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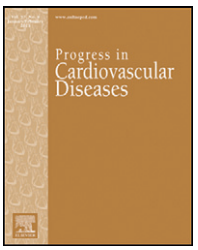

New Concepts in Hypertension Management: A Population-Based Perspective

Richard V. Milani, Carl J. Lavie, Jonathan K. Wilt, Robert M. Bober, Hector O. Ventura*

Department of Cardiovascular Diseases, John Ochsner Heart and Vascular Institute, Ochsner Clinical School – University of Queensland School of Medicine, and the Center for Healthcare Innovation, Ochsner Health System, New Orleans, Louisiana

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ABSTRACT

Hypertension (HTN) is the most common chronic disease in the U.S., and the standard model of office-based care delivery has yielded suboptimal outcomes, with approximately 50% of affected patients not achieving blood pressure (BP) control. Poor population-level BP control has been primarily attributed to therapeutic inertia and low patient engagement. New models of care delivery utilizing patient-generated health data, comprehensive assessment of social health determinants, computerized algorithms generating tailored interventions, frequent communication and reporting, and non-physician providers organized as an integrated practice unit, have the potential to transform population-based HTN control. This review will highlight the importance of these elements and construct the rationale for a reengineered model of care delivery for populations with HTN.

Hypertension (HTN) remains the most common chronic condition, affecting 30% of U.S. adults and is the leading diagnoses made during a primary care office visit.[1] In the U.S. alone, the estimated annual cost of HTN exceeds $50 billion, and across the globe, HTN is responsible for approximately 10% of all healthcare spending.[2,3] Roughly half of individuals with HTN have not achieved guideline-recommended blood pressure (BP) targets; as a result, HTN is one of the nation's leading causes of death, responsible for one in six deaths among adults annually. Additionally, uncontrolled HTN increases non-fatal myocardial infarction and stroke and remains the second leading cause of renal failure. Since the year 2000, HTN-related deaths in the U.S. have risen by 23% whereas all other causes of death combined over this same period have fallen by 21%.[4] Achieving improved population-based BP control remains a primary objective of public health policy and healthcare financing organizations across the globe yet efforts have been limited to minor adjustments in the current model of office-based care delivery.[5,6]

Improving hypertension control in the population

Why such a large percentage of HTN patients fail to achieve BP control remains an area of intense interest. When comparing patients with controlled versus uncontrolled HTN, routine characteristics such as age, gender, health insurance, and visit frequency are remarkably similar. In NHANES III, 92% of patients with uncontrolled HTN possessed health insurance, and 86% reported a regular source of healthcare.[7] In fact, patients with uncontrolled HTN saw

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* Address reprint requests to Richard V. Milani, MD, Center for Healthcare Innovation, Ochsner Health System, 1514 Jefferson Highway, New Orleans, LA 70121.
E-mail address: rmilani@ochsner.org (R.V. Milani).

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Abbreviations and Acronyms

BP = Blood pressure

CV = Cardiovascular

HTN = Hypertension

IPU = Integrated practice unit

PGHD = Patient-generated health data

their physician an average of 4.3 times per year, a frequency similar to that of patients with controlled HTN. What is noteworthy however, is in only 22%–38% of these visits was pharmacologic therapy either started or intensified. The failure to augment therapy in order to achieve disease-specific treatment goals has been coined "therapeutic inertia", and consists of three domains of responsibility: the clinician, the patient, and the healthcare system.[8] (Table 1) When evaluating patients with uncontrolled HTN, the prevalence of therapeutic inertia has been reported to be as high as 87% of provider visits, thus offering the potential for quality improvement initiatives targeting this shortcoming in clinical care.[9] This failure at the provider level can be ameliorated by use of guideline-based protocols executed by non-physician providers working in a "focused-factory" model of care delivery.[8] Organizing care utilizing specialized integrated practice units (IPUs), offers such a potential.

An IPU utilizes non-physician personnel dedicated to a specific disease condition for the full cycle of care.[10,11] Members of the care team may include pharmacists, advanced practice clinicians, nurses, health educators, dieticians, social workers, counselors and therapists, all organized around the patient's medical condition. In this model, patients can be more frequently and effectively connected to the health delivery system utilizing apps as well as home-based and wearable devices, and communication can be consistent and at regular intervals between the care team and the patient.[8] Patients can achieve a higher level of engagement in the care process via enhanced education, real-time feedback via wearable and home-based devices, and enriched communication with both the care team and other patients via social networks, thus achieving high satisfaction and improved outcomes within the healthcare system (Fig 1).

