Comparing standard office-based follow-up with text-based remote monitoring in the management of postpartum hypertension: a randomised clinical trial

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ABSTRACT

Background Monitoring blood pressure at 72 hours and 7–10 days post partum in women with hypertensive disorders is recommended to decrease morbidity. However, there are no recommendations as to how to achieve this.

Objective To compare the effectiveness of text-based blood pressure monitoring to in-person visits for women with hypertensive disorders of pregnancy in the immediate postpartum period.

Methods Randomised clinical trial among 206 postpartum women with pregnancy-related hypertension diagnosed during the delivery admission between August 2016 and January 2017. Women were randomised to 2 weeks of text-based surveillance using a home blood pressure cuff and previously tested automated platform or usual care blood pressure check at their prenatal clinic 4–6 days following discharge. The primary study outcome was a single recorded blood pressure in the first 10 days post partum. The ability to meet American Congress of Obstetricians and Gynecologists (ACOG) guidelines, defined as having a blood pressure recorded on postpartum days 3–4 and 7–10 was evaluated in the text message group. The study was powered to detect a 1.4-fold increase in a single recorded blood pressure using text messaging. All outcomes were analysed as intention to treat.

Results 206 women were randomised (103 in each arm). Baseline characteristics were similar. There was a statistically significant increase in a single blood pressure obtained in the texting group in the first 10 days post partum as compared with the office group (92.2% vs 43.7%; adjusted OR 58.2 (16.2–208.1), p<0.001). Eighty-four per cent of patients undergoing text-based surveillance met ACOG criteria for blood pressures at both recommended points.

Conclusions Text-based monitoring is more effective in obtaining blood pressures and meeting current clinical guidelines in the immediate postdischarge period in women with pregnancy-related hypertension compared with traditional office-based follow-up.

Trial registration number NCT03185455, Remote Surveillance of Postpartum Hypertension (TextBP), https://clinicaltrials.gov.

INTRODUCTION

Hypertensive disease is a leading cause of maternal morbidity and mortality[1 2] and obstetrical readmissions in the USA.[3] The majority of patients readmitted with hypertension in the postpartum period have a diagnosis of hypertensive disorder of pregnancy on initial admission for delivery; therefore, persistence of disease and disease progression, in contrast to new-onset disease, is more common in the postpartum period. Moreover, peak blood pressure in these patients usually occurs 3–6 days post partum, after hospital discharge, and is typically unaccompanied by warning symptoms.[4–6] As such, the Hypertension in Pregnancy guidelines provided by the American Congress of Obstetricians and Gynecologists (ACOG) recommend monitoring blood pressure at 72 hours post partum (inpatient or outpatient) and again in 7–10 days in women diagnosed with a hypertensive disease of pregnancy.[6]

Although there is a clear need for effective and reliable blood pressure surveillance for high-risk women soon after delivery, there are no recommendations as to how to best achieve this. Our own high-risk blood pressure transition clinic had an average of only 30% attendance over a 2-year period, and did not improve despite text message and phone call reminders as well as expanded visit availability in individual practices.[7] A postpartum quality improvement pilot project that we previously performed, in which patients were discharged with a home blood pressure cuff, showed greater patient engagement and participation in postpartum blood pressure monitoring with a text message-based programme.[8] The pilot data suggest there is potential for earlier intervention, reduction in

readmissions and decreased overall morbidity using this innovative approach.

To allow for use on a large scale, we developed an automated text-based platform that enables healthcare providers to monitor patient blood pressures in a more patient-centred manner. Our objective was to compare the effectiveness of an innovative text-based strategy using this platform versus our usual care with in-person office visits in monitoring women with hypertensive disorders of pregnancy in immediate postdischarge period. Our hypothesis was that text-based surveillance would result in more blood pressure values obtained in the first 10 days post partum. This, in turn, would result in greater ability for providers to meet ACOG guidelines for blood pressure monitoring at the two time points recommended.

MATERIALS AND METHODS

This was a randomised controlled trial that took place from August 2016 to January 2017. All women with pregnancy-related hypertension who delivered at the home institution were eligible to be considered for enrollment in the study. The study was approved by the Institutional Review Board prior to initiation.

