

Mobile Phone–Based Remote Patient Monitoring System for Management of Hypertension in Diabetic Patients

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Background: Rising concern over the poor level of blood-pressure (BP) control among hypertensive patients has prompted searches for novel ways of managing hypertension. The objectives of this study were to develop and pilot-test a home BP tele-management system that actively engages patients in the process of care.

Methods: Phase 1 involved a series of focus-group meetings with patients and primary care providers to guide the system's development. In Phase 2, 33 diabetic patients with uncontrolled ambulatory hypertension were enrolled in a 4-month pilot study, using a before-and-after design to assess its effectiveness in lowering BP, its acceptability to users, and the reliability of home BP measurements.

Results: The system, developed using commodity hardware, comprised a Bluetooth-enabled home BP monitor, a mobile phone to receive and transmit data, a central server for data processing, a fax-back system to send physicians' re-

ports, and a BP alerting system. In the pilot study, 24-h ambulatory BP fell by 11/5 ($\pm 13/7$ SD) mm Hg (both $P < .001$), and BP control improved significantly. Substantially more home readings were received by the server than expected, based on the preset monitoring schedule. Of 42 BP alerts sent to patients, almost half ($n = 20$) were due to low BP. Physicians received no critical BP alerts. Patients perceived the system as acceptable and effective.

Conclusions: The encouraging results of this study provide a strong rationale for a long-term, randomized, clinical trial to determine whether this home BP tele-management system improves BP control in the community among patients with uncontrolled hypertension. Am J Hypertens 2007;20:942-948 © 2007 American Journal of Hypertension, Ltd.

Key Words: Blood-pressure monitoring, self-care, mobile phone, computers, handheld.

Uncontrolled hypertension is an ongoing challenge to health care systems worldwide. Blood pressure (BP) surveys in most countries show that $<25\%$ of patients with hypertension are under good BP control.¹ Cited reasons include patient-related factors, inadequacies of the health care system, and the clinical inertia of health care providers.²⁻⁴ Other barriers include type of hypertension, with lower control rates for systolic BP, and the presence of diabetes mellitus.⁵

One strategy to improve hypertension control in the community involves the use of specialized clinics.⁶ While effective, this approach partitions health care into undesirable silos and is neither cost effective nor practical for highly prevalent conditions such as hypertension and diabetes mellitus. As a consequence, new health care delivery models that promote patient self-management and incorporate advanced communication systems are being developed and tested.⁷ Recent surveys indicate that patients are

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willing to become more actively involved in managing their own care,⁸ and that self-monitoring at home is one way to increase their involvement.⁹

A wide assortment of health care aids designed for the home is now available.¹⁰ For hypertension, they range from simple home BP monitoring devices to sophisticated tele-management systems.^{11,12} Experience with these aids to improve BP control has not been encouraging. Lack of reliable home BP monitoring devices, the need for wired connections of tele-management systems, the challenges of the Internet (especially for older individuals), the disruption of a normal workflow pattern for physicians, and the lack of direct communication with patients have greatly limited their effectiveness and contributed to their low level of adoption by physicians and patients.¹³ New solutions are required.¹⁴

This study describes the development and pilot-testing of a mobile phone-based remote patient monitoring system to improve BP control of hypertensive patients with diabetes. The system was developed (Phase 1) using an iterative process based on feedback from users. A pilot study (Phase 2) was undertaken to assess the system's effectiveness in improving BP control in diabetic patients with uncontrolled hypertension, its acceptability to users, and the reliability of home BP measurements.

Methods

Phase 1: Designing the Home BP Tele-Management System

Two sets of focus groups were held with patients and family physicians to gather information about their experience with diabetes and hypertension and to seek their opinions about the concept of a home BP tele-management system and its design. In each set, 24 hypertensive type 2 diabetic patients and 18 family physicians were interviewed in one of four group sessions. Each session, lasting approximately 2 h, was led by a trained professional who used a semistructured interview guide. Sessions were recorded, transcribed, and analyzed with the assistance of the data-management software program QRS NVivo 2.¹⁵ The design principles of the system were derived from these sessions.

Phase 2: Pilot Study of the System

In the pilot study, 33 type 2 diabetic patients with uncontrolled ambulatory BP (24-h ambulatory BP, $\geq 130/80$ mm Hg) were recruited from the practices of 25 family physicians. Staff at four Diabetes Education Centers in the greater Toronto area identified potentially eligible patients, introduced them to the study, determined their willingness to participate, and obtained the names of their family physicians. The family physicians were contacted, and if they also agreed to participate in the screening, 24-h ambulatory BP monitoring was performed to determine patient eligibility.

