Practical Laboratory Medicine 44 (2025) e00450

Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

Observational assessment of the utilization of donated point of care tests and glycemic control at free and charitable clinics across the United States

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ARTICLE INFO

Keywords:
Free and charitable clinics
Diabetes
Point of care labs
HbA1c
Philanthropy

ABSTRACT

Introduction: Populations experiencing poverty often lack access to convenient lab tests. This analysis assesses trends observed from a national point of care (POC) lab donation program for free and charitable clinics across the United States.

Methods: A total of 16 clinics were selected to receive a comprehensive package of POC lab tests. De-identified data on POC test utilization and results were assessed to descriptively identify trends in utilization (primary objective) and glycemic control (secondary objective). A paired *t*-test was utilized to identify statistically significant changes in HbA1c from baseline to predefined 90-day time intervals for all people living with diabetes (PLWD) and those with a baseline HbA1c $\geq$ 9.0 % (75 mmol/mol). The main comparison of interest was the change in HbA1c from baseline to 90–179 days.

Results: A total of 17,563 POC tests were completed for 9658 patients with 3223 tests being HbA1c's. In the secondary analysis of PLWD with a baseline HbA1c $\geq$ 9.0 % (75 mmol/mol), patients who completed an HbA1c between 90 and 179 days (n = 188) demonstrated a statistically significant mean reduction from baseline of -1.2 % (95 % CI, -1.6 % to −0.9 %, $p < 0.01$, -10 mmol/mol [95 % CI, -6 mmol/mol - -14 mmol/mol]).

Discussion: The provision of POC labs helped support the care populations experiencing poverty received at free and charitable clinics, especially for chronic diseases like diabetes.

1. Introduction

The burden of diabetes continues to grow in the United States with populations experiencing poverty facing the biggest challenges as they have a disproportionately higher prevalence and higher rate of complications [1–3]. Free and charitable clinics play a vital role in addressing gaps in screening and follow-up care by providing free and/or heavily subsidized care in these communities. Unfortunately, there is only limited guidance on how the limited resources these clinics have can be used to optimize the impact for the

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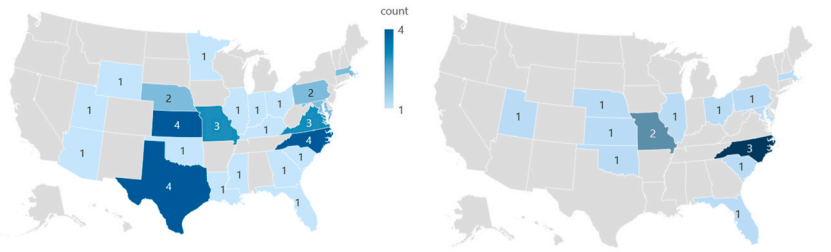
https://doi.org/10.1016/j.plabm.2025.e00450
Received 7 November 2024; Received in revised form 8 January 2025; Accepted 9 January 2025
Available online 10 January 2025

patients they serve [4]. Amongst the many issues patients face with access to clinical care, the availability of timely, accessible, and reliable labs is a commonly overlooked need [5,6].

It is for these reasons that Heart to Heart International (HHI) (https://www.hearttoheart.org/our-mission), in partnership with the National Association of Free and Charitable Clinics (NAFC), Eversana InTouch, Wylie Foundation, and Becton Dickinson (BD), has been trying to address laboratory access deficiencies by providing donations of point of care (POC) labs to free and charitable clinics across the United States (see Fig. 1). HHI is a not-for-profit organization working to improve access to care for under-resourced populations and communities facing disasters in the US and around the world [7]. HHI first started installing POC lab units within settings facing disasters in 2007 and subsequently started scaling up this approach in 2016 at free and charitable clinics to improve access to timely laboratory testing. HHI's approach is supported by numerous previous studies which have assessed the potential impact of POC lab inclusion and have documented positive trends especially amongst people living with diabetes (PLWD) [7–11]. This includes a recently completed meta-analysis and systematic review which found that POC HbA1c testing in community settings was effective in increasing access to screening, providing a definitive diagnosis, promoting uptake of lifestyle change, and improving glycemic control [12]. Similarly, evaluation of the role of POC HbA1c amongst patients relying on care from a public health department have also shown positive trends in glycemic control when combined with medication management and education [11]. Unfortunately, there is only limited published data on the potential role of POC HbA1c testing when scaled up amongst populations experiencing poverty utilizing free and charitable clinics across the United States. Furthermore, there has been limited assessment of whether philanthropic foundations should include the provision of POC laboratory supplies as part of their efforts to assist these populations.

