

# Evaluating Alternative Methods of Comparing Antihypertensive Treatment Intensity

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To modify blood pressure (BP) treatment intensity, clinicians can modify the number and/or dose of antihypertensive medications. Although trials to reduce cardiovascular events have frequently achieved better BP control through the addition of new medications, for older adults, increasing doses before starting new medications can reduce polypharmacy and the risk of potential new adverse effects.<sup>1</sup> Optimizing treatment intensification vs deintensification is particularly relevant to older multimorbid adults, in whom the absolute magnitude of this effect is greatest given increased baseline risk of adverse cardiovascular outcomes, in addition to increased vulnerability to adverse effects and drug-disease interactions.<sup>1</sup> Moreover, large administrative data sets provide a key opportunity to compare change in antihypertensive treatment intensity in this population most frequently excluded from randomized trials.<sup>2-6</sup> Studies to date have typically measured treatment modification in terms of medication count,<sup>4,5,7-11</sup> a method that could falsely report clinical inertia in patients who actually increased only the doses of their medications.

To overcome this challenge, we previously developed and validated an algorithm that uses Veterans Health Administration (VHA) and Medicare Part D pharmacy fill data to measure hypertension treatment intensity by capturing total daily dose equivalents (standardized doses used by hypertension trials), using prefills and refills within 186 days to determine the most likely antihypertensive regimen (medication name and dose) on any day of outpatient care.<sup>12,13</sup> Unlike previous measures that focused on toxicity, this measure is based on evidence-based doses of clinical benefit demonstrated in trials of hypertension treatment and provides standardized doses allowing for the comparison of treatment intensity across all antihypertensive medications.

In this paper, we used this approach to compare the measurement of treatment change by the change in medication dose vs change in medication count.

## ABSTRACT

**OBJECTIVES:** To change blood pressure treatment, clinicians can modify medication count or dose. However, existing studies have measured count modification, which may miss clinically important dose change in the absence of count change. This research demonstrates how dose modification captures more information about management than medication count alone.

**STUDY DESIGN:** Retrospective cohort study.

**METHODS:** We included patients 65 years and older with established primary care at the Veterans Health Administration (July 2011-June 2013). We captured medication count and standardized dose change over 90 to 120 days using a validated pharmacy fill algorithm. We determined frequency of dose change without count change (and vice versa), no change in either, change in same direction ("concordant"), and change in opposite direction ("discordant"). We compared change according to systolic blood pressure (SBP) and compared concordance using a minimum threshold definition of dose change of at least 50% (instead of any change) of baseline dose modification.

**RESULTS:** Among 440,801 patients, 64.2% had dose change; 22.0%, count change; 35.6%, no change in either; 42.4%, dose change without count modification; and 0.2%, count change without dose modification. Discordance occurred in 2.1% of observations. Using the minimum threshold definition of change, 68.7% had no change in either dose or count. Treatment was more frequently changed at SBP greater than 140 mm Hg.

**CONCLUSIONS:** Measuring change in antihypertensive treatment using medication count frequently missed an isolated dose change in treatment modification and less often misclassified regimen modifications where there was no modification in total dose. In future research, measuring dose modification using our new algorithm would capture change in hypertension treatment intensity more precisely than current methods.

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## TAKEAWAY POINTS

- ▶ The measure of antihypertensive medication count frequently missed modification in treatment intensity when there was an isolated dose change, but it rarely misclassified regimen modifications when there was no change in treatment intensity.
- ▶ We provide a measure of hypertension treatment intensity over time that uses standardized antihypertensive medication doses, which is more precise than medication count alone and would offer a better way to assess hypertension treatment intensity over time in further studies aiming to improve hypertension management.
- ▶ Measuring antihypertensive dose modification instead of medication count alone may be particularly relevant in older adults because of their vulnerability to dose-related adverse medication events.

## METHODS

## Study Population and Data

We used administrative and clinical information from the Veterans Affairs (VA) Clinical Data Warehouse, which includes all ambulatory care encounters and VHA pharmacy records, between July 1, 2009, and June 30, 2013. Patients' records are linked with Medicare Part D medication claims (Department of Veterans Affairs, VA Health Services Research and Development Service, VA Information Resource Center [#02-237 and 98-004]). This research was conducted under Human Subjects review (VA IRB 2015-286).

