NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Design and Pragmatic Trial of COACH

A patient portal/EHR information system for home blood pressure monitoring in hypertension

May 12, 2023

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University of Missouri

Acknowledgements

This work is supported by **Agency for Healthcare Research and Quality (AHRQ)** grants

- R01 HS023328 "Optimizing Display of Blood Pressure Data to Support Clinical Decision Making" PI: Koopman
- R18 HS028579 "Collaboration Oriented Approach to Controlling High blood pressure (COACH)" PIs: Dorr, Koopman

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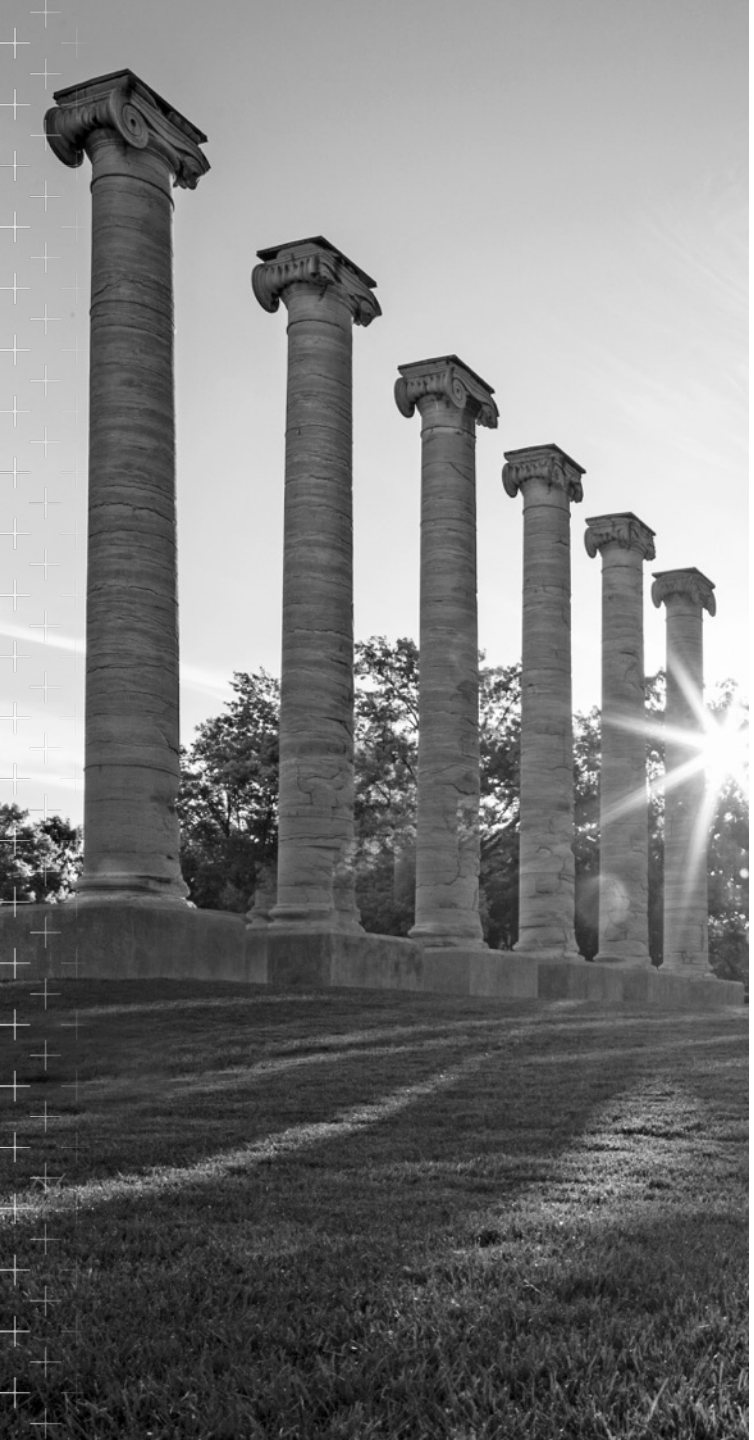
No relevant financial interests or conflicts to disclose.



Presentation Overview and Learning Objectives

1. Present our past work designing and testing an intuitive health data visualization of patient reported data and explain how the visualization tools lead to better-informed patients and improved care decisions
2. Describe our ongoing work on the refinement and implementation of the Collaboration Oriented Approach to Controlling Hypertension (COACH) EHR/patient portal app
3. Discuss decisions made in designing a pragmatic trial of COACH