It is for these reasons that HHI decided to evaluate its POC donation program to assess the overall utilization of the package of POC tests (primary objective) and a more detailed assessment of the longitudinal glycemic control (secondary objective) amongst the clinics selected to receive support between 2021 and 2023. These secondary analyses were designed to assess the changes in HbA1c over time



A – Since 2016 **B – Recent Sites Included in This Analysis**

List of Sites Included in this Analysis

City	State	Clinic
Kansas City	Missouri	Care Beyond the Boulevard
Salisbury	North Carolina	Community Care Clinic of Rowan County
Chicago	Illinois	CommunityHealth at Onward House
State College	Pennsylvania	Centre Volunteers in Medicine
Omaha	Nebraska	Heart Ministry Center
Greenwood	South Carolina	La Clinica Gratis of Community Initiatives
Grandview	Missouri	The Medina Clinic
Fort Myers	Florida	Premier Mobile Health Services
Hendersonville	North Carolina	The Free Clinics
Great Barrington	Massachusetts	Volunteers in Medicine Berkshires
Wooster	Ohio	Viola Stratzman Clinic
Kansas City	Kansas	Mercy and Truth Medical Missions
Weatherford	Oklahoma	Agape Medical Clinic
Elkin	North Carolina	Grace Clinic of Yadkin Valley
Park City	Utah	People's Health Clinic
Baltimore	Maryland	Esperanza Center Health Services

Fig. 1. Heart to Heart International Point of Care (POC) lab test donation sites per state since inception in 2016 (A) and Recent Sites Included in this Analysis (B) *(the numbers in each state represent the number of implementation sites per state).*

for all PLWD along with those with poorly controlled diabetes (HbA1c ≥ 9.0 %) who had a baseline measurement and a second result at least 60 days later.

2. Methods

This retrospective observational analysis relies on routinely collected individual, de-identified, POC laboratory data obtained through the provision of care at free and charitable clinics partnering with HHI. Free and charitable clinics who were interested in being considered for this partnership were required to submit a proposal to NAFC and HHI, who then selected the top scoring partners to receive POC lab support without any additional financial support. HHI then deployed staff to provide on-site training and established a train-the-trainer model. After HHI set up POC laboratory equipment and provided on-site training over 2–3 days, HHI continued to provide monthly virtual check-ins and collected patient results and consumption data on the different POC tests to inform quarterly reagent deliveries. HHI then visited six months later to perform a simulated regulatory audit to ensure clinics were appropriately using the donated supplies, reagent, and equipment. Towards the end of the donation program, upon request, HHI linked the clinics to the vendors providing POC supplies to facilitate continuation of the service, as partners were allowed to keep the equipment free of charge.

The range of available POC tests included HbA1c (Siemen's DCA Vantage), lipid panel (Alere Cholestech LDX), hemoglobin (HemoCue Hb 801 system), urinalysis (Siemens Clinitek Status Plus Analyzer with MULTISTIX 10 SG reagent strips), urine microalbumin (Siemens Clinitek Status Plus Analyzer with Microalbumin reagent strips), urine pregnancy (Henry Schein One Step + hCG Urine Cassette Test), HIV ½ Antigen/Antibody (Alere Determine HIV-1/2 Ag/Ab Combo Test Kit), Hepatitis C antibody tests (OraQuick HCV Rapid Antibody Test), Group A Streptococcus (BD Veritor System for Rapid Detection of Group A Strep), Flu A/B (BD Veritor System for Rapid Detection of Flu A + B), Respiratory Syncytial Virus (BD Veritor System for Rapid Detection of RSV), Prothrombin Time/International Normalized Ratio (Roche CoaguCheck XS System), and COVID (BD Veritor System for Rapid Detection of SARS-CoV-2). All the clinics received the same devices and received ongoing supplies consistent with their utilization patterns. Each partner was trained on how to appropriately calibrate the devices and perform routine quality control checks. Quality control was recommended when using a new lot number, receiving a new shipment, training a new operator, discordance is noted between the clinical presentation and lab results, scanning a new calibration card, and at least once a month.

