of this study was to evaluate the reach and effectiveness of a HEARTS implementation pilot project in the MOH primary care health system in three rural municipalities in Guatemala.

METHODS

The HEARTS pilot in Guatemala was conducted in the MOH primary care system in six primary health facilities in three rural, indigenous municipalities in the department of Sololá. The MOH was the implementing institution; all clinical care was provided by MOH health workers using MOH-purchased medications in MOH primary care facilities. The Institute of Nutrition of Central America and Panama (INCAP) and the Center for the Study of Equity and Governance in Health Systems (CEGSS) provided technical assistance to the MOH in HEARTS implementation. The pilot began in April 2022 and technical assistance was provided until December 2022. The combined population in the three included municipalities was approximately 16 000 individuals, including 9 500 adults. The MOH and investigators selected the three municipalities for the HEARTS pilot based on three factors: (i) they were representative of rural, indigenous populations across the country served by the MOH system; (ii) there was strong interest from municipallevel MOH officials in participating in HEARTS; and (iii) the collaborating institutions providing technical assistance had a prior presence in the communities.

The implementation project consisted of HEARTS-aligned strategies adapted to the MOH of Guatemala (4) as well as complementary patient-centered strategies to enhance program sustainability: (i) coordination with MOH leadership to ensure availability of antihypertensive medications and blood pressure (BP) monitoring devices; (ii) dissemination and training on standardized hypertension treatment protocols; (iii) task sharing, as nurses (professional and auxiliary) primarily delivered care under physician supervision; (iv) implementation of an electronic monitoring tool, the District Health Information System 2; (v) establishing and training of community self-help groups to generate patient demand for MOH services and to monitor the MOH's implementation; and (vi) implementation of a municipal pharmacy with low-cost and generic antihypertensive medications.

The hypertension treatment protocol used by health workers in this pilot project was from the 2018 MOH guidelines for managing hypertension in primary care (5). MOH health workers must follow these protocols in MOH primary care facilities. The protocol recommends thiazide diuretics as first-choice agents, followed by angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs) as second-choice agents. The MOH procured one drug in each of these classes of antihypertensive drugs for use at the primary care level: hydrochlorothiazide (thiazide class), enalapril (ACE inhibitor class), and losartan (ARB class). Other antihypertensive drug classes, such as calcium channel-blockers, mineralocorticoid receptor antagonists, beta-blockers, and loop diuretics, were unavailable at the primary care level. Other features of the MOH protocol included (i) using a threshold of <130/80 mmHg to define BP control among all patients, (ii) incorporating CVD risk assessment to refine medication choices, and (iii) recommending the use of 2 antihypertensive drug classes for initial treatment in patients with BP ≥140/90 mmHg. Of note, MOH protocols were developed before the release of the 2021 WHO Guideline for the Pharmacological Treatment of Hypertension in Adults (6) and the most recent PAHO guidance on the HEARTS clinical pathways. The same treatment protocol was used in all MOH primary care facilities. MOH health facilities used the OMRON HEM-7122 automatic BP monitor (Omron Corporation, Japan), validated through the STRIDE BP initiative (https://www.stridebp.org/).

We used the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework to guide our implementation evaluation of this HEARTS pilot project (7). The present publication reports on outcomes of reach and effectiveness outcomes. In the RE-AIM framework, reach or "uptake" refers to the absolute number of individuals covered by a program, and effectiveness refers to the impact on important patient-level outcomes (7). Other RE-AIM outcomes—adoption, implementation, and maintenance—will be reported in future studies.

The primary *reach* outcome was treatment count, defined as the absolute number of patients each month receiving medication treatment for hypertension. Patients who were less than 20 years of age, pregnant, or treated for acute hypertension were excluded. The MOH requires medications to be refilled monthly, so this outcome is a meaningful indicator of population coverage. The data source for this outcome was the MOH's Health Management Information System (Sistema de Información Gerencial de Salud [SIGSA]), which tracks dispensed medications with high fidelity. Using SIGSA data, we defined treatment as any patient who received a prescription for at least one of the three available antihypertensive agents in the MOH system, was dispensed at least seven tablets, and had an associated hypertension-related diagnosis coded during the visit (i.e., essential [primary] hypertension, renovascular hypertension, or unspecified secondary hypertension). We calculated the treatment rate in the 15 months before the HEARTS pilot began in April 2022 and over the 16 subsequent months until August 2023. Therefore, this evaluation extended beyond December 2022 when INCAP and CEGSS stopped providing technical assistance. We aggregated SIGSA data by calendar month and then analyzed the data using a single-group interrupted time-series approach with segmented linear regression and Newey-West standard errors to account for autocorrelation.