We included all veterans 65 years and older with hypertension (*International Classification of Diseases, Ninth Revision* code 401.x), established VHA primary care ( $\geq 2$  visits between 7/1/2009 and 6/30/2011), and at least 2 primary care visits during the study period (7/1/2011-6/30/2013). Using providers' codes (**eAppendix Text** [eAppendix available at [ajmc.com](http://ajmc.com)]), we identified all outpatient visits from primary care and hypertension-managing specialties (cardiology, endocrinology, nephrology, neurology) over the 2-year study period. The dates of these visits were used to calculate treatment intensity.

To assess short-term (3-month) treatment modification, we identified all pairs of visits during the study period (7/1/2011-6/30/2013) with a 90- to 120-day interval between the visits. We refer to the earlier visit (baseline visit) as "visit 1" and the later as "visit 2" (**eAppendix Figure**). The 90-day minimum interval was chosen because it is a typical medication fill duration. We added the 120-day upper limit to allow for a small degree of delay in refill while ensuring that the visit interval was still short term. To assess longer-term (1-year) treatment modification, we used an interval of 365 to 395 days to pair the visits during the study period. For each time interval-based analysis, we included only the first available pair of visits per patient, so that no patient could appear in any analysis more than once.

## Main Study Variables

To identify antihypertensive treatment from pharmacy fills, we employed a calibrated algorithm that we previously developed and validated in a sample of this cohort.<sup>12,13</sup> Briefly, this algorithm

uses VA and Medicare Part D pharmacy prefills (within 186 days before an outpatient visit) and refills (within 186 days after) to determine the most likely antihypertensive medication on any day, including name, medication, and dose. To allow comparison across antihypertensive medications, we assigned hypertension daily dose (HDD) units, where 1 HDD corresponds to a standardized moderate dose, defined as half of the maximum beneficial dose demonstrated in trials for a given antihypertensive medication. These doses are published in the Joint National Committee 7 and 8 guidelines<sup>14,15</sup> and the

American Heart Association/American College of Cardiology hypertension guideline.<sup>16</sup> For example, hydrochlorothiazide's maximum beneficial trial-proven dose is 50 mg, thus 25 mg represents 1 HDD. To capture dose reduction that might occur by splitting pills during a supply, we adjusted doses downward if a medication was refilled more than 30 days after planned refill (eg, we halved the dose for a 90-day supply that was first refilled after 180 days). We summed all antihypertensive medication doses to assign a total dose to a patient for each visit. All data were extracted electronically. The algorithm measures were validated by chart review.<sup>13</sup>

## Main Measures

We calculated the change in both total standardized dose and in medication count between the 2 visits (ie, total dose at visit 2 minus total dose at visit 1, and medication count at visit 2 minus medication count at visit 1). We specified 3 levels of treatment modification for both dose and count: deintensification (total dose or medication count decrease between visits), intensification (total dose or medication count increase between visits), and stable treatment (no change by either definition between visits). To assess how much the relationship between dose and count changed according to the amount of dose modification, we conducted sensitivity analyses in which we defined dose change (ie, deintensification or intensification) as modification of at least 25% or 50% of baseline dose.

## Statistical Analyses

To assess agreement between dose and medication count change, we compared the proportions of each possible combination of dose and count modifications, and specifically measured no change in either dose or count, a concordant change (dose and count change in the same direction), an isolated change (dose change without medication count modification, or the opposite), and a discordant change (change in the opposite direction). We performed those analyses for both time intervals separately. Furthermore, in a sensitivity analysis, we assessed the relationships between dose and count change by baseline systolic BP (SBP), grouped as less than 120 mm Hg, 120 to 140 mm Hg, and greater than 140 mm Hg. Finally, in another sensitivity analysis, we assessed those relationships in

which a dose change was defined as an at least 25% or 50% change in the baseline dose.

We used  $\chi^2$  tests to assess statistical significance. We conducted all analyses with Stata 16 software (StataCorp LP) and SAS Enterprise Guide 7.1 (SAS Institute).

## RESULTS

Among 1,331,111 patients with 7,026,781 visits, we identified 440,801 patients with a paired visit interval of 90 to 120 days and 499,207 patients with a paired visit interval of 365 to 395 days. Baseline characteristics are described in the [Table](#).

### Change Over 3 Months

Among our 440,801 patients, 64.2% had a dose change, whereas 22.0% had a count change in the 90- to 120-day visit interval ( $P < .001$ ). No change in either dose or medication count was observed in 35.6% of patients, a concordant change in 19.7%, and a discordant change in 2.1% ([Figure \[A\]](#), column 1). Dose modification without medication count change was observed in 42.4% of patients, whereas 0.2% had count change with no change in dose ([Figure \[A\]](#), column 1).