While POC devices have some level of inaccuracy compared to standard laboratory testing, program staff carefully selected devices which have a strong base of evidence to support the relatively high accuracy of their use. Specifically, the DCA Vantage HbA1c device has demonstrated higher levels of concordance with venous laboratory tests than other POC HbA1c tests with high levels of correlation ($r^2 = 0.9776$) with gold standard HPLC methods[13–15]. Hemoglobin variants would not be expected to have a significant impact on this test as the DCA Vantage relies on testing for antibodies on the first few amino acids of the glycated β-chain of hemoglobin A. The more common hemoglobin variants typically occur on more distal parts on the hemoglobin chain thus limiting their impact on this particular test [16]. In addition, despite emerging evidence suggesting establishing separate thresholds for diagnosing diabetes when utilizing POC tests, national diabetes guidelines were followed when utilizing these results in clinical care as formal POC based thresholds have not been recommended [17,18]. Leadership from the partner clinics collaborated with the team from HHI and a consultant to develop a mutually agreed upon monitoring framework that would not interfere with their routine clinical activities. Partner clinics agreed to provide data on the types of POC labs they utilized and the individual results of all HbA1c tests performed. Partners provided this data monthly throughout the duration of the collaboration which occurred between July 9, 2021, and December 31, 2023.

2.1. Statistical analysis

Any patient receiving POC labs provided through the HHI program was eligible for inclusion with this analysis. For the primary objective, descriptive statistics were used to assess the utilization of the different POC tests available through this program. With the relatively higher demand for HbA1c tests, the secondary analysis focused on identifying how HbA1c was used in addition to tracking the changes in glycemic control patients experienced over the course of the program. Because of the observational nature of this analysis, inconsistent follow-up amongst participants was expected and longitudinal analysis only included participants who had a baseline HbA1c and a follow-up test at least 60 days later. HbA1c data was grouped into 90-day intervals with HbA1c measurements closest to the end of the interval being utilized whenever two measurements co-occurred in the same interval. The partners also requested additional analyses on patients with poorly controlled HbA1c's ≥ 9.0 % (75 mmol/mol) as the clinic partners highlighted the important role free clinics play in assisting highly vulnerable populations at an elevated risk for clinical complications. An HbA1c ≥ 9.0 (75 mmol/mol) was selected as the cutoff for poorly controlled diabetes based on the Health Effectiveness Data and Information Set (HEDIS) indicators recommended by the US National Committee on Quality Assurance. While the exact interventions these patients received were not tracked, patients typically received a mix of counselling on lifestyle modifications and clinical care from the free clinics and their regular providers if they had one. The secondary outcome of interest was the mean difference in HbA1c between baseline and 90–179 days for patients with a baseline HbA1c ≥ 9.0 % (75 mmol/mol). Based on a priori sample size calculations, 165 paired responses would be needed to detect a 0.5-point difference in HbA1c with 80 % power and an allowable type 1 error of 0.05 with a paired *t*-test. In addition, 95 % confidence intervals were calculated around the point estimates for the mean HbA1c and mean difference in HbA1c compared to baseline at subsequent time points with analysis by the paired *t*-test. Similarly, analogous analyses were completed for PLWD with a baseline and/or follow-up HbA1c ≥ 6.5 % (48 mmol/mol) (consistent with a diagnosis of diabetes) at any time point during the program [12].

Institutional Review Board (IRB) approval for analyzing the de-identified data was obtained from the Indiana University IRB.

