NBER ROYBAL CENTER – Proposed Trial 7.1: A Prospective Randomized Trial of Patient- and Clinician-Facing Nudges to Increase Medication Prescriptions for Hypertension

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Evidence Base

Hypertension (HTN) is a leading global health burden, contributing to 10.9 million deaths worldwide in 2021—more than any other modifiable risk factor, including smoking (6.2 million deaths) and high blood sugar (5.3 million deaths) (IHME, Global Burden of Disease, 2024 - with minor processing by Our World in Data). For instance, patients with HTN are at increased risk for heart disease, stroke, and diabetes, among other deadly complications (CDC, 2024). The prevalence of HTN (defined as systolic blood pressure (SBP) ≥130 mmHg and/*or* diastolic blood pressure ≥ 80 mmHg) increases markedly with age, with over 80% of adults ages 75 and above expected to have HTN in the US and worldwide (Martin et al., 2024).

However, despite its prevalence and severe health consequences, HTN remains underdiagnosed, undertreated, and poorly controlled. Only 62% of those with hypertension are estimated to be aware of their HTN; of those, 85% are treated for the condition, and only half of those treated are successful at keeping it under control (Martin et al., 2024)—meaning that about 75% of people diagnosed with HTN have inadequately controlled blood pressure. The American Heart Association (AHA) 2017 Hypertension guideline recommends a BP goal of <130/80 mmHg for patients with HTN (Whelton et al., 2018), though this definition has not been adopted universally: the European Society of Hypertension recommends <140/90 mmHg (Kreutz et al., 2024). HTN control rates are often described using the less stringent <140/90 mmHg target.

Randomized controlled trials (RCTs) have consistently shown that meeting lower BP goals (e.g., SBP <130 or <120) decreases the risk of cardiovascular disease (Whelton et al., 2017). RCTs testing behavioral interventions in real-world settings have largely focused, with modest success, on mitigating nonadherence to prescription medications among patients already diagnosed with HTN or related cardiac conditions. These patient-facing interventions have focused on patient education, reminders, and prescription monitoring (Bobrow et al., 2016; Glynn et al., 2010; Ho et al., 2024; Wald et al., 2014). However, little is known about patient-facing interventions among patients who are unaware that they have HTN. Relatively little is also known about clinician-facing interventions, although a recent RCT showed that such interventions can significantly increase statin prescribing (Adusumalli et al., 2023). Collectively, the existing evidence suggests that clinician-facing or perhaps a combination of patient- and clinician-facing nudges (including patients unaware of their HTN diagnosis) could be effective for improving HTN medication prescribing.

The proposed study will evaluate the effectiveness of clinician- and/or patient-facing nudges to improve upon past behavioral interventions for HTN care. Specifically, we aim to increase the prescription of anti-hypertensive medications, and therefore reduce BP, by incorporating key behavioral science principles: awareness, risk perception, social norms, and/or timeliness. Co-I Chang leads, and Co-PI Meyer is a member of, Geisinger's Hypertension Steering Committee; improving HTN control at Geisinger has been identified as a system priority.

Our interventions will focus on improving HTN care in either or both of two critical populations:

1. Patients with stage 1 HTN (>130/80 but <140/90 mmHg), who are at elevated cardiovascular risk (clinical atherosclerotic cardiovascular disease [ASCVD] or ≥10% ASCVD risk), are often overlooked and undertreated or untreated in routine practice. This population stands to benefit from earlier detection and intervention, given evidence from trials such as SPRINT (Wright et al., 2015; Zhang et al., 2021; Bi et al., 2024; Liu et al., 2024), which show considerable cardiovascular benefits of intensive BP control (e.g., targeting SBP < 130 (or perhaps < 120) mmHg).
2. Patients with stage 2 HTN (BP ≥ 140/90 mmHg), where failure to initiate, adhere to, or escalate treatment (by increasing a dosage and/or introducing additional medications) contributes to persistently high BP.

Strategy

Using Geisinger as a test site, we will test at least two interventions, likely one patient-facing and one clinician-facing, to improve HTN care. The interventions may be tested as one study with two distinct interventions (e.g., a 2x2 design with one patient-facing and one clinician-facing intervention) or as two separate studies with partially or fully overlapping samples.

Interventions are likely to be linked to existing primary care and/or specialty appointments where HTN can be addressed.

