FINAL PROGRESS REPORT

Optimizing Display of Blood Pressure Data to Support Clinical Decision Making

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Abstract

Despite known risks and available treatment, 46-75% of adults with diagnosed hypertension have uncontrolled blood pressure. Home blood pressure monitoring now plays an important role in defining hypertension control. However, patient-generated data can be copious, and typically arrive outside EHR workflow, increasing cognitive load and fueling clinical inertia. Patient-clinician shared decision making is predicated on a shared understanding of blood pressure control. We hypothesized that clinical decision support tools will help physicians and patients better understand blood pressure control, informing shared treatment decisions during time-limited clinic visits.

Therefore we created, implemented, and evaluated a point-of-care EHR data visualization including home and clinic blood pressures. Our user-centered design process leveraged usability and design principles and discovered patient and physician information needs through a series of focus groups, including user preferences for the amount and type of data to display. To determine how this decision support tool influenced patient/physician perceptions of control and risk, we conducted online experiments examining the effect of specific display elements and user health literacy, graph literacy, and numeracy. We worked with our health system EHR vendor to implement the FHIR-based data visualization and patient portal entry decision support tools. Finally, we recorded and analyzed videos from 89 patient visits for hypertension to understand how EHR visualization decision support vs. paper list presentation influenced hypertension care decision-making. To date over 1000 patients have entered 15,000 home blood pressures. We effectively integrated home blood pressure into clinical workflow, enabling meaning-making and greater patient engagement in hypertension management decisions.

Purpose

The overarching Aim of the study was to design and test a data visualization of both home- and clinic-derived blood pressure data as a clinical decision support (CDS) tool that would help patients and physicians use both home and clinic blood pressure data to better understand hypertension control and inform shared treatment decisions. The Aims of the study were:

Specific Aim 1: Determine patient and physician information needs about clinic and home blood pressure data. Design a data display for physicians and patients that supports these information needs and promotes better informed shared decisions about hypertension control and treatment at the point of care.

Specific Aim 2: Evaluate how characteristics of blood pressure data interact with characteristics of the data display to influence patient and physician perceptions of blood pressure control. Based on these displays, determine how patient factors of health literacy and numeracy influence patient perception of blood pressure control.

Specific Aim 3: Iteratively design a shared display of blood pressure and medication data that will inform the work of patients and physicians making decisions together in the ambulatory setting.

Specific Aim 4: Examine patient-physician encounters to determine how effective shared display influences shared decision making and goal-setting in ambulatory clinic visits for patients with hypertension.

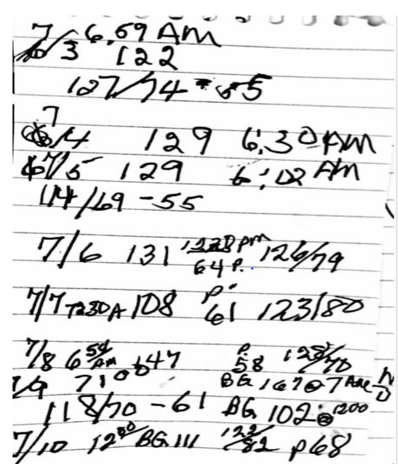
Scope

Background, Scope of the Problem:
Hypertension is a serious and prevalent disease affecting over 100 million American adults.[1] High blood pressure contributes 40.6% of attributable risk to heart and cardiovascular disease mortality, more than double the attributable risk from smoking, poor diet, inactivity, or diabetes.[2] With over 1.4 million annual deaths, heart and cardiovascular disease are the leading causes of death in the United States prior to the Covid-19 pandemic.[3] Yet only 24-54% of Americans with diagnosed hypertension have controlled blood pressure in national estimates.[4] Clearly, improving hypertension diagnosis and control can positively affect the health of many people.

Abbreviations Used in this Report
API: application programming interface
CDS: Clinical Decision Support
EHR: Electronic Health Record
FHIR: Fast Healthcare Interoperability Resources
HIMSS: Health Information and Management Systems Society
ICC: Interclass correlation coefficient
MU: University of Missouri
SD: Standard deviation

One factor contributing to low levels of control among people with diagnosed hypertension is the variability of blood pressure measurement. This variability causes increased cognitive load, creating barriers to therapeutic action and contributing to clinical inertia.[5] Compounding the problem of variable blood pressure data is the recommendation to use blood pressure data from outside the clinical setting for hypertension decision making, adding yet more data to review to arrive at a decision.[6] In addition, patient-generated home blood pressure data arrives for consideration from outside the clinician's electronic workflow, often arriving as paper lists, **Figure 1**, further increasing cognitive load and clinical inertia.

Figure 1: Page from patient blood pressure journal



Graphic presentation can represent large amounts of data in a format that enables viewers to quickly comprehend that data, leveraging principles of human cognition and visual perception.[7,8]

Effective data visualizations “emphasize relationships, focus interest, save time in analyzing data, help recall, uncover previously hidden facts and break down the language barrier.”[9] An effective data visualization that combines home and clinic blood pressures with a medication timeline could be effective CDS, assisting primary care physicians and patients to better understand blood pressure control and improve their shared work of deciding on next steps for hypertension management.

Context:
The context for our work included the profound impact of hypertension on morbidity and mortality, poor rates of hypertension control in the United States, and mounting evidence and emphasis for the role of home blood pressure in hypertension management decision making. To that context we brought expertise in human-centered design and a multidisciplinary team including practicing family physician-researchers, a computer science engineer, human factors engineer, psychologist, and expert in primary care practice improvement. Our overarching team philosophy was to design decision support tools jointly for two principal actors in hypertension management decisions, the primary care physician and the patient.

Settings:
We designed our EHR decision support tools for use in the primary care setting because 85% of hypertension care occurs in that setting.[10] The patients and clinicians who informed the information needs and completed the testing of the implemented design (Aims 1, 3, 4) came from general internal medicine and family medicine practices in and around Columbia, Missouri. While these are University of Missouri (MU) faculty network practices, they are based in the community and serve over 70,000 of the area’s 160,000 residents, including over 18,000 patients served in rural practices. Aim 2 used a national sample of patients with hypertension with online survey recruitment and implementation by Qualtrics panels.[11,12] The final prototype was implemented in the health system EHR as a modular application programming interface (API) using Fast Healthcare Interoperability Resources (FHIR).

Participants:
Aim 1 (information needs prototype development) and Aim 3 (confirmatory member checks) included a total of 10 focus groups with 24 MU primary care physicians (family medicine and general internal medicine) and 16 of their adult patients with hypertension. Aim 2 included a national sample of 1,442 total adult patients with hypertension participating in 7 online experiments and surveys. Aim 4 examined use of the home blood pressure and data visualization CDS tool in real time during 89 patient visits for hypertension with 15 physicians, employing video recording with screen capture.