For eligible patients, special training sessions were held to teach them the correct measurement technique that was

demonstrated to improve accuracy.¹⁶ Patients were asked to take two consecutive BP readings in the morning and evening at a minimum of 2 days per week for 4 months. If the number or time of measurements did not correspond to the expected schedule, they received automated adherence reminders. Patients' physicians had the option of increasing the number of monitoring days per week.

"High" and "low" BP alerts for patients were pre-established. The threshold values for "high" BP alerts were an average of four consecutive readings $>180/110$ mm Hg or a 2-week average BP $>160/100$ mm Hg. The levels for "low" BP alerts were an average of four consecutive readings $<90/50$ mm Hg or a 2-week average BP $<110/60$ mm Hg. Patients automatically received BP alert messages requesting additional readings if their BP exceeded these threshold values. Action messages (eg, to set up an appointment with their physician) were sent if their BP remained persistently elevated or low.

Threshold values for critical BP alerts were established at the baseline visit of patients with their physicians. Critical alerts were sent automatically by fax to the physician if the average of 12 consecutive readings measured over a 3-day period exceeded the preset threshold values (default values, $>180/110$ mm Hg and $<90/50$ mm Hg). At any office visit, a patient's physician had the option of changing the threshold values for critical BP alerts.

Patients were instructed to call the day before their appointment to generate an automated fax report to their physician. Treatment of the patient was at the discretion of the attending physician.

Although the mobile phones provided to patients were dedicated to the study, they could be used as regular phones by the patients, eg, to call the study center for technical assistance. Communication fees were covered by the research funding.

The outcome measures of the pilot trial study were:

- Change in 24-h ambulatory and 2-week average home BP readings from baseline
- Control rate of BP, defined as 24-h ambulatory BP of $<130/80$ mm Hg and 2-week average home BP of $<130/80$ mm Hg
- Adherence to the measurement schedule, expressed as a percentage of readings expected based on the preset schedule and also as a function of the number of adherence reminders sent
- The number and types (high or low) of BP alerts sent to patients
- Patients' perceptions of the BP tele-management system, assessed during a semistructured qualitative interview at the end of the study in a sample of 20 patients

Mean values (\pm SD) for continuous variables, and percentages for categorical variables, were computed. Using SAS software version 8.1 (SAS Institute, Cary, NC), paired Student's *t* (two-tailed) and McNemar χ^2 tests were performed for inference analysis. An intraclass correlation

coefficient test was used to determine the reliability of home BP measurements, using a random-effects model.

The Research Ethics Boards of Mount Sinai Hospital and the University Health Network (both in Toronto, Ontario, Canada) reviewed and approved both phases of the protocol, and written, informed consent was obtained from participants.

Results

Phase 1

During the focus-group meetings, patients were enthusiastic about the self-care aspects of the proposed system, were confident in their ability to use it, and were comfortable using a mobile phone. They were less familiar with a personal digital assistant (PDA). Surprisingly, there was little concern about the security of the proposed electronic transmission of personal medical data. Their experience with computers and the Internet was far below that expected; their use at that time was described as infrequent and simplistic, such as the occasional e-mail. Many accessed the Internet through a proxy, such as a family member.

In the physicians' focus-group meetings, physicians were skeptical that patients would measure their BP regularly and feared that self-measurements would needlessly induce anxiety. Their most serious concerns were legal liability and disruption of workflow. There was concern that they would be accountable to address unsolicited BP alerts in a timely fashion. As well, they would not be compensated for their work related to addressing alerts and reports, because this work was not tied to a face-to-face patient visit. Physicians insisted that the reporting of data should be tied to a patient visit. Physicians rarely used computers and the Internet during the course of seeing

patients, preferring instead to peruse a paper copy of BP results attached to the patient's chart.

Design Principles Based on the results of the focus-group meetings, the following design principles were formed:

- Personal computers and the Internet should not be used as the principal means of information input, retrieval, or review by patients or physicians.
- The mobile phone should be the information hub for the patient, with the following considerations:
 - Data gathering must not require user intervention.
 - User interface must consider limited or no previous knowledge of the operation of a mobile device.
 - User interface must consider visual and physical impairments. Messages to the patient must be in lay terms.
 - Short messaging service (SMS) should not be used, because it requires an operation to retrieve messages.
- Preferable ways to communicate with patients would be to send written messages directly to the screen of their mobile phone and voice messages to their home phone.
- Fax would be the preferred method of sending reports and alerts to physicians, because fax machines are almost universally available in doctors' offices.

