

# Effect of a Patient Activation Intervention on Hypertension Medication Optimization: Results From a Randomized Clinical Trial

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**D**eprescribing refers to the process of removing, reducing, or switching medications to reduce risks and improve patient outcomes.<sup>1</sup> A conceptually overlapping process is that of medication optimization, which seeks to maximize medication benefit through appropriate prescribing; it shares similar strategies with deprescribing and may involve removing, reducing, or switching medications.<sup>2</sup> Both concepts are important given the pervasiveness of polypharmacy; half of older adults take 5 or more medications, at least 1 of which may be potentially inappropriate.<sup>3</sup> Achieving optimal medication usage thus may improve numerous outcomes in this population, including quality, cost, adherence, and reduction of adverse drug events,<sup>4,5</sup> but it remains difficult to achieve in practice.<sup>6</sup> Several factors that may inhibit optimal medication usage have been identified, including clinical inertia, provider assumptions about patient treatment preferences, patient beliefs about the appropriateness of the medication in question, and patient fears related to cessation (eg, withdrawal effects).<sup>7-10</sup>

Such factors underscore the need to employ a patient-centered process to achieve medication optimization, which emphasizes increased communication and shared decision-making between the patient and provider in clinical encounters.<sup>5,11,12</sup> Studies in the deprescribing literature employing patient-centered approaches have reported favorable results,<sup>13-15</sup> and a review by Ostini and colleagues<sup>16</sup> suggests that interventions designed to actively involve the patient are more effective than those that do not (eg, those focused solely on prescribers).

Direct-to-consumer (DTC) marketing has been used by the pharmaceutical industry for some time to motivate discussions between patients and physicians to affect prescribing.<sup>17</sup> Fundamentally, DTC marketing seeks to increase patient activation, a term that refers to the patient-centered process of imparting knowledge, skills, and confidence, which may facilitate patients becoming more active and informed participants in health care delivery.<sup>18,19</sup> Patient activation interventions have shown benefit in terms of better health outcomes and care experiences,<sup>20,21</sup> and interventions that facilitate patient initiation of discussion about medication optimization may be especially beneficial as they

## ABSTRACT

**OBJECTIVES:** To examine the effect of a patient activation intervention with financial incentives to promote switching to a thiazide in patients with controlled hypertension using calcium channel blockers (CCBs).

**STUDY DESIGN:** The Veterans Affairs Project to Implement Diuretics, a randomized clinical trial, was conducted at 13 Veterans Affairs primary care clinics.

**METHODS:** Patients (n=236) with hypertension previously controlled using CCBs were randomized to a control group (n=90) or 1 of 3 intervention groups designed to activate patients to talk with their primary care providers about switching to thiazides: Group A (n=53) received an activation letter, group B (n=42) received a letter plus a financial incentive to discuss switching from a CCB to a thiazide, and group C (n=51) received a letter, a financial incentive, and a telephone call encouraging patients to speak with their primary care providers. The primary outcome was thiazide prescribing at the index visit.

**RESULTS:** At the index visit, the rate of switching to a thiazide was 1.1% in the control group and 9.4% (group A), 26.2% (group B), and 31.4% (group C) for the intervention groups ( $P < .0001$ ). In adjusted analysis, patients randomized to group C were significantly more likely to switch from a CCB to thiazide at the index visit (odds ratio, 4.14; 95% CI, 1.45-11.84;  $P < .01$ ).

**CONCLUSIONS:** This low-cost, low-intensity patient activation intervention resulted in increased rates of switching to a thiazide in those whose hypertension was controlled using another medication, suggesting that such interventions may be used to overcome medication optimization challenges, including clinical inertia.

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provide opportunities for shared communication and decision-making.

