Title

Home blood Pressure: Good or Bad choice for Hypertension Management

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Dr. Anu Banerjee has been working in healthcare with multiple roles and currently working as a Chief Quality and Innovation Officer. He holds an extreme passion in improving healthcare through innovation and process improvement. His research includes chronic disease management, mobile health and tele-health methods to improve patient care.

Keywords.

Hypertension, hypertension management, Telemedicine, m-health, innovation, blood pressure, vital signs, blood pressure variability. health monitoring, patient centered medical system, BP monitoring, chronic disease management, continuous blood pressure and blood sugar monitoring.

Unstructured Abstract

Millions of Americans suffer from hypertension. The extent to which this population commits to make clinical care givers better informed requires more frequent clinic visits. In general, repeated interaction improves compliance, literacy and trust. The need to make frequent clinic visits can be resolved partly, by patients or family taking over routine actions common in every day clinical care. Acting as agents with responding to explicit measures with implicit actions is necessary in blood pressure management. The responsibility to connect with clinical care givers with tacit actions is mutual repetitive activity, critical in the management of diabetes, hypertension, obesity and other metabolic conditions. In this report the authors provide qualitative method to formalize collection of home blood pressure and pulse measurements continuously or otherwise in real life setting. This approach recognizes the value of patient – provider interaction critical to guide treatment. We attempt to better understand latent factors missed in present setting for traditional practice. We also identify potential feature selection on repeated measures to assemble estimates on blood pressure, pulse and variability. Then we provide information exchange platform for interaction and rapid patient care further explaining the framework for continuous systematic report integration in the electronic medical record. After collecting patient vital signs and demographics data for more than 300 patients we provide an in-depth analysis that would help present the model to adapt better ways to utilize home blood pressure monitoring.

Manuscript Text

Introduction

Hypertension is the most common modifiable risk factor for cardiovascular disease at global level (1). The treatment of elevated blood pressure is well accepted to prevent cardiovascular events in healthcare. Generally diagnosis of hypertension is made in the clinics and treatment can achieve desired level of control through low cost medication. Hypertension is on the increase in the United States and across the globe. In the U.S according to revised guide line, approximately 96 million adults are affected by hypertension (2) and, this is an increase by 32% since 2000(3). In this context of increasing certainty of "elevated blood pressure is bad" there is growing pressure on general clinical care givers' to go low in achieving goals. Measuring blood pressure for testing hypothesis in research and endorsement to enable clinical care givers is much-debated issue. The process of Blood pressure measurement and technical details (manual or automated), number of observations, time of measurement, knowledge on observed or otherwise, selecting patients with dry urinary bladder status and such other steps are common in research. In every day clinical practice blood pressure measurement is routine and observations are made under different circumstances. How good is the data collected in the clinic remains unsolved yet? In practice clinical significance to blood pressure over several generation, has remained static. Two discrete set points, systolic and diastolic blood pressure values are used as define success or failure in every day clinical practice. The detection of blood pressure heterogeneity requires a challenging quantifiable operational process. There is admittedly, increase in interest to use out of office blood pressure as a tool to provide additional information on blood pressure phenotypes (4). There is common interest in other areas of blood pressure such as; better define various classes and phenotypes of blood pressure to support clinical practice, data estimates to support clinical confidence during intervention, report format to detect variability(5) and mean blood pressure,

integration of pulse readings and assembling risk categories to assist better patient care based on disease association. Another critical issue in clinical practice is data collection, validation, facilitative synchronous or asynchronous interaction, report design, integration in sequence and exchange during cross collaboration. The model for mobile health using the application is shown in Figure 1.

Ambulatory Blood Pressure Monitoring (ABPM)

In this context characterization of blood pressure, a non-static phenomenon, influenced by system level interaction (intrinsic or extrinsic). The significance and convincing superiority of ABPM over other method of blood pressure monitoring is due to inference drawn by summarizing a variable continuously as time series. This ability to monitor detect biological phenomenon in AMBP over extended time frame lends to, avoid any error inflation. However, the major challenges are many such as; cost, training, standards for usage, device and data validation, data integration, equal access to population, upgrading software, protocol for repeated measures and more. (4,6)

Home Blood Pressure Measurement (HBPM)