### Change According to Amount of Dose Modification

When we defined a dose modification as occurring only if there was at least a 25% change in baseline dose, 5.8% of patients had an isolated medication count modification (as opposed to 0.2% using any dose change to define dose modification), 19.8% had a dose change without any modification of medication count (as opposed to 42.4% for any dose change definition), and 58.2% had no change in either dose or medication count (as opposed to 35.6% for any dose change definition) ([Figure \[A\]](#)).

### Concordance of Change Over 1 Year

Similar to what we observed over 3 months, dose change was more frequent than medication count modification over 1 year (70.1% vs 32.0% of the 499,207 patients with a 365- to 395-day visit interval;  $P < .001$ ), whereas 29.5% of patients had no change in either dose or count, 28.6% had concordant change, and 3.0% had discordant change ([Figure \[A\]](#), column 4).

### Concordance According to Baseline SBP

The relationship between dose and medication count modification was mostly similar for baseline SBP less than 120 mm Hg vs 120 to 140 mm Hg ([Figure \[B and C\]](#)). However, compared with patients with SBP 140 mm Hg or less, those with SBP greater than 140 mm Hg had a concordant or discordant change with greater frequency, and no change in either dose or medication count with lesser frequency. When treatment was modified, it was most frequently intensified in patients with higher SBP and deintensified in those with lower SBP. The relationships were similar over the 2 time intervals.

**TABLE.** Baseline Characteristics of the Patients for the 90- to 120-Day Visit Intervals (N=440,801)

Characteristics	Mean (SD) or n (%)
Demographics	
Age in years, mean (SD)	75.1 (7.5)
Male, n (%)	431,700 (97.9%)
BP	
SBP in mm Hg, mean (SD)	130.6 (15.8)
DBP in mm Hg, mean (SD)	70.6 (10.2)
SBP < 120 mm Hg, n (%)	96,856 (22.0%)
SBP 120-140 mm Hg, n (%)	242,024 (54.9%)
SBP > 140 mm Hg, n (%)	101,941 (23.1%)
Chronic conditions	
Number, mean (SD)	5.1 (3.8)
Multimorbidity ( $\geq 2$ chronic conditions), n (%)	375,250 (85.1%)
Cardiovascular, cerebrovascular, or peripheral vascular disease, n (%)	188,654 (42.8%)
Heart failure/valve disorder, n (%)	98,539 (22.4%)
Diabetes, n (%)	183,143 (41.6%)
Arrhythmia, n (%)	65,405 (14.8%)
Baseline BP medication regimen	
Medication count, mean (SD)	2.2 (1.1)
$\geq 2$ medications, n (%)	313,632 (71.2%)
$\geq 4$ medications, n (%)	53,003 (12.0%)
HDD, unit, mean (SD)	2.3 (1.8)
$\geq 2$ HDDs, n (%)	220,250 (50.0%)
$\geq 4$ HDDs, n (%)	78,343 (17.8%)

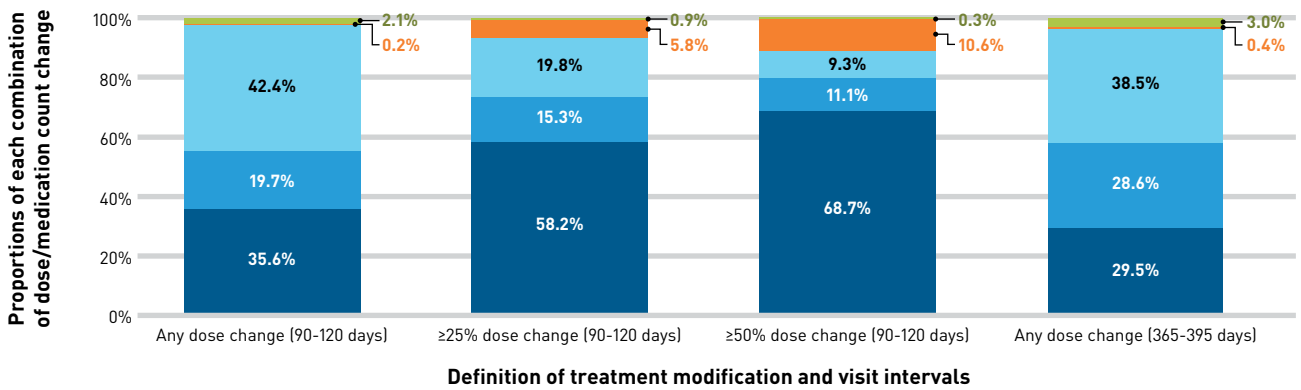
BP, blood pressure; DBP, diastolic BP; HDD, hypertension daily dose; SBP, systolic BP.