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Part 1

Data Visualization to Support Hypertension Decision Making

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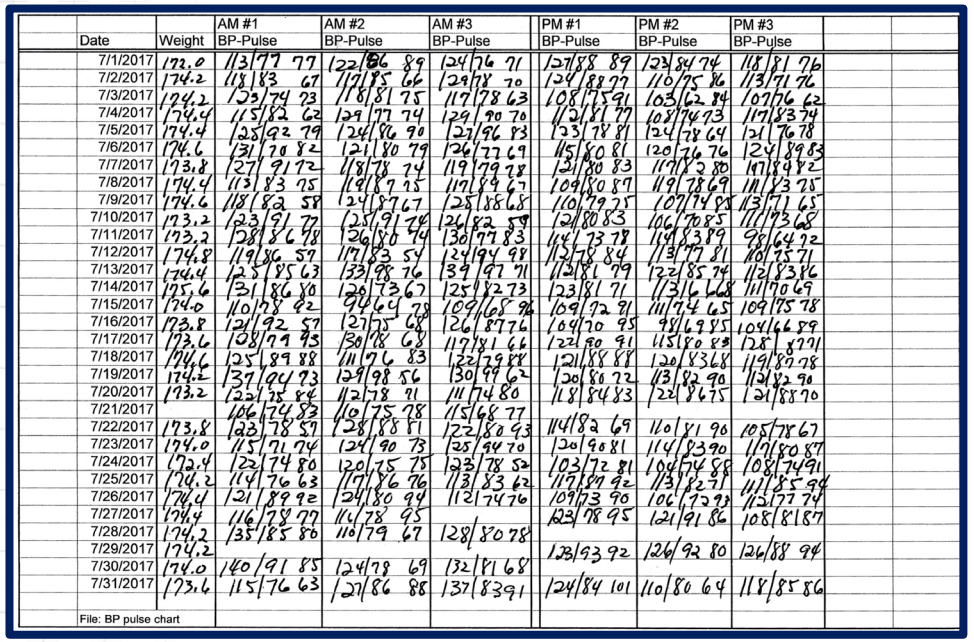
The Problem and The Solution

- The problem: Incorporate patient-generated home BP data into clinical workflow
- The solution: EHR data visualization of home bp data entered via the patient portal



Date	Weight	AM #1 BP-Pulse	AM #2 BP-Pulse	AM #3 BP-Pulse	PM #1 BP-Pulse	PM #2 BP-Pulse	PM #3 BP-Pulse
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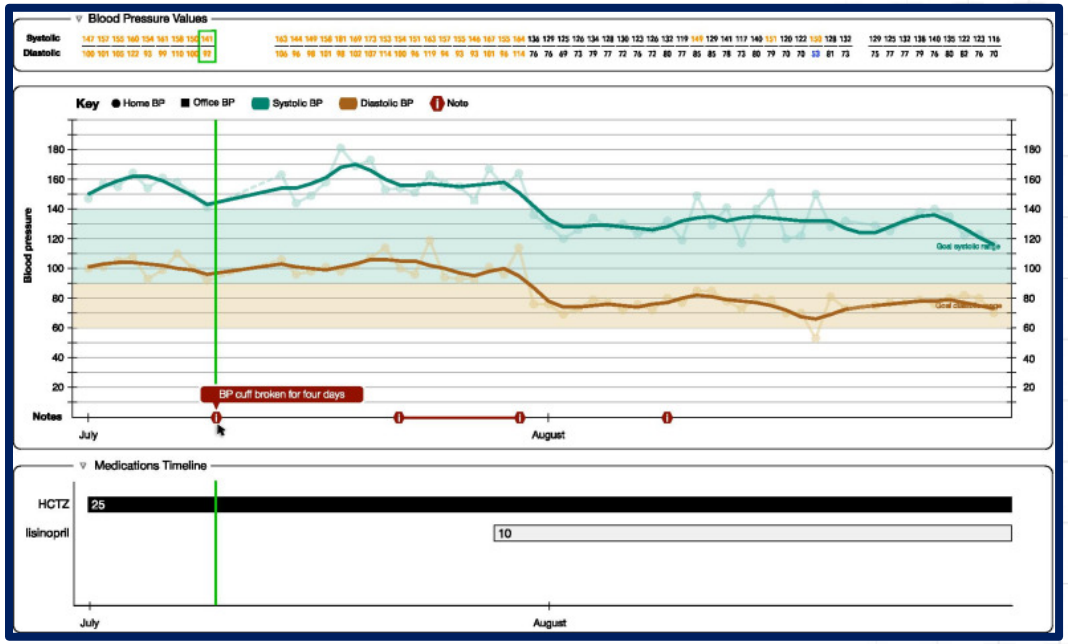
7/2/2017	174.2	118/83 67	117/85 66	129/78 70	124/88 77	110/75 86	113/71 76
7/3/2017	174.2	123/74 73	118/81 75	117/78 63	108/75 91	103/62 84	107/76 62
7/4/2017	174.4	115/82 62	129/77 74	129/90 70	112/81 77	108/74 73	117/83 74
7/5/2017	174.4	128/92 79	124/86 90	121/96 83	123/78 81	124/78 64	121/76 78
7/6/2017	174.6	131/70 82	121/80 79	126/77 69	115/80 81	120/76 76	124/89 83
7/7/2017	173.8	127/91 72	118/78 74	119/79 78	121/80 83	119/82 80	117/89 82
7/8/2017	174.4	113/83 75	119/87 78	117/89 67	109/80 89	119/78 69	111/83 75
7/9/2017	174.6	118/82 58	124/87 67	125/88 68	110/79 75	107/74 88	113/77 65
7/10/2017	173.2	123/91 77	125/91 74	124/82 59	121/80 83	106/70 85	111/73 68
7/11/2017	173.2	128/86 78	126/80 74	130/77 83	114/73 78	114/83 89	98/64 72