We may decide to intervene on patients (and the clinicians of patients) who have stage 1 HTN (BP 130–139/80–89), stage 2 HTN (≥ 140/90), or all of these patients, with messaging tailored to each patient's blood pressure history.

Patient-facing nudges will build on our team's prior Roybal trials, where we sent timely pre-appointment messages (Milkman et al., 2021; Moran, Rosenbaum et al., in preparation) and/or messages with personalized risk information (Rosenbaum et al., resubmitted) to improve vaccination. For HTN, these patient-facing messages will extend prior nudge studies that demonstrated the impact of tailored messaging on blood pressure control and health behaviors (Bobrow et al., 2016; Ho et al., 2024; Wald et al., 2014).

Examples of potential patient-facing studies include:

1. Patient messages: messages via SMS, patient portal, or another modality to encourage patients to ask their provider about HTN care (e.g., antihypertensive medication, lifestyle changes); examples of nudges we may test include:
    a. Information nudge: Patients with stage 1 HTN may not be aware that their blood pressure is problematic, so nudges informing patients that their blood pressure readings are high may be particularly effective.
    b. High risk and present bias nudge: Our team has found evidence that high risk information nudges are effective for boosting flu vaccination (Rosenbaum et al., resubmitted). Patients with HTN are at high risk for many other conditions such as heart failure and diabetes. Informing patients about their increased risk, and varying how that risk is described, may motivate them to discuss HTN with their providers and take action. We may experimentally vary which complications, time frames, and/or temporal perspectives are included in the messages. For example, we may randomize patients to be told (1) the *10-year cardiovascular disease risk* for patients with HTN (i.e., 2.80% absolute risk, 35% increased relative risk) or (2) their *lifetime risk* (i.e., 16.61% absolute risk, 36% increased relative risk; (Peng et al., 2023). We may also randomize patients to be told patients with their stage of HTN on average are (1) expected to live until age X or (2) estimated to have Y years remaining to live, to test whether a time-limited frame influences behavior (Gellert et al., 2012; Hill et al., 2024; Payne et al., 2013). These approaches are all aimed at overcoming present bias, or the tendency to discount future outcomes in the present, by making future consequences more salient (H. Hershfield, 2023; H. E. Hershfield, 2011; Trope & Liberman, 2000).
    c. Timely vs. less timely nudges: We may randomize patients to receive presumably timely messages (e.g., 3 days prior to their eligible appointment) or less timely messages (e.g., sent 3 days and/or 3 weeks following the patient's appointment). This evaluates whether coordinating information receipt around a natural decision point (i.e., an appointment) is more effective than follow-up messages. While pre-appointment messages can help form patients' implementation intentions (Gollwitzer & Sheeran, 2006; Hagger & Luszczynska, 2014; Milkman et al., 2011), post-appointment messages could capitalize on foot-in-the-door effects, as patients who have already initially discussed their health may be more receptive to taking action following a later message (Cialdini & Goldstein, 2004). This design would also let us experimentally test the widely-held assumption that health prompts before appointments are obviously better than prompts not preceding an appointment at which HTN can be addressed conveniently.
    d. Interactive vs. less interactive nudges: We may randomize patients to receive one of two types of text messages: (1) interactive messages (as in Adusumalli et al., 2023), where patients can reply directly to the text to express interest in learning more or discussing with their doctor or to take a diagnostic health survey, or (2) noninteractive messages, which provide basic information without the opportunity to reply. This comparison allows us to evaluate whether providing

patients a chance to exert personal control—by engaging in a back-and-forth exchange—and experience self-efficacy in response to communications from the hospital system is more effective than simply receiving basic one-way messages.

2. Patient portal pre-visit prompt: randomizing patients with patient portal access to receive or not receive a pre-visit check-in message prompting them to discuss HTN care at their appointment. Patient responses will be available to clinicians during the visit, so this is a combined patient- and clinician-facing intervention.

For clinicians, we will leverage electronic health record- (EHR-) based clinical decision support (CDS) tools that present relevant information and prescribing options during clinical encounters.