The present study examines data from the Veterans Affairs Project to Implement Diuretics, a randomized clinical trial designed to test the efficacy of a patient activation intervention with financial incentives to promote thiazide prescribing (ClinicalTrials.gov identifier: NCT 00265538). When the trial was initiated in 2006,<sup>22</sup> the prevailing hypertension (HTN) guidelines from the Joint National Committee (JNC) 7 for the Management of Hypertension in Adults specifically stated that “thiazide-type diuretics should be used in drug treatment for most patients with uncomplicated [HTN].”<sup>23</sup> In addition to being recommended for first-line therapy, thiazides were considerably cheaper than many other antihypertensives, with a favorable efficacy and safety profile. The 2014 guidelines (formerly JNC 8) recommend selection among 4 classes, including thiazides.<sup>24</sup> The arm of the trial examined in the current study aimed to promote switching to thiazides in a group of patients with controlled blood pressure (BP) using calcium channel blockers (CCBs) due to the recommendations at the time and considerable cost savings, aligning with the concept of medication optimization in which medications that may not pose significant harm—but are suboptimal—are targeted for switching or reduction. Although much of the deprescribing literature focuses on medication discontinuation, switching is also an important

### TAKEAWAY POINTS

Medication optimization remains difficult to achieve in practice. Patient-centered interventions in this context, which emphasize increased communication and shared decision-making between the patient and provider, have shown promise.

- ▶ In this patient activation intervention for hypertension, intervention patients with their hypertension already controlled using another medication were more likely to switch to a thiazide diuretic compared with usual care control patients. Specifically, adjusted odds of switching were greatest for patients randomized to receive a custom letter, modest financial incentive, and brief nurse-led reminder call.
- ▶ These findings suggest that low-cost, low-intensity patient activation interventions may be useful in addressing medication optimization challenges and clinical inertia.

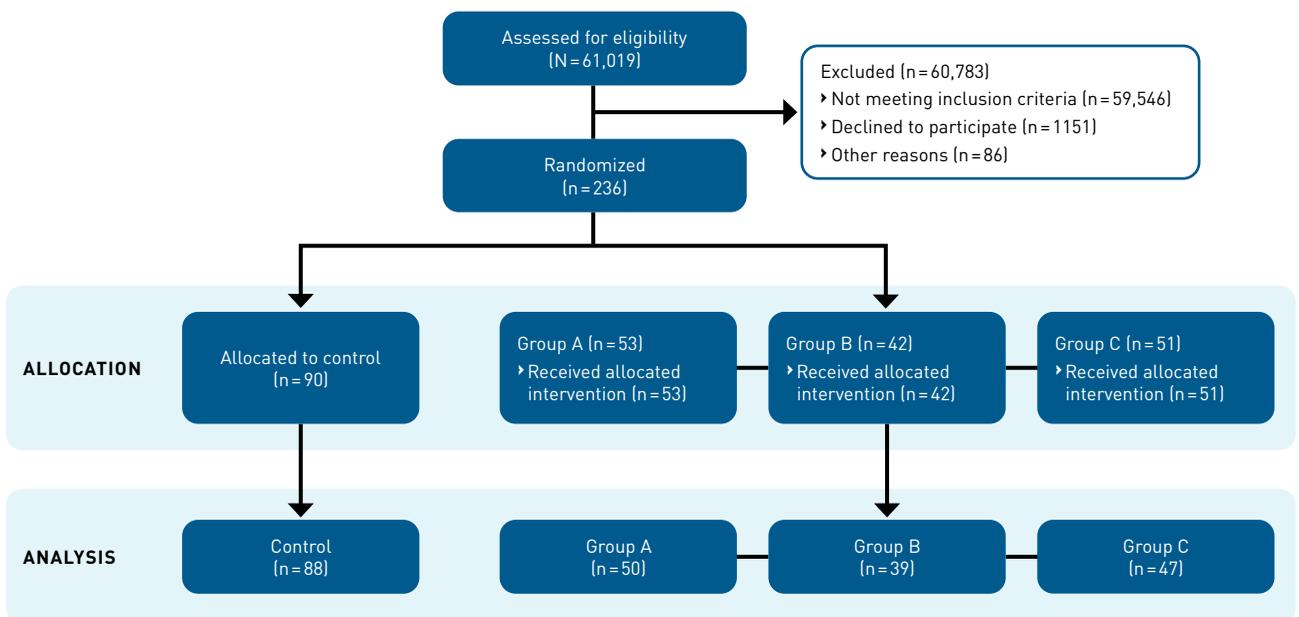
principle of deprescribing/medication optimization and deserves further attention.<sup>19</sup> Thus, our primary interest in this study was to examine whether a low-cost, low-intensity intervention would affect medication switching for those already at their BP goal taking a nonpreferred agent. We hypothesized that patients assigned to the most “active” arm of the intervention would exhibit the greatest degree of medication switching.