## DISCUSSION

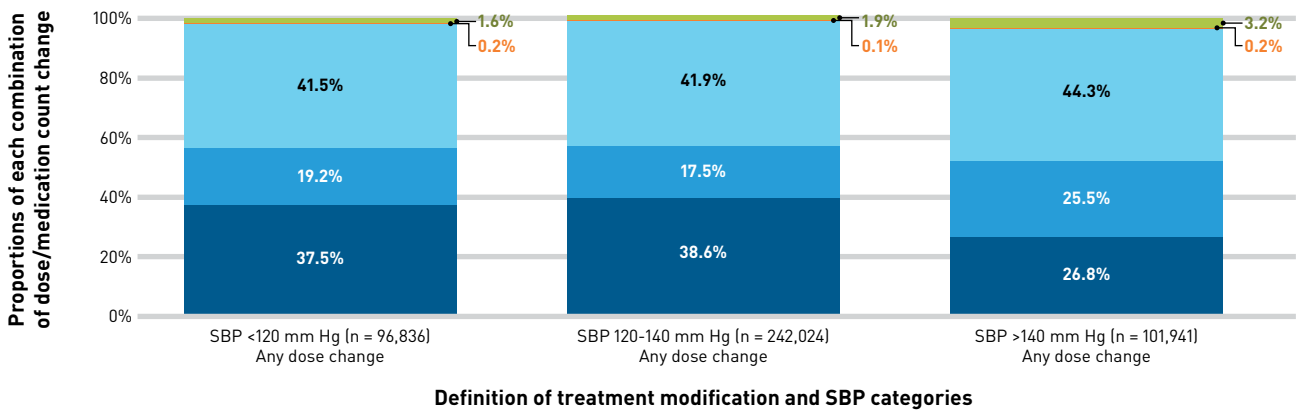
In this large study using a validated pharmacy fill algorithm in older veterans with hypertension, measuring changes in standardized total dose identified more modifications in treatment intensity than counting medications alone. A dose change without a concurrent medication count modification was frequent: 42% of patients had a change in treatment intensity that would have been missed if only medication counts had been considered. On the other hand, a change in medication count without a change in dose was rare. The daily dose and medication count methods agreed more when we increased the criteria stringency required to define a treatment change from any change to at least 25% or 50% of the baseline dose. Discordant changes were uncommon. This underestimation of treatment modification rates when using medication count alone vs dose change was more pronounced for patients with SBP greater than 140 mm Hg, in whom treatment changes between visits were more common compared with patients with SBP of 140 mm Hg or less. Our results suggest that future research to improve hypertension management care that measures dose changes would capture clinical action and the continuum of treatment intensity more precisely than medication count alone. Our algorithm offers

**FIGURE.** Proportions of Changes for Each Possible Combination of Dose and Medication Count Modification, According to Intensity of Dose Change to Define Treatment Modification, Visit Intervals (n = 440,801 patients for 90-120 days and n = 499,207 patients for 365-395 days), and Baseline SBP<sup>a</sup>

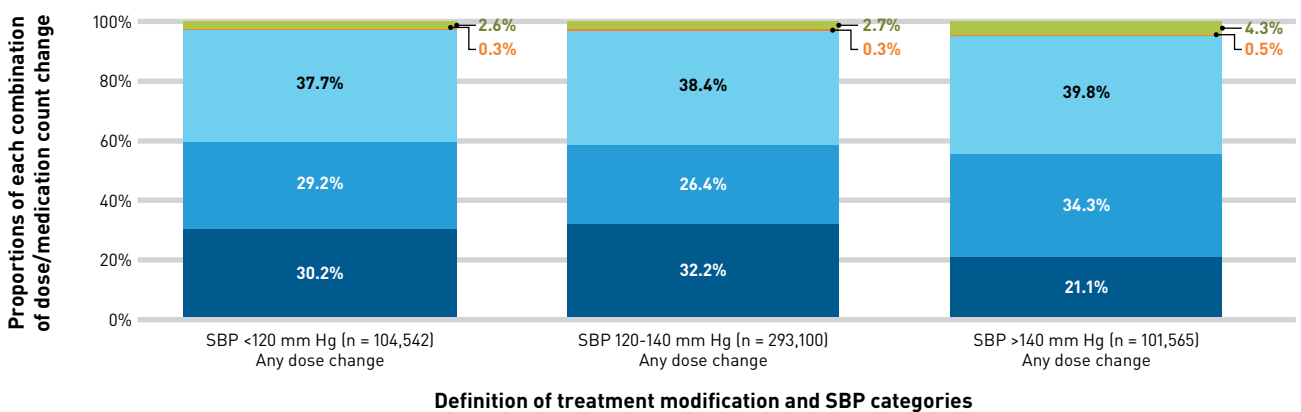
**A.** All patients, 90-120 days and 365 days