Methods

Timing of Aims: This project employed mixed methods, with quantitative and qualitative Aims occurring both in parallel and sequentially, and informing each other. Aims 1 and 2 were concurrent and iterative, with both user information needs focus groups and online experiments informing each other and each iteration of the prototype. Aim 3 followed Aims 1 and 2 with confirmation of the design of final prototypes through member checks with the Aim 1 participants and subsequent programming of the prototype using FHIR into the health center EHR (PowerChart™) and patient health portal (MU HealthConnect). Aim 4 examined use of the CDS tool in real time during patient visits for hypertension, employing video recording with screen capture, with qualitative analysis as the primary analysis method.

Aim 1: Discovering User Information Needs and User-Centered Design Process

Specific Aim 1: Determine patient and physician information needs about clinic and home blood pressure data. Design a data display for physicians and patients that supports these information needs and promotes better informed shared decisions about hypertension control and treatment at the point of care.

Study Design:

Iterative user-centered design process with 7 formative design focus groups, alternating between physicians and patients, with qualitative content analysis of focus group data, and iterative revision of the prototype between each focus group

Data Sources/Collection:

Iterative design of the prototype was informed by data from 3 principal sources:

1. Literature review and team expertise input for best practices in data visualization
2. Four physician and three patient focus groups, and 1 senior physician stakeholder interview
3. Concurrent Aim 2 online perceptual experiments

Using our multidisciplinary expertise and informed by known visual display concepts and evidence from our literature review, we first designed several candidate data visualizations that included a data table of BP values, and an aligned medication timeline.[7-9,13-20] Family medicine and general internal medicine physicians and their patients age 18 years and older with a diagnosis of hypertension were recruited from eight community-based practices to comprise 7 focus groups, 4 with physicians and 3 with patients, alternating between patients and physicians. Prior to the focus groups, we educated physicians about the evidence for home blood pressure use in clinical care in several voluntary grand rounds-type seminars.

Focus group questions were designed to elicit broad feedback regarding usability and preferences. Participants were presented with candidate designs, with iteration of designs between each focus group. Because we were aiming for an intuitive design, focus group participants were challenged to construct meaning from the data visualizations with little to no orientation from the facilitators and to construct stories about the patient represented in the data visualization[21] We iterated prototype designs based on focus group feedback after each focus group. Concurrently and in parallel, the Aim 2 series of online cognitive perceptual experiments with patients with hypertension also informed our design iterations.[11,12]

Focus group qualitative data was analyzed in three phases: an immediate team debrief, preliminary rapid qualitative analysis immediately following each focus group, and final analysis of compiled data. We used the immediate team debrief and rapid qualitative analysis method after each focus group to quickly identify participant responses to design features, to confirm our designs or identify a need to iterate design features, and to quickly develop a preliminary understanding of patient/physician information needs and preferences.[22-24] Final analysis took a more comprehensive and traditional qualitative content analysis approach.

We quickly realized that there would be great value in presenting blood pressure data graphically together with a medication timeline so that changes in medications could be easily correlated with corresponding effects on blood pressure. We were fortunate to have Dr. Belden on the team, who developed some preliminary prototypes.[25] For design and evaluation of the medication timeline, we additionally reviewed 12 EHR products for methods of displaying medications and consulted with the Electronic Health Records Association Clinician Experience Workgroup. We then presented 23 practicing primary care physicians with data visualizations and clinical scenarios using an electronically-delivered task analysis survey with measurement of time on task and task accuracy.[20]

Limitations:

While we were inclusive of both patients and physicians, the primary users of these blood pressure data, we did not include other significant stakeholder groups: nurses and other members of the patient's health care team. Also, we chose to focus on the site of 85% of hypertension care, the primary care office, and thus we have not specifically considered the needs of specialty physicians or other settings.[10] We have focused on adults with hypertension; pediatric blood pressure data visualization is a more complex design problem as younger children have norms based on both age and height.[26] These limitations in the scope of the project all represent fertile areas for future work.

Aim 2: Online Experiments with Patients with Hypertension to Determine Effect of Display Elements and Patient Characteristics on Perception of Hypertension Control and Risk

Specific Aim 2: Evaluate how characteristics of blood pressure data interact with characteristics of the data display to influence patient and physician perceptions of blood pressure control. Based on these displays, determine how patient factors of health literacy and numeracy influence patient perception of blood pressure control.

<u>Study Design:</u>
For this Aim, we conducted a series of 7 online experiments with patients with hypertension with the overarching goal of informing the prototype design (Experiments 1-6), and evaluating the effect of patient characteristics for different data presentations (Experiment 7), Experimental objectives and numbers of participants for each experiment are represented in **Table 1**.

Table 1: Aim 2 Online Experiment Objectives and Sample Sizes

Exp.	N	Objective
1	51	Examine effect of **data variability** on perception of control
2	50	Examine effect of **data trends** on perception of control
3	53	Examine effect of **data outliers** on perception of control
4	50	Examine effect of **raw vs. smoothed data** presentation on perception of **control**
5	81	Examine effect of **raw vs. smoothed data** presentation on perception of **trends**
6	78	Examine effect of **tabular vs. graphical data** presentation on perception of control
7	1,079	Examine the effect of **patient health literacy, numeracy, and graph literacy** on perception of control for different forms of data visualization.

<u>Data Sources/Collection:</u>
Each online experiment was conducted with patients with hypertension recruited via Qualtrics, a survey company that maintains an opt-in demographically diverse Internet panel that participates in survey research in exchange for small incentives. Participants with hypertension were identified via a single self-reported measure: "Has your doctor ever diagnosed you with hypertension, also known as high blood pressure?"[27]

<u>Interventions:</u>
For each experiment, participants viewed 12 unique vignettes of fictitious patients accompanied by a blood pressure data visualization varying the element under study. This was a within-subjects design, where all participants viewed all vignettes and designs and provided judgement about hypertension control for each patient vignette, with blocks presented to participants in random order.

<u>Measures:</u>
Primary outcomes for all experiments included perceived blood pressure control and need for medication change. Secondary outcomes were perceived risk for stroke and heart attack. Experiment 7 also examined the additional outcomes of perceived comprehension of presented data and level of alarm after viewing the data and vignette, as well as measures of cognitive load using questions similar to those from the NASA Task Load Index, including how mentally demanding the task was, how successful they believed they were at completing it, how hard they had to work to complete it,

and how much frustration they felt at the task.[28,29] Outcomes were rated by patients in the online survey using a slider bar that ranged from 1-100.

All experiments collected data about participant age, gender, race, ethnicity, education, income, and frequency of home blood pressure monitoring. We assessed literacy using the Subjective Numeracy Scale and the Single Item Literacy Screener for health literacy.[30,31] Experiment 7 also assessed numeracy and graph literacy using the Berlin Numeracy Test and Graph Literacy Scale.[32,33]

Limitations:
One limitation of these studies is the use of Internet patient samples given that decisions about treatment for hypertension are typically made in conjunction with physicians during clinic visits. Also, we focused only on patients in these studies; there would be value in future work examining the effect of data visualization on physicians' judgments of hypertension control.

