

Nurse Management for Hypertension

A Systems Approach

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Background: Standard office-based approaches to controlling hypertension show limited success. Such sub-optimal hypertension control reflects in part the absence of both an infrastructure for patient education and frequent, regular blood pressure (BP) monitoring. We tested the efficacy of a physician-directed, nurse-managed, home-based system for hypertension management with standardized algorithms to modulate drug therapy, based on patients' reports of home BP.

Methods: We randomized outpatients requiring drug therapy for hypertension according to the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) criteria to receive usual medical care only (UC, $n = 76$) or usual care plus nurse care management intervention (INT, $n = 74$) over a 6-month period.

Results: Patients receiving INT achieved greater reductions in office BP values at 6 months than those receiving

UC: 14.2 ± 18.1 versus 5.7 ± 18.7 mm Hg systolic ($P < .01$) and 6.5 ± 10.0 versus 3.4 ± 7.9 mm Hg diastolic, respectively ($P < .05$). At 6 months, we observed one or more changes in drug therapy in 97% of INT patients versus 43% of UC patients, and 70% of INT patients received two or more drugs versus 46% of UC. Average daily adherence to medication, measured by electronic drug event monitors, was superior among INT subjects (mean \pm SD, $80.5\% \pm 23.0\%$) than among UC subjects ($69.2 \pm 31.1\%$; $t_{113} = 2.199$, $P = .03$). There were no significant adverse drug reactions in either group.

Conclusions: Telephone-mediated nurse management can successfully address many of the systems-related and patient-related issues that limit pharmacotherapeutic effectiveness for hypertension. Am J Hypertens 2004;17:921-927 © 2004 American Journal of Hypertension, Ltd.

Key Words: Hypertension, nurse management, home-based management.

The control of blood pressure (BP) remains a major challenge in clinical practice. Only half of those individuals with hypertension receive the diagnosis, and only half of these achieve BP goals established by the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC VI) and other scientific organizations.^{1,2} Contributing factors for the failure to achieve goal BP cluster as patient related, provider related, and system related. Patient factors include medication side effects, drug regimen complexity, and unawareness of the need for long term therapy.³ Physician-linked issues may involve timely access to relevant clinical data, ignorance of evidence-based management guidelines, and sense of nonaccountability for patient outcomes. The system-related factors reflect little if any attention or resources to design, implement,

evaluate, and refine systems for guiding individual and groups of patients. Specialized hypertension clinics staffed by nurses have shown significant improvements in hypertension control compared with usual care.⁴⁻⁶ The present study extends the model of nurse management to home-based treatment.

Methods

Study Population

We conducted a randomized controlled trial in which patients received either usual care alone (UC) or usual care supplemented by nurse management for hypertension (INT). For initial screening purposes we defined hypertension as BP ≥ 140 mm Hg systolic or ≥ 90 mm Hg diastolic, recorded in the medical record at least once in the previous

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6 months, or a history of drug treatment for hypertension. In addition, patients had to be eligible for hypertensive drug therapy according to JNC VI criteria.² Clinical risk criteria assessed the presence of coronary risk factors (smoking, dyslipidemia, or diabetes mellitus), age >60 years, or a family history of premature cardiovascular disease or target organ damage. According to JNC VI criteria,² only patients with elevation of BP to levels greater than 140 to 159 mm Hg systolic and/or 90 to 99 mm Hg diastolic are considered eligible for BP lowering drug therapy. We adopted a more stringent BP threshold for hypertension: 150 mm Hg systolic, 95 mm Hg diastolic, or both.

Baseline BP Measurement

During the baseline clinic visit, before randomization, the nurse care manager measured BP with a mercury sphygmomanometer using the arm with the higher reading as the "reference" arm for all subsequent BP recordings. The nurse used a second BP measurement, taken 5 min later, to establish the mean baseline BP. For study entry, subjects needed the mean of two BP values to be $\geq 150/95$ mm Hg on two screening visits conducted on separate days at least 1 week apart.

Sampling

We screened a total of 1580 patients, finding 743 (47%) who were ineligible because they lacked the risk factors specified by the JNC VI or had major medical comorbidity. An additional 603 (40%) either could not be contacted or refused participation after contact, and 84 (5%) had mean baseline BP values below the criterion of 150 mm Hg systolic or 95 mm Hg diastolic. We ended with 150 patients, representing 10% of the screened population, for randomization.

