Hypertension affects nearly one third of adults and is a leading risk factor for cardiovascular morbidity and mortality, contributing to nearly half of all cardiovascular disease deaths in the United States. Despite the importance and prevalence of hypertension, control tends to be poor. Findings suggest that if all hypertensive patients achieved adequate blood pressure control in concordance with current clinical guidelines, approximately 46,000 deaths could potentially be prevented per year. Longitudinal studies have found evidence that hypertension is associated with clinical depression but also that clinical depression is an independent risk factor for hypertension. Depression has been found to be associated with poor adherence to hypertension treatment. In addition, several risk factors for hypertension have important lifestyle and psychosocial components affected by depression, including obesity, excess sodium consumption, excess alcohol consumption, and physical inactivity. Research also shows that psychosocial stress and concomitant sympathetic nervous system reactivity may play a role in hypertension and increases in blood pressure.

In this pilot study, we examined whether an intervention integrating depression treatment into care for hypertension and carried out by Licensed Practical Nurses (LPNs) who are already working in primary care practices improved blood pressure control and depressive symptoms. Our previous work provided evidence that integrating depression into hypertension management can improve both blood pressure control and depression outcomes when carried out by a master’s-level interventionist. The current study differs from our previous work by involving existing office staff taking on the new role of providing depression treatment in addition to their responsibilities in primary care.

**BACKGROUND AND OBJECTIVES:** Depression is a risk factor for hypertension, and risk of depression is increased substantially in patients with hypertension. Our objective was to examine whether an intervention carried out by Licensed Practical Nurses (LPNs) integrating depression treatment into care for hypertension improved blood pressure control and depressive symptoms.

**METHODS:** In all, 60 patients ages 41 to 92 years with hypertension and depressive symptoms at a large primary care practice in Philadelphia were randomly assigned to an integrated care intervention carried out by LPNs (n=30) or usual care (n=30). Intervention and control groups did not differ statistically on baseline measures. Outcomes assessed at baseline and 12 weeks included standard laboratory procedures to measure blood pressure control and the Patient Health Questionnaire (PHQ-9) to assess depression.

**RESULTS:** Patients in the integrated care intervention had lower diastolic blood pressure (intervention 74.2 mmHg versus usual care 82.0 mmHg) and fewer depressive symptoms (PHQ-9 mean scores, intervention 2.4 versus usual care 7.1) compared with patients in the usual care group at 12 weeks after adjustment for baseline values. Patients in the integrated care intervention also had lower systolic blood pressure (intervention 130.0 mmHg versus usual care 140.6 mmHg) compared with patients in the usual care group at 12 weeks although the results approached but did not reach conventional levels of statistical significance.

**CONCLUSION:** Training existing primary care practice office staff will facilitate implementation in real world practices with limited resources and competing demands.

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**Pilot Trial of a Licensed Practical Nurse Intervention for Hypertension and Depression**

Hillary R. Bogner, MD, MSCE; Heather F. de Vries, MSPH; Elise M. Kaye; Knashawn H. Morales, ScD

**BACKGROUND AND OBJECTIVES:** Depression is a risk factor for hypertension, and risk of depression is increased substantially in patients with hypertension. Our objective was to examine whether an intervention carried out by Licensed Practical Nurses (LPNs) integrating depression treatment into care for hypertension improved blood pressure control and depressive symptoms.

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increasing roles in the treatment of chronic medical conditions in place of adding personnel to the structure of the practice. LPNs have relationships with patients and physicians developed over many years and therefore a unique understanding of the health care needs of primary care patients. Our conceptual framework adapted from Cooper and colleagues\(^7\) is based on the Theory of Reasoned Action and is both practical in its approach and provides a framework that allows for flexible, tailored interventions (Figure 1). Our intervention addresses each factor resulting in nonadherence in the conceptual model through a multifaceted, individualized approach in which patients work with the LPN to develop strategies to overcome barriers to adherence to medications (Table 1).