**B.** 90-120 days, according to baseline SBP



**C.** 365-395 days, according to baseline SBP



■ No change   ■ Concordant change   ■ Dose change only   ■ Medication count change only   ■ Discordant change

SBP, systolic blood pressure.

<sup>a</sup>The figure displays the proportions of change for each possible combination of dose change (or no change) and medication count change (or no change). No change was defined as no change in either medication dose or count. A concordant change was defined as a dose and medication count change in the same direction. A discordant change was defined as a dose increase with medication count reduction, or a dose decrease with medication count increase. "Dose change only" refers to a dose change without any medication count modification. "Medication count change only" refers to a medication count change without dose modification (or with dose modification <25% or <50% of baseline dose for the second and third columns of the first panel).

a validated way to apply such measures into health care practice and health outcome research.

A main finding of this study is the high frequency of dose modification without medication count change. Although medication count remains the most common method of assessing a change in hypertension treatment intensity,<sup>4,5,7-11</sup> our results suggest that this may miss some trajectories of treatment intensity modification. Capturing dose change may be particularly relevant in older adults with polypharmacy and higher vulnerability to adverse drug events<sup>1</sup> and should thus be considered in further studies. We observed a slightly higher proportion of treatment intensity modification when looking at paired visits over 1 year rather than over 3 months. This is likely due to a greater opportunity for clinical encounters, more time to make a change, and a larger window in which to capture the change in dose on the subsequent refills. In addition, older, multimorbid patients have more health events per unit of time than younger, healthier ones. A cardiovascular event might justify intensification, whereas a global health deterioration may lead to deintensification, and more of these events will be seen over longer time intervals. The lower rates of treatment modification in shorter intervals may also be due to patient, physician, system-level, and environmental barriers to treatment modification that may lead to therapeutic inertia,<sup>17,18</sup> potentially exacerbated by a lack of recognition of the benefits of controlling SBP even among very old patients. In the presence of barriers, more time may also be required to allow for reflection and shared decision-making. Finally, because BP fluctuates over time, physicians may wait to document BP measurements over several visits before modifying treatment intensity. However, the higher proportion of treatment modification (mostly intensification) for patients with baseline SBP greater than 140 mm Hg suggests that physicians are more reactive when SBP is high.

Modifications in medication count without dose change are not necessarily paradoxical and may result from the management of nonhypertension conditions. For example, a physician might start a  $\beta$ -blocker for rate control in atrial fibrillation while reducing the dose of another antihypertensive medication to keep treatment intensity the same. Discordant changes might occur when an antihypertensive medication at a low dose is discontinued due to adverse effects or to reduce treatment complexity and polypharmacy, but the dose of another antihypertensive medication is increased with a goal of net intensification to treat a BP still above goal. Nonhypertension conditions may be more frequent in patients with higher SBP, potentially explaining a higher proportion of discordant observations for those with baseline SBP greater than 140 mm Hg. Discordant changes represented only 2.1% of all observations, and a medication count modification without dose change occurred in 0.2%. Therefore, our findings suggest that whereas antihypertensive medication count will frequently miss dose modifications (false negatives), a medication count change rarely will classify an episode with no change in dose as having treatment modification (false positives).