Recruitment and Randomization

The same research staff implemented the same protocol for screening and enrollment of patients at each of two participating medical clinics, the Kaiser Permanente Mountain View Clinic and the Primary Care Clinics of the Stanford University Medical Center in California. We identified patients by physician referral or review of medical records. Patients received a postcard indicating their physician's knowledge of the study and inviting study participation. Research staff telephoned patients to establish their medical eligibility and willingness to participate in the study.

After establishing eligibility, patients gave written informed consent and underwent randomization using computer-generated assignment. All patients provided baseline measurements of nonfasting blood urea nitrogen, creatinine, glucose, and potassium. These measurements guided drug therapy. At 3 and 6 months after randomization, a research assistant blinded to group assignment measured

clinic BP and interviewed patients about medications taken since the previous visit.

Nurse Management Protocol

The nurse care manager conducted baseline counseling on intervention (INT) patients' correct use of the automated BP device, regular return of the automatically printed BP reports, tips for enhancing drug adherence, and recognition of potential drug side effects. Printed materials extended this instruction, and patients confirmed their ability to operate the BP device. The nurse initiated follow up phone contacts at 1 week and at 1, 2, and 4 months. The calls averaged 10 min in duration, or 40 min in all. During phone contacts, the nurse asked INT patients about each medication dosage and any problems experienced since the previous contact. The nurse also encouraged patients to telephone anytime during regular hours with questions or concerns.

The nurse care manager contacted physicians to obtain permission to initiate any new BP drug but did not contact physicians regarding changes in medication dosage. Changes in drug therapy were categorized as either an increase (a drug added or dose of drug increased) or as a decrease (a drug withdrawn or dose of drug decreased). The nurse care manager implemented a management algorithm based on patients' current medications, laboratory values, and BP measurements.

From prior studies, systolic pressures measured at home generally run about 10 mm Hg lower than those measured in the office, and diastolic pressures are approximately 5 mm Hg less.⁷ Accordingly, we chose a treatment goal of 130/85 mm Hg, as measured with the home BP device over a 2-week period.^{8,9} When 80% of the home BP readings achieved this treatment goal, the nurse made no further changes in drug therapy. When <80% of measurements met this criterion, the nurse increased drug dosage to the maximal level recommended for each drug or added one or more additional drugs in accordance with the protocol. The project cardiologist consulted by phone with the nurse care manager about problematic cases as needed.

Measurements of BP

We used the same semiautomated portable device to measure BP at home and during each clinic visits. This device (UA 751; A&D, Milpitas, CA), validated with a random zero mercury sphygmomanometer,¹⁰ provided a digital display of BP values. At the end of each week, the device generated a printed report of up to 14 measurements. Patients recorded BP twice-daily at the same times each day. Every 2 weeks, patients mailed the values printed by the BP device to the nurse care manager, who used these BP data to guide drug therapy.

Physician Review of Protocol

Before the study, the investigators met with the medical staffs at the two sites to discuss the study protocol and management algorithm, based on the JNC VI report,² that were used by the nurse care manager for INT patients. After the 6-month clinic visit, all physicians received a final report of their patients' medications and BP values. The Stanford University institutional review board reviewed and approved the project protocol.

Usual care patients in both groups continued to receive the routine care that they had received before the study. No attempt was made to alter the frequency of office visits or any other aspect of doctor-patient interactions. Only patients randomized to nurse management received portable BP monitors.

Patient Monitoring

Patients in both groups returned to the clinic at 3 and 6 months for BP measurements, which were performed by study staff blinded to group assignment. Patients in both groups received instruction in the use of the electronic drug event monitor (eDEM; AARDEX-USA, Union City, CA). Each monitor contained a microchip in the pill bottle lid^{11,12} to dispense the BP medication used most frequently. At 3- and 6-month clinic visits, project staff downloaded the data from the electronic drug event monitor but provided no feedback on drug adherence to patients, physicians, or nurse care managers.

Statistical Analysis

The primary outcome measure was change in BP from baseline to 6-month visit, considering both systolic and diastolic BP and using a wall-mounted clinic sphygmomanometer. The primary statistical analysis was a two-sample *t* test comparing the change in BP measured between baseline and 6 months. We performed secondary analyses of BP medication, frequency of drug changes, and adherence to medication with the Student *t* test. The level of significance was a two-sided probability value of $P < .05$.

