

Treatment Intensification in a Hypertension Telemanagement Trial

Clinical Inertia or Good Clinical Judgment?

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Abstract—Clinical inertia represents a barrier to hypertension management. As part of a hypertension telemanagement trial designed to overcome clinical inertia, we evaluated study physician reactions to elevated home blood pressures. We studied 296 patients from the Hypertension Intervention Nurse Telemedicine Study who received telemonitoring and study physician medication management. When a patient’s 2-week mean home blood pressure was elevated, an “intervention alert” prompted study physicians to consider treatment intensification. We examined treatment intensification rates and subsequent blood pressure control. Patients generated 1216 intervention alerts during the 18-month intervention. Of 922 eligible intervention alerts, study physicians intensified treatment in 374 (40.6%). Study physician perception that home blood pressure was acceptable was the most common rationale for nonintensification (53.7%). When “blood pressure acceptable” was the reason for not intensifying treatment, the mean blood pressure was lower than for intervention alerts where treatment intensification occurred (135.3/76.7 versus 143.2/80.6 mm Hg; $P < 0.0001$). Blood pressure acceptable intervention alerts were associated with the lowest incidence of repeat alerts (hazard ratio: 0.69 [95% CI: 0.58 to 0.83]), meaning that the patient home blood pressure was less likely to subsequently rise above goal, despite apparent clinical inertia. This telemedicine intervention targeting clinical inertia did not guarantee treatment intensification in response to elevated home blood pressures. However, when physicians did not intensify treatment, it was because blood pressure was closer to an acceptable threshold, and repeat blood pressure elevations occurred less frequently. Failure to intensify treatment when home blood pressure is elevated may, at times, represent good clinical judgment, not clinical inertia. (*Hypertension*. 2011;58:552-558.)

Key Words: hypertension ■ blood pressure telemonitoring ■ clinical inertia ■ treatment intensification
■ medical decision making

Despite nationwide efforts to generate awareness of blood pressure (BP) goals and improve hypertension treatment, half of all hypertensive patients in the US remain inadequately controlled.¹ Studies have suggested that clinical inertia, or provider failure to initiate or intensify hypertension therapy when indicated based on clinical guidelines, is a prime contributor to inadequate BP control.^{2,3} One study examined ≈46 000 clinic visits and found that, in 87% of visits where patients had BP >140/90 mm Hg, providers did not intensify therapy.⁴ Others have attempted to evaluate

underlying causes for clinical inertia.^{5–8} One such study used a conceptual model to systematically identify provider factors associated with a lower likelihood of medication intensification in hypertensive patients with diabetes mellitus.⁹ These factors included reported clinical uncertainty regarding BP measurements, competing demands during clinic appointments, inappropriate physician BP goals, lack of timely follow-up of elevated BP, and concern for patient treatment nonadherence.

Home BP telemonitoring may facilitate management of patients with hypertension by removing traditional contribu-

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tors to clinical inertia, such as provider uncertainty about the accuracy of BP measurements and competing demands. BP telemonitoring provides a greater number of readings over longer periods of time than any individual clinic visit, thereby allowing physicians to better understand patients' usual BP.¹⁰ Previous studies provide evidence for improved BP control using telemanagement models in selected patient populations.^{11–13} Compared with clinic BP measurement, home telemonitoring may also better predict cardiovascular risk and is less subject to observer bias (white-coat hypertension and masked hypertension).^{14–18}

The Hypertension Intervention Nurse Telemedicine Study (HINTS) was an 18-month randomized, controlled trial designed to circumvent factors contributing to clinical inertia.¹⁹ We examined data from the medication management arms of HINTS to determine how physicians reacted to elevated BP values, why they reacted as they did, and how their decisions impacted subsequent patient BP control after episodes of elevated BP. Our goal was to determine whether clinical inertia persisted in HINTS despite the efforts to overcome it.

Methods

HINTS Design

HINTS randomized 593 eligible veterans into 4 groups: (1) a nurse-administered behavioral management intervention; (2) a nurse-administered, physician-directed medication management intervention using a validated clinical decision support system; (3) a combined behavioral management and medication management intervention; and (4) usual care. Eligible patients received primary care at the Durham Veterans Affairs Medical Center, had a diagnosis of hypertension, used BP-lowering medication, and had inadequate BP control ($>140/90$ mm Hg for all patients) based on the average of the previous 12 months' clinic BP measurements obtained from electronic medical charts. Exclusion criteria were receipt of dialysis; a serum creatinine >2.5 or no documentation of renal function; history of organ transplant; hospitalization for stroke, myocardial infarction, or coronary artery revascularization within 3 months of contact; diagnosis of metastatic cancer or dementia; lack of a home telephone; residence in a nursing home; receipt of home health care; or severely impaired hearing or speech.