## METHODS

### Participants

Participants were sampled from all patients who received primary care at 13 Veterans Affairs (VA) outpatient clinics affiliated with 2 large VA medical centers (N = 61,019) (Figure). To be eligible for

**FIGURE.** Consolidated Standards of Reporting Trials 2010 Flow Diagram



participation, patients must have had a prior diagnosis of HTN, not be taking a thiazide diuretic, have 2 or more VA clinic visits in the past 12 months, not be in a long-term care facility, and have no known thiazide or sulfa allergy or prior adverse drug event. From this, 2 subpopulations were derived: (1) patients not at an appropriate BP goal at the 2 most recent clinic visits, referred to as *uncontrolled-HTN*, and (2) patients at an appropriate BP goal, but taking a CCB, referred to as *controlled-CCB*. Attainment of goal BP at baseline was determined using the mean of all clinic-recorded BPs from the 2 clinic visits immediately preceding the initial study clinic appointment (hereafter referred to as the index visit). Complete inclusion and exclusion criteria, as well as primary trial results focusing on those not at an appropriate BP goal, have been reported elsewhere.<sup>22</sup> This paper reports findings from the *controlled-CCB* group only.

### Procedure

Participants were recruited following a staged protocol that randomized 168 primary care providers (71 affiliated with the Iowa City VA Medical Center and 97 affiliated with the Minneapolis VA Medical Center) to intervention and control groups and then selected eligible patients within these groups. Upon primary care provider randomization, patients with a primary care appointment within 30 days were identified and screened using the electronic health record. Eligible patients (n = 2853) were mailed a letter describing the study objectives, enrollment process, and data collection. One week later, patients were contacted by telephone to obtain informed consent and administered the Pfeiffer Short Portable Mental Status Questionnaire (SPMSQ) to exclude patients with cognitive impairment (defined as > 2 errors on the SPMSQ).<sup>25</sup> Of the 2853 patients who were contacted by mail, 2019 were attempted by phone; 1151 declined to participate, including 86 with no telephone. Enrollment ended when the target number of participants were enrolled. Consenting patients (n = 236) were randomized to an intervention (n = 146) or 1 of 2 usual care control groups (n = 90), one group of approximately 50 who were seen by providers with no intervention patients and another group of approximately 50 seen by providers also with intervention patients. We conducted several analyses that demonstrated that these patient groups were no different from one another and thus collapsed them for this study. Sample sizes were selected to provide sufficient ( $\geq 80\%$ ) power to detect an 18% absolute difference in thiazide use between the control group and a single treatment group. All study procedures were approved by The University of Iowa's institutional review board (#200506705).

Patients randomized to the intervention were assigned to 1 of 3 intervention groups. Group A (n = 53) received a customized letter 1 to 3 weeks before their scheduled index visit. Information was tailored to the patient's treatment regimen, BP, and cardiovascular risk factors. The letter requested that the patient initiate a discussion with their primary care provider about switching to a thiazide and provided specific options for doing so. It included a postcard for

patients to have providers sign and return, documenting whether thiazides were discussed during the visit.

Group B (n = 42) received the same patient education letter in addition to a financial incentive (\$20 by check) to initiate a discussion with their primary care provider (see [eAppendix](#) [available at [ajmc.com](#)] for an example letter representing group B). The incentive was awarded upon receipt of the signed postcard. For patients with a prescription co-pay (55/93; 59.1% across groups B and C), the letter also indicated that thiazide co-pays for 6 months (\$48) would be reimbursed upon receipt of the postcard and confirmation that a thiazide was prescribed.

Group C (n = 51) received the same letter and financial incentives as group B in addition to a brief telephone call within 1 week before their clinic visit. Calls were conducted by a trained health educator who discussed the mailed information, the patient's role in initiating a discussion with the primary care provider about BP medications, and potential strategies for initiating these conversations. All patients received up to 5 call attempts prior to their scheduled index visit; the mode number of calls was 2. Calls lasted, on average, between 5 and 10 minutes.