Results

Population Characteristics

The two patient samples, representative of hypertensive patients in the two participating clinics, exhibited similar sociodemographic and clinical characteristics, so data were pooled (Table 1). Patients were typically of middle age, high educational status, and modest rates of cardiovascular comorbidities. The usual care only (UC) and usual care plus nurse care management intervention (INT) randomization successfully produced similar groups except for higher rates of married status and dyslipidemia among usual care patients. A total of 13 patients (9%), eight in the UC group and five in the intervention group, did not return for the 6-month visit and were classified as dropouts. Five of the eight dropouts in the UC group

Table 1. Study Population

	Usual Care (n = 76)	Intervention (n = 74)
Sex		
Female (% of total)	56	50
Age (y; mean ± SD)	60 ± 9	59 ± 10
Marital status* (%)		
Married	80	60
Divorced	8	15
Separated	2	5
Widowed	4	3
Single	6	17
Ethnicity (%)		
White	72	76
African American	8	11
Asian American	4	4
Hispanic	8	1
Other	8	8
Educational status (%)		
Some high school	5	5
High school graduate	19	17
Some college	23	24
College degree	31	27
Postdoctoral degree	22	27
Occupational status (%)		
Full time	51	49
Part time	7	7
Disabled or unemployed	4	4
Retired	32	32
Other	6	8
Coronary risk factors (%)		
Dyslipidemia*	30	16
Current smoker	2	4
Diabetes	14	14
Family history of CAD	18	22
CAD	4	8
Cerebrovascular Disease	5	10

CAD = coronary artery disease.

* $P < .05$ by χ^2 analysis.

moved out of the area; the remainder declined to return for the 6-month follow-up visit. Two of the INT patients experienced difficulty in using the BP device and declined continued participation; three moved out of the area.

Patterns of BP

The UC and INT groups displayed similar patterns of baseline BP: 36% had elevation of both systolic and diastolic pressure, 55% had elevation of systolic pressure only, and 9% had elevation of diastolic pressure only. Between baseline and 6 months, systolic BP fell by 14.2 mm Hg in the INT group (95% CI -18.1 to -10.0) and by 5.7 mm Hg in the UC group (95% CI -10.2 to -1.3; $P < .01$). One-way ANOVA confirmed significant decreases in both systolic ($F_{2,12} = 17.30$; $P < .01$) and diastolic BP ($F_{2,12} = 6.22$; $P < .01$) among INT patients but nonsignificant changes among UC patients. Figure 1 depicts changes in office-based systolic BP.

Between baseline and 6 months, diastolic BP fell by 6.5 mm Hg in the intervention group (95% CI -8.8 to -4.1)