The primary *effectiveness* outcomes were mean systolic BP, mean diastolic BP, and proportion with BP control of <130/ 80 mmHg. This threshold aligned with the MOH guidelines described previously (5). The data source for this outcome was a panel of community-based patients with hypertension who each were followed for 6 months during the HEARTS implementation period. This supplemental data collection method was necessary because SIGSA does not capture BP data. Panel eligibility criteria were age 20 years or older and either (i) previously diagnosed hypertension; (ii) BP \geq 140/90 mmHg; or (iii) BP \geq 130/80 when also taking an antihypertensive medication, having a 5-year CVD risk of 10% or greater (8), or reporting a history of CVD. Potentially eligible patients were recruited by

study personnel using MOH records, referrals from community members, and screenings conducted through door-to-door community visits. While the panel of patients was not selected using a formal sampling frame, we purposefully recruited patients who (i) were previously diagnosed and engaged in MOH care, (ii) were previously diagnosed and not engaged in MOH care, and (iii) were previously undiagnosed. Study visits took place in the patient's home. Two study visits were made within 1 week to confirm baseline eligibility. We used a BP measurement protocol that had been reported previously and was based on the American Heart Association recommendations (4). Specifically, three BP measurements were obtained after the participant was seated for at least 5 minutes before the first measurement. Subsequent measurements were separated by 1-minute intervals. All participants reported avoiding alcohol, coffee, energy drinks, tobacco, tea, and exercise for 30 minutes before the measurements were taken. An OMRON 907-XL digital monitor with the appropriate cuff for the participant's arm was used in these study visits. The average of BP measurements was used in this analysis.

A total of 1 320 individuals were screened, from whom 171 individuals with hypertension were identified and referred to MOH health facilities for clinical management. We analyzed the data of the 102 individuals who completed the 6-month follow-up visit using a pre-post approach with multilevel linear and logistic regression models for continuous and dichotomous outcomes, respectively. We specified a random intercept for participant and fixed-effects for intervention time, municipality, age, and sex. Analyses were performed using Stata, version 17 (StataCorp).

Ethics

Ethics approval was obtained from the MOH (protocol No. 26-2021) and INCAP (protocol CIE-REV 109/2021). Participants provided informed consent.

RESULTS

Reach

During the 16 months after HEARTS implementation, there were 986 encounters at MOH primary care facilities in which a patient was treated for hypertension. The median (IQR) age of treated patients was 58 (49-70) years and 82% were women. Figure 1 shows the monthly treatment count in the health district during the 15 months before the HEARTS pilot and the 16 months after implementation, using SIGSA data. In the pre-implementation period, approximately 20 to 25 patients with hypertension were treated per month with no significant monthly trend. In the first month of the post-implementation period, there was a significant increase of 25 patients treated

(P = .002), which was followed by a significant increase thereafter of 2.4 additional patients treated each month (P = .005). By month 16 post-implementation, approximately 80 patients with hypertension were treated per month.

Effectiveness

In the community-based hypertension panel, 85% of participants were women, and the median (IQR) age was 67 (56-75) years. Table 1 shows BP results over 6 months. The mean change in systolic BP was -4.4 (95% CI, -8.2 to -0.5; P = .028) mmHg, and the mean change in diastolic BP was -0.9 (95% CI, -2.8 to 1.1; P = .376) mmHg. The proportion of the cohort with BP control increased from 33.4% at baseline to 47.1% at 6 months (adjusted change, 13.7%; 95% CI, 2.2% to 25.2%; P = .027).

DISCUSSION

In this small-scale HEARTS implementation pilot project in the MOH of Guatemala, we observed a 4-fold relative increase in the treatment count and a 14% absolute increase in the proportion of patients achieving BP control. These findings support the feasibility of implementing the HEARTS model for BP control in the MOH primary care system where nearly all residents with hypertension seek care.

An important secondary finding was the extremely low baseline coverage of MOH hypertension treatment at the population level, with just 20 patients treated per month across the three municipalities. Assuming a hypertension prevalence of 20% (9) and a total adult population of 9 500, we estimate that there were 1 900 people with hypertension in the three municipalities. These calculations imply a population-level hypertension treatment coverage of approximately 1% at baseline. While the 4-fold increase in treatment observed in this HEARTS pilot is noteworthy, there is still a critical need to dramatically expand coverage at the population level.