The primary outcome was thiazide prescription at the index visit; switching to a thiazide from a CCB was determined by reviewing each patient's progress note and medication list after the index visit, which included discontinued orders to establish that CCBs were stopped. Intervention and control groups were compared at baseline in terms of sociodemographic characteristics and other clinical variables of importance (eg, baseline BP, smoking, mental status, diabetes) using standard univariate tests including *t* tests and  $\chi^2$  tests. Variables showing a (conservative) significant difference between groups at  $P < .10$  were included as covariates in adjusted analyses.

Because of the clustered nature of these data, statistical analyses must account for correlation in order for the observed results to be valid given that traditional regression models assume independence of observations. Therefore, analyses utilized hierarchical logistic regression using the generalized linear mixed model procedure in SPSS version 24.0 (IBM). Models incorporated random physician effects to account for within-physician clustering; clinic sites were included as fixed effects. Analyses tested whether there was a significant difference between the log odds of thiazide prescription for the control group vs the 3 intervention groups at the index visit.

## RESULTS

During recruitment, 2853 eligible patients were identified. Of these, 236 who were at an appropriate BP goal and taking a CCB for HTN treatment were consented and enrolled. These patients were randomized to either intervention (n = 146: group A = 53; group B = 42; group C = 51) or control (n = 90) groups. Mean age for the intervention groups was 66.7 years and mean systolic/diastolic BP at baseline was 121.5/74.5 mm Hg (see [Table 1](#), which also includes a breakdown by intervention group assignment). Mean age for the control group

**TABLE 1.** Baseline Characteristics

Characteristic	Intervention overall (n = 146)	Intervention group A (n = 53)	Intervention group B (n = 42)	Intervention group C (n = 51)	Control (n = 90)	P for all intervention vs control <sup>a</sup>
Age in years, mean (SD)	66.7 (8.8)	65.9 (9.1)	66.9 (7.9)	67.2 (9.3)	66.9 (8.9)	.86
Male sex, n (%)	145 (99.3)	52 (98.1)	42 (100)	51 (100)	89 (98.9)	.73
Education, n (%)						.75
Grade school	12 (8.2)	4 (7.5)	4 (9.5)	4 (7.8)	7 (7.7)	
High school	45 (30.8)	16 (30.2)	14 (33.3)	15 (29.4)	32 (35.6)	
Beyond high school	89 (61.0)	33 (62.2)	24 (57.1)	32 (62.7)	51 (56.6)	
Race, n (%)						.02
Caucasian	92 (63.0)	35 (66.0)	25 (59.5)	32 (62.7)	72 (80.0)	
African American	3 (2.0)	1 (1.9)	2 (4.8)	0 (0)	4 (4.4)	
Hispanic	1 (<1)	1 (1.9)	0 (0)	0 (0)	1 (1.1)	
Other	40 (27.3)	13 (24.5)	12 (28.5)	15 (29.4)	11 (12.2)	
Unknown	10 (6.8)	3 (5.6)	3 (7.1)	4 (7.8)	2 (1.1)	
Systolic blood pressure, mean (SD) mm Hg	121.5 (12.3)	120.5 (11.2)	120.3 (12.8)	123.6 (13.0)	122.2 (12.2)	.67
Diastolic blood pressure, mean (SD) mm Hg	74.5 (9.2)	74.5 (9.8)	73.7 (8.9)	75.3 (8.4)	73.2 (9.6)	.30
Smoking status (yes), n (%)	26 (17.8)	10 (18.8)	6 (14.3)	10 (19.6)	16 (17.7)	.99
Diabetic status (yes), n (%)	28 (19.2)	10 (18.8)	8 (19.0)	10 (19.6)	14 (15.5)	.48

<sup>a</sup>P values represent intervention groups collapsed vs control.

was 66.9 years and mean BP at baseline was 122.2/73.2 mm Hg. Only race varied significantly between groups and was added as a covariate in the adjusted model. No differential attrition by group was observed, which includes appointment no-shows and elective study dropouts. Only 2 of 51 (3.9%) group C participants were not reached by phone, making them functionally more like group B participants; these participants were analyzed according to the group they were randomized to.

