Measuring Blood Pressure in Primary Care for Accurate Diagnosis and Decision Making: Implementing Evidence-based Protocols Across a Health System

Gertrude W. Manchester a, Deirdre C. Donahue b, Catarina I. Kiefe c, Lori Pelletier d, Marie A. Sosa e, Sheri A. Keitz f,*

a Office of Clinical Integration, UMassMemorial Health, Worcester, MA, USA
b MCPHS University School of Nursing, Worcester, MA, USA
c University of Massachusetts Medical School, Burlington, MA, USA
d University of Connecticut School of Medicine, Chief Quality and Patient Safety Officer, Connecticut Children’s, Hartford, CT, USA
e Division of Nephrology, University of Miami Miller School of Medicine and Jackson Memorial Hospital, Miami, FL, USA
f Department of Medicine, Lahey Hospital and Medical Center, Burlington, MA, USA

Abstract

Background: Evidence-based blood pressure (BP) measurement is required for optimal clinical decision-making while improper measurement risks daily diagnostic and therapeutic errors.
Objective: To implement and sustain an evidence-based BP measurement protocol without extra resources and disseminate the protocol across a primary care network.
Design, setting, and participants: A Plan-Do-Study-Act (PDSA) framework for quality improvement was used to design a standardized BP measurement protocol including a 5-minute rest period only for patients with persistently elevated blood pressure. The protocol was developed using Goldratt’s Theory of Constraints and Layers of Resistance to ensure multidisciplinary buy-in and was implemented in 3 groups of primary care clinics. The protocol was developed in Group 1 with high leadership engagement and disseminated to Group 2 (self-selected clinics) and Group 3 (the remainder of the network). Participants included all primary care patients ≥18 years seen during the measurement period.
Measurements: BP readings and compliance with elements of the protocol.
Results: Clinic engagement within Group 1 was high with increase in protocol adherence from 30% to >90% for measurement of 2nd BP and from 21% to approximately 40% for the 3rd BP. The number of patients classified as “in control” with BP goal <140/90 increased by 10%. Protocols were implemented and sustained with high fidelity in Group#1 over 3 years and thousands of BP measurements. Protocol adherence and improvement in BP control were improved, but less so in Groups 2 and 3.
Conclusions and relevance: A modified BP measurement protocol was actionable and accepted in a busy primary care clinic without extra resources. Implementation of the protocol was associated with a sustained 10% improvement in patients with BP <140/90, decreasing possible diagnostic and therapeutic errors. This protocol avoided the need for the 5-minute waiting period in approximately 80% of patients, while focusing the scarce resources of time and space on those patients for whom the full blood pressure measurement protocol might change clinical decision-making. Dissemination of the protocol across the wider primary care network was more variable depending on local processes and leadership engagement.

Keywords: Blood pressure measurement, Hypertension, Quality improvement

Abbreviations: BP, blood pressure; BPMP, blood pressure measurement protocol; HEDIS, Healthcare Effectiveness Data and Information Set; PDSA, Plan, Do, Study, Act; PIF, practice improvement facilitator; TOC, Theory of Constraints,

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* Corresponding author at: Department of Medicine, Chair Lahey Hospital & Medical Center, 41 Mall Road Burlington, MA 01805, USA.
E-mail address: Sheri.A.Keitz@lahey.org (S.A. Keitz).

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Introduction

Forty-six percent of American adults have hypertension.1 However, well-documented differences exist between blood pressure (BP) measured in clinical practice and scientific protocols.2–5 Failure to implement proper BP measurement technique is associated with falsely elevated readings6–9 and risks misclassification of BP putting patients at risk for diagnostic and therapeutic errors.9

Guidelines, based on evidence generated by clinical trials using scientific BP measurement protocols, suggest that clinical decisions should be based on the average of two or more seated BPs with a 5-min rest period prior to first measurement. During measurement, the patient should be quiet, in a sitting position with back supported, legs uncrossed, feet on the ground, and with a properly sized cuff on the patient’s bare arm supported at heart level.4,10,11 Failure of real world adoption of this protocol may reflect time pressure, space limitations, practice culture, provider factors, resistance to change and/or competing priorities.

Theory of Constraints (TOC) has been used in healthcare to address such barriers.12–14 Our primary goal was to use TOC to develop, implement and sustain an evidence-based BP measurement protocol (BPMP) for primary care patients in a busy general internal medicine clinic without extra resources. A second goal was to disseminate workflows across a large primary care network.