7/12/2017	174.8	119/86 59	117/83 54	124/94 98	113/78 84	113/77 81	110/75 71
7/13/2017	174.4	125/85 63	133/98 76	139/97 91	112/81 79	122/85 74	112/83 86
7/14/2017	175.6	131/86 80	120/73 67	125/82 73	123/81 71	113/76 68	111/70 69
7/15/2017	174.0	110/78 82	94/65 78	109/68 96	109/72 81	111/74 65	109/75 78
7/16/2017	173.8	121/92 57	127/85 68	126/89 76	109/70 95	98/69 85	104/66 89
7/17/2017	173.6	108/79 93	130/98 68	117/81 66	122/80 91	115/80 83	128/87 71
7/18/2017	174.6	125/89 88	111/76 83	122/79 88	121/88 88	120/83 68	119/80 78
7/19/2017	174.2	137/94 93	129/98 86	130/99 62	120/80 72	113/82 90	112/82 90
7/20/2017	173.2	123/78 84	112/78 91	111/74 80	118/84 83	122/86 75	121/88 70
7/21/2017		106/74 83	110/75 78	115/68 77			
7/22/2017	173.8	123/78 57	128/88 81	122/80 63	114/82 69	110/81 90	105/78 67
7/23/2017	174.0	115/71 74	124/90 73	125/94 70	120/90 81	114/83 90	117/80 87
7/24/2017	172.4	122/74 80	120/75 75	123/78 52	103/72 81	104/74 88	108/74 91
7/25/2017	174.2	114/76 63	117/86 76	113/83 62	117/89 92	113/82 71	111/85 94
7/26/2017	174.4	121/89 92	124/80 94	112/74 76	109/73 90	106/72 93	112/77 74
7/27/2017	174.4	116/78 77	114/78 95		123/78 95	121/91 86	108/81 87
7/28/2017	174.2	135/85 86	110/79 67	128/80 78			
7/29/2017	174.2				128/93 92	126/92 80	126/88 94
7/30/2017	174.0	140/91 85	124/78 69	132/81 68			
7/31/2017	173.6	115/76 63	127/86 88	137/83 91	124/84 101	110/80 64	118/85 86