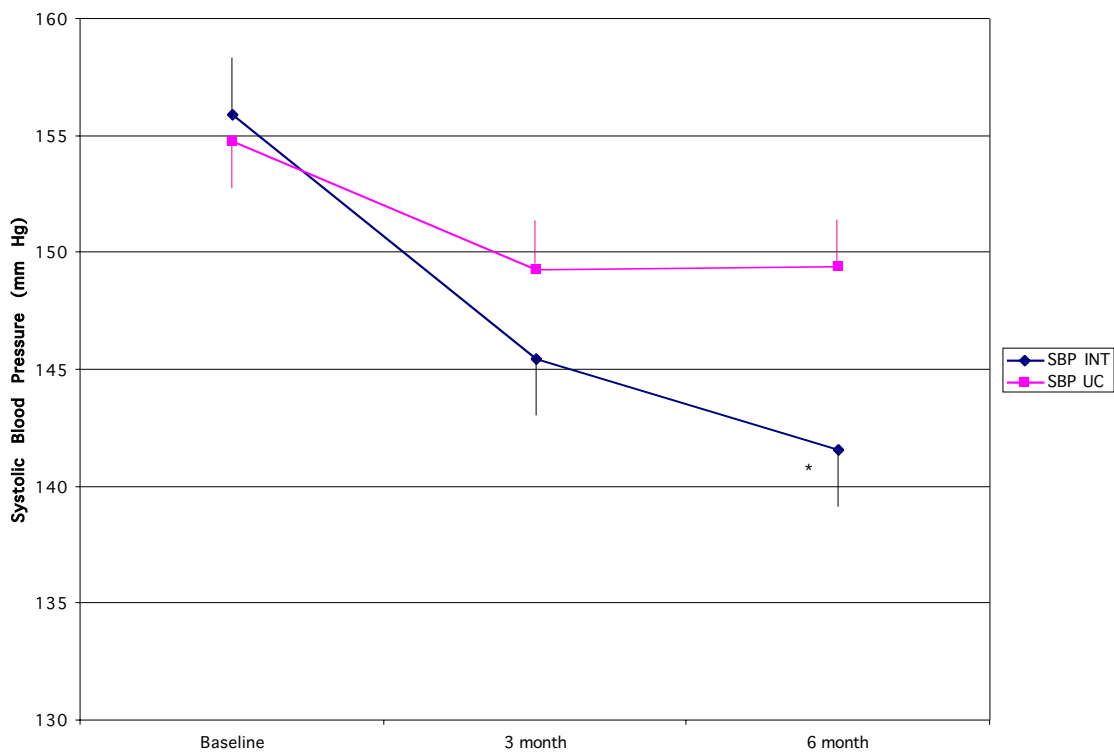


FIG. 1. Change in office-based systolic blood pressure (SBP). INT = usual care plus nurse care management intervention; UC = usual care only.

and 3.4 mm Hg in the UC group (95% CI of -5.3 to -1.5 , $P < .05$). Figure 2 depicts changes in office-based diastolic BP.

Blood pressure measured with the mercury sphygmomanometer during clinic visits averaged 1 to 2 mm Hg higher than that measured with the semiautomated device.

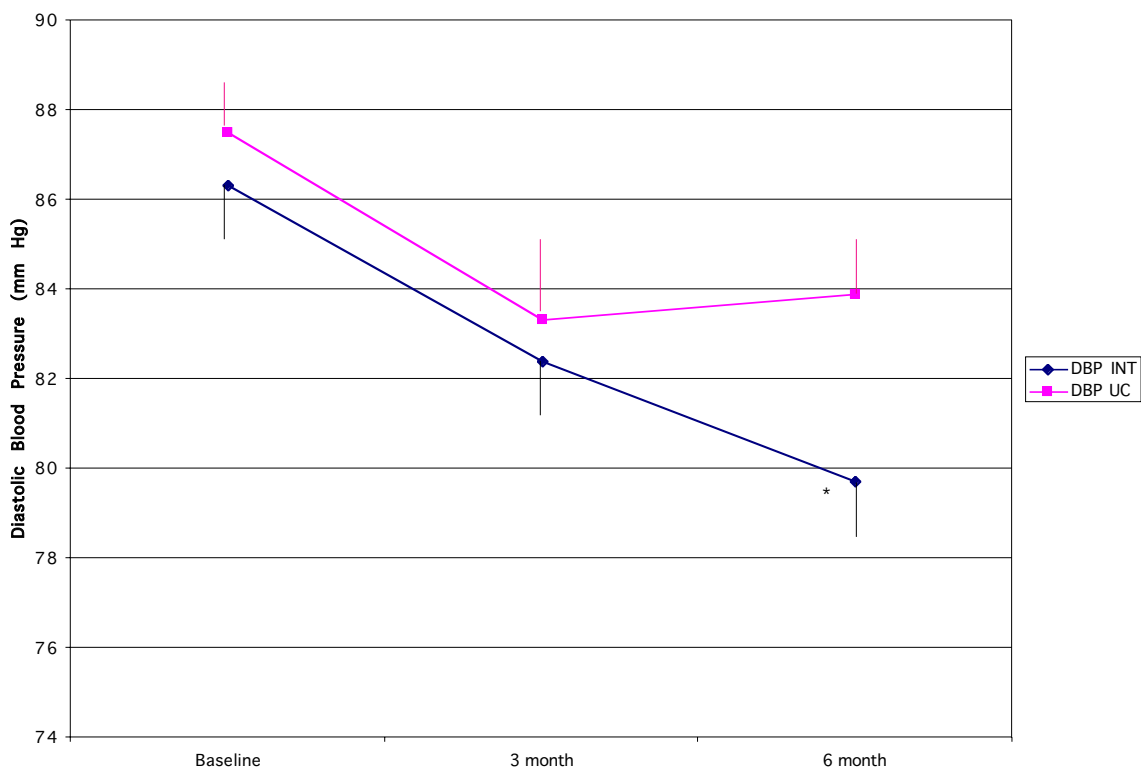


FIG. 2. Change in office-based diastolic blood pressure (DBP). INT = usual care plus nurse care management intervention; UC = usual care only.