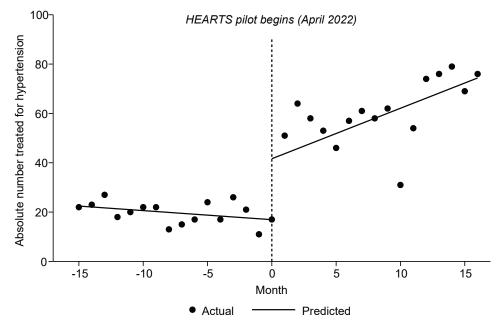
Our team's experiences in the HEARTS implementation pilot study provided several insights that could be instrumental in scaling up the HEARTS initiative within the MOH in Guatemala and other countries in the Region. First, as in many countries, Guatemala's health system predominantly focuses on maternal and child health. There are fewer resources and less focus on noncommunicable diseases. We hypothesize that this pilot's success was partly due to INCAP's catalytic role of aligning MOH stakeholders at multiple levels with the importance of HEARTS implementation to address the burden of noncommunicable diseases. Second, HEARTS is a package of implementation strategies that vary by target level in the MOH system, complexity, and resource requirements. We are limited in our ability to quantify which HEARTS components are most impactful and sustainable. In the future, we will use qualitative and mixed-methods approaches to assess the

TABLE 1. Effectiveness outcomes of mean blood pressure (BP) and percentage BP control in 102 participants

Outcome	Baseline (95% CI)	6 months (95% CI)	Adjusted difference (95% CI)	P value
Systolic BP, mmHg	134.8 (131.1 to 138.4)	130.4 (126.8 to 134.1)	-4.4 (-8.2 to -0.5)	0.028
Diastolic BP, mmHg	72.1 (70.1 to 74.1)	71.2 (69.3 to 73.2)	-0.9 (-2.8 to 1.1)	0.376
BP control (<130/80), %	33.4 (24.6 to 43.1)	47.1 (37.9 to 56.4)	13.7 (2.2 to 25.2)	0.027

Note: The total patients with hypertension were recruited at baseline and monitored over 6 months. Data were analyzed using multilevel linear and logistic regression models for continuous and dichotomous outcomes, respectively. **Source:** Prepared by the authors using data from the Ministry of Health of Guatemala's Health Management Information System.

FIGURE 1. Monthly treatment counts pre- and post-implementation of HEARTS pilot program



Note: The data underlying this figure were obtained from the Guatemala MOH's Health Management Information System. The lines reflect the single-group interrupted time series approach with segmented linear regression. Source: Prepared by the authors using data from the Ministry of Health of Guatemala's Health Management Information System.

relative importance of HEARTS components. Third, there have been few rigorous evaluations of HEARTS in Latin America, despite nearly all countries in the Region having committed to implement the HEARTS model. Our pilot provides a roadmap for future HEARTS evaluations by leveraging routine administrative data and applying a robust quasi-experimental methodology to assess causality. Finally, our experiences in this pilot have shown us that there is a need for more evidence on how best to implement training on key HEARTS topics. This is critical because, fundamentally, HEARTS is a capacity-building and training initiative for stakeholders at different levels of the health system. Key training-related questions from our pilot are whether its format, duration, and pedagogical approach are ideal and how do we best maintain competencies despite the high turnover among MOH health workers.

Limitations

Our HEARTS project and study design had a few limitations. First, the HEARTS project was implemented in MOH facilities in a small area of Guatemala that may not be representative of MOH facilities throughout the country. At the same time, MOH procedures and norms are the same across the country, and our small-scale study has shown promising results. Second, we could not assess BP control using MOH data. Our community-based panel may not have been representative of patients treated at MOH facilities or the overall population. Third, the demographic profile of hypertension patients skewed strongly toward women and older ages. Future HEARTS projects in Guatemala must innovate strategies to capture more men and younger patients. Finally, as mentioned previously, we could not assess the relative importance of different HEARTS components within the program.

Conclusions

Since our pilot was launched in April 2022, the Guatemalan MOH has officially pledged to implement HEARTS (10). We are now focused on supporting the MOH in its efforts to scale up HEARTS in 30 health districts in the MOH system, representing approximately 10% of all health districts nationally. We also are developing strategies to integrate the primary care management of other CVD risk factors, such as diabetes, into the HEARTS hypertension model (11). We also hope to generate evidence to support HEARTS implementation projects in other countries, including making causal estimates of impact, providing guidance on adapting HEARTS to new health systems, and calculating cost-effectiveness.

Author Contributions. AL and DF conceived the original idea and outline for the paper. DF conducted the analysis and prepared the initial figures and tables. AL and DF wrote the initial and subsequent versions of the article, with input from all co-authors. MRZ and DF were responsible for obtaining funding. All co-authors were engaged in the implementation project throughout its duration and have read and approved the work.