There is good quality evidence to suggest Home Blood Pressure measurement ABPM are in agreement and interchangeable in patient care. (4,6,7) Home blood pressure devices are easy to use automatic, affordable, reliable and easy to validate in the clinics. The cuff size is appropriated before purchase, patients can easily become technically skilled and interact with providers to set personal goals with flexible time lines. Patients therefore can generate large number of observations continuously or in intervals. Access to unbiased HBP can be advantageous to clinical management. HBM can have positive influence on patient's care provided clinical care givers have a tool to overcome additional demand on time to collect, filter, react and design raw data in to a

meaningful summary report. There is general consensus across the globe on HBPM can potentially improve quality of care in hypertension by improving the complexity in the method of data processing. The important factors for continued usage should also consider cost, reliability, quality and value in this process to connect end users for dependable interaction (8). transmitted data, reduce reaction time to abnormal values and design condensed information and report pattern capturing accepted network of risk with in the infrastructure of electronic medical record and additional risk signals enabled through the application device (CMV) to exchange ecological and momentary information. Figure 2 shows the master view of the database with vitals signs such as systolic, diastolic, pulse, blood sugar, diet and alert collected for patients 1….n.

HBP data processing

The process of collection of home blood pressure being continuous or otherwise requires approach to analyze the interaction between continuous and discrete elements with in a system and a unique formalism on the basis of space discretization; **[**x ∈ **D**, x(t) + ε **]** where x is a finite set of linear data grows (X) where, ∈ a positive time lapse clearly represented by rounding weekly (D), monthly (C), quarterly (B) yearly (A) time series. These constitute serial observation or episodes (α) where A α≤ B α≤ C α≤ D α≤ x Timed automation defined ∫ **# X** = |A| |B| |C| |D| **x**. The above sequence assists in threshold detection and partitioning based on expert knowledge, identify interaction between continuous and discrete elements. Furthermore, this assist in mapping parallel episodes (risk factors) and their connection to linear data components and its destination in the analysis of structural equation modeling and causal inference.

Formula used to calculate variability:

Standard deviation (SD) d= $\sqrt{\frac{\sum_{i=1}^{n}(x_i-\bar{x})^2}{(n-1)}}$

Average real variability ARV $\frac{1}{n-1}\sum_{i=1}^{n-1}\left|x_{i+1}-x_i\right|$

Coefficient of variation CV = 100 x SD/ $\bar{x}$

Mean arterial pressure = $\frac{\text{Systolic} + \mathbf{2} \times \text{Diastolic}}{\mathbf{3}}$

Successive variation SV $\sqrt{\frac{1}{n-1}\sum_{i=1}^{n-1}(x_{i+1}-x_i)^2}$

Method

To begin with Figure 3 shows a reporting format view in the Electronic Medical Records during the clinic visit. The time and resources used to collect patient generated biometric data (PGBMD) is time consuming and activities, personnel needed to design the raw data and integration of information in the electronic medical record (EMR) is a daunting task. With this understanding we describe the procedure followed in recognition of financial barriers, equality of access and patient's factors. From a clinical perspective, our model took in to consideration demand on participatory activities, incursion on workflow, quality data sets and investment cost.

Diabetic care associates an independent practice started collecting continuously starting in 2102. In the 2014 Diabetic care associates officially introduced Checkmyvitals® (CMV) app. By enabling patients to install CMV on their personal device (Smart phone, computer, laptop or tablets), they were allowed to upload their readings periodically to the clinic for synchronized interaction. The decision to upload the data is simply decided by the patient. Our emphasis was CMV is primarily information exchange device to assist and opportunity for care givers to be better informed of dynamics on blood pressure, pulse and blood sugar, collaborate with supporting

clinical sectors in the management task. The process enabled us to advance virtual care coordination in the management of diabetes and hypertension. Furthermore, we briefly discuss data report design, features on reporting and distribution format in this scheme.

Sample Demographics

Variables	Mean	Standard Deviation	Coefficient of Variation	ARV	SV
Age					
Gender					
Race					
Ethnicity					
Smoking					
Number of medications					

This qualitative study is based on prospective collection of patient generated biometric data (PGBMD) in diabetes and hypertension clinic (Diabetes care associates.Whiting Spring Center for hypertension Management). The method and model developed is the result of series of changes made since 2009 to improve data collection and interaction with patients. This was accomplished in stages with incremental knowledge gained from patient's and clinical care givers to support diabetes and hypertension management. The paramount consideration given in this process was to enable patient's access information to clinical care giver rapidly and to be better informed on day to day needs as it happens with blood sugar, blood pressure, pulse, weight and more. The process led to more practical, meaningful and virtual interaction and integrate care coordination. These initial mutual rewarding steps, were possible due to new communication platform (smart phones)

and affordable patient monitoring devices. Aided by this m-health system, we were able to access raw data and design incoming data into accountable quality information. The platform for interaction and collaboration within the setting was a major factor in care coordination and synchronize interaction between the end-users. Furthermore, with additional support from Electronic medical record vendor (**MEDENT**®) sequential data integration and care coordination became routine.