Technical Architecture The BP tele-management system consists of the patient components, a data repository and decision support system, and the physician-reporting and alerting component (Fig. 1).

The patient component of the system comprises a commercially available Bluetooth-enabled BP monitoring device and a dedicated, preprogrammed mobile phone. The phone receives home readings transmitted wirelessly from the BP monitor and transmits them securely to the server. Bluetooth technology is a uni-

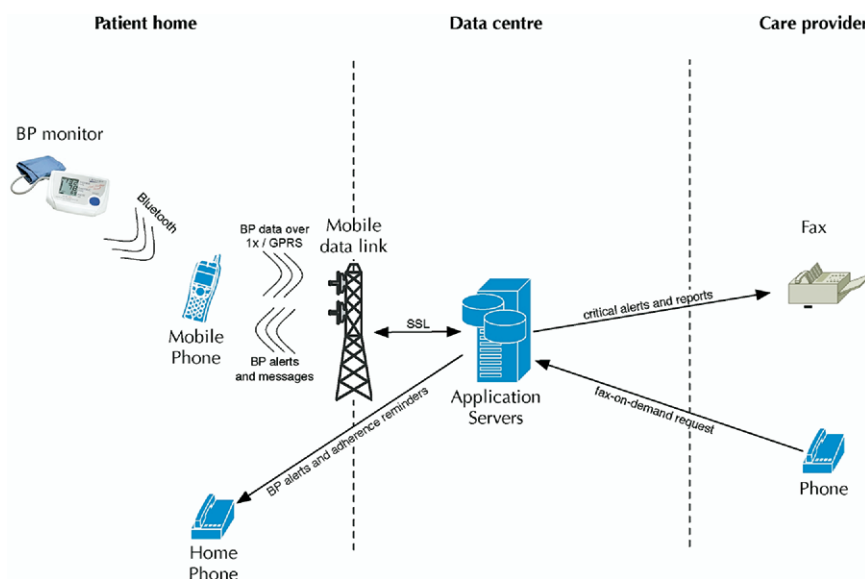


FIG. 1. Mobile phone-based, remote patient blood-pressure monitoring system. BP = blood pressure; GPRS = general pocket radio service; SSL = secure sockets layer.

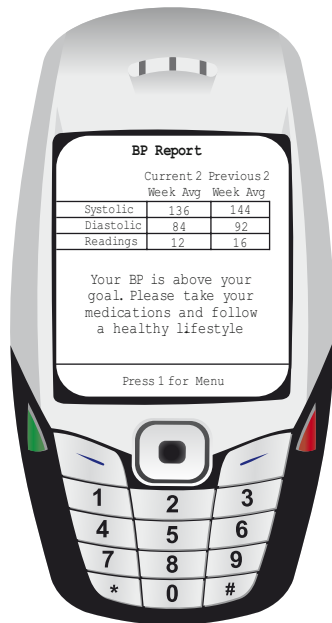


FIG. 2. Screen on mobile phone of patients, for reviewing previous readings in summary format.

versal, short-range, wireless data-transmission protocol operating in the unlicensed 2.4-GHz frequency band.¹⁷ Patients have the option of reviewing previous readings that are stored on the phone in tabular, graphic, and summary formats (Fig. 2).

The back end of the system is a Web-based server, which gathers results from client devices, stores them in a database, and applies a set of clinical rules on the BP monitoring schedule and BP alerts. The rules trigger events handled by the reporting and alerting component of the system.

The reporting and alerting system sends secure written progress and coaching messages automatically to the mobile phone after every reading. Nonadherence to the preset home BP-monitoring schedule, and BP readings that exceed threshold values, trigger automated voice messages that are sent to the patient's home phone. The system also automatically sends BP alerts to patients as a popup on their mobile phones. Physicians, on a patient-by-patient basis, can set and change the number of monitoring days per week and the threshold values for critical BP alerts. Default options are available.