All of the patients randomized to an intervention arm were provided a wireless home BP monitor (A&D Medical Digital Blood Pressure, model UA-767PC) and telemedicine device (Carematix Inc, model No. 102) and advised to measure their BP once every other day. BP measurements were automatically transmitted to a secure server for review by study staff, which included 2 study nurses and 2 study physicians. The study physicians were both board-certified, experienced general internal medicine attending physicians at the Durham Veterans Affairs Medical Center. The HINTS was approved by the Durham Veterans Affairs Medical Center institutional review board, and all of the participating subjects provided informed consent.

The main results of HINTS indicated that the behavioral management and medication management interventions each resulted in significantly improved BP control at 12 months relative to usual care, but these improvements were not sustained at 18 months. The combined intervention group did not exhibit a statistically significant improvement in BP at either 12 or 18 months relative to usual care.¹⁹

Intervention Alerts in HINTS

In the intervention arms of HINTS, an elevation in the mean home BP over 2 weeks (consisting of a minimum of 3 separate BP measurements) triggered an intervention alert. Consistent with current guidelines, the home BP target was defined as $<135/85$ mm Hg

for patients without diabetes mellitus.^{14,20} Home BP targets for patients with diabetes mellitus were not well defined at study initiation, and a target of $<135/80$ mm Hg was chosen based on the recommendations of an internal consensus panel. In the medication management and combined arms of the trial, receipt of an intervention alert prompted the study team to consider medication intensification. When an intervention alert occurred, a study nurse first contacted the patient to ascertain self-reported adherence, any illnesses during the 2-week period that might affect BP control, and other circumstances that may have contributed to the intervention alert; all direct patient interaction was through the study nurse via telephone. Next, the study nurse provided the study physician with all home BP measurements, medication lists, pharmacy refill information, relevant self-reported information, and any medication change recommendations generated by a clinical decision support system.²¹ The study physician reviewed this information, as well as recent data from the patient's electronic medical chart, and decided whether to intensify the hypertension regimen. When treatment intensification was enacted, the study nurse contacted patients 3 weeks after the medication change to ascertain adverse effects and address patient questions. After generation of an intervention alert, there was a 6-week lockout period before any subsequent intervention alert could trigger. All of the patients concurrently received hypertension management per the discretion of their primary care provider, although primary care providers did not have access to home BP values obtained through the study.

Countering Clinical Inertia in HINTS

The HINTS medication management intervention was designed to counteract clinical inertia in several ways. To reduce clinical uncertainty about participants' BP measurements, study physicians were provided with a display of all of the patient home BP measurements and recent clinic BP measurements. Study physicians had protected time to review intervention alerts so that BP management was the only issue to address, thereby removing competing demands. To remove clinical uncertainty regarding BP goals, study physicians agreed on BP targets at the beginning of the study. The study protocol ensured active and timely nurse follow-up. Study physicians and nurses had information to facilitate informed assessment of treatment adherence, which allowed study physicians to make decisions about treatment intensification without ascribing poor BP control to nonadherence.

Assessment of Treatment Intensification

While implementing the medication management intervention, study physicians and nurses interacted electronically through a secure database in which they maintained detailed notes regarding the medical decision-making process. We created a standardized abstraction tool to code aspects of this decision-making process for each intervention alert. We then coded the intervention alerts in terms of intervention alert type (systolic BP out of control, diastolic BP out of control, or both systolic and diastolic BP out of control); medication adherence based on patient self-report and medication refill information; study physician recommendation regarding whether to intensify therapy; rationale for study physician decisions not to intensify therapy in response to an intervention alert (options included perceived acceptable BP, recent medication changes outside study, study enrollment too recent, recent or current illness that might temporarily elevate BP, concern for risk of harm, measurement error, and other); whether treatment intensification recommendations were successfully implemented at the time the study nurse relayed the recommendation to the patient; reasons for nonimplementation of treatment intensification recommendations (options included receipt of new information that changed the recommendation, patient refusal, recent medication changes outside the study, and other); and patient adherence to treatment intensification determined at a later assessment. To evaluate consequences of study physician decisions about treatment intensification, we also collected information on repeat intervention alert occurrence after previous intervention alert episodes. This analysis of clinical inertia in the HINTS medication management intervention was not specified

a priori but was initiated before the results of the main HINTS analysis were available. All of the patients randomized to the 2 study arms in which patients received study physician medication management were included in this analysis.