All postpartum women with gestational hypertension, pre-eclampsia, chronic hypertension with superimposed pre-eclampsia, or haemolysis, elevated liver enzymes, low platelets syndrome (with or without inpatient hypertension), based on ACOG criteria, were approached for the study as these are the patients targeted for postpartum blood pressure surveillance in the ACOG recommendations.[6] Women had to be over 18 years of age, be able to speak and read English and have access to a cellphone with unlimited text message capabilities to be included. Women were only approached for the study if pregnancy-related hypertension was present on their initial delivery admission; therefore, readmissions for new-onset postpartum hypertension were not eligible.

Women who met eligibility criteria were approached in the postpartum recovery unit by the research team. Written informed consent was obtained and four-block randomisation was performed using REDCap.[9] Women randomised to standard office-based follow-up were instructed to follow-up at the location of their prenatal care 4–6 days post partum for a nursing blood pressure visit. There were only two different prenatal practices within the medical system that were included in the office-based follow-up. The date and time of the office appointment was specified in the discharge document and reviewed with the patients. Nurses and physicians in the office followed a pre-established outpatient clinical algorithm, developed in coordination with the department of medicine, for escalation of care and initiation of antihypertensive medications (online supplementary appendix 1). This office-based follow-up was the standard of care implemented more than 3 years prior to the study.

Women randomised to the text-based surveillance arm were given an automatic Omron blood pressure cuff and instructed on its use by research team members prior to discharge. Patients were enrolled into the texting program platform developed through Way to Health, a web-based platform within the institution, with secure technological infrastructure developed for research.[10–12] Through its connection to a variety of devices, such as cellular phones, Way to Health has the ability to communicate with patients using text messaging with automated delivery of feedback to the patients. A starting introductory text message was sent by the Way to Health platform to the phone number provided on day of discharge. Patients received reminders to text message their blood pressures twice daily for 2 weeks post partum, starting on the day after discharge, in order to keep the protocol consistent with our pilot project. Immediate feedback was provided to the patient based on a preprogrammed automated algorithm (online supplementary appendix 2). The primary investigator was alerted with prespecified severe range blood pressure values (systolic blood pressure >160 mm Hg or diastolic >110 mm Hg) via text message or email and care was escalated as needed based on the same outpatient algorithm used in the office (online supplementary appendix 1). However, instead of repeat office visits for blood pressure checks for severely elevated values, patients in the texting intervention were instructed to continue to text back blood pressure readings through the platform.

For safety purposes, the primary investigator logged into Way to Health at least once a day to review the inputs into the system, to ensure that no severe range blood pressures were missed due to system errors or that any blood pressure sent in the incorrect format or outside the time frame requested needed to be addressed. Additionally, although patients were instructed to text only blood pressure numerical values, as words or emergency questions could not be addressed by this texting system, the log was reviewed daily to ensure that no other medical concerns or comments needed a response.

All patients were contacted to complete a patient satisfaction survey, via telephone, at the 2–3 week postpartum period. The survey included questions regarding communication preferences, helpfulness of office visits, barriers to postpartum care, and if in the text messaging arm, ease and satisfaction with the text messaging platform. Scoring was based on a 5-level Likert scale, with a score of '1' indicating strong disagreement, '3' indicating neutral and '5' indicating strong agreement.

Maternal delivery and readmission information was obtained through detailed chart abstraction using the electronic medical record and managed using REDCap. Blood pressure values in the text message group were tracked and abstracted from Way to Health. Patients and healthcare providers were not

blinded to the assigned treatment group because of the need to provide patient care and ensure appropriate surveillance. However, trained research personnel, uninvolved with clinical care, were blinded to study arm during data abstraction.

The primary outcome measure was the percentage of patients in which a single blood pressure was obtained in the first 10 days following discharge. We also determined the percentage of patients in the text messaging group in whom blood pressure values were obtained at 72 hours and 7–10 days post partum, in accordance with ACOG recommendations. A texted blood pressure on postpartum day 3 or 4 was used as a surrogate for a 72-hour blood pressure in patients who were discharged on postpartum day 2 or 3. Patients discharged on postpartum day 4 or later only needed a blood pressure recorded on postpartum days 7–10 to meet criteria, as their 72-hour blood pressure would have been documented during their hospital admission. Secondary outcome measures were initiation of antihypertensive medication, number of additional postpartum office or emergency room visits and readmission for persistent hypertension, attendance of the 4–6 week postpartum visit, patient satisfaction with blood pressure surveillance and future health awareness in relation to the long-term effects of pre-eclampsia on cardiac health.