File: BP pulse chart



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Our Methods by Objective

Overarching iterative human-centered design process beginning April 2015

Determine patient/physician information needs

- 10 focus groups and key informant interviews
- n =16 patients, n = 24 FM/GIM physicians, and n = 1 CMIO

Assess effect of form of data visualization on patient risk perception

- 6 online experiments each with n = 50-75 people with hypertension, US national sample

Assess interaction of health literacy, numeracy, and graph literacy with form of data visualization

- 1 large online experiment, n = 1079

Our Methods by Objective

Explore use of fuzzy logic and linguistic summarization of data

- Data experiments with patient home blood pressure data, n = 40 patients with 90 days of data

Pair blood pressure data visualization with medication timeline

- Usability task analysis, n = 21 physicians

EHR Implementation, phased July 2018 – May 2019

Examine effect of implemented data visualization on physician-patient communication about hypertension

- Video recordings including screen capture of 89 patient visits with 15 physicians with conversation analysis

Visualization Design

Our Team's Principles

1. Design for primary care setting
2. Design for shared decision making
    - Patient information needs and comprehension
    - Physician information needs and workflow
3. Intuitive design
4. Cognizant of how data visualization can affect decision making

What will people expect to see?

What will help them with their work?

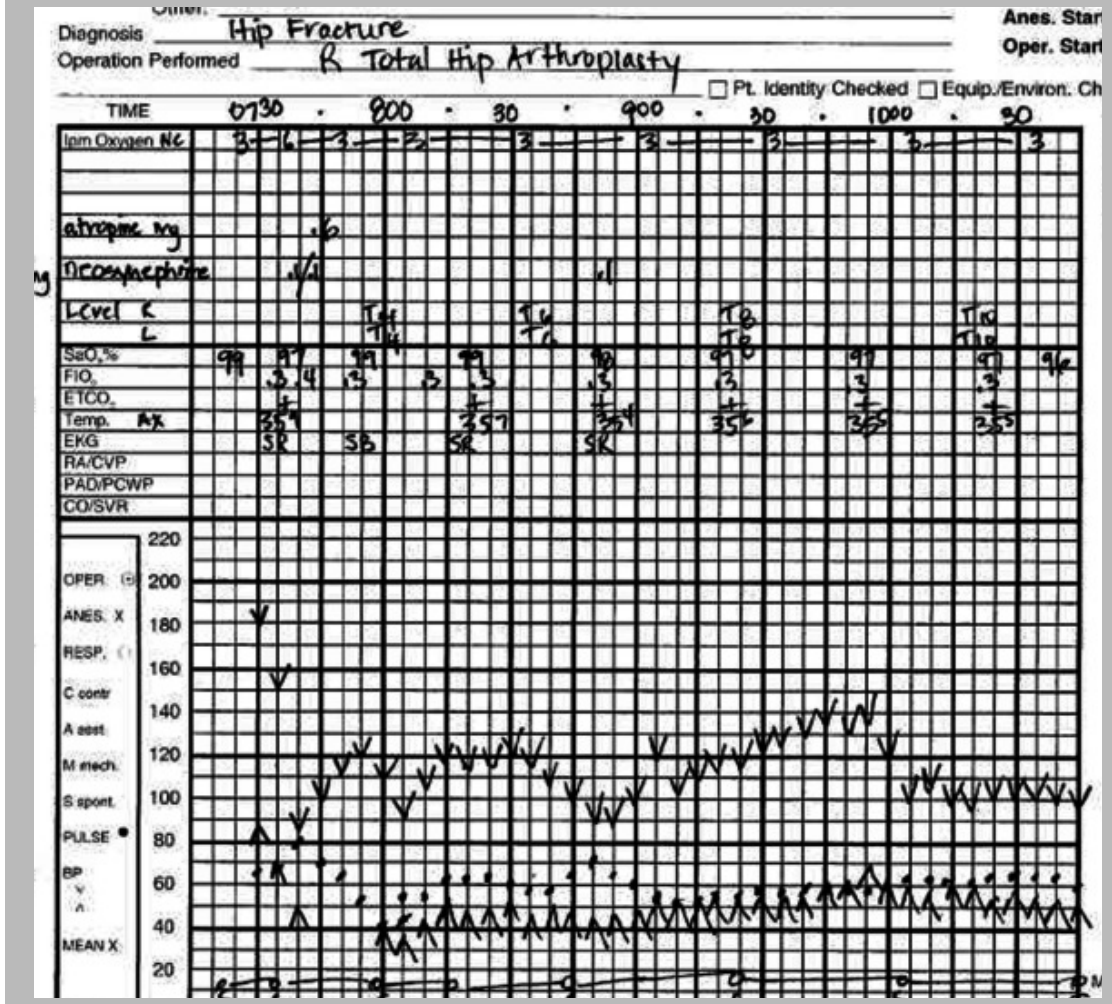
Fang J, Alderman MH, Keenan NL, Ayala C, Croft JB. Hypertension Control at Physicians' Offices in the United States. *Am J Hypertens.* 2008;21(2):136-142

Design for Primary Care Setting –

NOT Primary Care Example

Typical anesthesia intra-operative display

Caret and inverted caret, include heart rate and other data



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Principle: Design for Primary Care Setting

Information Need	Design Element
Systolic and diastolic data	Two-line graphs, Color to differentiate
Clinic and home data	Different symbols, same graph, same line
See the raw data numbers	Stack with values/hover over
Effect of medications on blood pressure	Stack graph with medication timeline
Understand goal ranges	Shaded goal ranges, default setting
Emphasize out of range values	Color, symbols (both rejected)
Customizable goal ranges	Radio buttons vs. manual entry
Patient burden of entry	Automated data upload
Understand data variability relative to control	LOWESS smoothing line
Contextual life event data	Annotations (version 3.0?)