Aim 3: Final CDS Tool Prototyping, Aim 1 Participant Member Check, EHR Implementation

Specific Aim 3: Iteratively design a shared display of blood pressure and medication data that will inform the work of patients and physicians making decisions together in the ambulatory setting.

Study Design:
- Confirmation of our user-centered design process with evaluation of the final prototypes with 3 member check focus groups with Aim 1 participants, including 1 physician focus group and 2 patient focus groups
- Implementation of the prototype in the health system's Cerner PowerChart™ EHR using FHIR and creation of a home blood pressure data entry screen in the MU HealthConnect patient portal

Data Sources/Collection:
We invited physician and patient participants from the Aim 1 focus groups back to review the final prototype designs as a member check. In addition to checking the prototypes for fit with their respective information needs, we asked questions about how they would use the new visualization in their hypertension management, self-management, and shared decision making tasks.[21]

Intervention:
To implement our new CDS tools, we worked with the Tiger Institute, a joint collaborative between University of Missouri and Cerner Corporation. We first advised on the development of a screen for the MU HealthConnect patient portal to facilitate home blood pressure entry. Given new recommendations for use of home blood pressure in hypertension care, we sought and obtained approval from MU clinical EHR governance to allow patient home blood pressures entered in the patient portal to flow to the clinical EHR.

Initially patient home blood pressures populated an existing EHR structured data element "average home blood pressure" (systolic and diastolic) that had previously been used for nurses to enter average home blood pressures. Advocating for the need to represent individual patient-generated home blood pressure values and considering our new methods to collect this information in the patient portal, we were successful in advising the clinical and EHR governance in our health system to incorporate a new structured data element for individual home blood pressures to accommodate each entered home blood pressure (systolic and diastolic).

The Tiger Institute Team used our final prototype to program a FHIR-based API in the EHR that closely resembled the prototype. Their programming effort was estimated to take 5000 hours and was not financed by the grant, perhaps an indication of the perceived value of our rigorous prototype development work.

Measures:
Focus group qualitative analysis involved rapid and content qualitative analysis methods similar to that described for Aim 1.

Limitations:
Most, but not all of the elements of our prototype were incorporated into the EHR. Elements for incorporation in future designs include the use of patient and physician annotations to give context to the data visualizations. Such annotations could incorporate the use of linguistic summarization to describe data and trends, as described by our group and resulting from this project.[34] Additionally, while we employed a rigorous user-centered design process to create the EHR data visualization, the programming of the patient portal entry screen did not receive this type of developmental work and therefore lacks user features that might make it more useful for patients, such as immediate feedback on entered values. This remains a fertile area for future research.

Aim 4: Observing Hypertension Patient Visits Using the Implemented CDS Tool

Specific Aim 4: Examine patient-physician encounters to determine how effective shared display influences shared decision making and goal-setting in ambulatory clinic visits for patients with hypertension.

Study Design:
Qualitative comparative case study of recorded clinic visits (n=89 patients, n=15 physicians).

Data Sources/Collection:
89 video-recorded hypertensive patient follow-up visits with 15 primary care physicians in primary care practices.

Interventions:
We compared visits where home blood pressure data were recorded and provided on paper with visits where home blood pressure data were uploaded via the patient portal and represented in the new EHR visualization tool.

Measures:
We assessed the characteristics of doctor-patient communication and treatment decisions, perceptions of visualization tool use (e.g., ease of use, engagement) among both physicians and patients, and time needed to use the tool. We used a conversation analytical approach to understand the blood pressure discussion, with an emphasis on physician and patient actions, the order of these actions, the form these took, and the implications for decision making.

Limitations:
We designed this Aim with the primary objective of investigating how physicians and patients used home blood pressure information during a visit to negotiate a shared understanding of blood pressure control, choosing sample size with the primary objective of informing qualitative analysis of video data from primary care visits. Based on this sampling decision, resulting small sample size (n = 89 visits), and the limitation of a new intervention in a single setting, we did not judge it appropriate to present statistical analysis of the quantitative data. Visits were observed where the physician and patient were sitting across the room from each other, often when the patient was sitting on the examination table and the physician was sitting by the computer monitor. In these cases, when exploring use of the EHR visualization tool, it was difficult to determine if the patient could truly see what was shown on the monitor. Finally, future work could be informed by a range of future models that framed our thinking, but were not explicitly included.