A 1.4-fold increase in blood pressure ascertainment using text messaging was considered clinically meaningful as historical data from our institution yielded a show rate of 30%–50% at office blood pressure checks[7] and 85% blood pressure ascertainment using text messaging.[8] However, to be more conservative we assumed a usual care office show rate of 50% and a text messaging ascertainment rate of 70%. Therefore, with an alpha of 0.05% and 80% power, we needed 103 patients in each arm for a total sample size of 206 women.

All analyses were performed using STATA V.14.0 for Windows (STATA, College Station, TX). X^2 or Fisher's exact tests were used to compare categorical data. T-tests and Mann-Whitney U tests were used to compare continuous variables. Multivariable logistic regression models were used to control for potential confounders for all dichotomous outcomes. Confounders for adjusted models were selected based on clinical judgement and statistical evidence of confounding. Multivariable ordinal regression was used to analyse follow-up survey results. All outcomes were analysed as intention to treat. Statistical significance was determined by a p value of less than 0.05.

RESULTS

There were 303 women with pregnancy-related hypertension who underwent delivery during the study period of August 2016 to January 2017. Of the 278 (92%) who met eligibility criteria and were approached for enrolment, 72 declined enrolment, and 206 (74%) women were randomised into one of the two monitoring groups (figure 1). Sixty-two (60%) women in the usual care office visit group and 77 (75%) women in the texting group completed follow-up phone call surveys.

Demographics and clinical characteristics were similar among the two groups, including age, insurance, presence of significant medical history, timing of hypertension diagnosis, gestational age at diagnosis and delivery, and disease severity (tables 1 and 2).

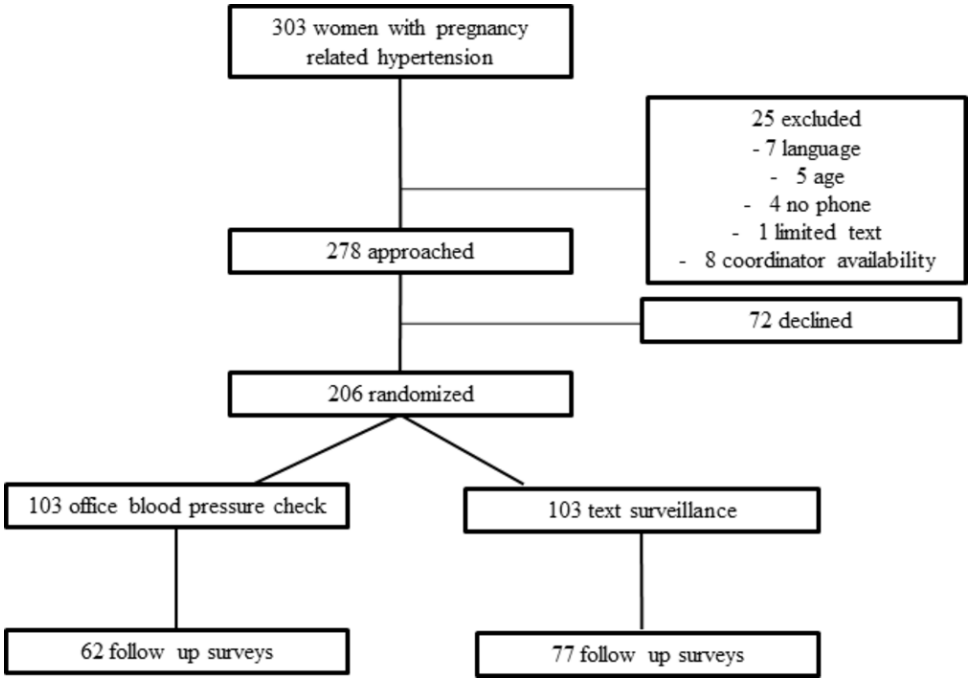

Figure 1 Flow chart of patients enrolled. Flow diagram showing patient enrolment.