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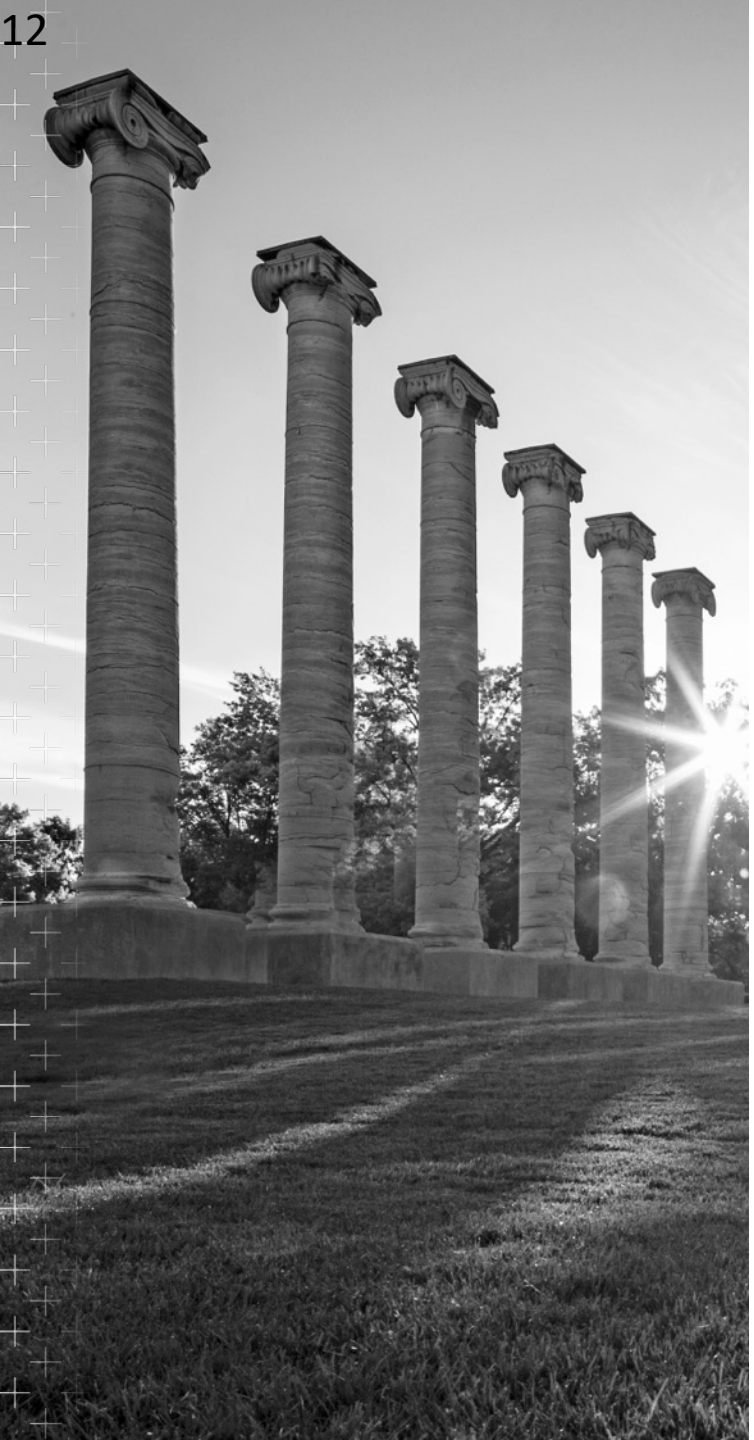

Iterating Based on Patient-Physician Needs

From our ideas to what they need

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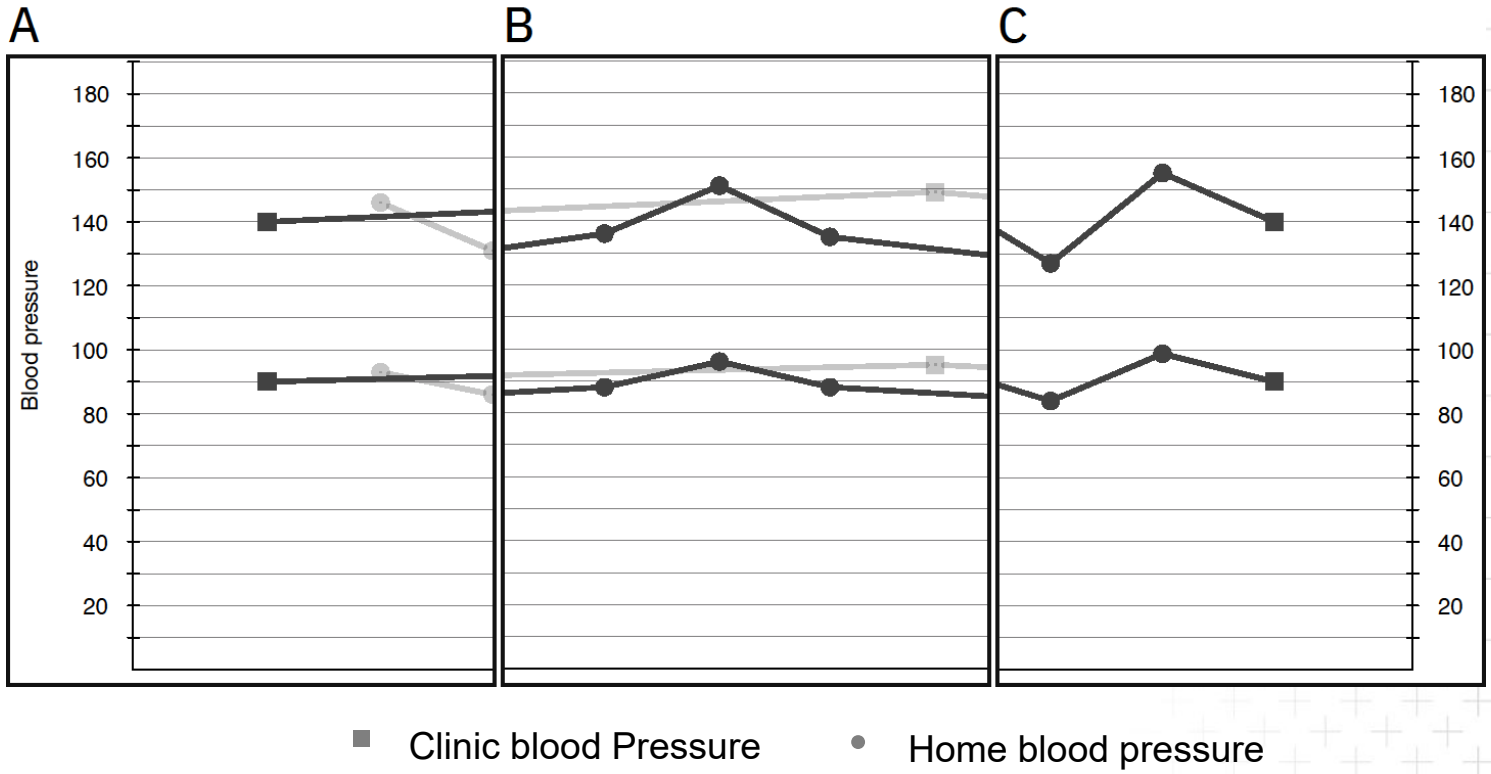
Early Design