Rate of thiazide prescribing, representing a switch from a CCB to thiazide, was the primary outcome of interest. At the index visit, the unadjusted thiazide prescription rates were 1.1% (1/90) for the control group and 9.4% (5/53) for group A, 26.2% (11/42) for group B, and 31.4% (16/51) for group C ( $P < .0001$ ). Adjusted odds ratios (ORs) for the 3 intervention groups relative to control are presented in **Table 2**. At the index visit, the odds of switching to a thiazide were not significantly greater compared with the control group for group A (OR, 2.37; 95% CI, 0.82-6.82;  $P = .11$ ) and only marginally so for group B (OR, 2.77; 95% CI, 0.96-8.01;  $P = .06$ ). Group C (OR, 4.14; 95% CI, 1.45-11.84;  $P < .01$ ) had significantly greater odds of switching to a thiazide than the control group, the magnitude of which has been suggested to be equivalent to a medium effect size.<sup>26</sup>

## DISCUSSION

This study suggests that a relatively low-cost, low-intensity intervention may affect medication optimization behavior in the context of HTN, even for patients currently controlled on another medication. At the index visit, approximately one-third of patients in group C switched from a CCB to thiazide, which was significantly different

**TABLE 2.** Adjusted Results: Thiazide Prescribing at Index Visit<sup>a</sup>

Group	Outcome: thiazide prescribing		
	Odds ratio	95% CI	P
Control (n=88)	Referent	–	–
Intervention A (n=50)	2.37	0.82-6.82	.11
Intervention B (n=39)	2.77	0.96-8.01	.06
Intervention C (n=47)	4.14	1.45-11.84	<.01

<sup>a</sup>N = 224; analysis adjusted for race.

from the control group in the adjusted analysis. Perhaps most noteworthy is the fact that these patients had HTN that was controlled at the time of intervention and, presumably, most had no pressing reason to switch other than those primarily tied to financial benefit (ie, nominal monetary incentive, prescription co-pay assistance).

Patients were first activated to engage their primary care providers through a customized letter, which only modestly improved switching compared with control (group A; see unadjusted rates above and adjusted odds ratios in **Table 2**). Adding financial incentives resulted in a marginally significant increase in the odds of switching for group B and, further, a brief reminder phone call resulted in significantly increased odds for group C. The use of financial incentives to drive behavior change has shown success across multiple health-related contexts, including medication adherence, smoking cessation, and weight loss.<sup>27-29</sup> It has, however, notably failed in others.<sup>30</sup> In this study, a letter plus modest financial incentives were not enough to achieve statistically significant switching ( $P = .06$ ), but adding a brief reminder call previsit was enough to reach significant change ( $P < .01$ ). Although a formal budget impact analysis was not part of

the study, the financial incentive was considerably less than the ongoing cost of a CCB and the letters were automatically generated from data in the electronic health record and thus low cost. The phone calls took approximately 5 to 10 minutes but improved the potency of the intervention and served to remind patients about their appointments as well as to bring their medications with them, a frequent part of usual care.

Given that group C participants received a tailored letter encouraging discussion with the provider, modest financial incentives, and a brief phone call, it is likely that successful interventions will require a multifaceted approach to facilitate medication optimization, including active engagement of the patient.<sup>5</sup> This is further underscored by calls to implement interventions designed to address patient, provider, and/or systems-level factors.<sup>10,31,32</sup> In the present study, the tailored letter not only provided information specific to the patient's condition but also served as a means of facilitating discussion about medication options. Although, on its own, it was not enough to drive significant change, it does represent a key first step in shared decision-making and presumably resulted in some dialogue about the benefits vs harms of switching. Because a majority of (although not all) patients prefer to be actively involved in the decision-making process,<sup>33</sup> which includes being offered choices and the freedom to express opinions, it would seem that simple tools such as a patient-directed letter may hold value as one instrument toward broader medication optimization when combined with additional elements like financial incentives and other means to further engage the patient. Even for those preferring to leave final decisions to the provider, such letters could serve as a prompt for discussion, which itself may combat clinical inertia and misperceptions about patient preferences on the part of the provider.<sup>34</sup> Indeed, a companion qualitative study of participating intervention providers found that, in addition to very favorable overall perceptions of the intervention and belief in its suitability for wider use, providers specifically noted that the intervention helped align patient objectives with their own.<sup>35</sup>