Table 1 Maternal demographics

Demographic	Office visit n=103 (%)	Text messaging n=103 (%)
Age (years)	28±5	28±6
Race		
Black/African-American	73 (70.9)	68 (66.0)
White	25 (24.3)	28 (27.2)
Asian	4 (3.9)	2 (1.9)
Other	1 (1.0)	5 (4.8)
Insurance		
Private	42 (40.8)	44 (42.7)
Medicaid	61 (59.2)	59 (57.3)
Body mass index at first prenatal visit, median (IQR)	31.0 (25.1–38.3)	30.1 (24.3–33.8)
Nulliparous	52 (50.5)	61 (59.2)
Tobacco use		
Prior to pregnancy	12 (11.6)	8 (7.8)
During pregnancy	5 (4.8)	5 (4.9)
Pregestational diabetes	3 (2.9)	5 (4.8)
Gestational diabetes	8 (7.8)	6 (5.8)
Chronic hypertension		
Yes—no medication	7 (6.0)	9 (8.7)
Yes—on medication	6 (5.8)	5 (4.8)
Renal disease	5 (4.8)	5 (4.8)
Timing of diagnosis		
Antepartum	56 (54.4)	45 (43.7)
Intrapartum	31 (30.1)	44 (42.7)
Postpartum	16 (15.5)	14 (13.6)
Gestational age at diagnosis, median (IQR)	38 (36–39)	38 (36–39)
Gestational age at delivery, median (IQR)	38 (37–39)	38 (37–39)
Disease severity		
GHTN/PEC without SF	68 (66.0)	63 (61.2)
Superimposed PEC	10 (9.7)	14 (13.6)
PEC with SF	22 (21.4)	25 (24.3)
HELLP	3 (2.9)	0
Eclampsia	0	1 (1.0)

Continuous: mean ±SD, categorical: n (%).
GHTN, gestational hypertension; HELLP, haemolysis, elevated liver enzymes, low platelets; PEC, pre-eclampsia; SF, severe features.

Patients in both groups had similar rates of induction, mode of delivery, magnesium sulfate use and initiation of furosemide or oral antihypertensive prior to discharge. Of note, about 40% of the women in the study had a form of severe hypertensive disease. Most women were discharged home on postpartum day 2.

There was a statistically significant increase in at least one blood pressure ascertained in the first 10 days post partum in the texting group as compared with office visits (92.2% vs 43.7%; p<0.001; table 3). This increase remained significant when the analysis was adjusted for age, race, insurance, body mass index, parity, disease severity, mode of delivery and presence of chronic hypertension or diabetes (adjusted OR (aOR): 58.2, 95% CI 6.2 to 208.1; p<0.001).

On average, 16 (±9) of a maximum 28 total blood pressure values were received per patient in the text messaging group, and blood pressure values were received on 10 (±5) of the 14 days requested. Eighty-seven (84%) patients in the text messaging group had a recorded blood pressure at 72 hours and again at 7–10 days post partum in accordance with ACOG guidelines.

There was no difference in outpatient antihypertensive medication initiation by treatment group (22.2% office vs 16.5% text, p=0.41); however, only 45 women (44%) in the office group attended their office visit (table 3). There was also no difference in additional office or emergency room visits for hypertension that did not result in readmissions within 2 weeks post partum between the two groups (1.9% vs 2.9%, p=0.65). However, there was a statistically significant increase in hypertension-related readmissions in the office arm (3.9% vs 0%, p=0.04).

Of note, there were 24/95 (25%) patients in the text messaging group who had at least one severe range

Table 2 Obstetrical outcomes

Obstetrical outcome	Office visit n=103 (%)	Text messaging n=103 (%)
Induction	58 (56.3)	54 (52.4)
Caesarean delivery		
In labour	18 (17.5)	23 (22.3)
Planned	16 (15.5)	10 (9.7)
Intravenous antihypertensive medication		
Intrapartum	10 (9.7)	7 (6.8)
Postpartum	13 (12.6)	11 (10.7)
Magnesium sulfate use	32 (31.1)	35 (34.0)
Live birth	100 (97.1)	100 (97.1)
Discharged on oral antihypertensive medication	19 (18.4)	24 (23.3)
Furosemide course initiated	5 (4.8)	11 (10.7)
Postpartum discharge day, median (IQR)	2 (2–3)	2 (2–3)
Breast feeding	72 (69.9)	71 (68.9)

n (%).

blood pressure, and in total, 82 severe range blood pressure values were reported in the 2-week period. This is in comparison to 7/45 (16%) women who attended the office visit with severe range blood pressures noted during the blood pressure check. Antihypertensive agents were initiated on postpartum days 3–5 for most women; however, medications were started as early as postpartum day 1 and as late as postpartum day 12 according to our care management algorithm. As instructed, none of the patients sent in other questions or concerns by text messaging.