Methods

Design and setting

UMassMemorial Health (UMMH) is a not-for-profit healthcare system with 275 physicians in 61 primary care practices. Practices in the network are organized into pods, each with a physician pod leader and Practice Improvement Facilitator (PIF) trained in facilitating performance metrics in primary care.

Participants

Every primary care patient age ≥18 seen during the measurement period. There were no exclusion criteria.

Quality improvement framework

Our goal was to provide accurate BP measurements using an evidence-based protocol to support clinical decision-making. We identified barriers to the protocol based on Goldratt’s Layers of Resistance15 (Appendix Fig. 1). We used a Plan-Do-Study-Act (PDSA) approach at a single site to develop the BPMP.

BPMP development

A trained observer utilizing a checklist passively monitored the baseline measurement process in Group#1 compared to the American Heart Association recommendations for BP measurement.4,7

We convened stakeholders including nurses, primary care providers, front line clinic staff, clinic leaders, trainees, and a renal physician with expertise in hypertension. Several group members voluntarily self-disclosed their status as patients being treated for hypertension. This group reviewed relevant literature and baseline observations, identified barriers to evidence-based measurement and potential solutions.

The key constraints identified were time and space for the 5-min rest period prior to BP measurement. Thus, we developed a BPMP that required the 5-min wait period only for the subset of patients with persistently elevated BPs, which was accepted by providers, nurses and clinic staff.

The protocol has 3 steps (Fig. 1): 1) initial BP measurement using existing clinic flow without 5-min wait period; 2) for patients with BP > 139/89, immediately repeat the BP measurement without 5-min wait period; and 3) for patients who continued to have BP > 139/89 on second measurement, the patient is roomed with a visual reminder for the provider and the 3rd BP is measured in the exam room.

The medical assistant places a mobile electronic cuff outside the room when available. The patient was told their BP was elevated and that the provider will likely repeat the measurement. This 3rd BP measurement was done by providers and was expected to adhere to the protocol, including the 5-min rest period. All BPs were expected to be entered individually in the medical record. We did not average pressure measurements.

Tools created to standardize protocol implementation include workflow posters at each nursing station (Fig. 1), laminated yellow cards as a visual reminder in both English and Spanish (Appendix Figure 2) and posters illustrating proper technique (Appendix Figure 3; also available at https://targetbp.org/wp-content/uploads/2017/02/Measuring-blood-pressure-new.pdf).

Medical assistant training included PowerPoint and short videos modeling the BPMP (Appendix Figure 4). An audit tool (Appendix Figure 5) and patient instructions for home BP measurement were developed (Appendix Figure 6).
Measurements

Baseline measures

Trained observers documented body position, arm position, cuff on bare arm, cuff size, patient quiet during measurement, and resting times for BP measurements.

Blood pressures

Every BP recorded in the electronic record for all visits for patients aged ≥18 between 01/01/2014 and 12/31/2018 was included for analysis. BP were directly extracted from Allscripts and Epic.

Provider survey

Group #1 providers participated in an open-ended survey regarding barriers to taking the third BP when indicated.

Dissemination of BPMP

The BPMP was initiated in 3 groups: Group#1: Benedict Internal Medicine; Group#2: 9 self-selected primary care practices; and Group#3: the remaining 51 primary care practices. Presentations to physician pod leaders occurred in October of 2016, 2017, 2018, and 2019 including detailed information on protocol adherence and improvements in BP measurements.
Group#2 practice leaders volunteered to implement the BPMP following the presentation in October 2016. Group#3 was formally launched in October 2017 with agreement that all network practices would adopt the BPMP.

Performance Improvement Facilitators (PIFs) were trained in the BPMP, patient and provider facing materials. PIFs worked with all 61 primary care practices, visiting every 4–6 weeks to educate providers and staff with standardized tools, to identify barriers to BPMP and problem solve.

Audits

Three cycles of audit and feedback were done in Group#1 in February 2016, February 2017 and July 2017. A single round of audit and feedback was done in Group#2 (9 volunteer primary care practices) but not Group#3 (remaining 51 practices).

All practices received aggregate data on BP control (<140/90) in their patient population.

Analysis

Groupings

Practices were divided into the 3 groups (Appendix Table 1). BP Protocols were implemented 1/1/2016 (Group#1), 11/1/2016 (Group#2), and 10/1/2017 (Group#3). BP measurements were included for five years (1/1/2014–12/31/2018) for Group#1 to provide two years of baseline and four years (1/1/2015–12/31/2018) for Groups #2 and #3.