Representing Both Home and Clinic Blood Pressure

Fig. A and B: Toggle between clinic and home (vivid/soft)

- [x] Fig. C: Both on same line, different symbols



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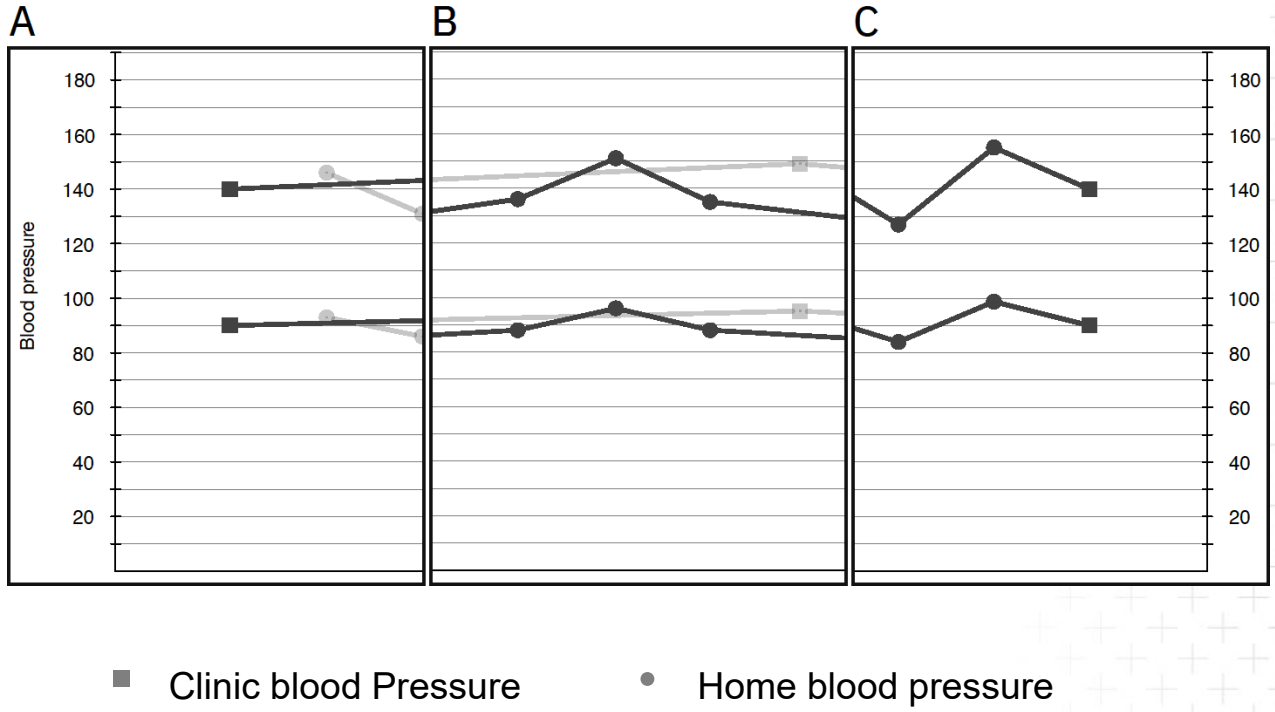
More Early Design Decisions