Other investigators have examined whether expanding the role of ancillary health staff in the clinic such as health care assistants, medical assistants, or LPNs modifies behavior and/or improves health outcomes (eg, \(^{28-34}\)). These studies have had varying degrees of success with only two reporting statistical significant improvements in clinical outcomes when comparing the intervention to usual care.\(^{20,31}\) In Germany, Gensichen and colleagues found that case management provided by primary care practice-based health care assistants reduced depressive symptoms for patients with major depression.\(^{29}\) In the United States, Tsai and colleagues found using medical assistants as weight loss counselors resulted in significant weight loss during the 6-month intervention period.\(^{33}\) No studies have used LPNs to integrate treatment for mental and physical health. Several reviews have highlighted the gap between the large amount of information on efficacy compared to the limited information on effectiveness.\(^{35-37}\) An effectiveness intervention designed to address depression in the context of hypertension, a major risk factor for CVD, among older adults in primary care practices would have a major public health impact. Training existing primary care practice office staff will facilitate implementation in real world practices with limited resources and competing demands. We hypothesized that in a sample of primary care patients with depressive symptoms and hypertension, patients who were randomized to receive the intervention carried out by LPNs compared with usual care would demonstrate the following after a 12-week period: (1) lower systolic blood pressure and diastolic blood pressure and (2) fewer depressive symptoms.

**Methods**

**Recruitment Procedures**

The study was conducted at a community-based primary care practice in Philadelphia. All study activities were guided by a research protocol approved by the University of Pennsylvania Institutional Review Board, and all patients gave written informed consent. From December 2010 to August 2011, adults with hypertension and depressive symptoms with upcoming appointments were recruited. Patients were initially identified through an electronic medical record with the following inclusion criteria: (1) ages 40 and older, (2) a diagnosis of hypertension and a prescription for an antihypertensive medication within the past year, and (3) a prescription for an antidepressant within the past year. The age cut-off was chosen because of its significance for prevention and management of hypertension.\(^{28}\) Exclusion criteria were (1) inability to give informed consent, (2) significant cognitive impairment at baseline (Mini-Mental State Examination (MMSE) \(<21\)^\(^{39}\)) and (3) residence in a care facility that provides medications on schedule.

In all, 127 patients were identified by electronic medical records as potentially eligible and were approached for further screening. At the baseline visit, to be eligible for the study, patients had to have a diagnosis of hypertension, a current prescription for an antihypertensive medication, and a current prescription for an antidepressant. To include as many persons who were willing and able to participate as possible we chose to include patients with a range of depressive symptoms reflecting the concept of

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**Figure 1: Conceptual Framework From Cooper et al\(^7\)**

- Hypertension
- Depression
  - Function
  - Cognition
  - Social support
  - Cost of medications
  - Side effects
  - Past experiences
  - Ethnicity, Age, Gender, Education
- Integrated Care
  - Adherence to depression treatment
  - Depression outcome
- Adherence to hypertension treatment
  - Blood pressure control
- System-level factors such as physician and structural factors
### Table 1: Intervention Approaches to Addressing Nonadherence

<table>
<thead>
<tr>
<th>Factor</th>
<th>Approaches to Addressing Nonadherence</th>
</tr>
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</table>
| Depression                   | • Discuss importance of taking antidepressants to better address factors leading to hypertension  
                                 | • Emphasize duration of adequate adherence needed for optimal effect                                                                                                  |
| Hypertension                  | • Assess whether symptoms such as fatigue are attributed to medications, chronic conditions, or underlying depression in collaboration with physician  
                                 | • Help patient develop a system to refill medications before they run out                                                                                            |
| Function                      | • Make suggestions such as involving a family member, asking pharmacist for larger labels or easily opened medication bottles  
                                 | • Facilitate communication with the physician and pharmacist                                                                                            |
| Cognition                     | • Involve family members in developing cognitive aids  
                                 | • Encourage placement of prompts in the home as time cues in relation to routine activities (eg, tooth brushing at arising) for taking medications  
                                 | • Help create memory tools to prevent forgetting to take doses                                                                                                  |
| Cost of medications           | • Serve as liaison between patient and physician to evaluate generic alternatives to medications, free samples, filling out the necessary forms to get free medications from pharmaceutical companies  
                                 | • Assist patient in navigating and understanding Medicare Part D                                                                                                  |
| Side effects of medications   | • Discuss expected adverse effects of antihypertensives and antidepressants and emphasize that side effects might be worse when first starting a medicine and often ease up over time for patients beginning a new medication  
                                 | • Provide medication-specific information on effects and discuss potential treatment options for adverse effects  
                                 | • Discuss side effects with physician including alternatives to medication if patient is experiencing unwanted effects                                                                 |
| Past experiences              | • Elicit past experiences and provide information and encouragement  
                                 | • Discuss concerns based on past experiences with physician                                                                                                  |
| System level factors (physician and structural) | • Inform physician of patients’ progress or difficulties  
                                 | • Suggest changes in medication prescriptions (eg, if a medication dosage is low, and patient has poor blood pressure control, an increase in dosage will be recommended)  
                                 | • Communicate with physicians using various strategies adapted to each physician’s style (eg, physicians may prefer to receive e-mails)                                                                 |