Outcomes

We examined several outcomes for this analysis. We described the intervention alerts triggered during the study according to the process detailed in the assessment section above and determined the mean 2-week home BP that led to all of the intervention alerts. Among patients adherent to therapy based on study team assessment, we determined the proportion of intervention alerts that resulted in treatment intensification by study physicians. In addition, we divided the intervention alerts into 4 categories based on study physician decision making: (1) treatment intensification recommended and implemented; (2) treatment intensification recommended but not implemented by the patient; (3) treatment intensification not recommended because BP deemed acceptable; and (4) treatment intensification not recommended for other reasons. Based on these 4 categories, we analyzed the mean 2-week home BP that prompted the intervention alerts in each category, ascertained the likelihood of repeat intervention alerts after previous intervention alerts in each category, and determined the median time to repeat alerts in each category.

Statistical Analysis

The mean systolic and diastolic BPs that prompted an intervention alert were estimated for each intervention alert category using generalized estimating equations with an identity link and an exchangeable correlation structure. The association between intervention alert category and the occurrence of repeat intervention alerts was examined using a Cox proportional hazards model. The time of interest was defined as the number of days after the study nurse addressed the previous alert until occurrence of a repeat alert or the end of the study. Censoring occurred when a patient completed the study, withdrew, or was lost to follow-up without triggering a repeat alert. A robust sandwich estimate of the covariance matrix was used to account for correlation within individuals who incurred multiple intervention alerts during the course of the study.²²

Factors associated with the study physician decision to intensify treatment (yes/no) were examined using generalized estimating equations with a logit link and an exchangeable correlation structure. Factors included in the model were the patient's age, sex, race, and diabetes mellitus status, the magnitude of the BP elevation above goal (for both systolic and diastolic BPs), the number of antihypertensive medications the patient was taking at the time of the intervention alert, and the study physician making the intensification decision.

Results

Baseline Data

This analysis included 296 patients, 149 from the medication management intervention arm of HINTS and 147 from the combined intervention arm (Table 1). The patient population was predominantly male, and approximately evenly divided between black and white patients. The patient 30-day mean home systolic BP before beginning the intervention was 135.4 (SD 19.9) and diastolic BP 76.8 (SD 13.4).

Summary Description of Intervention Alerts

Over the 18-month course of the study, 1216 intervention alerts were triggered by 257 patients (Figure). Intervention alert types included high systolic BP (56.6%), high systolic and diastolic BPs (25.6%), and high diastolic BP (17.7%). Study staff deemed patients to be adherent to their antihypertensive regimen in 922 (75.8%) of these intervention alerts

Table 1. Baseline Demographic Data for Patients in the Medication Management Arms of the Hypertension Intervention Nurse Telemedicine Study

Baseline Characteristics*	Total (n=296)	Medication Management Intervention (n=149)	Combined Intervention (n=147)
Demographics			
Mean age (SD)	63.4 (10.5)	64.2 (10.2)	62.6 (10.7)
Race, %			
White	46	49	44
Black	50	48	52
Other	4	3	5
Male, %	90	93	86
Married, %	63	65	61
Completed <12 y of school, %	15	12	18
Low literacy level (<9th grade; REALM score ≤60), %	35	32	37
Employed, %	34	34	35
Current smoker, %	21	20	22
Mean body mass index (SD)	30.4 (5.1)	30.2 (5.0)	30.5 (5.1)
Medical history, %			
>10 y history of high blood pressure	76	77	74
Diabetes mellitus	42	43	40
Mean No. of hypertension medications (SD)	2.3 (1.1)	2.3 (1.1)	2.4 (1.1)
Home blood pressure†			
Mean systolic (SD)	135.4 (19.9)	137.3 (21.1)	133.3 (18.2)
Mean diastolic (SD)	76.8 (13.4)	76.2 (14.2)	77.5 (12.6)

REALM indicates Rapid Estimate of Adult Literacy in Medicine.

*All of the data except blood pressure, age, body mass index, diabetes status, sex, and No. of hypertension medications (national Veterans Affairs database) were patient reported. When missing values existed, they were included in the calculation of percentages.