Adherence to the BPMP

We calculated how often a second BP was recorded when the patient’s first BP measurement was >139/89 and the percent of time a third BP was recorded when the BP was >139/89 on both first and second BP measurements.

BP control for each patient within each visit

We applied the HEDIS (Healthcare Effectiveness Data and Information Set) methodology of the National Committee for Quality Assurance as the standard for BP control within each visit. HEDIS defines BP control as the best systolic BP < 140 and the best diastolic BP < 90 for a visit.

Population blood pressure control

At the population level, HEDIS classifies a patient as being in control or not, based on the final BP measurement in each calendar year. We identified all BP measurements at the final primary care visit for each unique patient in each group to determine the population based % of patients with BP control (<140/90).

Statistical analysis

Our project was not designed to test any hypothesis, thus we focused on descriptive statistics. We used run charts to examine time trends in adherence to our protocol.

Ethical considerations

The project was reviewed by the institutional IRB and determined not to be human subject research. This follows SQUIRE 2.0 reporting guidelines. There were no external sources of funding.

Results

Baseline measurements

Group#1 baseline observations confirmed high adherence with evidence-based BP measurement technique for 77 consecutive patients. However, “resting” time prior to BP measurement did not meet recommended 5 min (mean time 33.3 s; maximum 120 s, minimum 3 s); only 8% of patients were sitting for >1 min (Appendix Table 2).

Provider survey

Seventy-nine percent of Group#1 providers (20/29) responded to a survey about the BPMP; 65% of respondents reported that time constraints were the most common reason that the 3rd BP was not performed. Other reasons included a) BP monitor not easily available, b) 3rd BP would not change management, and c) home BPs were being used for decision-making. Eighty-three percent of respondents reported that protocol implementation changed management decisions in the visit with 75% noting that the visual reminder helped set the visit agenda.

Patient and practice characteristics (Appendix Table 1)

Group#1 is an academic practice with 25 attending physicians, 5 nurse practitioners, and 30 medical residents. Group#2 practices include four family medicine, three internal medicine, and two medicine/pediatrics practices. Seven of the Group#2
practices are community-based and three are training sites for family medicine or med/peds residents. Group#3 includes the remaining 51 practices in the network. All practices were using the All-Scripts Electronic Medical Record system at the onset of the study and transitioned simultaneously to Epic in October 2017.

Group#1 has a higher percentage of patients >65 years, Medicare beneficiaries, prevalence of co-morbidities on problem lists, and lower percentage of rural patients compared to the other two groups.

**Intervention by group**

**Table 1** summarizes interventions in the 3 Groups. Group#1 had the highest intensity intervention with visible leadership, high provider engagement, audit and feedback, focus groups, and provider survey. Group#2 interventions included additional PIF assistance with problem solving as well as a single round of audit and feedback. All three groups received periodic practice-level reports on BP control.

**BPMP audits Group#1**

BPMP audits completed in February 2016 (n = 220), February 2017 (n = 92) and July 2017 (n = 100) demonstrated high compliance with patient position and measurement technique. By the 3rd audit, these elements were followed 94%–100% of the time (Appendix Table 2).

**Table 1. Intervention by group.**

<table>
<thead>
<tr>
<th>Practices</th>
<th>Start Date</th>
<th>Interventions</th>
<th>Leadership Involvement</th>
<th>Institutional Metrics Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benedict Primary Care</td>
<td>01/01/2016</td>
<td>Developed protocol with multidisciplinary input</td>
<td>Multiple leaders as champions (physicians, advance practice provider, and nursing)</td>
<td>All clinics received aggregate feedback on practice performance for BP &lt;140/90</td>
</tr>
<tr>
<td>9 self-selected volunteer practices</td>
<td>11/01/2016</td>
<td>Created tools to support and sustain the protocols</td>
<td>Self-selected practices with practice leaders demonstrating buy-in and messaging importance to their practices</td>
<td></td>
</tr>
<tr>
<td>51 remaining medical group practices</td>
<td>10/01/2017</td>
<td>4 PDSA cycles including audit and feedback, focus groups and provider surveys</td>
<td>Remaining practice and pod leaders agreed as a group to adopt the BPMP</td>
<td></td>
</tr>
</tbody>
</table>

**Protocol adherence for 2nd and 3rd BPs**

Group#1: Median 2nd BP protocol adherence (Fig. 2a, blue line) increased from 30% to 80% after launch and then to 93% after two additional PDSA cycles. Median 3rd BP protocol adherence (Fig. 2a, red line) increased from 21% to 43% after launch and then declined slightly to 41% in the final year.