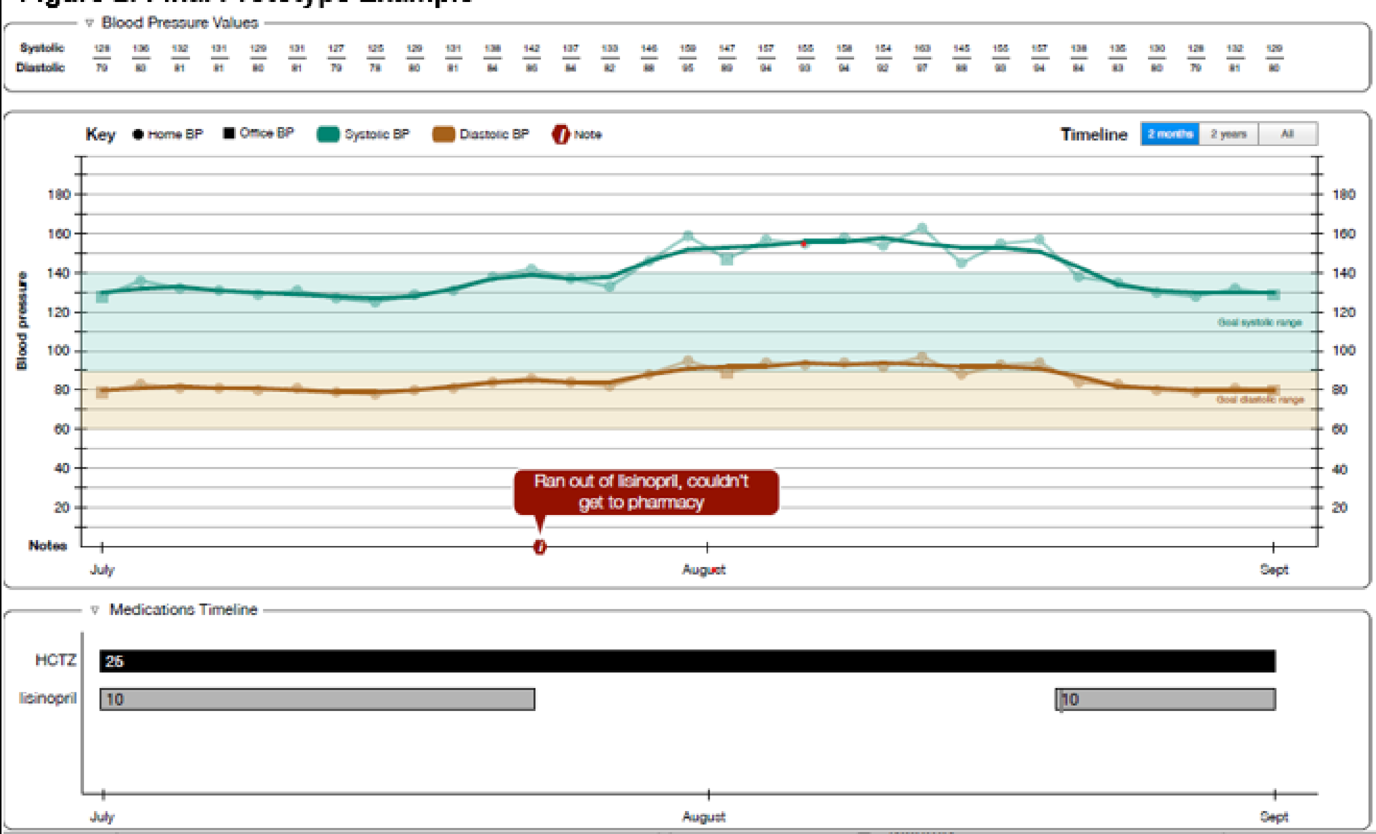
Results

<u>Principal Findings:</u>

Baseline patient and physician behavior around home blood pressure data and monitoring (Aims 1-4) Among patients with hypertension we sampled both locally and nationally, 65-88% monitored their blood pressure on at least a monthly basis, however only half of those reported sharing that data with physicians.[11,12,21] In our survey of primary care physicians prior to our CDS intervention, 88% reported that any patient home blood pressure data they received was entered into the EHR as a gestalt average using unstructured narrative data in the body of their clinical note.[21] These findings confirm our baseline impressions that while home blood pressure monitoring is common, much of this data is not reported to physicians. Further, when data was shared at a visit, this data was overwhelmingly brought to physicians outside of their clinical workflow, and was therefore condensed to gestalt averages, entered in narrative form, and thus uncaptured as structured data. These actions are consistent with the human capabilities of clinicians acting within time-limited patient visits but unnecessarily compresses valuable patient-generated health data, failing both to honor the patient's work in collecting them and capitalize on an important source of information for clinical decision making. This brief review of home blood pressure data was further confirmed in our Aim 4 video recordings of visits in which these data were presented on paper.

Human factors and design principles informing effective blood pressure data visualization (Aims 1, 3) Our research and design process yielded several key takeaway points for design of primary care blood pressure data visualization, as described in our published paper in *BMC Medical Informatics and Decision Making* and our *JAMIA* manuscript describing design of the medication timeline.[20,21,35] Some of these key takeaways are deeply rooted in human perception and cognition, others are further informed by principles of human factors engineering, and still others were discovered in our patient focus groups. One of the final prototypes, depicted in **Figure 2** shows many of these features, and **key features** are detailed below.

Figure 2: Final Prototype Example



- **Style of plot:** The most effective data presentation for primary care physicians proved to be a simple pair of line graphs, with one line each for systolic and diastolic blood pressure, graphed on the same field rather than separate graphs. The style of display frequently used in anesthesia settings, with an inverted caret for systolic connected by a vertical line to a caret for diastolic blood pressure, was judged unfamiliar and ineffective for use by primary care physicians for their more longitudinal review of these data.
- **Denoting source of data:** Participants found it helpful to have different symbols for different sources of data. Our prototype and eventual EHR implementation used solid circles for patient-generated data and solid squares for clinic data, a graphing convention that was quickly and intuitively understood by both physicians and patients. We conceptualized open circles for home blood pressure data from patient machines that had not yet been validated by the practice for accuracy. Taking the concept of open data points one step further, open squares may be considered for clinical settings where blood pressure data may be more variable and potentially less reliable for managing hypertension, e.g. data from an emergency room visit.
- **Goal ranges:** Banded goal ranges help users determine if readings are in range. Rather than simply an upper and lower line boundary, a band of background color denoting acceptable ranges allows the user's visual cognition centers to capitalize on pre-attentive attributes of color and 2-dimensional position to make judgment of control simple.
- **Color:** Our initial conceptualization used a greyscale color palette with the rationale that this presentation would allow for basic printing without a loss of information. But users had a very strong preference for color-coded goal ranges, citing that greyscale variations were less easy to differentiate. Our initial picks of orange systolic and blue diastolic (both color-blind safe) conflicted with the EHR style for normal and critical values, so we switched to mint for systolic and cocoa for diastolic. We employ "like with like" coloring of range bands, data points, and connecting lines such that systolic blood pressure data points, bands, and lines are all different hues of mint while diastolic data are different hues of cocoa.
- **Out of range values:** Despite our expert idea to use the pre-attentive attributes of color to draw user attention to out of range values, our vivid orange shading of values above the upper normal range was soundly characterized as duplicative and unnecessary by both patients and physicians:

  > *"Right. It [orange squares] doesn't seem to have a purpose. It doesn't seem to clarify anything; it doesn't seem to add anything to me… I can see that [orange fill means out of range]. I don't need the orange."* — Round 1 patient focus group participant
- **Data tables:** Users, especially physicians, still want to see the numbers associated with data points so that they can dig deeper into the initial impression of the display. Our prototype used a data table stacked on top of the graph as shown in **Figure 2**, but a subsequent update to the EHR visualization effectively uses hover-over to reveal the number associated with a data point which satisfies user information needs with a less cluttered display.
- **Data density:** We developed binning algorithms, presented in the Wegier manuscript, to aggregate data into a single point when data was too dense for the display parameters.[35]
- **Smoothing line:** Our Aim 2 results showed that increased blood pressure data variability very much affects user perception of control.[11] Therefore, we used a LOWESS algorithm to smooth the data and added a smoothing line to the display, superimposed on the raw data line graph.[34,35] This feature was included in both the final prototype and implemented EHR visualization.
- **Annotations:** The Wegier paper presents a detailed discussion of different ways to present user annotations without cluttering the display, including annotating events that happen at a single point vs. those that persist over time.[35] It may also be helpful to tag annotations or sort into categories. Linguistic summarization of the numeric data is another possibility for annotations as described in our manuscript led by Jain.[34]

- **Medication timeline:** Stacking the graphical display on top of, and corresponding in time to, a medication timeline helps users to correlate medication changes to blood pressure results, a key link in deriving meaning that influences decision making.[20] The medication timeline shown in **Figure 2** was implemented in the MU health system EHR, also stacked just below the graph display of blood pressure to facilitate those same blood pressure – medication comparisons.
- **Scrubber bar:** A movable vertical scrubber bar can help users navigate the data over the time displayed and link the data "story" across the blood pressure graph and medication timeline, and was also included in the MU EHR implementation.[35]

Patient and physician user information needs for hypertension management, and for incorporating home blood pressure in management (Aims 1, 3) Our focus groups highlighted the information needs of patients and physicians, as detailed in our 2020 *BMC Medical Informatics and Decision Making* manuscript.[21] Major themes for patient and physician users around blood pressure CDS and home blood pressures are listed in **Table 2**.