- 2-Line graph form with systolic and diastolic in same graph space
- Lines continuous despite gaps in data
- Y axis remains constant despite no values below 80 mm Hg
- Home blood pressure given equal weight to clinic blood pressure
- Experimented with open vs. closed data points for home blood pressures depending if home monitor had been validated



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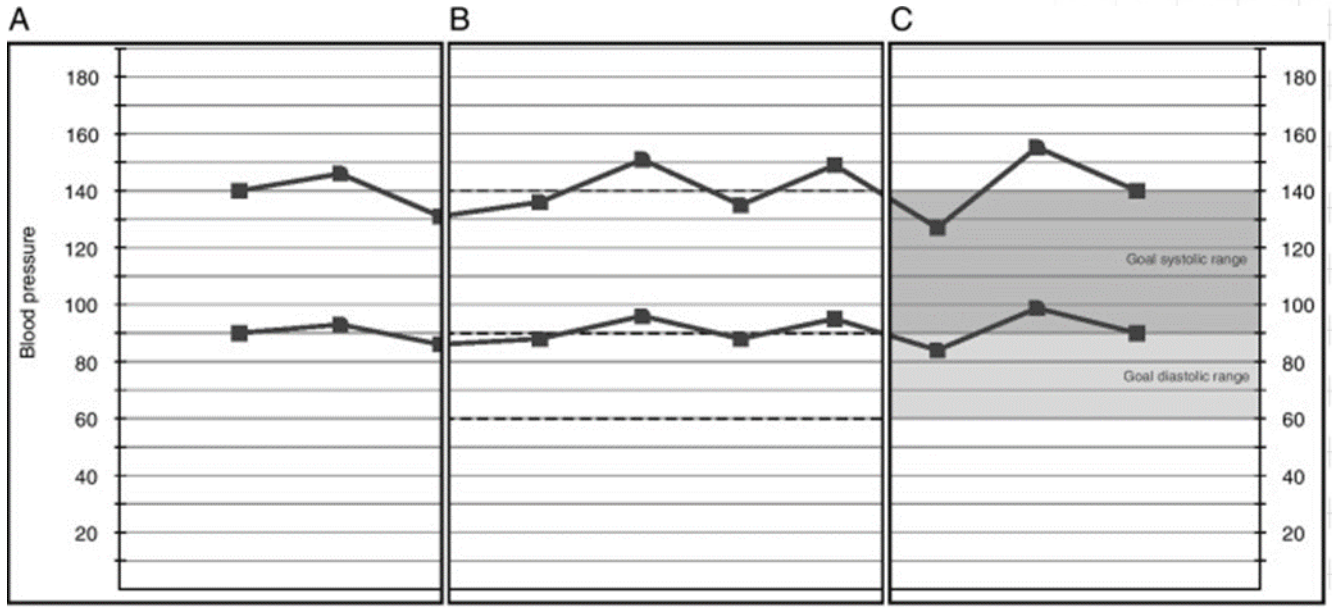
Goal Range Design Decisions

- Patients and physicians strongly desired indicators of goal
- Capitalizes on pre-attentive attributes of color and enclosure to simplify visual processing – easier to see that data is “in” or “out” of range
- Color – we thought that people might want to print these graphs, so we designed in grayscale, a decision we would quickly abandon



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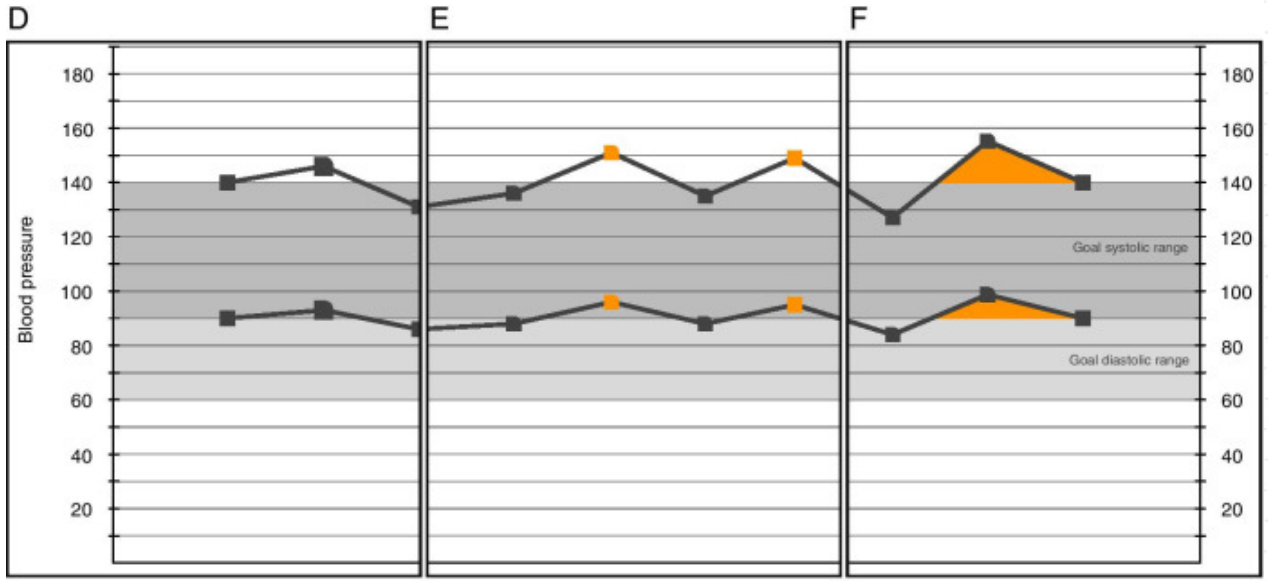
Belden JL, Patel J, Lowrance N, Plaisant C, Koopman RJ, Moore JL, Snyder TR, Sonin J. Inspired EHRs: Designing for Clinicians. 2014. Ebook available at InspiredEHRs.org