3. Results

Through this partnership, a total of 17,563 POC tests were completed for 9658 patients across 16 clinics. All 16 clinics were able to provide descriptive data on the utilization of the different POC tests available while 15 clinics were able to provide individualized, de-identified data on the HbA1c results as one of the clinics was not able to provide individualized patient data. Clinics demonstrated considerable variability in the utilization of POC lab testing supplies but consistently utilized tests for chronic diseases (HbA1c and lipid), more than any of the other tests for infectious diseases or pregnancy as seen in Fig. 2. The two clinics with the highest utilization of HbA1c testing supplies were responsible for 20.2 % (n = 1031) and 15.7 % (n = 803) of the overall consumption of HbA1c tests. A total of 3223 patients had at least one HbA1c test performed with 67.4 % (n = 2171) having only one HbA1c test completed as seen in Fig. 3. Amongst the patients with only one result, most patients would be classified as not having diabetes (n = 1,077, 49.6 %) or pre-diabetes (n = 568, 26.2 %) based on the most recent diagnostic guidelines recommended by the American Diabetes Association [12]. Conversely, 24.2 % (n = 526) of participants with only one result had an HbA1c consistent with a diagnosis of diabetes with 228 (10.5 %) PLWD meeting the definition for poorly controlled diabetes.

In the analysis of longitudinal HbA1c trends, a total of 751 PLWD had at least one baseline or follow-up result that was≥6.5 % (48 mmol/mol). Of those 751 PLWD, 57 had a baseline HbA1c<6.5 % (48 mmol/mol), which then increased above 6.5 % (48 mmol/mol) at some point during the period of follow-up and were still included in the longitudinal analysis. In the longitudinal analysis of the 751 PLWD and a follow-up result, the mean baseline HbA1c was 8.9 % (95 % CI, 8.7 %–9.0 %, n = 751, 74 mmol/mol [72 mmol/mol – 75 mmol/mol]). Between 90 and 179 days, the mean HbA1c was 8.4 % (95 % CI, 8.3%–8.6 %, $p < 0.05$, n = 495, 68 mmol/mol [67 mmol/mol – 70 mmol/mol]) with a mean reduction from baseline of -0.4 % (95 % CI, -0.5 % to −0.2 %, $p < 0.05$, -19 mmol/mol [95 % CI -18 mmol/mol - -21 mmol/mol]). In the analysis of patients with a baseline HbA1c ≥ 9.0 % (75 mmol/mol), there were 301 PLWD with a mean baseline HbA1c of 11.1 % (95%CI, 10.9 %–11.3 %, 98 mmol/mol [95 % CI 96 mmol/mol – 100 mmol/mol]). The 188 PLWD who completed an HbA1c between 90 and 179 days demonstrated a statistically significant reduction from baseline with a mean HbA1c of 9.8 % (95 % CI, 9.5 %–10.1 %, $p < 0.01$, 84 mmol/mol [80 mmol/mol – 87 mmol/mol]) and a mean reduction of -1.2 % (95 % CI, -1.6 % to −0.9 %, $p < 0.01$, -10 mmol/mol [95 % CI, -6 mmol/mol - -14 mmol/mol]). Statistically significant reductions from baseline were observed at all subsequent timepoints as seen in Fig. 4.