the relapsing, remitting nature of depression in primary care. Of those approached, 60 (47.24%) provided consent for screening, completed enrollment procedures, and were randomly assigned by the flip of a coin to an integrated care intervention (n=30) or to usual care (n=30). Physicians were told which patients were enrolled in the integrated care intervention to allow for collaboration with the LPN but were blinded to enrollment in the usual care group.

**Intervention**

The intervention consisted of three 30-minute in-person sessions carried out by LPNs during a 12-week period. Two LPNs attended six 1-hour training sessions on site to ensure feasibility in primary care settings. LPNs received specialized training in relation to pharmacotherapy for depression and hypertension management including the assessment of side effects as well as monitoring of symptoms. While under the supervision of the principal investigator, the LPNs conducted mock study activities with two participants and thereafter received ongoing weekly supervision for all study activities. Guided by our conceptual model (Figure 1), the intervention involved the patient, physician, and LPNs working together to set and modify goals as needed. LPNs collaborated with physicians to offer education to patients, guideline-based treatment recommendations, and to monitor adherence and clinical status. The LPNs were trained in a problem-solving process that included identifying and defining the problem, resulting in nonadherence and brainstorming about potential solutions. The brainstorming activities allowed for the patient and LPN to both suggest options to be considered for implementation. Encouragement was offered as needed, for example, by reminding the patient of the goals of treatment or the rationale for continuing to take an antidepressant medication when one feels much improved (or when one does not feel better yet) and for continuing to take an antihypertensive medication when one doesn’t have any symptoms. The key components of this integrated care intervention were (1) provision of an individualized program to improve...
adherence to antidepressants and antihypertensives (Table 1), and (2) integration of depression treatment with hypertension management. The intervention was presented to patients as a supplement to, rather than a replacement for, existing primary care treatment. Specific treatment intensification decisions and primary responsibility for the treatment of depression and hypertension remained with the physicians. The patients continued to receive regular care from their primary care physician and other medical specialists. The LPNs had relationships with patients and physicians developed over many years and therefore had a unique understanding of the health care needs of the patients and the workflow of primary care practice.

Usual Care
At baseline, 6 weeks, and 12 weeks, patients underwent the same assessments as patients in the integrated care intervention. Assessments were conducted in-person (as were assessments in the integrated care intervention). The PI randomly monitored 25% of sessions conducted weekly to ensure that there was no carry-over of the intervention into the usual care group. Research assistants conducted all assessments blinded to patient’s randomization status.

Measurement Strategy
Potential study patients were screened for cognitive impairment using the Mini-Mental State Examination (MMSE), a short standardized mental status examination widely used for clinical and research purposes. The MMSE was used to evaluate cognitive impairment (defined as MMSE<21). Patients were asked whether they resided in a care facility that provided their medications on schedule. At baseline, sociodemographic characteristics were assessed using standard questions. Blood pressure and depressive symptoms were measured at baseline and 12 weeks. Blood pressure was assessed in accordance with American Heart Association Guidelines using the BPTru. The BPTru is an automated device that avoids observer bias and unlike the traditional mercury technique, is an oscillometric monitor that takes six consecutive blood pressure readings and is designed for clinical settings. The BPTru drops the first reading and averages the remaining five. Depressive symptoms were measured using the nine-item Patient Health Questionnaire (PHQ-9). The PHQ-9 is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. The PHQ-9 depression module, which scores each of the nine DSM-IV criteria as “0” (not at all) to “3” (nearly every day), is a reliable tool for screening and monitoring designed for primary care settings.

Analytic Strategy
We compared characteristics of patients at baseline in the integrated care intervention or usual care using the t test and Fisher’s exact test (for continuous or categorical variables as appropriate). In addition, characteristics of patients who refused were compared to enrolled participants in the study using t tests and Fisher’s exact tests. Blood pressure and depressive symptoms were compared in the intervention group and usual care groups at 12 weeks using linear regression. Covariates included in the models were baseline measures (systolic blood pressure, diastolic blood pressure, or PHQ-9) and intervention condition. For each outcome, systolic blood pressure, diastolic blood pressure, and depressive symptoms, we calculated a mean group difference with a 95% confidence interval from a linear regression model adjusting for baseline values. Analysis was conducted using SPSS version 12.0 (SPSS, Chicago). We used a level of statistical significance set at α=.05, recognizing that tests of statistical significance are approximations that serve as aids to interpretation and inference.