Using an interactive telephone system, patients and physicians or their assistants can initiate a request for a fax report to be sent to the preprogrammed office fax number of physicians. The initiator has to input a numeric user identification and password, which the database validates and authenticates before issuing a report. The report displays the average of a patient's BP readings over the past 30 days, the number of readings used to derive the average, the previous 30-day average, and a graph of the readings with dates (Fig. 3).

Phase 2

Two of 33 patients dropped out of the pilot study for unrelated reasons. The clinical and demographic data of patients are presented in Table 1. The average number of monitoring weeks per patient was 19.2 (± 4.4), and the average number of readings per patient received by the server was 237 (± 178).

The reliability of home BP measurements, determined by intraclass correlation coefficient, revealed a high degree of agreement between baseline 24-h ambulatory and first 2-week average home BP (0.700 for systolic BP and 0.888 for diastolic BP). Baseline and end-of-study 24-h ambulatory and 2-week average home BP values are presented in Fig. 4. All showed a highly significant improvement during the trial. The control rate of hypertension based on 24-h ambulatory BP readings was 34.6% by the end of the study (all had uncontrolled hypertension at baseline as an entry criterion) and increased for home BP from 16.1% at baseline to 38.7% by the end of the study ($P = .023$).

The average number of readings per week was 12.3 ± 8.8 , and the average weekly adherence rate was above expectations, at $149\% \pm 110\%$, although considerable variability was observed (Table 2). The average number of adherence reminders was 8.7 ± 5.3 . The weekly adherence rate fell, and the number of adherence reminders rose, by the last 4 weeks of the study, although these changes were not significant.

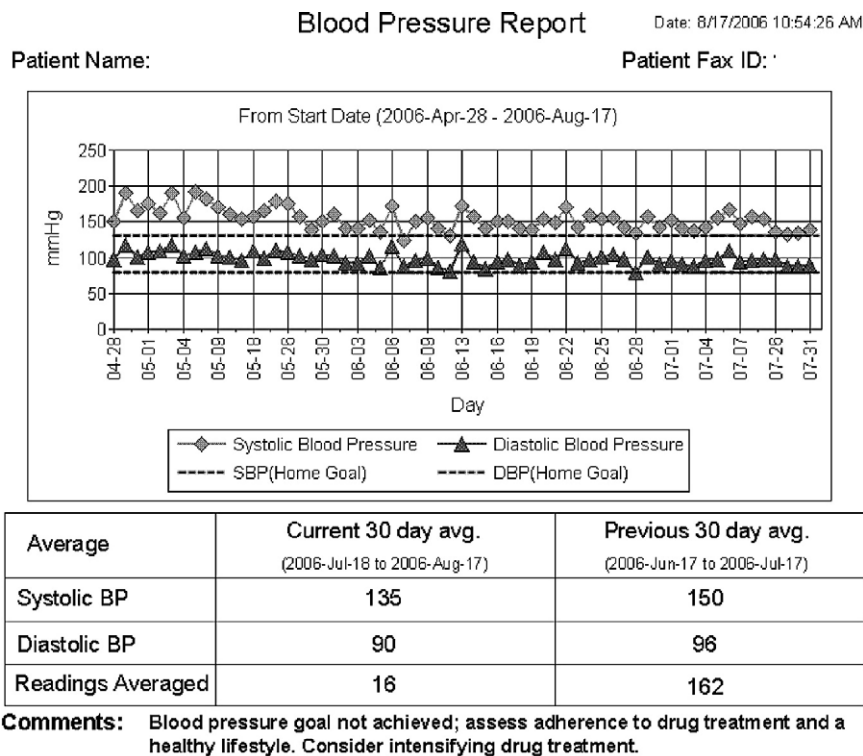
The system sent 42 BP alerts to patients. Of these, 22 were for high BP, and 20 were for low BP. Home BP values never exceeded the critical threshold limits.

In the qualitative interviews, 17 of 20 patients indicated that they would like to continue using the system or use it in the future. Of the remainder, one patient was unsure, and two did not endorse the system. In terms of system utility, 18 believed that the BP reports helped them and their doctor decide how best to treat their BP. When asked if they would pay for the system, seven said yes, and of these four gave a dollar amount, which ranged between \$12 and \$40 (US) per month. Of the remainder, three patients indicated that they would only use the system if the costs were covered by the Ontario Health Insurance Plan, five were unsure, and five said they would not pay for this service.

Discussion

In this study, we report on the construction of a home BP tele-management system that accommodated the concerns and met the expectations of patients and physicians. To our knowledge, this is the first study to describe the development of a hypertension management system that was based on systematic evaluation of the opinions of end users. The design principles that were derived from focus-group meetings were strictly adhered to during development.