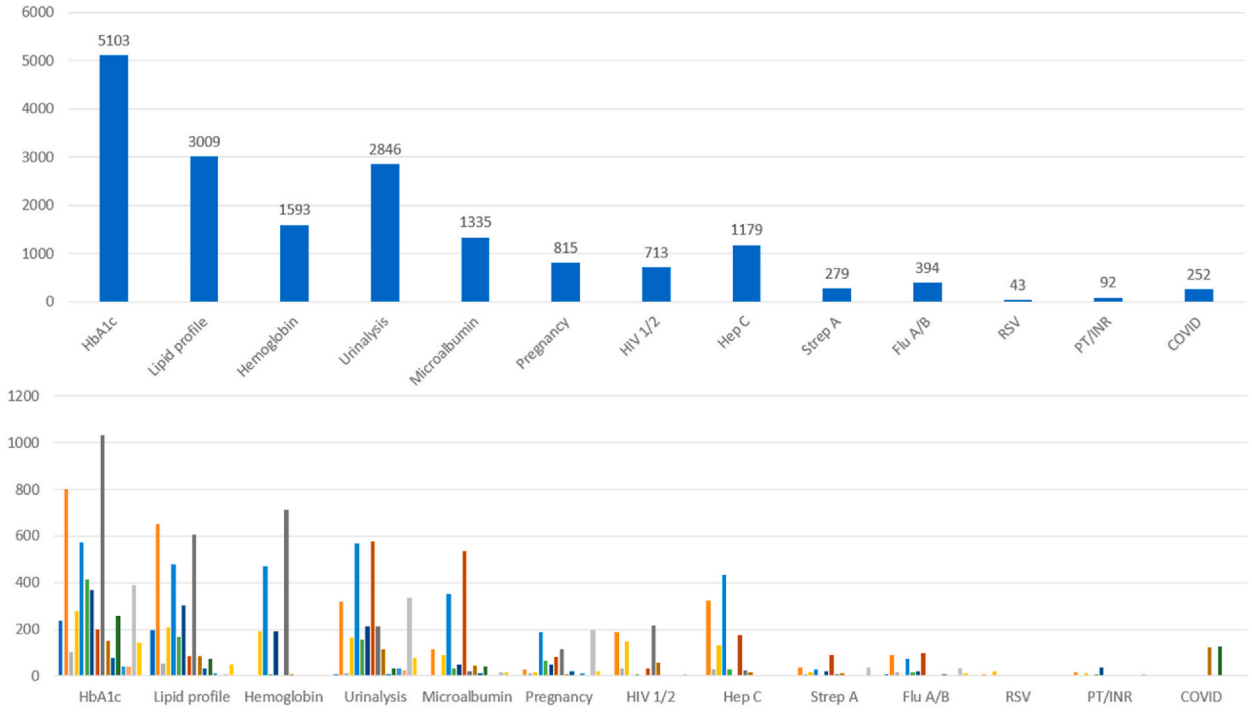


Fig. 2. Utilization of different point of care tests by type (A) and variability by clinic (B). (*each bar in graph B illustrates the consumption of each test by each of the 16 different partner clinics)*

HbA1c-glycosylated hemoglobin, HIV-Human immunodeficiency virus, Hep C – hepatitis C, Strep A – Group A Streptococcus, Flu A/B – Influenza type A/B, RSV-respiratory syncytial virus, PT/INR – prothrombin time/international normalized ratio, COVID – coronavirus disease.

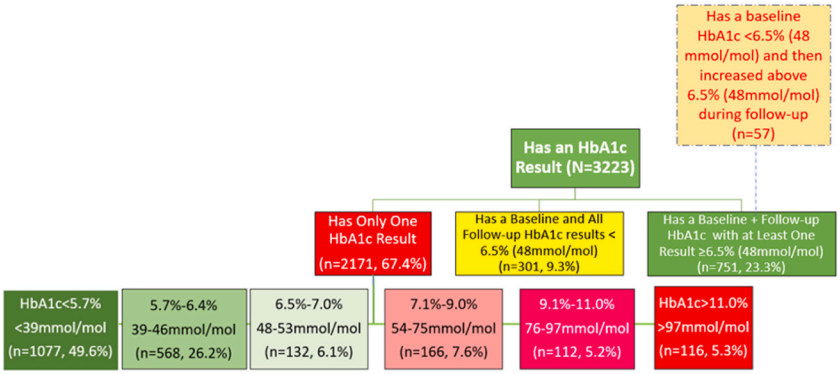


Fig. 3. – Summary of utilization of HbA1c.

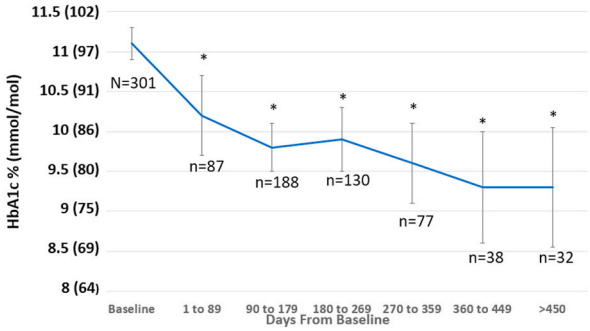


Fig. 4. – HbA1c Trends for Patients with a Baseline HbA1c $\geq$ 9.0 % (75 mmol/mol) and subsequent follow-up results
*$p < 0.01$ via paired *t*-test.