Results
Sample Characteristics
Patients ranged from 41 to 92 years old, with an average age of 67.1 years (SD=11.0 years). Thirty-nine (65.0%) of the 60 patients were women. In all, 30 (50.0%) self-identified as white, 23 (38.3%) patients self-identified as black/African-American, six (10.0%) self-identified as Hispanic/Spanish, and one (1.7%) self-identified as Asian/Pacific Islander. Characteristics of patients in the integrated care intervention did not differ significantly from patients in the usual care group (Table 2). There were no statistically significant differences in characteristics of patients who agreed to participate in the study and those who did not. All patients attended the required sessions at baseline, 6 weeks, and 12 weeks. The amount of time the LPNs spent with each patient was approximately 90 minutes over the 12-week period.

Outcomes
Patients in the integrated care intervention had lower diastolic blood pressure (intervention 74.2 mmHg versus usual care 82.0 mmHg, P=.035) and fewer depressive symptoms (PHQ-9 mean scores, intervention 2.4 versus usual care 7.1, P<.001) compared with patients in the usual care group at 12 weeks after adjustment for baseline values. Patients in the integrated care intervention also had lower systolic blood pressure (intervention 130.0 mmHg versus usual care 140.6 mmHg, P=.079) compared with patients in the usual care group at 12 weeks although the results approached but did not reach conventional levels of statistical significance (Table 3).

Discussion
The primary goal of this preliminary study was to examine whether an intervention carried out by LPNs integrating depression treatment into care for hypertension improved blood pressure control and depressive symptoms. Primary care patients
randomized to an integrated care intervention in comparison with patients randomized to usual care showed lower diastolic blood pressure and fewer depressive symptoms at the final study visit (12 weeks). Although not statistically significant, patients randomized to the integrated care intervention also experienced lower systolic blood pressure in comparison with usual care at the final study visit. Primary care visits have multiple competing demands, including prevention, acute care, chronic care, and addressing the psychosocial needs of patients. Our results offer support for the usefulness of an LPN approach to extend the primary care team’s ability to improve outcomes for hypertension and depression.

Before discussing the implications of the findings for our next steps, the limitations require discussion. First, our results were obtained from patients who receive care at one primary care site that might not be

### Table 2: Sample Characteristics at Baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n=30)</th>
<th>Usual Care (n=30)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (SD)</td>
<td>68.3 (7.3)</td>
<td>65.8 (9.7)</td>
<td>.38</td>
</tr>
<tr>
<td>Ethnicity, African American, n (%)</td>
<td>12 (40.0%)</td>
<td>11 (36.7%)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Gender, women, n (%)</td>
<td>21 (70.0%)</td>
<td>18 (60.0%)</td>
<td>.59</td>
</tr>
<tr>
<td>Less than high school education, n (%)</td>
<td>3 (10.0%)</td>
<td>3 (10.0%)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Other covariates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker, n (%)</td>
<td>3 (10.0%)</td>
<td>8 (26.7%)</td>
<td>.18</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>14 (46.7%)</td>
<td>19 (63.3%)</td>
<td>.30</td>
</tr>
<tr>
<td>Number of blood pressure medications, n (%)</td>
<td>1.9 (1.3)</td>
<td>1.5 (0.9)</td>
<td>.20</td>
</tr>
<tr>
<td>MMSE, mean (SD)</td>
<td>28.2 (2.5)</td>
<td>28.4 (2.2)</td>
<td>.67</td>
</tr>
<tr>
<td>Dyslipidemia, mean (SD)</td>
<td>24 (80.0%)</td>
<td>24 (80.0%)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Outcome measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mean (SD)</td>
<td>133.6 (17.6)</td>
<td>139.4 (14.9)</td>
<td>.17</td>
</tr>
<tr>
<td>Diastolic blood pressure, mean (SD)</td>
<td>76.5 (10.4)</td>
<td>76.4 (11.6)</td>
<td>.98</td>
</tr>
<tr>
<td>PHQ-9, mean (SD)</td>
<td>4.1 (5.1)</td>
<td>5.8 (5.3)</td>
<td>.21</td>
</tr>
</tbody>
</table>