Table 2: User Information Needs Major Themes for Patients and Physicians

Theme	Patient Users	Physician Users
Data visualization enhances patient engagement and readiness to act	X	X
Colored goal bands make judgement of control easier	X	X
Customizable goals for different patients		X
Visualization and medication timeline help construct the blood pressure "story"	X	X
Design is intuitive	X	X
Facilitates hared understanding of control	X	X
Fitting in workflow, understanding who will receive and act on data	X	X

Patients and physicians emphasized the data visualization tools value for sensemaking as CDS, and how it contributed to the blood pressure "story". This was especially true for connecting blood pressure changes to medication changes shown in the medication timeline, as highlighted by these quotes from a physician and patient describing the trends seen in **Figure 2**:

> "It shows clearly that when you add, the Hydrochlorothiazide…and then when you added the additional Lisinopril, that looks like the combination of those… made the blood pressure come down." — Round 1 patient focus group participant
>
> "Neato…It's really just creating a story where you see what the blood pressure was, when the medicine was started, where it changed." — Round 4 physician focus group participant

In this manuscript, we also present patient and physician user ideas for annotations to help satisfy their information needs, as well as the type of annotations that would be most helpful.[21] For example, physicians frequently commented that identifying that an ACE inhibitor medication was stopped due to cough was a common need that is not well addressed by current systems, where physicians must commonly categorize this reaction as a medication allergy, which it is not; physicians consider this a necessary but unsatisfying and inaccurate work-around. Patients wanted to be able to document the effect on their blood pressure trends of lifestyle change such as stress or an exercise program.

Evaluation of the Medication Timeline (Aim 1) Use of the designed medication timeline, compared to conventional medication tabular lists, improved physician performance for 4 of 5 common medication-related tasks as shown in **Table 3**. While both forms of data display supported identifying current medications, the medication timeline better supported the four more complex tasks.[20]

Table 3: Task Accuracy and Task Time for table display vs. timeline				
	Mean Accuracy (% Correct)		Mean Time on Task (seconds)	
Task	**Table**	**Timeline**	**Table**	**Timeline**
Identify current medication	50	64	44	69
Identify a past medication	17	91	68	50
Identify length of time medication has been prescribed	44	93	22	16
Identify new prescriptions in a given time interval	50	62	65	30
Identify a dosage change in a given time interval	0	18	36	30

Effect of data visualization elements on patient perception of risk (Aim 2) With our Aim 2 online experiments, we empirically evaluated the effect of different data presentations on user perceptions. As detailed in the methods section, these were 6 small experiments followed by one larger experiment employing larger sample sizes to evaluate effects of several dimensions of user literacy on perception.

Table 4: Level of agreement (0 "Strongly Disagree" to 100 "Strongly Agree") with statement "the patient's blood pressure is well controlled" for graphed blood pressure data with different means and SD			
	SD = 5 Mean (95% CI)	SD = 15 Mean (95% CI)	SD = 25 Mean (95% CI)
Mean BP = 130	79 (73-85)	57 (49-65)	29 (22-37)
Mean BP = 145	40 (31-48)	23 (16-31)	22 (14-30)
Mean BP = 160	23 (15-31)	17 (9-24)	18 (10-25)

Of the 156 adults with hypertension participating in Experiments 1-3, 65% were female, 74% white, 26% had a high school education or less and the mean age was 47 years with a range of 19-79 years. In Experiment 1, participants viewed 12 permutations of graphs with combinations of different mean blood pressure and standard deviation. The participant level of agreement with the statement "the patient's blood pressure is well controlled" decreased in a statistically significant manner with greater variability (standard deviation) of blood pressures, **Table 4**. To highlight a striking finding, note the sharp decline in perception of control for a mean blood pressure of 130 mmHg when standard deviation (SD) of the presented data rises from 5 to 25 mm Hg, line 1 of **Table 4**.[11] Clearly the standard deviation of blood pressure data influences the judgement of control for patients. In Experiment 2, blood pressure was also more likely judged to be controlled with a decreasing data trend compared to increasing, despite having the same overall mean.[11] In Experiment 3, participants judged blood pressure data with the same overall mean to be more out of control in the presence of outliers, with the number and magnitude of outliers being a significant driver of judgements toward less control.[11]

An additional 209 adults with hypertension completed Experiments 4-6, with 69% female, 77% white, 26% had a high school education or less and the mean age was 50 years, with a range of 18-80 years. Experiments 4 and 5 demonstrated that participants were more likely to judge blood pressure data with different means and trends as not controlled when presented with raw data than with data presented with a "smoothed" line using a LOWESS algorithm, in agreement with experiment 1, and providing an additional empiric foundation for our choice of a smoothing line for the final prototype.[12] Experiment 6 demonstrated that blood pressure was perceived to be less well controlled when presented in a graph than in a data table, although recall of the number of blood pressures outside goal range was more accurate with the graph presentation than the table.[12]

Experiment 7 examined the effect of user health literacy, subjective and measured numeracy, and graph literacy on participant judgments of control using these graphical displays. Of the 1,079 participants with hypertension, 65% were female, 78% white, 26% had a high school education or less and the mean age was 54 years with a range of 18-99 years; 65% of this national sample reported monitoring their blood pressure at home on at least a monthly basis. As in the smaller

Experiments 1-6, judgments about hypertension control were significantly influenced by mean SBP value, standard deviation, and data visualization type. Judgments about hypertension data presented as a smoothed graph were significantly more positive (i.e., hypertension deemed to be better controlled) then judgments about the same data presented as either a data table or an unsmoothed graph. Hypertension data viewed in tabular form was perceived more positively than graphs of the raw data with regard to blood pressure control. These findings were moderated by patient graph literacy, numeracy, and health literacy. Data visualization format had the greatest impact on participants with high graph literacy (Shaffer, et. al., revision submitted to *Annals of Family Medicine*).

Linguistic summarization of data trends (Aim 1) We investigated the use of linguistic summarization of numeric data, with the hypothesis that this type of text-based summarization would help users in interpreting copious numeric data. We were able to develop a decision support system based on a fuzzy rules system for decisions about blood pressure control over time, which also generated linguistic protoform summaries. This involved automated processing of numeric blood pressure data and trends using a fuzzy rule system to create text summaries of the data such as "The blood pressure was above the goal range for a few days in the last two weeks." This fuzzy rule system had an average interclass correlation coefficient (ICC) of 0.97 with three clinical experts; ICC for the three experts was 0.95.[34]

While the linguistic summarization was effective from an accuracy perspective, our focus groups of physicians and patients roundly dismissed the text summarizations as redundant and less effective than the graphic presentation of data in the CDS visualization. Although we hypothesized that linguistic summarization would be effective, and planned to incorporate this feature, we ultimately abandoned this type of automated processing for the final prototypes. In addition to the lukewarm response from users, linguistic summarization adds a level of sophistication and programming that would make the FHIR-based API more complex and potentially unattractive for EHR vendors. Essentially, it was a "long run for a short jump".

