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TOOLS FOR ADVANCING PHARMACY PRACTICE

Medication adherence and activity patterns underlying uncontrolled hypertension: Assessment and recommendations by practicing pharmacists using digital health care

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ABSTRACT

Objectives: This report summarizes the first use of a digital health feedback system (DHFS) by practicing pharmacists to establish evidence-based blood pressure (BP) management recommendations.
Setting: Fifteen commercial pharmacies and 39 patients in the Isle of Wight participated.
Practice description: The pharmacists were experienced in providing New Medicine Services to patients in their communities.
Practice innovation: The pharmacists utilized a commercially available DHFS. The DHFS utilized FDA-cleared and CE-marked class 2 medical devices passively captured and shared information about medication-taking using an ingestible sensor, and daily patterns of rest, activity, and exercise using a wearable patch that incorporates an accelerometer.
Interventions: Pharmacists provided targeted counselling for BP management as guided by the digital information.
Evaluation: Blood pressure was measured serially, and patient and provider experiences with DHFS use were assessed using satisfaction surveys.
Results: The mean change in SBP over the 2-week evaluation period was -7.9 ± 22.1; mean change in DBP was -2.8 ± 12.9. A root cause for persistent hypertension was determined for all of these 34 patients: 68% had pharmaceutical resistance, and 32% had inadequate medication use. Specifically, 29% were found to be capable to achieving blood pressure control on their currently prescribed medications, 68% were found to have a need for additional pharmacological treatment, and 3% needed additional adherence support. Pharmacists found that the DHFD helped in targeting specific recommendations, and to create a collaborative experience with their patients. Patients found the experience to be positive and helpful.
Conclusion: DHFS that provides confirmation of medication taking and objective measures of lifestyle patterns can help pharmacists to identify specific factors contributing to uncontrolled hypertension, to make evidence-based prescribing and lifestyle recommendations for achieving treatment goals, and to create a collaborative experience for patients in the management of their self-care.

Objectives

This report summarizes the first use of a digital health feedback system (DHFS) by practicing pharmacists experienced in providing New Medicines Service (NMS) for community patients. The DHFS was used by them to establish evidence-based blood pressure (BP) management recommendations. Patient and provider questionnaires were used subsequently to assess their experience with DHFS.

Setting

One-third of adults in the United Kingdom have hypertension.[1,2] Elevated BP exhibits a strong, positive, and dose-dependent relationship with the risk of cardiovascular disease throughout its entire range. The relationship is independent from other risk factors, shows no evidence of a

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Key Points

Background:

- The pharmacists of today have become essential care providers and integral to the patient care team practice model.
- Community pharmacists are actively involved even now in initiatives such as the New Medicines Service for the management of chronic conditions such as hypertension.
- A digital health feedback system is available for providing an objective evidence base that can be used to make individually tailored medication and lifestyle recommendations to manage persistent blood pressure elevation. No extra pharmacist certifications or training is required.

Findings:

- Community pharmacists evaluated its use for providing targeted counselling for blood pressure management as guided by the digital information.
- The system helped pharmacists to identify specific factors contributing to uncontrolled hypertension, to make evidence-based prescribing and lifestyle recommendations for achieving treatment goals, and to create a collaborative experience for patients in the management of their self-care.
- This paradigm fits well with the National Health Service Right Care agenda to deliver value from health care over the remainder of this decade through evidence-based planning, delivery and monitoring of health care delivery.

threshold for risk, and applies to all major manifestations of cardiovascular disease.[3] Current control rates are below the Healthy People goal of 50%, which was originally set as the year 2000 goal and has since been extended.[4] Poor adherence to antihypertensive therapy is a major cause of lack of BP control. A similar problem exists in incorporating lifestyle modification for BP management. In a European survey involving patients with established heart disease from 15 countries, only 66% practiced a physical activity.[5]

DHFS has been used previously in primary care practices for assessing and making evidence-based modifications in the treatment of 151 patients with uncontrolled BP while prescribed 2 or more antihypertensives. A root cause for uncontrolled BP was identified in 95% of patients: 57% had pharmaceutical resistance, and 43% had inadequate medication use. Overall, 38% were found to be capable of achieving BP control on their currently prescribed medications. Primary practices found the offering easy to use, and the majority of patients expressed a positive and collaborative experience in using it.[6]