Group#2: Median 2nd BP protocol adherence in Group#2 (Fig. 2b, blue line) increased from 24% to 34% after launch and then to 40% following the second pod leader presentation. Median 3rd BP protocol adherence (Fig. 2b, red line) increased from 13% to 20% after launch and remained stable.

Group#3: Median 2nd BP protocol adherence in Group#3 (Fig. 2c, blue line) increased from 25% to 29% after the first pod leader meeting and remained stable. Median 3rd BP protocol adherence (Fig. 2c, red line) increased from 12% to 21% following formal launch.

**Impact of BP protocol on classification of patients’ BP < 140/90 within visits**

Fig. 3 demonstrates change in Group#1 patient classification (BP < 140/90) following 2nd BP and 3rd BP during all patient visits during calendar years 2014–2018. Prior to protocol implementation, some 2nd and 3rd BP were being done, however patients with BP achieving goal did not reach 80% in any quarter.
Following protocol implementation in 2016, 2nd and 3rd BP measurement percent of patients achieving BP goal $<140/90$ exceeded 80% in every quarter.

Seasonal variability is seen in all five years of measurement. The impact of the protocol was consistent and did not vary by season. This was also observed in Groups 2 and 3 (data not shown).

**BP control as a quality metric**

Fig. 4 demonstrates BP control rate over five years in each of the three groups. Each patient is counted once and classified based on BP measurement at the final primary care visit for the calendar year. BPMP shows the greatest reclassification impact in Group#1, beginning in 2016 and is also seen in Group#2. No impact is seen in Group#3.

**Classification of patients’ BP $<140/90$ with and without hypertension in 2018**

Appendix Table 3 summarizes BP data for calendar year 2018 stratified by presence or absence of a problem list diagnosis of hypertension. In all three groups, the effect of the BPMP was greater in patients with hypertension than those without, with an increase in within-visit reclassification from “not at goal” to “at goal”: Group#1: 11.7% versus 5.9%; Group#2: 6.5% versus 2.5%; Group#3: 5.9% versus 2.0%.

**Discussion**

Our primary goal was to develop, implement and sustain a BPMP to provide clinicians with measurements for clinical decision-making that did not overestimate BPs. Our data confirm that use of an evidence-based BPMP reduces by 10% the number of patients classified as out of control based on a threshold of 140/90. These protocols were implemented and sustained with high fidelity in Group#1 over several years and thousands of BP measurements. Importantly, no additional resources were required.

Our efforts to disseminate the protocol were less successful across the network. For the nine self-selected practices (Group#2) there was a sustained improvement in BP control, but with smaller magnitude than in Group#1. For the larger network (Group#3), the effects were minimal.

We used HEDIS standards to evaluate population level BP control as this is commonly included in private and government payer contracts. With high adherence to BPMP, as seen in Group#1, we demonstrate a 7.2–9.5% improvement in HEDIS-defined population BP control.
The importance of this work was heightened in 2017 when the American College of Cardiology/American Heart Association lowered the recommended BP thresholds for both diagnosis and treatment compared to prior guidelines. These recommendations are based largely on the Sprint trial in which dose adjustments were based on a mean of three BP measurements at an office visit with the patient seated after 5 min of quiet rest. Lower thresholds heightened concerns about
Fig. 3. Impact of BP Protocol on within visit BP Control Rate in Group 1. Each column represents all visits that occurred in each 3-month quarter in Group 1 (Benedict Internal Medicine practice). Light blue represents % of visits in which the 1st BP was in control, i.e. <140/90. The dark blue in the column represents the % of visits in which a 2nd BP measurement reclassified the patient to controlled BP status, following a 1st BP that was ≥140/90. The red band represents the additional % of visits in which a 3rd BP measurement reclassified the patient to controlled BP status, following the initial two readings that were ≥140/90. Abbreviations: BP, blood pressure; QTR, quarter.

Fig. 4. Population based BP Control classification for all patients based on final BP measurement in each calendar year. The Healthcare Effectiveness Data and Information Set (HEDIS) performance improvement tool for hypertension, which is used by the majority of health insurance programs with quality metric monitoring programs, classifies blood pressure control status based on the final BP measurement of the calendar metric. The first set of columns show by year the % of patients considered in control (BP <140/90) at the time of the final primary care visit during that calendar year. Light blue shows BP control after 1st BP, dark blue shows BP control after 2nd BP, the red shows BP control after 3rd BP. All patients seen during the calendar year are included, whether or not diagnosed with hypertension. Group 2 and Group 3 practices are shown in the second and third set of columns. Abbreviations: BP, blood pressure; pts, patients.
potential over-diagnosis and over-treatment with associated harms in settings where BP measurement is not consistent with randomized trials.