The design goal of no manual intervention by patients, apart from measuring their BP, was achieved. For



Requests:

Change frequency of home readings to _____ Days/week
(3-7)

Change Treatment Goal BP Alert High BP Alert Low

Systolic	130	To: _____	180	To: _____	90	To: _____
Diastolic	80	_____	110	_____	50	_____

FAX BACK REPORT CHANGES TO () -

FIG. 3. Sample home blood-pressure report faxed to physician. avg. = average; BP = blood pressure; DBP = diastolic blood pressure; SBP = systolic blood pressure.

patients not interested in technology, they simply plugged the mobile phone into an electric outlet to maintain battery charge and left it unattended, as it

automatically relayed data back to the central server. More technically inclined patients used the tabular and graphic functions of the mobile phone to review all previous BP measurements. The fax-back system proved to be a simple and effective method of providing data to family physicians without significantly changing their work pattern. The high degree of agreement between 24-h ambulatory and first 2-week average home BP readings indicates the reliability of home BP data obtained from patients.

Table 1. Demographic and clinical data of patients with type 2 diabetes with uncontrolled 24-h ambulatory hypertension ($\geq 130/80$ mm Hg)

N	31
Age (y)	58.1 (9.9)
Male (n)	20 (66.7)
White (n)	21 (67.4)
Body mass index (kg/m ²)	32.2 (6.2)
Office blood pressure (mm Hg)	140 (15)/80 (11)
Dyslipidemia (n)	18 (58.1)
Current smoker (n)	3 (9.7)
HbA1C (%)	7.2 (1.2)
Creatinine (μ mol/L)	94.9 (36.3)
Number of antihypertensive drugs (n)	2.4 (1.8)

Data are mean (SD) for continuous variables and n (%) for categorical variables.

HbA1C = hemoglobin A1C.

The system was designed to ensure the confidentiality of patients' data. Data from the BP measuring device were only allowed to be transmitted to a predetermined mobile phone through the Bluetooth pairing process, ensuring the authenticity of received data. The mobile phone had no readily individually identifiable information stored about the patient, as results were only tied to a specific patient at the server. This mapping associated patients with a unique numeric Bluetooth identification of the patient's medical device and was known only to the server. Data from the mobile phone to the server were sent via a secured sockets layer

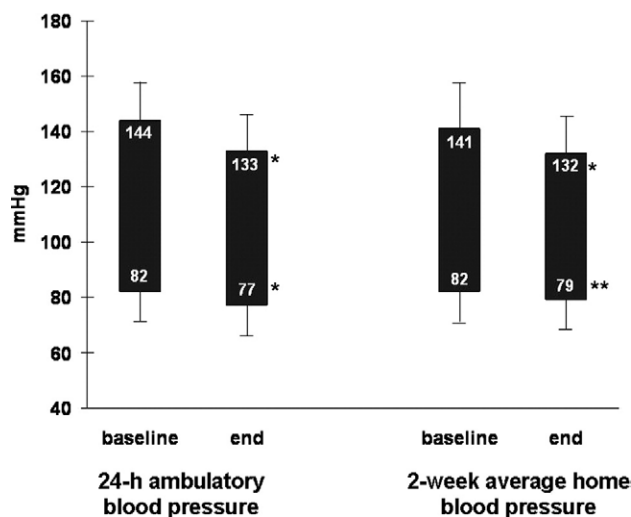


FIG. 4. The 24-h ambulatory and 2-week average home blood-pressure values at baseline and at end of study. **P* < .001 v baseline, ***P* = .005 v baseline. T bars = standard deviation.

(SSL) Web connection, providing an industry-standard level of security offered by the underlying mobile data network.