The NMS is a National Health Service (NHS) community pharmacy service that provides support for people with long-term conditions newly prescribed a medicine to help improve medication adherence. Since the introduction of the NMS in October 2011, more than 90% of community pharmacies in England have provided it to their patients. The goals of the NMS include supporting patients in making decisions about their treatment and self-management, reducing medicine wastage, receiving positive assessment from patients, improving the evidence base on the effectiveness of the service, and supporting the development of outcome and/or quality measures for community pharmacies.[7]

Among the challenges in meeting these goals is awareness of actual utilization of prescribed medicine. The NHS is looking to improve prescribing and dispensing systems, and is encouraging rational cost-effective prescribing.[8] Core to meeting the objective of evidence-based prescribing is identifying and targeting those patients who do not take their medicines appropriately.[9] This is a significant challenge because practitioners are unaware of how patients actually take their medications outside of the clinic.[10]

Of additional importance is the incorporation of lifestyle advice for BP control. National Institute for Health and Care Excellence (NICE) guidelines advise that ascertainment of exercise pattern and lifestyle advice should be offered initially and then periodically throughout the life cycle of BP management.[11] Yet, other than self-report, practitioners do not routinely determine how much patients are actually exercising, much less achieving the British Heart Foundation's recommended goal of 10,000 steps daily.[12]

Practice description

This service evaluation occurred in 15 community pharmacies in the Isle of Wight and included 39 patients with uncontrolled BP. Pharmacists performed an initial assessment of needs, made lifestyle recommendations, and administered antihypertensive therapy that was prescribed per NICE guidelines. The participating pharmacists who elected to introduce the DHFS into their practices did not have any extra certifications, training, or prior utilization of DHFS, and they had no characteristics that would differentiate them from the remainder of the general pharmacist population.

Practice innovation

The DHFS (Proteus Digital Health, Redwood City, CA) uses Conformité Européenne—marked type 2 medical devices consisting of a poppyseed-sized ingestible sensor made of foodstuff and a wearable sensor (also called “patch”) that may be utilized for 7-day wear during all activities, including exercising and bathing.

Description of the ingestible sensor

After entering the stomach, the ingestible sensor uses the gastric fluid to send a tiny and brief biogalvanic signal. The signal contains no radiation, is not pH dependent, and lasts approximately 7 minutes. The remainder of the ingestible sensor is then inactive and is eliminated like a poppyseed husk in the feces. More than 500 subjects have ingested more than 20,000 ingestible sensors in clinical studies that have included subjects with bipolar disorder, diabetes, heart failure, hypertension, renal transplantation, schizophrenia, tuberculosis,

seniors with fragile skin, and healthy volunteers. No device-related serious adverse events and no unanticipated adverse device effects have been reported. The ingestible sensor has been coingested with more than 400 different drugs without adverse interaction.[13]

Description of the patch

The signal from each ingestible sensor is unique and is recorded by the patch worn on the patient's torso. The patch can be worn for up to one week during all daily activities, including exercise and brief shower or bath. It passively and automatically records and reports: (1) the date, time, type, and amounts of ingested medicinals; and (2) physiologic data and habits of daily living. These include daily step count, sleep duration and quality, and circadian pattern. The patch passively and automatically transmits its stored data to a compatible computerized device for display and transmission to a secure cloud-based server (Figure 1).

Privacy, confidentiality, and anonymity

The information from the patch is made available for viewing with the use of a designated app on a mobile device or a secure webpage. All of an individual's information is encrypted and private; only that individual can determine who may see it. The data that are stored on the patch are automatically communicated to a computerized device (e.g., a smartphone) via encrypted Bluetooth transmission whenever the patch may come into range with the device. The device can display the information for the patient, and it forwards the encrypted information to a secure cloud server, where it can be monitored by doctors and other caregivers who are authorized by the patient. An individual's information is secure and handled in a manner that meets all privacy and information governance requirements.

Implementation

Participants were introduced to the DHFS as an assessment tool on an ad hoc basis and were not randomized. Pharmacists instructed patients, who provided written agreement to use the DHFS, in its use and patch changes. Patients were asked to ingest an inert tablet containing an ingestible sensor at the time of each of their prescribed periods of medication dosing. The DHFS was used by pharmacists to assess individual medication and lifestyle habits of patients with uncontrolled BP, and they used the information that was collected by the DHFS to individually tailor recommendations regarding medication use or lifestyle modification and to engage patients in their self-care. Using a paradigm similar to that which was already in existence for the NMS, patients returned to the community pharmacy after one and 2 weeks to discuss the information that was collected by the DHFS. BP was measured at each pharmacy visit per usual and customary care.