4. Discussion

The 16 free and charitable clinics involved in the HHI partnership were able to integrate donated POC labs into their clinics with a relatively higher utilization of tests for chronic diseases than infectious diseases. Chronic disease POC tests, like HbA1c, were frequently used to provide a one-time spot screening for patients as seen in Fig. 3. Based on discussions with the partner clinics, the majority of patients relied on these clinics to receive free screening but also sporadically requested HbA1cs when they were unable to afford the fees or navigate the wait times associated with completing HbA1cs at conventional labs as part of their routine follow-up. Amongst PLWD who used more than one POC HbA1c for routine follow-up, statistically significant reductions were seen amongst the overall population with diabetes with an even more pronounced response for those with a baseline HbA1c $\geq$ 9.0 % (75 mmol/mol). While this assessment was not designed to determine the precise impact increased accessibility to HbA1c testing has for populations experiencing poverty, the trends seen in this study help illustrate the important role free and charitable clinics can play. These populations frequently struggle with accessing comprehensive care and vital laboratory tests within the standard channels of the US healthcare system. While the per test cost of POC laboratory tests is typically higher than batched automated venous sample analyzers, the portability, convenience, and ease of use of POC tests is uniquely suited to addressing the many barriers populations experiencing poverty face. For these populations, POC tests help reduce the transportation costs and lost wages from multiple follow-up visits and ultimately reduce the frequently experienced delays in completing, conveying, and enacting clinical changes based on lab results [7]. The improvement in blood sugars is consistent with previous studies which have shown that monitoring HbA1c can independently have a beneficial impact on glycemic control in other populations [8,9]. While this study did not assess the trends in lipid control, this was the second most utilized POC test as seen in Fig. 2, further highlighting the gap in chronic disease screening and monitoring which free and charitable clinics can potentially fill through POC testing.

4.1. Limitations

The retrospective, observational nature of this evaluation and reliance on routinely collected data limited the ability to make more definitive assessments of the direct impact of HbA1c tests on glycemic control. It was also difficult to precisely track follow-up and the many interventions they receive, as there was considerable variability in how patients used free and charitable clinics as some used it as their primary medical home while others intermittently visited the clinic in between visits with their regular providers. It is also possible that selection bias impacted which patients contributed follow-up data, however, it is unclear if this resulted in sicker or

healthier patients being included in the longitudinal follow-up. Despite the limitations of trying to directly attribute the observed benefits to POC HbA1c testing, our study was able to demonstrate the potential utility of including POC HbA1c at free and charitable clinics. Furthermore, prior studies have demonstrated the benefits of POC testing in screening, diagnosis, and monitoring which are consistent with the observations from this assessment [12].

With the growing burden of chronic diseases amongst populations experiencing poverty, additional efforts to improve access to vital laboratory tests and other supportive services can help mitigate this growing burden. Future prospective studies should be designed to more rigorously assess the impact of POC lab tests on improving clinical outcomes by including a non-POC comparator group in addition to qualitative assessments to better understand the reasons for the observed trends amongst populations experiencing poverty.

CRediT authorship contribution statement

Sonak D. Pastakia: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Heidi Schutz:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Tena Tiruneh:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Ariana Gordillo De Vivero:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization. **Lindsey Dodds:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Formal analysis, Data curation, Conceptualization.

Funding sources

This work was coordinated by Heart to Heart International (HHI) and supported by funding and product support from Eversana InTouch, Wylie Foundation, and Becton Dickinson (BD).

SDP served as a consultant for HHI to complete this evaluation. He also serves as a consultant for BD.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Sonak Pastakia reports financial support was provided by Heart to Heart International. Sonak Pastakia reports a relationship with Heart to Heart International that includes: consulting or advisory. SDP serves as a consultant for the philanthropic activities of other pharmaceutical companies including BD and Abbott. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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