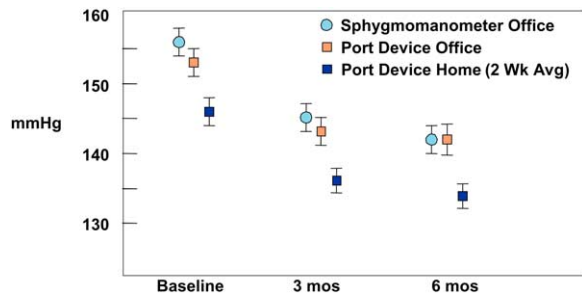


FIG. 3. Office versus home-based systolic blood pressure: intervention patients only.

Blood pressure measured at home over a 2-week period using the semiautomated device was approximately 10 mm Hg lower than that measured with the same device during clinic visits. This pattern was consistent throughout the 6 months of the study.

Figure 3 summarizes differences between office versus home-based systolic BP. The INT subjects performed most scheduled home BP measurements (range 89% to 94%). Systolic and diastolic BP measured at home fell rapidly during the first 3 months of the study and remained relatively constant through month 6.

Antihypertensive Medications

Patients in both INT and UC groups reported similar numbers of BP medications at baseline. At baseline, 22% of intervention patients and 30% of UC patients were taking no BP medications (NS). By 6 months, INT patients had significantly increased the number and variety of antihypertensive medications. The proportion of patients reporting two or more drugs at 6 months was 70% and 46%, respectively, among INT and UC patients. Similarly, the proportion of patients reporting no drug therapy at 6 months was 4% and 22%, respectively, among INT and UC subjects ($P < .01$). The maximal dose of each individual medication was similar in the two groups.

Figure 4 summarizes the pattern of medication use in the study subjects. The distribution of medications re-

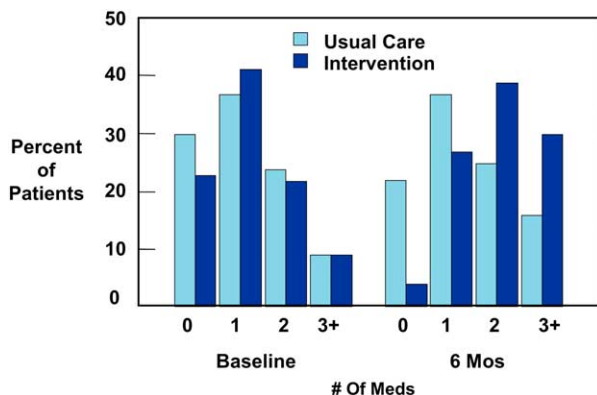


FIG. 4. Pattern of medication use.

mained similar in both groups at baseline and at 3 and 6 months. The proportion of patients taking angiotensin-converting enzyme inhibitors, diuretics, β -blockers, and calcium blockers approximated respectively 40%, 25%, 20%, and 15% at the three assessment points. Among UC patients, 43% reported one or more changes in drug therapy during the 6-month study period, mostly initiated during office visits. In contrast, the rate of patients reporting changes in drug therapy was more than doubled (97%) among those receiving nurse management. Most therapy changes among INT patients arose from scheduled phone contacts. The number of medication changes (mean \pm SD) reported by UC patients was 52 ± 1 (mean 0.69 changes/patient). The INT patients noted 223 ± 6 medication changes (mean 2.97 changes/patient; $P < .01$). Less than 5% of treatment decisions made by the nurse care manager required telephone discussion with a physician. Participating patients rarely telephoned the nurse care manager.

Medication Adherence

Drug adherence, tracked by the electronic drug event monitor, assessed daily adherence (that is, the average number of days on which patients took the correct number of doses as prescribed). The INT patients' rate of daily adherence during the 6-month study period was $80.5\% \pm 23.0\%$ (mean \pm SD, with 25th and 75th percentile values 77% to 95%), whereas the rate of UC patients was $69.2\% \pm 31.1\%$ (25th and 75th percentile values 50% to 93%; $t_{113} = 2.199$, $P = .03$).

In both groups, once-daily regimens yielded higher daily adherence rates than for more frequent dosing. The respective adherence rates were $82\% \pm 28\%$ and $75\% \pm 27\%$ for once-daily dosing and $69\% \pm 34\%$ and $49\% \pm 41\%$ for twice-daily or more than twice-daily dosing in the INT and UC groups. None of these differences reached statistical significance.