No changes occurred in antihypertensive therapy during this period. Per guidance in the existing NHS care pathway for hypertension, a 2-week period was considered to be sufficient to determine maximal BP response to the prescribed antihypertensive treatment.

Interventions

The pharmacists reviewed the BP changes, and the medication and lifestyle activities as recorded by the DHFS, with patients at the time of each visit, and provided targeted counseling as guided by the digital information and BP determinations. Figures, graphs and tables on the mobile displays summarized daily and cumulative taking adherence, timing adherence, step count, and hours of sleep and sleep interruption. Taking adherence consisted of the total number of ingestible sensors that were detected by the patch, divided by the total number of doses that were prescribed. Timing (also known as “scheduling”) adherence consisted of the number of ingestible sensors that were detected within a ±1-hour time window around the prescribed dosing time, divided by the total number of ingestible sensors that were detected during that dosing interval.

No hypotheses were generated or tested, and no investigational products were used in this evaluation. All physical and other assessments that occurred were those that are used as part of usual and customary care. There were no changes in treatment and patient care from accepted standards for any of the patients involved. Based on this and other precedents, there was no requirement for ethics approval.[14,15]

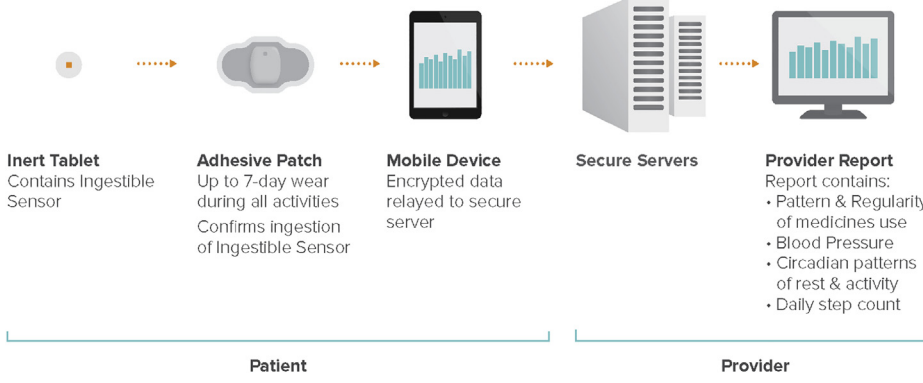


Figure 1. Digital health feedback device for assessment of hypertension therapy.

Evaluation

Blood pressures and information that was passively collected by the DHFS, along with pharmacist intervention and patient feedback data, were stored on an existing Web-based system already in routine use in the participating community pharmacies.

After completion of DHFS use, all patients were interviewed on site by their respective pharmacists regarding DHFS usability, and both patients and pharmacists subsequently completed a written satisfaction survey by mail. Commercial satisfaction surveys were used. The structure of the interviews and questionnaires were standardized but not validated surveys, and questions concerned comfort, ease of use, usefulness, and satisfaction with the pill, patch, and mobile displays.

All analyses for this report were performed subsequently with the use of anonymized data and standard existing NHS processes in routine use for assessing NMS care delivery performance. A threshold of 80% was used to define medication adherence, because this has been used for a majority of the studies in the literature on medication adherence, with data from both observational and randomized controlled clinical trials.[16]

Results

Table 1 summarizes the baseline demographics and BPs of the patients who used the DHFS. Figure 2 summarizes systolic and diastolic BP changes over 2 weeks. Table 2 summarizes pharmacist interventions that were made subsequently. Figure 3 summarizes the results of patient surveys on the usability and acceptability of the DHFS.

Among the 39 patients who used the DHFS, the mean age was 60.5 years, the mean baseline systolic BP (SBP) was 154.3 ± 18.9 mm Hg, and mean diastolic BP (DBP) was 88 ± 11.5 mm Hg. After 2 weeks of use, BP decreased overall among the patients who used the DHFS. The mean change in SBP over the 2-week evaluation period was −7.9 ± 22.1 mm Hg; mean change in DBP was −2.8 ± 12.9 mm Hg.