**Table 3: Blood Pressure and Depression Symptoms of Patients in the Integrated Intervention and in Usual Care at 12 Weeks**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention (n=30)</th>
<th>Usual Care (n=30)</th>
<th>P Value</th>
<th>Mean Difference (95%, CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic, mean (SD)</td>
<td>130.0 (19.8)</td>
<td>140.6 (17.0)</td>
<td>.079</td>
<td>-8.1 (-17.1, .97)</td>
</tr>
<tr>
<td>Diastolic, mean (SD)</td>
<td>74.2 (13.6)</td>
<td>82.0 (15.7)</td>
<td>.035</td>
<td>-7.5 (-14.4, -.55)</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9, mean (SD)</td>
<td>2.4 (3.2)</td>
<td>7.1 (5.5)</td>
<td>&lt;.001</td>
<td>-3.9 (-5.9, -1.9)</td>
</tr>
</tbody>
</table>

CI—confidence interval
SD—standard deviation
PHQ-9—nine-item Patient Health Questionnaire
* Mean group difference (95% CI) from a linear regression model adjusting for baseline values.
representative of most primary care practices. However, this practice was community based and probably similar to other primary care practices in the region. Second, our preliminary investigation was limited to 60 patients, but patients were randomized to the intervention or usual care. Therefore, a strength of our trial design is the inclusion of a control group. Third, we did not have information on the duration of depression or the duration of anti-depressant treatment so we were unable to adjust our measures of association for these variables. However, we did adjust our analyses for PHQ-9 score as a measure of severity of depression at baseline. Fourth, our preliminary investigation was limited to 60 participants, but participants were randomized to the intervention or usual care. Fifth, we did not have information on process measures such as exact time spent per patient, number of provider visits including visits to specialists, and cost of the intervention. Sixth, a potential limitation to these study results is the lower baseline systolic blood pressure and depressive symptoms in the intervention group. To compensate for the baseline differences, we adjusted our models for baseline values of systolic blood pressure, diastolic blood pressure, and depressive symptoms. Finally, our intervention would require additional training of LPNs in primary care settings. However, we have designed a simple intervention, and training existing primary care practice office staff will facilitate future implementation and dissemination.

Despite the limitations of this study, our results deserve attention because previous intervention trials in primary care using existing primary care practice office staff have addressed mental health (eg, depression) and physical health (eg, weight loss) separately. In our intervention, we integrated depression treatment into care for hypertension so a single program could assist patients with depression and hypertension. We seek to help close the gap between the development of new, research-tested interventions and their widespread use by those most in need. Consistent with our hypothesis, patients randomized to the integrated intervention had lower diastolic blood pressure and fewer depressive symptoms. Our findings of lower systolic blood pressure among patients randomized to the integrated intervention approached but did not reach statistical significance in our final models. Our results may have been due to the high rate of blood pressure control at baseline. However, overall the findings support the hypothesis that an integrated intervention carried out by LPNs can improve clinical outcomes and support an expanded role for an LPN. Increasing and redefining the roles of nonphysician staff in a community-based practice successfully improved outcomes for both physical and mental health.

Of note, this intervention had a high retention rate of study patients. Many patients were willing to enroll and once enrolled all the patients completed the follow-up visits. These findings are aligned with recent findings that primary care patients are more likely to be engaged when mental health is integrated into care for physical health than other forms of care provision, and integrated care models are particularly effective in improving access to and participation in mental health services among African American primary care patients. In addition, the LPNs’ relationships with patients and physicians developed over many years may have played a role in our high retention rate.

Our study provides a possible solution that can be implemented in primary care for patients being treated for both mental and physical health. We evaluated the effectiveness of a relatively brief pilot randomized controlled trial carried out by LPNs with a focus on adherence for the management of hypertension as well as depression in primary care. We designed our study carefully to not place excessive demands on a community-based primary care practice. Because of limited resources in primary care, simple and brief interventions are not only more acceptable to patients but are needed to achieve cost containment. Redefining the roles of nonphysician staff such as LPNs is a promising alternative allowing physicians to focus on issues specifically requiring their knowledge and skills. Integrated interventions carried out by nonphysician staff as part of the primary care team may be more feasible and effective in real world practices with competing demands for limited resources. Further research is needed to evaluate this intervention in a larger, more representative sample, with longer periods of follow-up.

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