Impact of Blood Pressure Visualization Tool Use on Hypertension Decision Making and Patient Engagement (Aim 4)

In recordings of 89 clinic visits for patients with hypertension (n=89) with their physicians (n=15), patient participants were 55% female, 87% white, 87% established users of the EHR patient portal, 73% had controlled blood pressure at the baseline visit (similar to mean for the practice), and mean age was 63 years. Use of the blood pressure decision support tool in the EHR did not produce any statistically significant change in the length of the visit compared to visits where patients brought home blood pressure on paper lists, a reassuring finding for time-pressed primary care physicians. Effect of data presentation modality on the decision process was also similar as, whether using paper or EHR visualization during the visit, discussion of home blood pressure during a visit typically had the following steps: 1) blood pressure topic initiated, 2) acknowledgement of receipt of home blood pressures, 3) trends of blood pressure readings reviewed, 4) assessment of these readings negotiated, 5) hypertension management discussed with a treatment decision being reached.

However, compared to paper lists, use of the EHR blood pressure data visualization conveyed advantages in ease of use, enhanced and faster sense making, and improved patient-perceived engagement in decision-making. To realize these benefits, practices needed to ensure 1) the room layout, including the positioning of the physician and patient relative to the computer monitor allowed for screen sharing, 2) that patients had access to equipment at home to measure blood pressure and knew how to use their monitor, 3) that patients collected these data, and 4) had the know-how to enter them into the EHR via a portal. Use of a computer with a flexible arm made screen sharing easier, allowing the physician to invite and the patient to see the visualization tool (Cohen et. al., manuscript submitted for review for publication). The clinic visit transcript and accompanying screenshot in **Figure 3,** from the submitted manuscript, illustrates how the data visualization was used during a patient visit to help create a shared understanding of the effect of a medication change on blood pressure control.

Figure 3: Visit Transcript and Screenshot

Physician and Patient are sitting across from each other, with the computer monitor between them.

Phys: So basically it's really nice because it shows you [*Physician points to the screen with her pen, to highlight what she is explaining; Patient leans forward to see the screen.*] here you were on the 50 milligrams and the blood pressure was above, you see, this is where we want it to be. The higher number in the green area and the- the lower number in the brown area and you can see that it was above

PT: Uh huh.

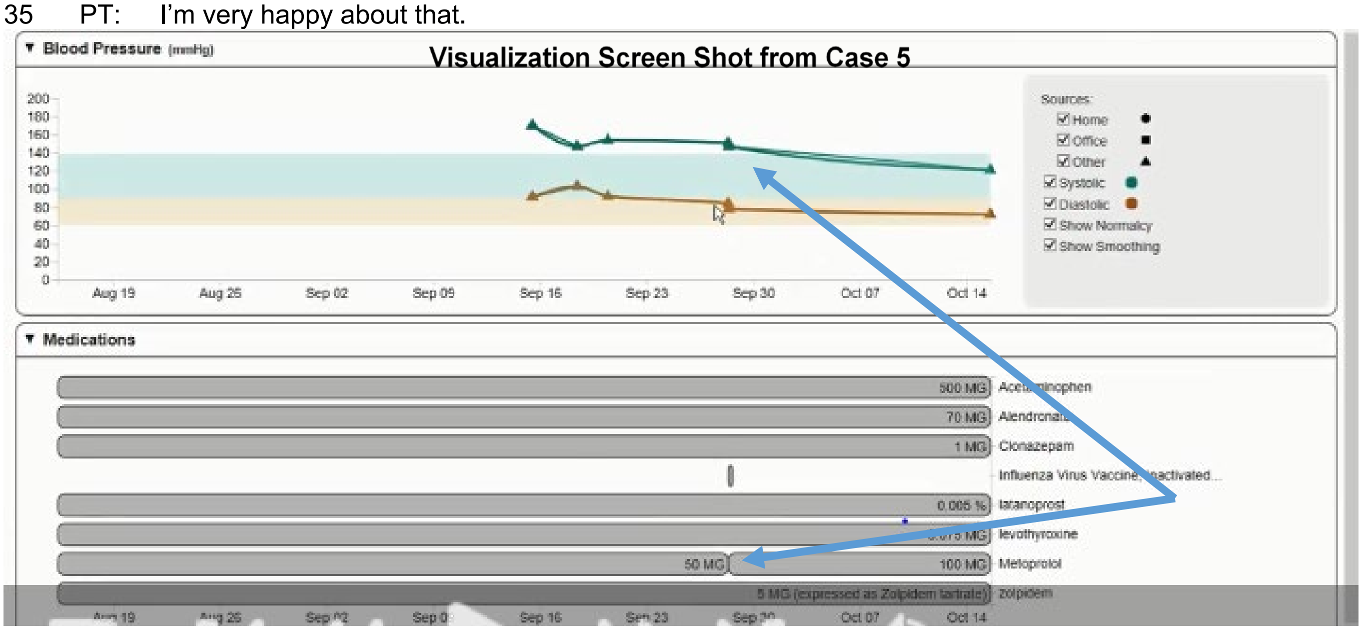
Phys: when you were on the 50. And, here is the 50. The- when it was increased to 100 milligrams of the Metoprolol [*Physician briefly turns her head to the patient to make sure she is tracking. Patient nods her head, showing she is tracking*] and today how beautiful it is.

PT: Yes. [*Patient sits back in her chair*]

Phys: The numbers are exactly in the middle where we want it to be. [*Physician directs her attention toward Patient*]

PT: Great. [*Patient laughs gently with pleasure, and gives Physician a thumbs up*]

PT: I'm very happy about that.



<u>Outcomes:</u>

Implementation of the clinical decision support tool in the EHR, impact on infrastructure

We developed and implemented a tool for patients to upload home blood pressure in the EHR patient portal (released April 2018) and linked this to an EHR blood pressure visualization displaying clinical and home blood pressure and a corresponding medication timeline (released September 2018). A critical aspect of this work has been our successful collaboration with the Tiger Institute, a research and development collaboration engine between University of Missouri and Cerner Corporation, a major US and global EHR vendor. Our collaboration in this work has resulted in the implementation of a mechanism for patients to enter home blood pressure values into the patient portal, flow of these data to the clinical EHR, and programming the FHIR-based CDS tool into the EHR.