†Data show the mean 30-d home blood pressure during period after study enrollment but before initiation of medication management intervention.

and, thus, eligible for medication intensification. The mean 2-week home BP for all of the intervention alerts was 139.7 systolic (SD 9.9) and 79.0 diastolic (SD 10.2).

Intervention Alerts for Which Treatment Intensification Was Recommended

Of the 922 intervention alerts in which study staff deemed patients to be adherent, study physicians recommended treatment intensification in 374 (40.6%). Of the 374 intervention alerts where study physicians recommended treatment intensification, 78.6% were successfully implemented at the time study nurses relayed the recommendations to patients. Reasons for nonimplementation included receipt of new information that changed the recommendation (47.5%), patient refusal (37.5%), and recent medication changes outside the study (20.0%). Patients were adherent to treatment intensification recommendations 4 weeks after successful implementation in 89.5% of cases.

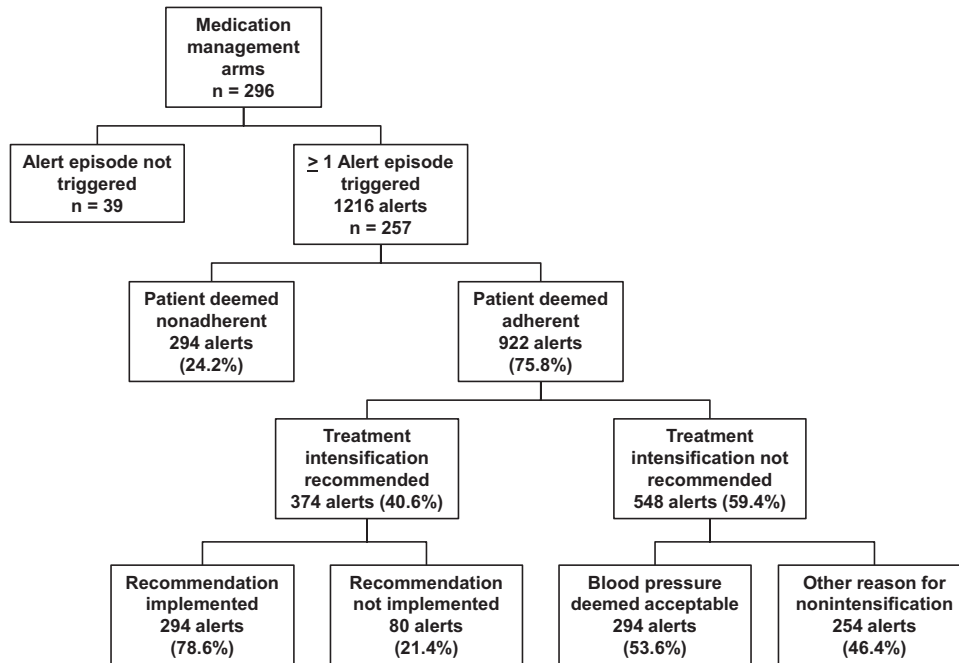


Figure. Analysis of intervention alerts triggered by elevations in 2-week mean home blood pressure in the medication management arms of the Hypertension Intervention Nurse Telemedicine Study.

Intervention Alerts for Which Treatment Intensification Was Not Recommended

Among the 548 intervention alerts (59.4%) for which study physicians did not recommend treatment intensification, justifications included study physician assessment that the observed home BP was acceptable (53.7%), recent BP medication changes outside study (20.6%), study enrollment too recent (12.8%), recent or current illness that explained elevated BP (8.4%), and concern for risk of harm (6.8%).

Intervention Alert Factors Associated With Treatment Intensification

Several factors were significantly associated with study physician decision to intensify treatment in response to an intervention alert. A higher number of antihypertensive medications at the time of the intervention alert was associated with a lower odds of treatment intensification (odds ratio: 0.81 [95% CI: 0.71 to 0.93] for each additional medication). A higher systolic BP at the time of an intervention alert was associated with a higher odds of treatment intensification (odds ratio: 1.14 [95% CI: 1.11 to 1.17] for each additional BP point above goal), as was, to a lesser degree, a higher diastolic BP (odds ratio: 1.03 [95% CI: 1.01 to 1.05] for each additional BP point above goal). Factors not significantly associated with the decision to intensify treatment included study physician, age, race, sex, and diabetes mellitus status ($P > 0.05$).