Patients selection

Patients registered in the clinic are routinely requested to sign consent to interact and acknowledge support from information technology to design data components. They are routinely informed of extended benefit from designed information derived from their incoming data during their regular registration process and regular interaction. Home blood sugar is measured with affordable personal device or one allowed through their insurance vendor. Blood pressure monitoring is usually done with affordable Omron device or one that is affordable. Omron is the common device recommended in the practice. As a routine validation of device, cuff size is first performed routinely followed by yearly or sooner based on any suspicion of validity. Wrist cuff is also permitted under circumstances where anatomy of the arm or other practical issues due to medical conditions limits patient's ability to monitor using arm device or due to cost. Patient monitoring as a routine is more complex so is accessing data in any organized manner. Patients in general begin to follow standards and over time the process is random or on demand. All patients are informed of the basic protocol but ratification during follow up is not practical. Accessed information can be routine, sporadic and some upload collection periodically. In practice patients also deputize family or friends to access data. Overall, patients are told to test blood pressure morning and night, minimum of 3 days a week or more. In reality, end up collecting several or any

other patient preferred design during follow up. Practical reasons such as; deputized interaction, travel, system failure in mechanism may enable episodic access to groups of data at variable intervals.

Discussion

The availability of affordable and reliable self-monitoring blood pressure and blood sugar testing device enables us to take additional steps such as; generating designed report components and solutions to integrate coordinated treatment and disease association. Formalization of the temporal process of data collection and report in every day clinical practice involves understanding flexible patient factors and actions to support evidence based guide lines. In this report we have explained a basic platform for continuous information exchange, facilitates monitoring critical subsets with patient's alerts, platform for bidirectional information exchange, (better insight to factors contributing to clinical care, sustenance) and linear multi-sector data integration in the electronic medical record. The effectiveness of HBPM was discussed in detail by (9) in their systematic review of 52 studies using random effect model meta-analysis. There was clear indication of support system enhancing the benefit. The duration in all of the studies are less than a year. Many studies support HBPM as useful adjunct to the conventional office measurement in children as well as adults (10,11,14) Our report extends supporting evidence that control of blood pressure is possible over several years with home blood pressure monitoring. Besides using m-health enabled data collection can be separated with discreteness and support care givers confidence to fine tuning process during point of care. Effective research grade hypertension control is possible, can be patient centered operation through device enabled data collection, composing supporting factors (collaboration) in every day practice. These adjunct activities have more potential for operational sustenance and impact multiple sectors in this hierarchy.

Blood pressure and variability

Blood pressure varies with each heart beat and the spread of this variation increases with age higher mean blood pressure and heart rate (15,18) and the size of this spread is considered added risk factor to cardiovascular health (16,17,18). There is increasing significance attached to blood pressure risk beyond absolute level of blood pressure. Furthermore, it is unclear if intermittent rapid change in variability has any clinical implication (19,20). We recognize the target for treatment in practice is blood pressure level and not variability. However, application of assessment of this variable and understand its implication in every day clinical care being a complicated process, we app device enabled HBP collection may aid in understanding significance. Besides, blood pressure measured during clinic visits are discrete single estimate and often assessment do not conform to recommended technical standards. In the electronic medical record, there is a limit on collection of repeated measurements during each encounter. The display of data can vary substantially in different settings. Despite this disparity in blood pressure measurements and design in report there is potential to develop a simple standard algorhythm to integrate clinic visit variability in the EMR. This information can assist research group for later routine use in the management of individual and population. In practice, generating research grade health data with fidelity is not always practical. Rules adopted in clinical research is not always easy to extend to field level practice especially, when patients are being empowered to generate and submit routinely. Information collection in practice can be continuous or episodic in the management of non-communicable diseases with no symptoms. Patient factor is a major influence in this process of data collection. With the above understanding we provide a reasonable and practical method to collect HBP data and facilitate device enabled variability data collection on home blood pressure and integration in the EMR. Understanding of blood pressure, quantify

different aspects of variability, clinical application and integration in the electronic medical record is desirable but is a complicated task to perform manually. The utility of this information should consider simple and practical operation in natural setting (18).