Tiger Institute has worked with Cerner Corporation, headquartered in Kansas City, Missouri, on technical coordination including server hosting, the FHIR API, and data security measures. The Tiger

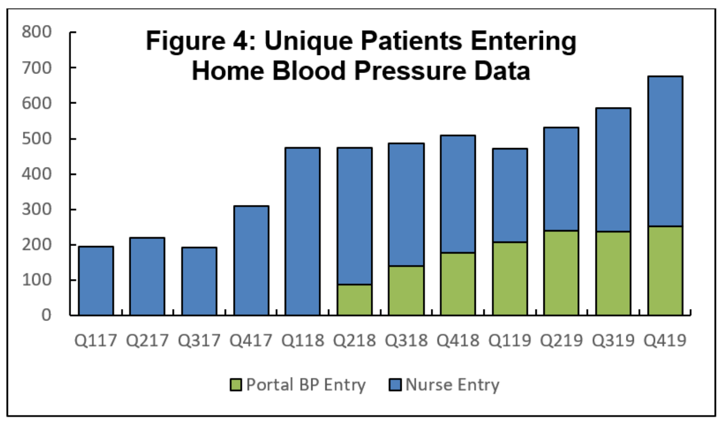
Institute dedicated over 5000 hours to this work with over 4,500 hours committed to results graphing in the EHR and 500 hours to update the patient portal for home blood pressure data entry. This commitment signals prioritization of this innovative work, recognition of its clinical value, and a desire to partner with our team moving forward.

The very visible outcome of this research is that physicians in the health system in the departments of family medicine, internal medicine, and obstetrics/gynecology all have access to the new data visualization in the EHR. Principal Investigator Dr. Koopman has given grand rounds in each of these three departments to educate over 200 physicians about the tool, with an enthusiastical response. A gynecologic oncologist commented that the tool would be quite useful in monitoring patients in clinical drug trials where monitoring blood pressure is often an important aspect of the work. Dr. Koopman also educated 35 health system primary care nurse care coordinators who help to manage complex patients with increased care needs; they also enthusiastically embraced the tool.

We have begun to see how patients and physicians now use home blood pressure data to influence clinical care now that these data are within their clinical electronic workflow. We believe that the routine availability of home BP data along with clinical BP data in the EHR at the point of care will be nothing less than transformative for the care of patients with hypertension. Below we present some of the subsequent effects of our work on clinical care.

Patient uploads of home blood pressure

Between the soft launch of the new home blood pressure portal entry screen in April 2018 and February 2020, over 1,000 unique patients uploaded over 15,000 home blood pressure data pairs using the new tool. Using EHR data analytics pre- and post-implementation of the patient portal home blood pressure entry, Tiger Institute documented both an increase in overall entered home blood pressures in the EHR and a replacement of clinician home blood pressure entry with patient entry, **Figure 4**.



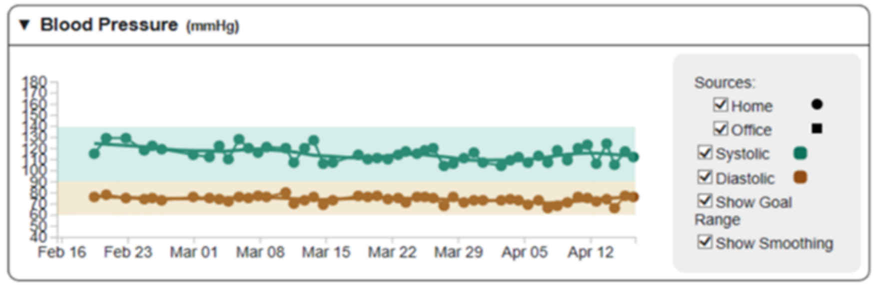
Saving clinician time in clinics

Prompted by the finding highlighted in **Figure 4**, communication with clinic nurses revealed that they estimated spending approximately 5 minutes per patient to average home blood pressure data and record it in the EHR. Therefore, patient entry of home blood pressure can save time for clinicians; in quarter 4 of 2019, this would have saved 36 hours of clinician time across the health system.

Impact on care during the Covid-19 pandemic

The Covid-19 pandemic produced a rapid transition from in-person to telehealth visits for primary care and other care settings.[36] Managing hypertension depends on evaluating blood pressure data; the sudden inability to measure blood pressure at clinic visits had the potential to create important gaps in care for this important and impactful chronic condition. While patients could certainly measure blood pressure at home, we have already detailed the difficulties of incorporating these data when not presented within clinical electronic workflow. Patients in the MU health system had the option to upload blood pressures to this new tool, making judgment of hypertension control easy during telehealth visits. Thanks to a system-wide implementation, enabled by this AHRQ grant, Principal Investigator Dr. Koopman and her primary colleagues caring for 70,000 patients with hypertension, of whom 74% are portal users, had the benefit of being able to easily view patient-generated home blood pressure data within their EHR digital workflow as shown in **Figure 5**, an EHR screenshot taken from a patient telehealth video visit with Dr. Koopman in April, 2020, one month into the onset of the Covid 19 pandemic. It is worth noting that **Figure 5** contains 49 patient submitted home blood pressures, with both systolic and diastolic values doubling the effective data load. This use case dramatically illustrates how our data visualization substantially lightens cognitive load, allowing the pandemic-burdened clinician or patient user to conclude “in control” with a single glance.

Figure 5: Data visualization enables hypertension care during Covid -19 pandemic



Discussion

We have tackled a tough problem in chronic care management, the integration of patient-generated health data with several forms of clinical data to inform shared management decisions at the point of care. Typically this onslaught of data from different sources and in different formats quickly overwhelms human cognitive processing ability. Highly educated physicians are simply human and therefore are constrained by these known limitations on active cognitive processing. The combined forces of “information chaos” at work during a visit with a patient with a chronic condition routinely include information overload, information underload, information conflict, information scatter, and erroneous information, and can lead to a decrease in situational awareness.[37] Because the provider is trying to simultaneously handle a barrage of inputs from multiple sources about many different problems, they can overlook important data such as a high blood pressure reading, especially as it does not typically produce symptoms.[37] An estimated 29% of family medicine errors are related to information handling problems.[38] Providers trying to reconcile the current clinic blood pressure, past blood pressures, and home blood pressures may make errors in assessing the magnitude of the patient’s blood pressure problem. Our data visualization provides needed CDS for this problem, easing the burden for physicians and patients and making the once overwhelming task now delightfully approachable.

Nowhere could this intervention have been more needed and more impactful. Hypertension management provided the “perfect storm” as a use case for our work for the following reasons:

- **Disease impact:** Lack of blood pressure control is the most significant risk factor for the most frequent cause of death in the United States prior to the Covid 19 pandemic, heart disease.[1-3]
- **Unacceptable quality of care:** Only 24-54% of Americans with diagnosed hypertension have controlled blood pressure in national estimates.[4]
- **Uncertainty:** Uncertainty in the judgement of control is a known factor in clinical inertia in hypertension care.[20] We have also observed this uncertainty in *patients*, leading to negotiations about treatment decisions during time-limited patient visits. We have further elucidated some of the cognitive and perceptual factors that contribute to this uncertainty.[11,12]
- **Patient-generated health data:** Mounting evidence supports the use of home blood pressure in hypertension care decision making, however incorporating home data increases cognitive load for physicians and patients, further contributing to uncertainty when discrepancies occur.