The role of patient-generated health data in hypertension management

Home BP collection has been endorsed by many HTN guidelines, and addresses several limitations of traditional office-based care, including a larger sample of biologic data, reducing misclassification due to white-coat or masked HTN, and an ability to take more timely action and course correct therapy.[12–15] Home measurements better predict cardiovascular (CV) risk than do office measurements, are more

Table 1 – Factors Leading to Therapeutic Inertia and Methods to Enhance Therapeutic Activation.

Therapeutic Inertia	Therapeutic Activation
Clinician	
Failure to initiate treatment	Guideline-based therapy using non-physician providers
Failure to titrate to goal	Guideline-based therapy using non-physician providers
Failure to set clear goals	Co-creation of treatment plan with patient
Underestimation of patient need	Needs assessment upon enrollment
Failure to identify & manage comorbidities	Screen for related co-morbidities
Insufficient time	IPU-model of care delivery
Insufficient focus on goal attainment	IPU-model of care delivery
Reactive rather than proactive	Weekly patient-generated health data
Patient	
Medication side-effects	Screening and close follow-up by care team
Too many medications	Medication simplification by clinical pharmacist
Cost of medications	Screening for medication affordability, use of generic alternatives, patient assistance programs
Denial of disease	Disease-focused education, patient engagement
Denial of disease severity	Disease-focused education, patient engagement
Forgetfulness	Medication reminders (apps, pill boxes, etc.)
Perception of low susceptibility	Develop concept of total CV risk
Absence of disease symptoms	Develop concept of total CV risk, patient education
Poor communication with MD	Monthly reports to patient, routine calls
Mistrust of clinician	Work towards building trust, regular communication
Depression, mental illness, substance abuse	Screening for depression, substance abuse
Low health literacy	Screening for health literacy; use of modified education, Rx. labeling
Health system	
Lack of clinical guideline	Use of current evidence-based guidelines
Lack of care coordination	IPU creates single point of contact
No visit planning	Calls and outreach built into EMR
Lack of decision support	CDS tools guide which patients need what help, when
Poor communication between MD & staff	Monthly reports to patients and providers, routine calls
No disease registry	Registry created in EMR
No active outreach	IPU creates active outreach to patient's home

Abbreviations: CDS = clinical decision support, CV = cardiovascular, EMR = electronic medical record, IPU = integrated practice unit

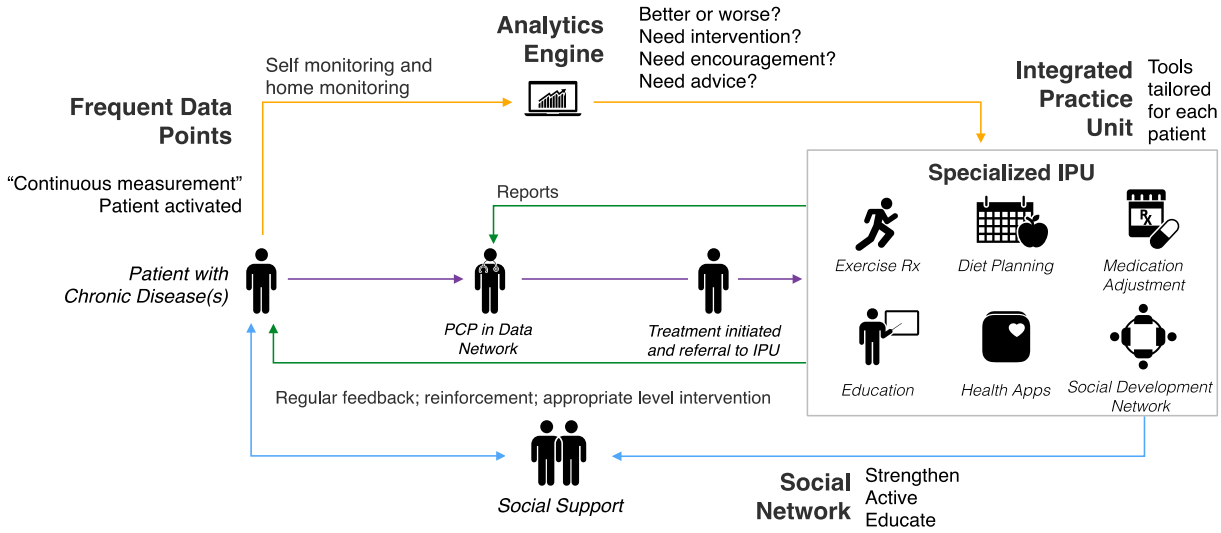

Fig 1 – Use of patient-generated health data in conjunction with an integrated practice unit in the management of hypertension. From: Milani RV, Bober RM, Lavie CJ. *Prog Cardiovasc Dis*. 2016; 58:579–83.