Summary

Blood pressure and its risk is due to insidious changes in the end organs such as brain, heart and kidney. Current solution for diagnosis is often late and based on association of pathological or adverse events. Even so, this done with very few measurements and exposed to contest with customers to accept intervention. In an attempt to optimize performance key issue to be considered is implementation at patient level. Our model is the initial process that aims to extend detection and management and assist research group to use variability data to support customized clinical care in every day practice

Collecting blood pressure from natural setting is critical in every practice to understand ecological influence and enable action on critical momentary changes. Guidance in clinical management of intrinsically variable health risk signal should aim to support practical and affordable tools to collect the data and refine risk assessment based on information collected in personal setting. These actions are truly patient centered operation to understand blood pressure management. Guidelines encourage and set goals derived from artificial setting, expensive and standardized operation (18). a basic platform for continuous information exchange, facilitates monitoring critical subsets with patient's alerts, platform for bidirectional information exchange, (better insight to factors contributing to clinical care and sustenance) and linear multi-sector data integration in the electronic medical record.

Conflict of Interest : NONE

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References (numerical format with in-text citations)

Figure Legend (if applicable)

Figure 1: Model for mobile health using app(CMV)

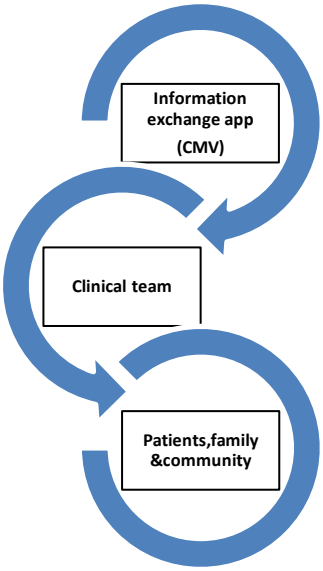
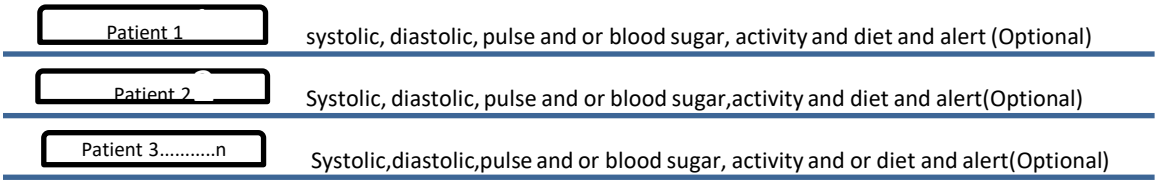


Figure 2: Master View of the database for patient vital signs



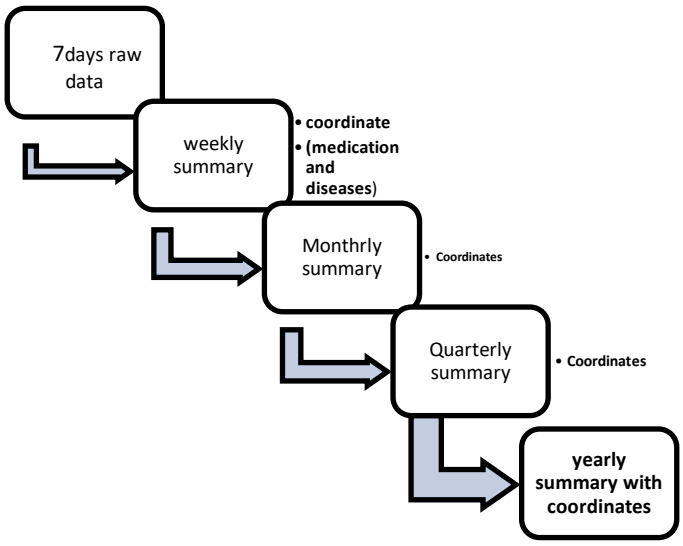


Figure 3: Report format view in the EMR during clinic visit.