Recommendations after DHFS use consisted of increasing activity level, improving medication adherence, or a combination of the two. Using a threshold of 80% for medication adherence, a root cause for persistent hypertension during existing antihypertensive treatment was determined for all patients (100%): 68% had pharmaceutical resistance, that is, they were found during DHFS to be incapable of achieving BP control on their prescribed antihypertensive medications; 32% had uncontrolled BP owing to inadequate use of their prescribed therapy.

Table 1
Baseline demographics and blood pressures

No. of patients	39
Age (y)	60.5 (32–83)
Smoking status	
Smoker	6 (15.6%)
Former smoker	10 (25.4%)
Nonsmoker	23 (59%)
Baseline blood pressure (mm Hg)	
Systolic	154 (124–200)
Diastolic	88 (60–116)

Values are presented as mean (range) or n (%).

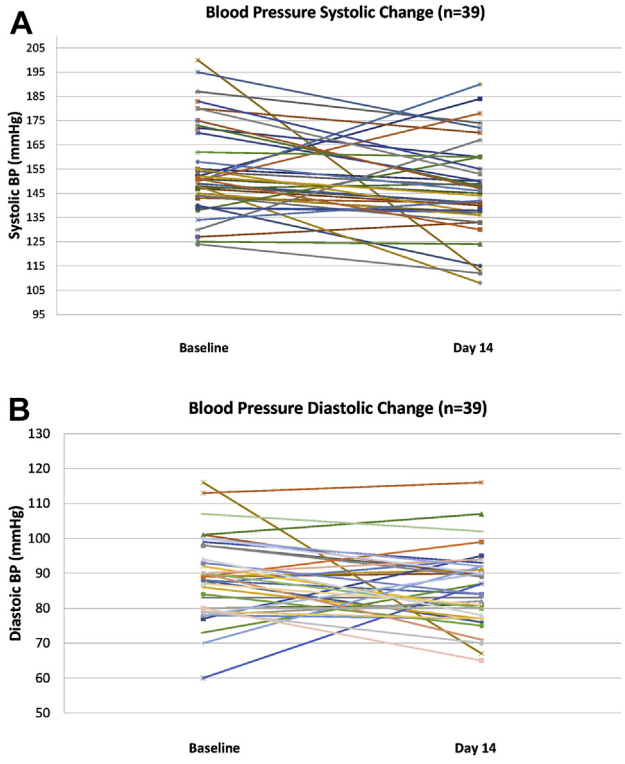


Figure 2. (A) Systolic and (B) diastolic blood pressure (BP) changes over 2 weeks.

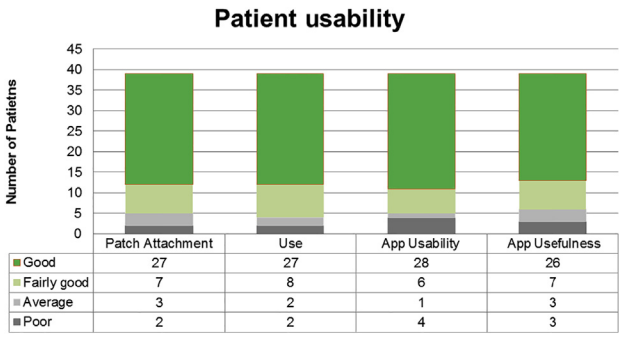
Recommendations for daily exercise were based on the British Heart Foundation's recommended goal of 10,000 steps daily to improve health, lose calories, and reduce disease risks.[17] Patients for whom the pharmacists recommended an increase in physical activity had a lower average step count recorded than those for whom activity was not part of the recommendation (10,132 ± 1147 steps vs. 6677 ± 709 steps, respectively).

Out of 13 pharmacists, 11 were surveyed and found that the DHFS helped to create a collaborative experience with their patients; 91% of those surveyed noted that the longitudinal trends in actual medication use and activity patterns aided them in counseling and making specific recommendations. A majority of patients found the overall usability of the devices and the app to be good. Of the 15 patients who returned additional satisfaction surveys by mail, 100% found the experience to be positive, 87% felt more involved with clinical care, and 87% also found that the information helped to improve compliance.