Discussion

In this randomized controlled trial, we found that home-based, physician-directed, nurse-guided drug therapy proved superior in BP control to standard office-based management among eligible hypertensive patients by JNC VI criteria. The size of achieved reductions in systolic and diastolic BP approximate those reported for intensive interventions in other trials.¹³ Pill-taking adherence by the electronic drug event monitor remained high in both groups but reached statistically higher levels among INT subjects. The greater variety of BP drugs, the greater proportion of patients on antihypertensive therapy, and the progressive medication adjustment contributed to the superior INT outcomes.

Most hypertension management studies reflect ambulatory settings.¹⁴⁻¹⁶ Inauspicious characteristics include large numbers of patients, diverse comorbidities, no consistent standards for antihypertensive management, and providers' nonaccountability for clinical outcomes. Ber-

lowitz et al¹⁴ reported that physicians defer changing drug therapy, even when BP remain elevated: “clinical inertia” from infrequent assessments, ignorance of established clinical guidelines, and distraction by unrelated medical priorities.¹⁷

The nurse management system in this study addressed some of the relevant obstacles. The system used external clinical guidelines (JNC VI²) to define entry criteria, treatment goals, preferred medications, and management of side effects. It closely linked ongoing surveillance of BP values and responsive changes in drug therapy. By periodic phone contacts, the nurse managers made timely medication changes, adjusting treatment intensity as needed. Over the 6-month trial, INT patients underwent more than four times the number of drug changes than UC patients and usually achieved control in less than 3 months. These results approximate those of Mehos et al applying pharmacists’ regulation of BP medications in a home-based intervention.¹⁸

Most prior studies of home BP measurement reported BP sampling over only a few days.⁷ In the present study, sampling twice daily over several months, commonly >300 measurements in all, offered more confidence about central tendency with day-to-day BP fluctuations. Home BP determinations closely approximated clinic BP with both portable device and mercury sphygmomanometer.

This study supports using home BP measurement as a reliable alternative to office BP measurement¹⁹ and suggests that it provides a more representative indicator of BP status, when the number of home determinations is large.^{20,21} The accuracy of clinic measurements may suffer from nonstandardized measurement and brief sampling. Training patients can standardize BP measurement¹⁹ and minimize so-called white coat effects.²²

The theoretical underpinning for the current study comes from social cognitive theory.²³ The behavioral model reflects self-regulation, enabling patients to differentially select health promoting behaviors. The core features of effective self-regulation of health habits include knowledge, self-monitoring, goal setting, and corrective self-regulation when most needed rather than at fixed intervals. Ongoing interactivity permits adjustment of interventions contingent on the progress being made.

This study assessed the efficacy of the home-based management system as a whole rather than the relative contribution of the various components: baseline instruction, patients’ measurement and reporting of home BP, modulation of drug therapy by standardized protocol, and systematic phone contacts. Despite its relative complexity, the management system was readily understood and accepted by physicians in both managed care settings (Kaiser) and fee-for-service academic settings (Stanford).

The study inescapably includes some limitations. The participating patients, given the larger recruitment pool, may be atypical in their willingness or ability to monitor home BP. By sociodemographic characteristics, the par-

ticipants represent an affluent and well educated cohort. The two clinical facilities are typical of similar settings, even if not representative of all primary care practices.

Several implications emerge for optimizing future antihypertensive management. Clinical inertia will likely continue in the absence of efforts toward standardization and accountability for outcomes. Individual clinicians—however devoted, knowledgeable, and skilled—may still fail to implement consistent and optimally effective guidelines of diagnosis, monitoring, and treatment adjustment. The present study provides a successful example of moving from general guidelines, as in JNC VI, to an operational protocol for nurses working with a consultant cardiologist.

Medical measurement devices for home use will soon permit guidance via the Internet similar to nurse-mediated case management. These technological innovations do not diminish the need for physicians’ active involvement in the creation, critical appraisal, and periodic refinement of management protocols. Physicians will remain vital to evaluating comorbid risk factors and to prescribing appropriate antihypertensive therapies.

The present care management system facilitates and expands the reach and scope of traditional health care by three interdependent means. First, it reduces the need for physicians to mediate the routine tasks of managing antihypertensive therapy. Second, the management system encourages physicians to focus their energies on problem cases, such as those individuals who fail to achieve satisfactory control. Third, the management system reinforces the value of collaboration among teams of health professionals. Formal study of such hypertension case management will likely confirm its cost-effectiveness.²⁴

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