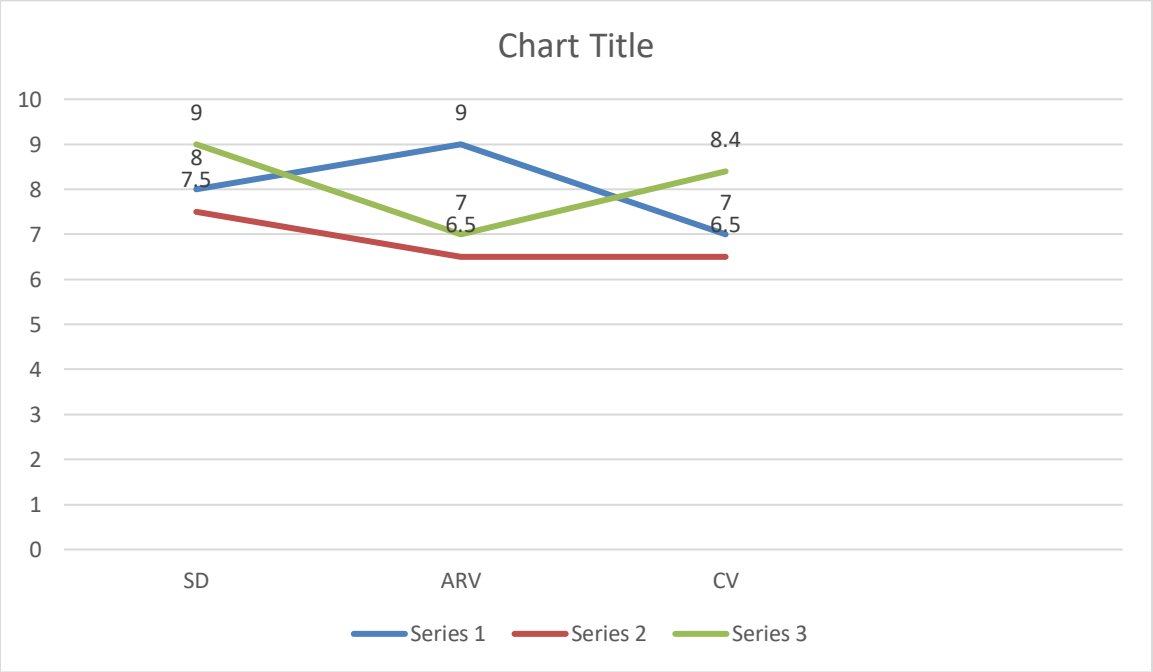


Figure 4: ARV to show variability of systolic blood pressure of patients.

Conflict of Interest; None

Each figure should be submitted as a separate file in .tif, .eps, .jpg, or .png , format with a minimum resolution of 300 dpi using the file designation “Figure”

Tables: should be submitted in Microsoft Word [.doc or .doc(x)] format as a separate file using the file designation "Table” using the Table menu.

Year 2015

Year 2015: ONLY Hypertension patients (HBP control standard of 140/90)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	677	444	65.58%
Patients using Home Bllod Pressure	484	438	90.50%
Total	1161	882	**75.97%**

Year 2015: All Hypertension and CKD patients (HBP control standard of 140/90)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	830	541	65.18%
Patients using Home Bllod Pressure	572	508	88.81%
Total	1402	1049	**74.82%**

Year 2015: ONLY Hypertension patients (HBP control standard of 135/85)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	677	444	65.58%
Patients using Home Bllod Pressure	484	392	80.99%
Total	1161	836	**72.01%**

Year 2015: All Hypertension and CKD patients (HBP control standard of 135/85)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	830	541	65.18%
Patients using Home Bllod Pressure	572	448	78.32%
Total	1402	989	**70.54%**

Year 2016

Year 2016: ONLY Hypertension patients (HBP control standard of 140/90)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	716	458	63.97%
Patients using Home Bllod Pressure	549	500	91.07%
Total	1265	958	**75.73%**

Year 2016: All Hypertension and CKD patients (HBP control standard of 140/90)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	875	562	64.23%
Patients using Home Bllod Pressure	637	570	89.48%
Total	1512	1132	**74.87%**

Year 2016: ONLY Hypertension patients (HBP control standard of 135/85)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	716	458	63.97%
Patients using Home Bllod Pressure	549	445	81.06%
Total	1265	903	**71.38%**

Year 2016: All Hypertension and CKD patients (HBP control standard of 135/85)			
	Total # of patients	# in Control	Percent in Control
Patients with office visits only	875	562	64.23%
Patients using Home Bllod Pressure	637	501	78.65%
Total	1512	1063	**70.30%**

Author Contributions

Dr. Ramanujan has contributed primarity towards implementing the methodology of a new method of treating patients with hyperten

Author contributions document reflecting the contributions of all authors detailing his/her contributions. The document, which must be uploaded as a separate file in .doc format using the file designation “Author Contributions”, will appear online as Supporting information when the article is published. Author Contributions document is only required for Original Papers and Review Papers and upload is only required for revised files or post-acceptance for papers accepted during the first-round submission process.

Original Paper: A report of research work or analyses conducted by the author(s) of the manuscript no more than 2500–4000 words and 25–50 references maximum (about 10–20 pages total)