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Cobertura y efectividad de un proyecto piloto HEARTS para el control de la hipertensión en Guatemala

RESUMEN El paquete técnico de la Iniciativa Global Hearts ("HEARTS") de la Organización Mundial de la Salud tiene como objetivo mejorar el control de la hipertensión y de otros factores de riesgo de enfermedades cardiovasculares a nivel poblacional en el ámbito de la atención primaria de salud de salud. Este estudio describe el primer proyecto piloto de implementación de HEARTS en el sistema de atención primaria de salud del Ministerio de Salud de Guatemala. El proyecto, que comenzó en abril del 2022 en seis centros de atención primaria de salud pertenecientes a tres municipios rurales indígenas, consistió en estrategias alineadas con HEARTS y adaptadas para mejorar la sostenibilidad del programa en Guatemala. Los criterios de valoración de los resultados se definieron mediante el marco estandarizado de evaluación de cobertura, efectividad, adopción, implementación y mantenimiento (RE-AIM, por su sigla en inglés). El criterio principal de la cobertura fue la cantidad de tratamientos, definida como el número absoluto de pacientes por mes que recibían tratamiento farmacológico para la hipertensión. Los criterios principales de la efectividad fueron la media de presión arterial (PA) sistólica, la media de PA diastólica y la proporción de pacientes con un control de la PA (<130/80 mmHg). En el primer mes del período posterior a la implementación, se registró un aumento estadísticamente significativo de 25 pacientes tratados al mes por encima del valor inicial de 20 a 25 pacientes (n = 25; p = 0,002), seguido de un aumento significativo de 2,4 pacientes adicionales tratados al mes (p = 0,005) posteriormente. El cambio en la media de la PA sistólica fue de -4,4 (IC del 95%: -8,2 a -0,5); p = 0,028) mmHg, en tanto que el cambio en la media de la PA diastólica fue de -0,9 (IC del 95%, -2,8 a 1,1); p = 0,376) mmHg. La proporción de la cohorte con control de la PA aumentó del 33,4% al inicio al 47,1% a los seis meses (cambio ajustado, 13,7%; IC del 95%, 2,2% a 25,2%; p = 0,027). Estos resultados respaldan la viabilidad de la implementación del modelo HEARTS para el control de la PA en la totalidad del sistema de atención primaria de salud del Ministerio de Salud de Guatemala, al que acude en busca de atención la mayoría de las personas con hipertensión.

Palabras clave Hipertensión; ciencia de la implementación; salud global; política de salud; Guatemala.

Alcance e efetividade de um projeto piloto de controle da hipertensão arterial da iniciativa HEARTS na Guatemala

RESUMO

O pacote de medidas técnicas da iniciativa Global Hearts ("HEARTS") da Organização Mundial da Saúde tem como objetivo melhorar o controle da hipertensão arterial e de outros fatores de risco para doenças cardiovasculares na atenção primária à saúde em nível populacional. Este estudo descreve o primeiro projeto-piloto de implementação da iniciativa HEARTS no sistema de atenção primária à saúde do Ministério da Saúde da Guatemala. O projeto-piloto começou em abril de 2022 em seis estabelecimentos de atenção primária à saúde em três municípios indígenas rurais. O projeto consistiu em estratégias alinhadas à iniciativa HEARTS e adaptadas para melhorar a sustentabilidade do programa na Guatemala. Os desfechos foram definidos usando a estrutura de avaliação RE-AIM (sigla em inglês para alcance, efetividade, adoção, implementação e manutenção). O desfecho primário de alcance foi a quantidade de tratamentos, definida como o número absoluto de pacientes por mês que receberam tratamento medicamentoso para hipertensão. Os desfechos primários de efetividade foram pressão arterial (PA) sistólica média, PA diastólica média e proporção de pacientes com controle da PA (<130/80 mmHg). No primeiro mês do período pós-implementação, houve um aumento estatisticamente significante de 25 pacientes tratados por mês acima da linha de base de 20 a 25 pacientes (n = 25; P = 0.002), seguido de um aumento significante de 2,4 pacientes adicionais tratados a cada mês (P = 0,005) depois disso. A mudança média na PA sistólica foi de -4,4 (intervalo de confiança [IC] de 95%: -8,2 a -0,5; P = 0,028) mmHg, e a mudança média na PA diastólica foi de -0,9 (IC de 95%: -2,8 a 1,1; P = 0,376) mmHg. A proporção da coorte com controle da PA aumentou de 33,4% na linha de base para 47,1% após 6 meses (mudança ajustada, 13,7%; IC de 95%: 2,2% a 25,2%; P = 0,027). Esses achados apoiam a viabilidade da implementação do modelo HEARTS para o controle da PA em todo o sistema de atenção primária à saúde do Ministério da Saúde da Guatemala, no qual a maioria dos indivíduos com hipertensão arterial procura atendimento.

Palavras-chave Hipertensão; ciência da implementação; saúde global; política de saúde; Guatemala.