Examples of potential clinician-facing interventions include:

1. Default problem list: for patients with a history of high blood pressure readings but for whom HTN is not on the problem list, we may test whether automatically adding HTN to the problem list increases HTN care, especially for those with stage 1 readings. This serves as an informational nudge, making otherwise hidden information available and salient (EAST framework, 2024). This has been done at Geisinger for other diagnoses, e.g., chronic kidney disease, and some clinicians have favorable impressions of its utility.
2. Actionable advisories: we may test the effectiveness of modified best practice advisories or related CDS tools to encourage HTN conversations and medication changes (Adusumalli et al., 2023). CDS design will adhere to the 5 rights of CDS (i.e., delivering the right information to the right person, through the right channel, in the right format, and at the right time—when prescribing decisions are most impactful) (Osheroff et al., 2007; Thaler & Sunstein, 2008; Tversky & Kahneman, 1974).
3. Peer comparison: we may test whether comparing clinicians' prescribing rates with those of their peers (Adusumalli et al., 2023) is more effective than not including such comparisons. This evaluates whether social norms are influential in such a context, above and beyond other nudges to prescribe according to guidelines (Meeker et al., 2016; Patel et al., 2018).

The primary outcome for any of the above studies will be HTN medication management (i.e., refilling HTN medication, increasing a medication dosage, and/or ordering a new medication) and/or documented lifestyle change recommendations in the EHR. Other pre-specified outcomes may include blood pressure, HTN medication adherence, mention of HTN or blood pressure in appointment notes (potentially using a large language model summary of visit notes), and/or ordering lab tests recommended for HTN care (e.g., basic metabolic panel).

Causal Mechanisms

By testing these scalable, low-cost patient- and clinician-facing interventions both in isolation and in combination, we aim to determine whether aligning nudges across both sides of the clinical encounter amplifies their individual effects.

Following these pragmatic trials, we may run an online post-trial survey experiment for further insights into the behavioral mechanisms underpinning our field findings. That is, we would present online participants with the messages from our field studies and ask whether they would be compelled to discuss HTN with their doctor if they received this message, along with other questions about the perceptions of the messages (e.g., whether timeliness or salience of key information served as likely mediators of the effect of our manipulations on outcomes). We successfully used a similar approach following a past Roybal trial (Rosenbaum et al., in revision): post-trial results allowed us to rule out an inattention account of our reported findings.

Sample Size and Power

Assuming one patient-facing and one clinician-facing intervention, patients will be independently randomized within each, and analyses will be conducted separately for the two. Analyses will be intent-to-treat. Exploratory follow-up analyses will examine whether there are additive or interactive effects of both interventions (as we are not predicting interactions or setting sample sizes to detect them).

Expected sample sizes for different study options are shown in the table below, broken down by patients who have recent BP readings consistent with stage 1 or stage 2 HTN prior to their appointments. We plan to enroll a minimum of 20,000 patients in each study and likely many more (as shown in the table).

A study with 20,000 patients allows for at least 10,000 in a passive control arm and 10,000 in an experimental arm. However, enrollment may be uneven across arms (e.g., with fewer patients in passive control arms and more patients in intervention arms), especially for study designs with more than two arms. This would increase power to detect differences between active experimental arms, which are expected to be smaller than differences between active and passive arms.

Baseline HTN medication management (i.e., refilling HTN medication or ordering any new HTN medication or changing dosage) on the appointment date is about 14%. With 10,000 patients per arm, we will have 80% power to detect an increase of 1.4 percentage points with two-tailed $p < .05$. If we increase the sample size to 15,000 patients per arm, that allows for 80% power to detect an increase of about 1.1 percentage points with two-tailed $p < .05$.

Depending on the final study design, we may choose to use a 30-day (or longer) time frame instead of considering medications only on the appointment date. For example, for a patient-facing messaging study where we test timeliness and with non-timely messages sent weeks following the appointment, we will need to extend the time frame so that patients in the non-timely arm can act on messages after they get them. For a 30-day time frame, baseline HTN medication orders (including refills) is about 25%. With 10,000 patients per arm, we will have 80% power to detect an increase of 1.7 percentage points with two-tailed $p < .05$. With 15,000 patients per arm, we will have 80% power to detect an increase of about 1.4 percentage points with two-tailed $p < .05$.

Study option		N stage 1	N stage 2	Total N
Patient-facing	Messaging or questionnaire study	14,000	33,000	47,000
Clinician-facing	CDS study	17,000	41,000	58,000
	Problem list study	6,000	13,000	19,000

Note. These estimates are based on a preliminary analysis of data from 2024; actual enrollment may differ substantially, pending final decisions about outcome calculations and inclusion criteria.

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