Table 2
Pharmacist interventions at weeks 1 and 2, n (%)

Recommendation	Week 1	Week 2
No. of patients	35	39
Activity	15 (42.9)	17 (43.6)
Medication adherence	9 (25.7)	7 (17.9)
Activity + medication adherence	3 (8.6)	2 (5.1)
Other recommendation*	8 (22.9)	13 (33.3)

* Diet (fat, refined sugar, salt reductions), weight loss, smoking cessation, hours of sleep, etc.



	Patch Attachment	Use	App Usability	App Usefulness
Good	27	27	28	26
Fairly good	7	8	6	7
Average	3	2	1	3
Poor	2	2	4	3

Figure 3. Results of patient surveys on the usability and acceptability of the digital health feedback system.

Discussion

Hypertension has been highlighted as a key target area for the NMS, but identifying which patients are not taking medicines properly is a challenge. In hypertension, the most obvious sign is poorly controlled BP. However, that may also be due to a worsening of the condition. Although there is a range of potential interventions that can be used to support patients with uncontrolled BP, at the core of clinical decisions for individual management is a need for objective, ready, and minimally burdensome identification of the reason for an individual being uncontrolled or appearing to require a considerable pharmaceutical burden to achieve control.[18,19] The essential question is whether nonadherence or pharmacologic unresponsiveness may be the root cause.[20]

The present report summarizes the first use of a commercially available DHFS by practicing pharmacists to establish evidence-based BP management recommendations. With the use of the DHFS, community pharmacists were able to identify a root cause for persistent hypertension for all of the patients who used the product. Two-thirds were identified to have pharmaceutical resistance, and one-third were found to have inadequate medication use as a root cause for their uncontrolled BP. Pharmacists found that the DHFS helped in targeting appropriate recommendations, as well as created a collaborative experience with their patients. Patients found the experience to be positive and helpful.

Because this was a real-world use of DHFS, a pre-post assessment was used to determine the relationship between medication use and ability to control BP. Although this reflects a different perspective from that of a randomized controlled trial, it nonetheless demonstrates how the product is used in actual practice. Patients may have increased their adherence while using the DHFS because of a Hawthorne effect; rather than a limitation, that actually provided a strength, because it made it possible to determine whether BP control was actually achievable on existing treatment. Coingestion of an ingestion sensor is a surrogate for actual medication ingestion, and patients may have been selective in the medications that they actually ingested. Despite this limitation, one-third of patients with uncontrolled hypertension were identified as actually being capable of controlling their BP on their existing therapy.

Experience from this first use of DHFS in community pharmacies builds on the experience of primary care practices in the recently completed UK Hypertension Registry.[6] This first use of DHFS by community pharmacists who currently offer the NMS demonstrates that they are well placed for including DHFS in their support for patients.

Application to practice

The role of today's pharmacists in the UK and the USA is evolving. Once limited to filling and dispensing prescription medications, the pharmacists of today have become essential care providers and integral to the patient care team practice model. Use of DHFS in this setting provides an objective means of reviewing medicine adherence and lifestyle. The information that is collected by the DHFS can be used to determine the root cause for uncontrolled hypertension during existing antihypertensive treatment, thereby providing an evidence base for appropriate prescribing recommendations, and a means for avoiding the medicine wastage that would otherwise occur from unnecessary overprescribing due to persistent "pseudoresistant" BP elevation.

DHFS also provides a means for pharmacists to support their patients in making decisions about lifestyle in addition to their pharmaceutical treatment. Use of DHFS created a collaborative experience with patients, and patients found the experience to be positive and helpful. These experiences are similar to those that have been reported by primary care practices who participated in the UK Hypertension Registry[6] and that have also been reported elsewhere when health care practitioners communicate and share complete and unbiased information with patients and families in ways that are affirming and useful, such that a shared understanding can occur and facilitate sustained and meaningful partnership in care.[21]

No extra pharmacist certification or training is required to use DHFS. In addition to providing an objective evidence base that can be used to make individually tailored medication and lifestyle recommendations to manage hypertension, DHFS data can be incorporated into objective outcome and/or quality measures when assessing community pharmacy activities and interventions in supporting patients.

Conclusion

DHFS is a practical and helpful means of assessing medication taking and objectively measuring of lifestyle patterns, thereby assisting practicing community pharmacists in identifying specific factors contributing to uncontrolled hypertension, making better informed recommendations regarding treatment escalation, and providing evidence-based lifestyle recommendations to achieve treatment goals. In addition, DHFS can create a collaborative, positive, and helpful experience for patients in managing their self-care.

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