Intervention Alert Follow-Up and Subsequent BP Control

Among the 922 intervention alerts in which study staff deemed patients to be adherent, there were 734 repeat intervention alerts. When the study physician provided “BP acceptable” as the reason for not intensifying treatment, the

estimated mean systolic BP was 135.3 (95% CI: 132.9 to 137.7) and diastolic BP 76.7 (95% CI: 74.3 to 79.1). These BP values were significantly lower than the estimated mean BP values for intervention alerts where medication intensification was implemented (Table 2). When the study physician provided “BP acceptable” as the reason for not intensifying treatment, a repeat intervention alert happened in 51.0% cases within 12 weeks of the previous alert and in 71.8% of cases by the end of the study. The hazard ratio for occurrence of a repeat intervention alert was 0.69 (95% CI: 0.58 to 0.83) compared with intervention alerts for which treatment intensification was implemented (Table 2). When repeat intervention alerts occurred, the median time to repeat alert was 66 days for intervention alerts where “BP acceptable” was provided as the justification for not intensifying treatment, 54 days when other reasons were provided as justification for not intensifying treatment, 55 days when treatment intensification was recommended and implemented, and 53 days when intensification was recommended but not implemented.

Discussion

For patients receiving study physician medication management in the HINTS, elevations in the 2-week mean home BP did not prompt treatment intensification $\approx 60\%$ of the time, despite the fact that the HINTS medication management intervention was designed to facilitate treatment intensification for eligible patients with elevated home BP. Study physician perception that BP control was actually acceptable despite the elevated mean home pressures was the most common justification for not intensifying treatment. A higher medication burden and a systolic or diastolic BP closer to goal were significantly associated with a decision to not intensify treatment in response to elevated home BP. Compared with patients receiving treatment intensification, pa-

Table 2. Estimated Mean 2-week Home BP for 922 Intervention Alerts in Which Patients Were Deemed Adherent and Eligible for Treatment Intensification, Along With the Likelihood of Subsequent Repeat Intervention Alerts

Analysis	Treatment Intensification Recommended (374 Alerts)		Treatment Intensification Not Recommended (548 Alerts)	
	Recommendation Implemented (294 Alerts)	Recommendation Not Implemented (80 Alerts)	BP Deemed Acceptable (294 Alerts)	Other Reason for Nonintensification (254 Alerts)
Mean systolic BP at intervention alert (95% CI)	143.2 (142.0 to 144.4)	142.5 (139.6 to 145.5)*	135.3 (132.9 to 137.7)†	139.6 (136.9 to 142.4)‡
Mean diastolic BP at intervention alert (95% CI)	80.6 (79.2 to 81.9)	79.8 (77.4 to 82.3)*	76.7 (74.3 to 79.1)†	79.1 (76.8 to 81.5)‡
Hazard ratio for repeat intervention alert following previous alert (95% CI)	1.0	0.94 (0.69 to 1.29)*	0.69 (0.58 to 0.83)†	0.97 (0.80 to 1.18)*

*Data show the *P* value for comparison to reference group >0.05.

†Data show the *P* value for comparison to reference group <0.0001.

‡Data show the *P* value for comparison to reference group=0.0042.

tients for whom BP acceptable was the reason for not intensifying therapy had a significantly lower incidence of repeat home BP elevations and a longer interval before repeat elevations occurred. Overall, although the HINTS intervention was designed to overcome clinical inertia, study physicians frequently still did not intensify therapy for patients who exceeded predefined BP thresholds. Our data suggest that, in many cases, however, treatment nonintensification may actually have represented good clinical judgment.

The contribution of clinical inertia to suboptimal BP management in the United States has been well documented. Home telemanagement of hypertension holds promise in a large part because it counters many of the factors known to contribute to clinical inertia. The HINTS created conditions where study physicians had easy access to detailed information on home BP readings, no competing demands to distract them from addressing BP, medication lists and refill information to help them easily assess patient treatment adherence, clear goals for target BP, and detailed follow-up arranged by study nurses. In short, study physicians had the opportunity to practice in an environment where clinical inertia should have been minimized.