Among those who responded to the phone call surveys, there was no difference in patient-reported importance of blood pressure follow-up for long-term health (table 4). However, women in the text messaging arm scored importance of face-to-face communication lower than the office visit arm (p=0.003). This remained significant after adjustment for age, race, insurance, body mass index, parity, disease severity, mode of delivery and presence of chronic hypertension or diabetes (aOR: 0.3, 95% CI 0.1 to 0.8; p=0.02). Additionally, all the patients in the text message arm who responded to the survey said they would recommend the programme to a friend or family member.

COMMENT

This randomised controlled trial compared text message-based surveillance and usual care in-person office visits in the monitoring of postpartum hypertension among women at risk for persistence or progression of disease. Providing a home blood pressure cuff coupled with text-based monitoring appears to be a superior, patient-centred solution to obtain blood pressures and meet current ACOG recommendations in the immediate postdischarge period in women with pregnancy-related hypertension. Text-based remote surveillance allowed us to meet ACOG recommendations for blood pressure monitoring in 84% of patients, representing a substantial and noteworthy improvement from our usual care standard.

Additionally, our results indicate that poor attendance at office visits results in missed opportunities for early intervention and subsequent readmissions. Assuming the same prevalence of severe range blood pressures in both arms, it is possible that we may have missed 17 patients with severe range pressures among those who failed to attend their office visit in the standard of care, office-based arm. Notably, the women in the text-based arm had no hypertension-related readmissions and a higher postpartum visit attendance rate; in comparison, four women in the standard of care, office-based arm had readmissions for hypertension. Three of the four patients were found to be hypertensive at their office visit and were sent to the hospital. The fourth patient was sent to the hospital based on hypertension at a home nurse evaluation. These readmissions underscore the importance of the multiple blood pressure data points obtained on patients in

Table 3 Postdischarge outcomes

Postdischarge outcome	Office visit n=103 (%)	Text messaging n=103 (%)	P values	aOR (95% CI)	P values
Blood pressure obtained within 10 days*	45 (43.7)	95 (92.2)	<0.001	58.2 (16.2 to 208.1)	<0.001
Outpatient antihypertensive medication initiated within 2 weeks post partum†	10/45‡ (22.2)	17/103 (16.5)	0.41	1.0 (0.3 to 3.1)	0.95
Additional emergency department or office visit for hypertension not resulting in readmission†	2 (1.9)	3 (2.9)	0.65		
Postpartum hypertension readmission	4 (3.9)	0 (0)	0.04		
Attended postpartum visit§	60 (58.2)	71 (68.9)	0.11	2.3 (1.05 to 5.07)	0.04

n (%).
aOR not calculated when outcome was rare.
*Adjusted for age, race, insurance, body mass index (BMI), parity, disease severity, mode of delivery, chronic hypertension/diabetes.
†Adjusted for age, race, insurance, BMI, parity, disease severity, timing of diagnosis, mode of delivery, chronic hypertension/diabetes, furosemide course given.
‡Denominator includes only women who attended office visit.
aOR, adjusted OR.

Table 4 Follow-up survey results*

Survey question	Office visit (n=62)	Text messaging (n=77)	P values	aOR† (95% CI)	P values
Importance of blood pressure follow-up for long-term health	5 (5–5)	5 (5–5)	0.61	1.4 (0.4 to 4.9)	0.59
Importance of face-to-face communication	5 (5–5)	5 (3–5)	0.003	0.3 (0.1 to 0.8)	0.02
Questions can be answered:					
In the office	5 (4–5)	5 (4–5)	0.83	1.4 (0.6 to 3.2)	0.42
Over the phone	5 (4–5)	5 (4–5)	0.65	1.1 (0. to 2.6)	0.82
Via text message	4 (3–5)	5 (3–5)	0.95	0.9 (0.4 to 1.9)	0.84

Median (IQR).
*Scoring based on 5-level Likert scale: 1—strongly disagree; 2—somewhat disagree; 3—neutral; 4—somewhat agree; 5—strongly agree.
†Adjusted for age, race, insurance, body mass index (BMI), parity, disease severity, mode of delivery, chronic hypertension/diabetes.
aOR, adjusted OR.

the text-based arm and the ability to more effectively manage patients in this arm compared with the office-based arm with a single blood pressure data point.