In Phase 2 of our study, patients with type 2 diabetes and uncontrolled ambulatory hypertension were recruited, because strict BP control is particularly desirable in this group. The majority of patients in our study were obese, because obesity is common in type 2 diabetes and is related to poor BP control.¹⁸

Both ambulatory as well as 2-week average home BP showed a significant, approximately 10/4 mm Hg improvement over the observation period. The design of the study does not allow us to form conclusions about the mechanisms of improved BP control. These may involve regression to the mean, improved compliance with medications, or more intensive therapy by the physician. We did not monitor medication compliance or physician practices, because such monitoring, in itself, may affect behavioral patterns.¹⁹ Nevertheless, the results of Phase 2 of our study are sufficiently encouraging to warrant the long-term, randomized, clinical trial that is now underway. Rogers et al, in an 8-week, randomized, controlled trial assessing a complex home BP tele-monitoring system, demonstrated a significant fall in 24-h ambulatory BP of 5/2 mm Hg for systolic and diastolic BP, respectively, in hypertensive patients.²⁰

The adherence of patients to the number of requested weekly measurements averaged approximately 150% over the trial. This high number may, in part, reflect the interest of patients in the novelty of the way care is provided to them. Indeed, there was a tendency for adherence to drop toward the end of monitoring, although the average number of readings continued to be higher than expected. The role of adherence reminders in achieving the high adherence rate and lowering of BP cannot be discerned from this pilot trial.

Although >7700 BP readings were transmitted during the trial, the number of BP alerts sent to patients was surprisingly small. Furthermore, it is notable that almost half of these were sent because of low BP. This phenomenon was not previously described, and its importance to patients on antihypertensive drug therapy needs to be explored. The home BP values never exceeded the limits for critical alerts. This indicates that the BP of participants was generally in a range that was not considered alarming by their physicians, who set the threshold values.

The high acceptance rate of the system by patients, and the consistency of positive remarks regarding its value, further underscore the feasibility of the system. No patient reported feeling concerned or anxious as a result of using the system. Indeed, many patients spoke of feeling reassured and comforted by the regular surveillance of their BP afforded by the system. This finding appears to mitigate the concern of physicians that the system would needlessly induce anxiety in patients.

One concern of physicians involved an increase in their workload, particularly if dozens of their patients were using the system. To avoid the transmission of unsolicited BP reports, they were generated and faxed to the doctor's office only on request of the patient or the physicians' office staff before or at the time of the scheduled patient visit. Critical BP alerts were sent automatically to the physician's office. The threshold values of alerts, however, were set by the physicians, and they had the option of changing the levels at any time. Although the current system was designed to facilitate the interaction of patients with their doctors, it could easily be expanded to accommodate other health care professionals, including specialized nurses or pharmacists.

Our system and study had limitations. First, some patients with low dexterity or visual impairment found the

Table 2. Adherence data collected during pilot study

	Whole study period	First 4 weeks	Last 4 weeks	<i>P</i> *
Number of readings per patient per week (<i>n</i>)	12.3 (8.8)	11.6 (7.6)	10.5 (7.7)	0.136
Weekly adherence† (%)	149 (110)	143 (96)	128 (96)	0.082
Adherence reminders per patient (<i>n</i>)	8.7 (5.3)	1.7 (1.5)	2.2 (1.3)	0.113

Data are mean (SD).

* First v last 4 weeks of data; † Number of readings received by server divided by number of readings expected, based on preset schedule × 100%.

small joystick of the mobile phone for navigating onscreen menus challenging and the narrow power button frustrating. Additionally, some had trouble viewing the screen when the backlight was off. These problems may be addressed by selecting other types of mobile phones. Second, because of the lack of a control group and the possibility of selection bias, the BP results of our trial should be viewed as hypothesis-generating and in need of testing in a long-term, randomized, controlled trial. That study is now underway. Third, we did not undertake a formal cost-effectiveness analysis in the pilot study. Nonetheless, the system was designed to minimize expenses. The cost of mobile phones was approximately \$110 (US) each, and the Bluetooth-enabled devices cost less than \$170 (US) each. The major ongoing cost was the service-provider fee to transmit data, which was approximately \$25 (US) per month. Because the system was fully automated, there was no need for health care personnel to triage BP readings.

Conclusions

The new tele-management system appeared to be effective in aiding physicians to lower the BP of their patients, had a high level of acceptance by patients, and provided timely and reliable information to physicians without disrupting their workflow pattern. It met the needs of users and avoided the use of the Internet, a major obstacle for both patients and physicians. The use of common inexpensive hardware and the elimination of health care personnel to triage BP readings greatly reduced costs. The system developed during this project may also serve as a template for the tele-monitoring and tele-management of other physiologic parameters (eg, blood glucose, oxygen saturation, and body weight) and opens up a new approach to chronic disease management. The encouraging results of this pilot study provide a strong rationale for undertaking a long-term, randomized, clinical trial to determine whether this home BP tele-management system improves BP control in the community among patients with uncontrolled hypertension.

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