Our designed and implemented visualization specifically addressed these human factors to create improved meaning for patients and physicians, easing cognitive load and their shared decision making process during patient visits. Further, our medication timeline tackled the tough problem of connecting medication changes to blood pressure trends, increasing accuracy and decreasing time for physicians in common medication-related tasks.[20] Physicians and patients responded very positively to the new designs, reporting enhanced and faster sense-making and patient engagement in decision making (Cohen, et. al., submitted for publication).

We should note some limitations and areas for continued study. This work responded to a program announcement that challenged us to investigate information needs and design decision support to meet these needs for patients *or* physicians – we did both. Because we had observed that hypertension management decisions were very often a negotiation about how the current clinic blood pressure represented control, we elected to pursue a deep understanding of information needs and design decision support for the patient-physician dyad that are the principle actors in that decision. We limited our work to that dyad; future work to investigate nurse and other team member information needs and decision support would be valuable. We also limited the work to adults as blood pressure and hypertension in children have both different norms, and frequently, different underlying etiologies, and therefore management considerations. The program announcement to which we responded focused heavily on discovering information needs; our successful implementation work and testing in a live environment during actual clinical visits was actually not something we were sure that we could accomplish in the original proposal, in which we had provided an alternate evaluation plan if we were unable to effect an EHR implementation. Additionally, we designed for qualitative examination of the completed tool rather than clinical effectiveness, focusing on how this might be used and how it might affect decisions, consistent with the priorities of the program announcement. As such our design, methods, and sample size supported that primary qualitative goal rather than the larger sample size and different design that would have supported an inquiry into the effect on clinical outcomes.

Conclusions

Home blood pressure data can be effectively integrated into clinical EHR workflow through our decision support and data visualization tools. Incorporating these patient-generated data into clinician workflow has the potential to not only improve clinical decision making and hypertension control, but likely also increases patient motivation to provide these data. Enabling effective representation of blood pressure data from outside the clinical setting, where blood pressure is often lower, can also help clinicians to increase safety for their patients by avoiding inappropriate anti-hypertensive medication intensification, which might lead to life-threatening hypotensive episodes. Our CDS is a FHIR-based API, making it scalable and transportable to other settings, with the potential to then impact the lives of many more patients. Further investigation into the effect of implementing the CDS on hypertension clinical outcomes, and work to improve the patient-facing decision and self-management support are fertile areas for future inquiry.

Significance

Our design and implementation work led to a CDS tool that is live and continues to be available in the EHR for the University of Missouri health system. This includes the following elements and capabilities:

- Secure patient portal-enabled upload of home blood pressures
- Flow of patient-entered blood pressures from the patient portal to the EHR
- Effective data visualization at the point of care for home and clinical blood pressures using a FHIR-based API
- An accompanying medication timeline to map medications to changes in blood pressure

This system became fully functional with all components in the EHR in September 2018; patient portal blood pressure uploads went live in April 2018. In the first two years, over 15,000 pairs of blood pressure data (systolic and diastolic) were uploaded by over 1000 unique patients. In 2019 and early

2020, over 200 physicians in family medicine, internal medicine, and obstetrics/gynecology, and 35 nurse care coordinators were educated on the use of the new CDS tool.

The local impact of this tool was magnified by the Covid-19 pandemic, allowing patients and physicians to effectively communicate and judge hypertension control using patient-generated home blood pressure data during remote telehealth video visits. In April 2020, PI Koopman herself experienced the possibility of upholding the quality of hypertension care with remote monitoring only during the early days of the pandemic, using the patient's home data, and sharing the data visualization with the patient via screen share during video telehealth visit.

Implications

This work has strong implications for incorporating patient-generated health data into EHR workflow and condition management. Our discovery and confirmation of physician-patient information needs and preferences, as well as key design elements can inform future implementations for CDS and data visualizations.[20,21,35] Additionally, our work incorporates not just good design practice, but also accounts for the context of care, designing to create meaning and to ease user cognitive load in the service of making good decisions. We have also placed our work in the primary care context, the site of 85% of hypertension care.[10] This work has begun to influence the science of patient-generated health data and will be the target of further AHRQ-sponsored dissemination efforts.[39]

We have based our work on principles of cognition, motivation, and human factors design. We have also empirically tested these principles at work in our designs, and in the contexts of data visualization, hypertension care, and primary care. In these perceptual experiments, we have specifically examined the effect of different data representations on patient decision-making.[11,12] This innovative investigation has strong implications for the study of motivation and behavioral economics in health interventions. We have been very cognizant of our potential to "nudge" patients and physicians by altering the form of data visualization, as well as the implications of such an influence on perception, and the potential clinical good and harm that these changes can produce. Our identification and quantification of the perceptual effects of altering display elements, such as a "smoothing line" that smooths variable blood pressure data, should influence the design of future CDS as well as the use of behavioral economics in clinical interventions.[12]

List of Publications and Products

Keywords: Hypertension, Clinical Decision Support, Data Visualization, User-Centered Design, Information Needs, Home Blood Pressure Monitoring, Electronic Health Records, Decision Making, Patient-Generated Health Data, Human Factors, Primary Care, Risk Perception

Publications

1. Jain A, Popescu M, Keller J, Belden JL, Koopman RJ, Patil SJ, Canfield SM, Steege LM, Shaffer VA, Wegier P, Valentine KD, Hathaway A. A Decision Support System for Home BP Measurements. In Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare 2017:231-234.
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7. Wegier P, Belden JL, Canfield SM, Shaffer VA, Patil SJ, LeFevre ML, Valentine KD, Popescu M, Steege LM, Jain A, Koopman RJ. Home blood pressure data visualization for the management of hypertension: Using human factors & design principles. In press, BMC Medical Informatics and Decision Making.

Submitted manuscripts under review

1. Shaffer VA, Wegier P, Valentine KD, Duan S, Canfield SM, Belden JL, Steege LM, Popescu M, Koopman RJ. Patient Judgments about Hypertension Control: The Role of Patient Numeracy and Graph Literacy. Revision submitted for publication in response to initial review.
2. Cohen DJ, Wyte-Lake T, Canfield SM, Steege LM, Koopman RJ. Impact of Blood Pressure Visualization Tool Use on Hypertension Medical Decision Making. Submitted and under review for publication.

Conference Presentations

The team made 26 presentations of the research at national and international conferences:

- 8 at North American Primary Care Group (NAPCRG)
- 8 at Society for Medical Decision Making (SMDM)
- 3 at Healthcare Information and Management Systems Society (HIMSS)

- 2, including 1 plenary presentation, at Improving Primary Care Through Industrial and Systems Engineering (I-PRACTISE)
- 1 at Pervasive Health Conference
- 1 at Human Factors and Ergonomic Society in Health Care (HFES)
- 1 at American Medical Informatics Association (AMIA)
- 1 for Journal Club of Journal of the American Medical Informatics Association (JAMIA)
- 1 at Million Hearts Mid-America Conference of the American Heart Association (AHA)

The team also made 11 presentations within the MU Health System as part of the design and implementation of the CDS system.

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