Not all multimodal interventions are equally feasible in practice, however. Many interventions have demonstrated success in improving deprescribing outcomes, but there is often a disconnect between research and practice in that many interventions may be unrealistic for widespread adoption in busy clinic settings.<sup>10</sup> Compared with interventions that require the involvement of multiple providers, considerable effort on the part of a lone provider, and/or complex referral or care coordination processes, the present approach may be more logistically practical and demand fewer resources. Future research should be designed with an eye toward what is reasonably attainable in the clinical setting to address this important issue.<sup>6</sup>

### Limitations

This study has several limitations. First, it is reasonable to argue that because some patients did not have a compelling reason to switch other than financial incentives and then-contemporary

practice guidelines, there may have been no need to switch at all. However, this study suggests that financial incentives, when coupled with other modest interventional components, can facilitate discussion of the issue, which is an important first step in the deprescribing/medication optimization process. Previous qualitative work from this trial found that patient participants liked being involved because it allowed them the opportunity to initiate discussions with the provider on a topic of importance.<sup>36</sup> Such empowerment may carry over to other aspects of the clinical encounter. Second, we do not have information regarding the exact reasons why patients and providers decided to switch from a CCB to a thiazide; it is assumed that the financial incentives and practice guidelines largely influenced this change, but it is possible that at least some patients were candidates for switching irrespective of our intervention, perhaps due to low tolerance of the medication at the time of visit. This concern is alleviated by the presence of a control group, however. Third, we do not have specific race/ethnicity information for a number of patient participants in this study, which is primarily due to issues with reporting and classification in the VA medical record at the time of this trial.<sup>37</sup> Fourth, we did not monitor downstream efforts to address the appropriateness of the switch (eg, follow-up laboratory tests, BP monitoring) and thus cannot speak to patients who did not respond well to the new medication. Finally, HTN guidelines evolved over time, making some recommendations obsolete. However, in addition to the clear connections to deprescribing/medication optimization, this study also may have implications specifically for therapeutic substitution (ie, when a lower-cost alternative within the same class is available), particularly when developing methods to inform and engage patients about less expensive options that are otherwise equivalent for the same indication.

## CONCLUSIONS

These results suggest that a low-intensity intervention activating patients toward increased communication (in this case, discussion of current HTN medications in clinic) may be relevant to deprescribing and broader medication optimization efforts, helping to overcome clinical inertia. Future work should evaluate the practical barriers of implementing even simple interventions into complex and busy clinical practices and develop ways to overcome those barriers. ■

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**DEPARTMENT OF VETERANS AFFAIRS**  
**Medical Center**  
**Iowa City, Iowa 52246-2208**

**October 1, 2005**

Dear **Mr. Johnson**,

The Iowa City VA Medical Center wants you to have the best possible health care and make sure your blood pressure is controlled. Your last blood pressure recorded in the clinic was **132/65**, which is excellent! Your blood pressure should be kept below **140/90 [or 130/80 DM]**. High blood pressure can cause heart attacks and strokes.

Your current blood pressure medications in our records are:

- **Atenolol**
- **Amlodipine**

According to VA blood pressure treatment guidelines, the best medication for the treatment of high blood pressure in most patients is a low-dose of a **diuretic**, also called a water pill. Diuretics are safe and help reduce your chances of having a heart attack or stroke. Like all medications, diuretics can have side effects that you should discuss with your doctor.

Based on this new scientific evidence, we would like you to **talk to your doctor** about replacing your **Amlodipine** with a **diuretic**.

Possible options for you would be to:

- Switch to a combination pill that includes a diuretic (**Atenolol 50mg/chlorthalidone 25mg**) in place of your **Amlodipine**  
or
- Add a tablet of **HCTZ 25mg or chlorthalidone 25mg** in place of your **Amlodipine**

Take this letter with you to your next VA Provider's appointment on **October 15<sup>th</sup>**. Ask if a **diuretic** is right for you to keep your blood pressure down and reduce your risk of a heart attack or stroke.

We want to know if you talk to your VA Provider at your next visit about your blood pressure to learn if this message is helpful to you and your VA Provider. Please take the enclosed self-addressed, stamped post-card with you to your next visit and have your doctor sign it if you discuss your blood pressure. To encourage you to have this discussion, we are going to send you **\$20** for simply discussing your blood pressure treatment with your VA Provider.

If you have any questions, you may call us at 319.XXX-XXXX.

Thank you,  
The Iowa City VA Medical Center