Given the critical importance of BP measurement for evidence-based care, an important question is: why is it so difficult to obtain guideline-based BP measures in clinical practice? We used Theory of Constraints (TOC) as a conceptual framework to explore this question.

Use of TOC in healthcare can improve quality, safety, and efficiency while simultaneously reducing cost. TOC is system focused and relies on identification of the most important constraint limiting a system from achieving a goal. Once identified, the constraint becomes the center of management strategy.

We identified the system constraint as the 5-min quiet period. We identified the subset of patients in whom the 5-min quiet period was necessary for clinical decision-making (patients with 2 consecutive BPs of ≥140/90). This procedure avoided the need for the 5-min waiting period in approximately 80% of patients, while focusing the scarce resources of time and space on those patients for whom the full BPMP might change clinical decision-making.

We used TOC layers of resistance (Appendix Fig. 1) to achieve sustainable process change. We highlighted case examples to make the case for the BPMP and swiftly had agreement on the problem of inaccurate measurement. A multidisciplinary panel agreed to the process to minimize the need for the 5-min waiting period and we achieved buy-in on the proposed solution. Implementation of the solution required multiple PDSA cycles to develop tools such as visual management systems (yellow cards) to ensure sustained compliance with the protocols.

We learned that implementation strategies needed to be clinic specific for sustained buy-in. This may explain, in part, the greater success in Group#1 where the tools and protocols were developed compared with moderate success in self-selected clinics in Group#2 and minimal success in Group#3 which was passive dissemination of protocol.

Leadership presence and ownership are critical to protocol adherence by staff and providers. Sustained success in Group#1 may relate to leadership visibility and consistent, sustained leadership messaging regarding the need for the BPMP. Differences in leadership engagement and the differential use of audit and feedback tools may account for variable performance between clinic groups.

Our study has limitations. First and most importantly, we altered the scientific-based guidelines for BP measurement by requiring re-measurement only when BP was above threshold and we did not require the average of two measurements after a 5 min rest to provide the “true” BP. Theoretically, this could result in BPMP under-estimating “true” BP, either because of regression to the mean or simply lack precision of a one-time measurement. It is generally assumed that adding the 5 min rest period will only reduce BP but if a patient’s “true” BP were, e.g. 143/91, regression to the mean might cause a single 1st measurement to be 139/89 and following BPMP would not identify the patient is not in control. Our data suggest that, indeed, BP most often decreases with re-measurement, so perhaps this is an acceptable trade-off and results in less misclassification than is theoretically possible. Additionally, while the literature suggests that an average of multiple BPs may provide the greatest certainty for clinical decision-making, our clinics did not have resources or equipment to incorporate the average of multiple measurements into our workflow. Second, the third BP was taken by the providers during the visit, and we do not have observations to confirm whether providers used all elements of the BPMP. Third, the third BP was done only about half of the time when first two measurements were above 139/89. Unlike the second BP, which was measured per protocol by clinic staff, clinicians may have decided that a 3rd BP was not needed if it would not change clinical decisions. Fourth, we used a clinical database, rather than a research database. Thus, we can only draw conclusions on BPs that were entered into the electronic record. Additional BPs may have been taken but not entered which could alter our results.

Conclusion
Implementing a BPMP designed to improve BP measurement accuracy while being less burdensome, can result in reclassification of up to 10% of patients, hopefully reducing over-diagnosis and treatment. While our approach has substantial face-validity, further research should examine whether the theoretical possibility of under-diagnosis or under-treatment may result from using BPMP. We believe that BPMP is an improvement over “usual care” as it can be implemented and sustained in a busy clinical setting without use of extra resources. However, successful implementation of the protocol at one site, did not reliably lead to dissemination of the protocol to other sites. While some aspects of protocol can be shared, sharing tools alone is not enough. The importance of physician and nurse leadership as champions and a higher level of
intensity of training and feedback are likely differentiators in sustained clinic performance.

Conflict of Interest
The authors have no conflicts of interest to disclose and confirm that the work is original and has not been published nor is currently under consideration for publication elsewhere.

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Meeting presentation
This work has not been presented in any public venue.

References