Despite these carefully designed treatment conditions, treatment intensification occurred in only 41% of instances where the mean 2-week home BP was elevated. Other recent trials using home BP monitoring with or without telemedicine management interventions have estimated rates of clinical inertia between 54% to 60%, which is comparable to our findings.^{23–25} Factors significantly associated with lower rates of treatment intensification by our study physicians included higher medication burden and home BP closer to goal. Systolic BP elevations had a greater impact on the decision regarding whether to intensify treatment than did elevated diastolic BP. Although we are unaware of any previous investigation of factors associated with clinical inertia in a BP telemonitoring study, our findings are consistent with previously published reports of clinical inertia based on clinic BP measurements.^{26,27} Ultimately, our study suggests that telemanagement interventions addressing clinical inertia may improve rates of treatment intensification in response to elevated home BP but not result in perfect intensification rates.

If implementing study conditions that counter known contributors to clinical inertia still results in frequent treatment nonintensification, an important question becomes whether all of what would typically be called clinical inertia can actually be overcome. A further question is to what extent this “refractory” clinical inertia actually represents good clinical judgment. In our analysis, study physicians frequently decided to tolerate episodes of elevated 2-week home BP that occurred at levels near the threshold value for treatment. Some have argued that this tolerance of borderline values, or “threshold effect,” is an important contributor to physician inability to achieve treatment goals.²⁸ However, physician tolerance of borderline BP values in this study was followed by acceptable BP control during the subsequent 12 weeks in nearly half of all cases, indicating that study physicians were correct not to intensify in many instances. This finding suggests that clinical inertia, while a reasonable label for physician failure to intensify therapy in the setting of markedly elevated BP, unfairly characterizes the decision not to intensify in cases when BP is near the threshold of acceptability. We observed that mild home BP elevations frequently did not recur even without treatment intensification; this observation argues against a one-size-fits-all understanding of treatment intensification and emphasizes that the “right” decision in response to a BP elevation may not be intensification in each case. Rather, the correct decision is whatever choice promotes the safe attainment of an acceptable BP for a given patient, and physicians must always exercise clinical judgment in determining whether to intensify therapy. This nuanced approach to treatment intensification is particularly relevant in light of recent trials that have targeted lower BP goals but failed to improve outcomes.^{29–31}

Limitations

This study has several limitations. The HINTS was conducted at single Veterans Affairs Medical Center in a veteran population, which may affect the generalizability of our results. Our patient population had relatively good baseline home BP control during the 30-day period between study enrollment and the initiation of the medication management intervention, which may affect the generalizability of our findings to more poorly controlled populations. However, all

of the subjects examined in this analysis did have documented suboptimal control in the 2 weeks preceding intervention alerts and had annual clinic BP values that were poorly controlled. Because this study presents a novel analysis of a home BP telemanagement trial, a further limitation is that differences between home- and clinic-based BP monitoring make our results difficult to compare directly with published studies of clinical inertia. Although the BP thresholds that we used for the HINTS differ from published guidelines for clinic-based management of hypertension, these differences reflect known disparities between home and clinic BP measurement.¹⁴ Thus, our thresholds should reflect similar levels of BP control as standard, clinic-based BP targets.

Although the HINTS medication management intervention was specifically designed to counteract known contributors to clinical inertia, it remains possible that the intervention failed to account for unknown contributing factors and that our results, therefore, do not reflect practice in an environment that is truly free from clinical inertia. Furthermore, only 2 study physicians participated in the medication management intervention, so it is possible that our observed rates of treatment intensification reflect practice patterns of these individuals rather than reflecting the care delivery system cultivated by the HINTS medication management intervention. Although it is difficult to determine whether physician decisions about treatment intensification represent the right choice in response to elevated BP, our follow-up data do provide a useful indicator of subsequent control after a previous episode of elevated BP.

Perspectives

Despite this study's limitations, our findings raise novel and important questions about the contribution of clinical inertia to processes of treatment intensification in hypertension management. Clinical inertia is unquestionably an important concept in understanding and addressing suboptimal hypertension management in the United States. However, because removal of factors that are known to contribute to clinical inertia may not guarantee treatment intensification, the term "clinical inertia" may not account for the full complexity of treatment intensification decision making. Our analysis illustrates that this is particularly true when home BP is at the borderline of acceptability, because failure to intensify treatment in these instances often did not result in recurrent BP elevations. When considering whether to intensify antihypertensive therapy when BP is only mildly elevated, physicians must consider factors such as patient preferences and values, medication burden, and other medical or personal circumstances along with absolute BP values. More work will be needed to further clarify how much of what is typically viewed as clinical inertia may actually represent good clinical judgment and thereby benefit patients rather than causing harm.³¹

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Disclosures

None.

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