Our findings are similar to studies investigating use of mobile technology in other healthcare settings, which have shown overall improvement in patient care. In a systematic review of 60 studies reporting use of text messaging, positive impacts were found on medication and treatment adherence, appointment attendance and positive attitudes towards medication and treatment, with improved outcomes in 77% of the studies.[13] Additionally, patients find access to physicians by means of mobile technology and text messaging highly desirable. While mobile technology has been studied in maternity care, none of the randomised trials related to pregnancy have focused on pregnancy-related hypertension and few have used text-based communication.[14 15]

Our study has significant clinical and healthcare cost implications for obstetric care. Pre-eclampsia is linked to one in five maternal deaths and drives over a quarter of obstetrical readmissions in the USA every year.[1–3] With up to 10% of pregnant women affected by a hypertensive disorder of pregnancy, the burden of the disease and need for follow-up is high and inadequate follow-up is costly. Text message surveillance using this bidirectional automated platform is a low-cost, patient and provider-friendly platform for remote blood pressure surveillance. It can safely and effectively allow for adequate, timely blood pressure ascertainment, limit in-person follow-up to those in need and reduce readmissions in the immediate postpartum period. As this is a time fraught with high morbidity and high patient inconvenience with in-person visits, this method of surveillance can change the way we care for women with pre-eclampsia and engage them in future health. An increase in attendance at the postpartum visit among women in the text-based intervention demonstrates the added benefit of this programme to enhance patient engagement; an important finding from a public health perspective.

Strengths of the study include that it was a large, appropriately powered randomised trial that studied a high-risk population with a significant amount of severe hypertensive disease. Standardised antihypertensive treatment algorithms were used in both inpatient and outpatient settings to limit variations in care based on providers managing the cases on a daily basis and among the two groups. Additionally, access to cellphone and unlimited text messaging was not a barrier to using this technology, as only 5 out of 303 eligible women were excluded for this reason, making it a generalisable technology.

Our study is limited to one model of obstetrical care, where a centralised responder addressed all blood pressures for patients randomised to the texting group. However, this responder used the same clinical algorithm as that used for the office-based group to determine management. The text messaging group relied on patient ascertainment of blood pressure and entry of their blood pressure readings into their cellphone. While wireless cuffs would eliminate this human factor, this method was chosen due to increased access to unlimited text messaging compared with wireless access among our population and the overall potential future scalability.[16] Additionally, it is important to note that the digital blood pressure cuff used in the texting arm was not the same as the cuff used in the office. Although both blood pressure cuffs are automated, the office visit allows for manual auscultation if necessary. However, all Omron blood pressure monitors are clinically validated to be within 3 mm Hg (https://omronhealthcare.com/service-and-support/faq/blood-pressure-monitors). While it is possible that patients may have used the cuff incorrectly and the readings being sent were not accurate, the cuff was tested prior to discharge from the hospital and the patients were given extensive instructions on use. Additionally, given the repeated blood pressure measurements per patient, trends were able to be evaluated and it is unlikely for multiple blood pressures to be incorrect. While we cannot confirm delivery of all text messages, we are reassured that messages were in fact received given the overall high rate of compliance with blood pressure readings sent back. Lastly, it is important to note that, by study design, women in the texting intervention

were discharged home with a home blood pressure cuff and educated on its use, and therefore the success of the intervention is a combination of providing a cuff with texting communication.

Future studies should continue to investigate implementation and evaluation of text-based monitoring in different obstetrical models of care, such as those where patients within an institution can be assigned to individual practices as well as in non-academic practices. Additionally, future evaluation of the lowest frequency or shortest duration of texting needed to obtain blood pressure values, meet current guidelines and decrease morbidity may allow for more patient-centred and cost-effective use of mobile technology. This technology and surveillance strategy also has important potential antepartum applications in monitoring for patients at high risk for pre-eclampsia. Further, a cost analysis comparing the two arms will be pursued to guide reimbursement strategies for this method of surveillance, as it leads to superior blood pressure ascertainment and lower readmission rates.

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