reproducible, and show better correlation with measures of target organ damage.[12] Current consumer technology is accurate, reliable, easy to use and relatively inexpensive. Moreover, home BP readings now have the capability of directly populating the patient's electronic medical record, and no longer necessitate each patient generating a hand-written diary of readings to bring to their provider.[16] Data can be safely transmitted through a Health Insurance Portability and Accountability Act (HIPAA)-secure enterprise portal, such as Apple's HealthKit®.[16] Additionally, home BP measurements can be visually displayed over time in various consumer-facing smartphone apps (such as Apple Health, Withings, iHealth) and have been demonstrated to independently enhance patient engagement and improve medication adherence.[1,17] The need to engage patients is now recognized as a primary strategy in chronic disease care, the importance of which highlighted via development of a "Patient Engagement Playbook" by the Office of the National Coordinator for Health IT (ONC).[12,16,18,19] Improving patient engagement not only improves overall patient satisfaction, an important strategy in the environment of HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) and CGCAHPS (Clinician and Group Consumer Assessment of Healthcare Providers and Systems), but also improves medication adherence in patients with chronic conditions, and further, reduces the risk of medical errors.[20] Strategies that encompass patient-generated health data (PGHD) together with focused efforts to enhance patient engagement have shown efficacy in improving outcomes in chronic disease.[16,21]

Phenotyping the patient with hypertension: The importance of precision medicine

Managing patients with chronic disease including HTN must include factors that play a role in achieving long-term, disease-based outcomes. These often include considerations that lie outside the traditional domain of the medical record. (Table 2) Based on the resulting patient phenotype, therapy and interventions can be directed that are tailored to the individual's unique circumstance. For instance, education programs and even prescription labeling can be adjusted based on health literacy, and focused interventions towards increasing patient activation can be promoted in populations with reduced medication adherence. Altering medications to generics and/or enrolling patients in patient assistance programs can help those with difficulties in paying for medicine, and inclusion of food preparers in dietary sodium education can significantly influence overall sodium consumption. All these efforts can dramatically assist in achieving BP control, and can be best achieved using an IPU model where comprehensive assessment and focused care delivery impacting lifestyle and pharmacologic management are available without the constraints of a 15-minute office visit.

Table 2 – Screening Attributes Necessary to Phenotype the Patient with Hypertension.

- Dietary sodium consumption
- Medication adherence
- Social circumstances (number in household, support system, meal preparation, etc.)
- Medication affordability
- Depression
- Alcohol consumption
- Patient engagement/activation
- Physical activity index
- Health literacy
- Sleep apnea screening survey
- Laboratory assessment (glomerular filtration rate, CO_2,sodium, thyroid function)
- Co-morbid conditions (i.e. diabetes)
- Cardiovascular risk factors (i.e. smoking, dyslipidemia, etc.)

Population-directed efforts in hypertension management

Timely communication and feedback can also play a large role in population-based efforts towards HTN control. Communication can include regular progress reports towards achieving BP goals as well as tips promoting and/or reinforcing lifestyle change (Fig 2). Communicating test results is also highly desired among patients with chronic disease and is typically mediated via a password-protected patient portal.[22] Lifestyle-focused texts offering advice, motivational reminders and support have also been shown to be effective in improving HTN and other chronic diseases.[23]

Up to 40 percent of patients with chronic conditions desire medication reminders, and today, these can be easily employed using many user-friendly free apps available on smartphones and smart-watches (i.e. Apple Watch) (Fig 3).[24] Many of these apps are interactive, providing a

Fig 2 – Monthly patient report in a hypertension digital medicine program. From Milani, RV, et al. Am J Med. 2016 (in press).