Our pharmacy fill algorithm that allows the measurement of change in standardized dose of antihypertensive medications has several potential implications. First, in light of recent more aggressive recommendations for hypertension management,<sup>16,19</sup> it will allow for more precise tracking of antihypertensive treatment intensity. Second, it could serve in future studies that assess the outcomes related to hypertension treatment intensity modification, which are required to improve hypertension care and management of older multimorbid patients, who are often excluded from clinical trials used for guideline development.<sup>2-6</sup>

### Limitations and Strengths

Our study has several limitations. First, pharmacy fills are not perfect to capture medication discontinuation when a patient stops taking their medication before the pill supply ends. Our algorithm partly accounts for this if there is no further refill but that the visit date is within 80% to 90% of the final pill supply duration, a criterion that was probabilistically determined in prior research.<sup>13,20</sup> Furthermore, some data suggest that pharmacy fills are a reliable source of information to capture medication consumption.<sup>21,22</sup> Second, although the data are from 2011 to 2013, the medications that we studied remain in widespread use today. Furthermore, although hypertension guidelines have changed following the SPRINT trial,<sup>4</sup> we do not expect the relationship between dose and count to have changed. Third, we included only patients 65 years and older, so the results may not generalize to younger patients. Nonetheless, older adults account for the large majority of hypertension and cardiovascular deaths such that older populations are of heightened clinical relevance. This study's strengths are its large national sample across US regions of the largest US health system, with excellent medication capture linking both VA and Medicare prescription data, and the use of a standardized method to assess antihypertensive medication doses.

## CONCLUSIONS

Applying standardized doses based on beneficial doses demonstrated in trials and using a near-universal medication data source for the largest US health care system, antihypertensive medication dose identified changes in hypertension treatment intensity more precisely than medication count. Using standardized medication doses may therefore better represent practice change. This method is an additional tool that can be used by health systems and in observational studies such as comparative effectiveness research in intensification and deintensification approaches. ■

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**Authorship Information:** Concept and design (CEA, CLC, TPH, JKH, WCC, JS, LM); acquisition of data (JKH, LM); analysis and interpretation of data (CEA, CLC, SWT, TPH, JKH, WCC, JS, LM); drafting of the manuscript (CEA, CLC, SWT, LM); critical revision of the manuscript for important intellectual content (CEA, SWT, TPH, WCC, JS, LM); statistical analysis (CEA, SWT, JKH, LM); obtaining funding (LM); administrative, technical, or logistic support (LM); supervision (LM); and editing of manuscript (WCC).

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## **SUPPLEMENTAL MATERIALS**

**eAppendix Text.** Identification of primary care and hypertension-managing specialty visits.

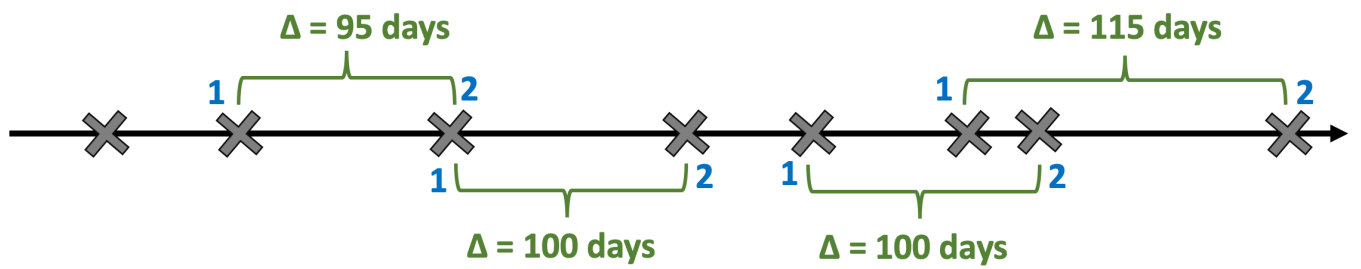
**eAppendix Figure.** Definition of sample visits.

**eAppendix Text.** Identification of primary care and hypertension-managing specialty visits.

Primary care and hypertension-managing specialty visits were identified using the following DSS Identifier primary and secondary stop codes: 118, 157, 170, 171, 172, 176, 177, 178, 301, 303, 305, 306, 309, 310, 312, 313, 315, 318, 319, 322, 323, 342, 348, 350, 701.



**eAppendix Figure.** Definition of sample visits.



**Legend:** For each patient, we paired visits separated by 90-120 days, including only once each visit as visit 1 or visit 2, but allowing for overlap. A visit 2 could be used as visit 1 for in a further pair.  $\Delta$  (delta) are the number of days elapsed between visit 1 and visit 2 of each pair. Blue numbers correspond to visit 1 (1) and visit 2 (2) of each pair. The same procedure was applied for the 365-395-day interval.