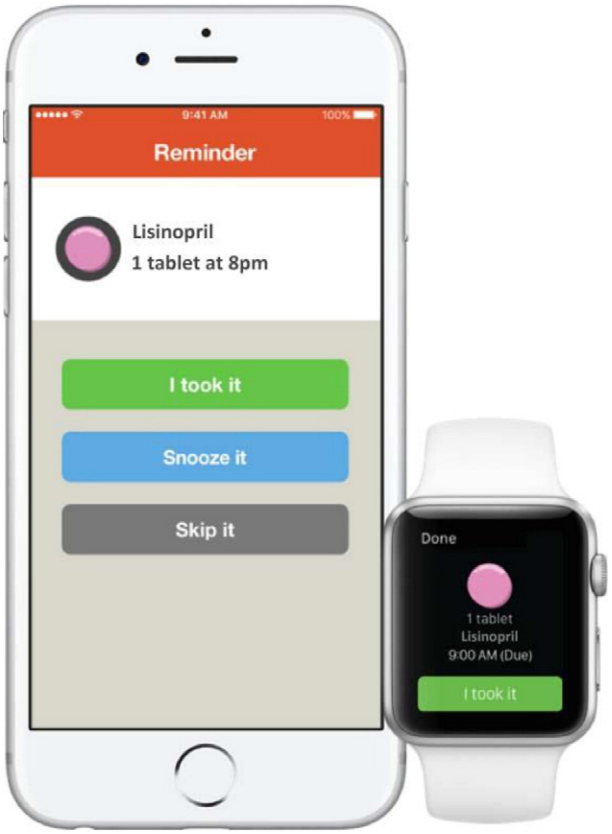

Fig 3 – Example of medication reminders available for the smartphone and smart-watch.

means for providers to monitor medication adherence and refill needs.

Large volumes of PGHD including home BP readings can be loaded into computer algorithms within the electronic medical record that can highlight which patients need what type of support and when. This can include advice, encouragement, lifestyle tips or medication adjustment; all delivered via the IPU in near real-time. Providing this comprehensive approach to population HTN management has now been demonstrated to be more effective than routine office-based management.[25]

Recent study

In a study comparing patients with uncontrolled HTN, more patients achieved BP control within 90 days using a digital-IPU model as described, compared to those managed conventionally. Table 3 describes the changes in BP metrics and other health metrics at 90 days in the digital-IPU model (a) and usual care (b) groups. BP including systolic, diastolic, mean arterial pressure, and pulse pressure improved significantly in both groups ($p < 0.001$). Moreover, at 90 days, 71% of patients in the digital-IPU group achieved BP control compared to 31% of usual care patients ($p < 0.001$). Over the 90-day period, the usual care group had an average of 3 ± 0.2 BP recordings in the electronic medical record compared to 161 ± 150 recordings (averaging 4.2/week) in the digital-IPU group ($p < 0.001$), who submitted BP data directly from home to the electronic medical record.

Table 3 – Changes in BP and health metrics after 90 days comparing patients enrolled in a digital medicine IPU versus office-based usual care.

	Baseline	90-days	*p*-value
(a) Changes in blood pressure and health metrics in the digital medicine/IPU model group at 90 days (n = 156)			
Systolic blood pressure (mmHg)	147 ± 19	133 ± 12	<0.001
Diastolic blood pressure (mmHg)	81 ± 12	76 ± 9	<0.001
Mean arterial pressure (mmHg)	103 ± 12	95 ± 9	<0.001
Pulse pressure (mmHg)	66 ± 16	57 ± 11	<0.001
High dietary sodium intake (%)	32%	8%	0.004
Patient activation score	41.9 ± 6.6	44.1 ± 6.7	0.008
Low patient activation (%)	15%	6%	0.03
(b) Changes in BP metrics in the office-based usual care group at 90 days (n = 400)			
Systolic blood pressure (mmHg)	147 ± 5	143 ± 14	<0.001
Diastolic blood pressure (mmHg)	81 ± 8	79 ± 9	<0.001
Mean arterial pressure (mmHg)	103 ± 6	100 ± 7	<0.001
Pulse pressure (mmHg)	65 ± 9	63 ± 9	<0.001

From Milani, RV, et al. Am J Med. 2016 (in press).

Patients received monthly reports, text reminders, and frequent interactions with the IPU care team, made up of clinical pharmacists and health coaches. Patient activation improved overall, as reflected by a 60% reduction in percent of patients with low patient activation. It is noteworthy that the mean age of the digital medicine cohort was 68 years, suggesting that use of technology from home was not a deterrent for an elderly population.

The differences highlighted between office-based care dispersed several times per year and a more continual care model are not trivial, and were accompanied by improved quality and engagement. Additionally, this model of precision-based, highly interactive care is cost-effective and is applicable across broad populations regardless of geographic distribution.

Conclusion

HTN management using an office-based model of care delivery has demonstrated suboptimal results in population level BP control, patient engagement, and HTN-related clinical outcomes. New models of care delivery, incorporating PGHD, high levels of patient connectivity and communication, tailored interventions incorporating individual social determinants, all administered through an IPU model, has been demonstrated to yield superior BP control, while at the same time achieving higher levels of patient engagement. Health delivery systems should reengineer care delivery to better meet the needs of the population they serve by incorporating new technologies and modes of patient interaction that focus on the real-time, continuous management of chronic conditions.

Statement of Conflict of Interest

None of the authors have any conflicts of interests with regard to this publication.

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