Emphasize Outliers?

- Experimented with color to emphasize outliers – used an “alarm” color
- Perhaps increase emotional salience for the viewer?
- Physicians and patients hated these – felt to be redundant with goal ranges

“It [orange squares] doesn’t seem to clarify anything… I can see that [orange fill means out of range]. I don’t need the orange.”
— Round 1 focus group, Patient 17



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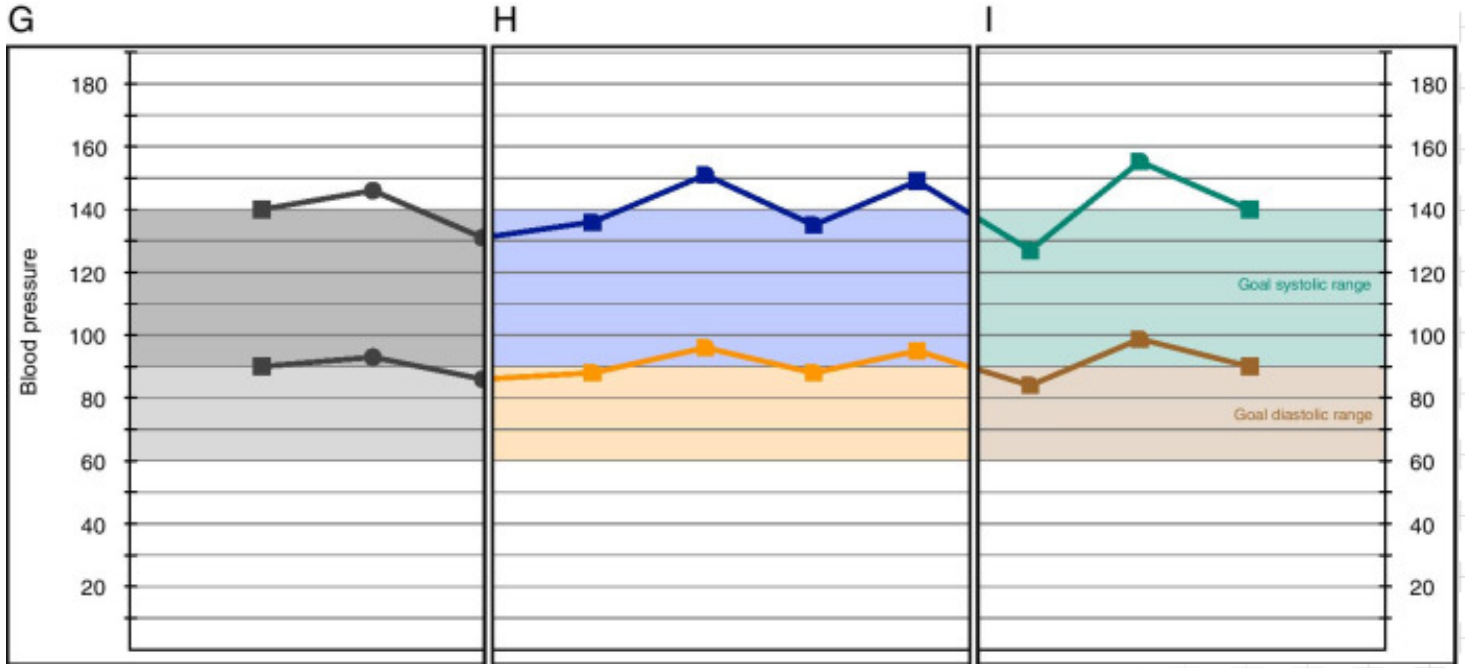
Color

- When diastolic is high, it strays into the systolic goal band → abandon gray scale, use distinct colors, data point and corresponding goal band in same color
- When used effectively, color informs, and even calms the user
- Color provides context for the user using a pre-attentive attribute
- Original choice of blue/orange conflicted with the EHR color scheme for normal (blue) and out of range (orange) data, implemented design is mint and cocoa



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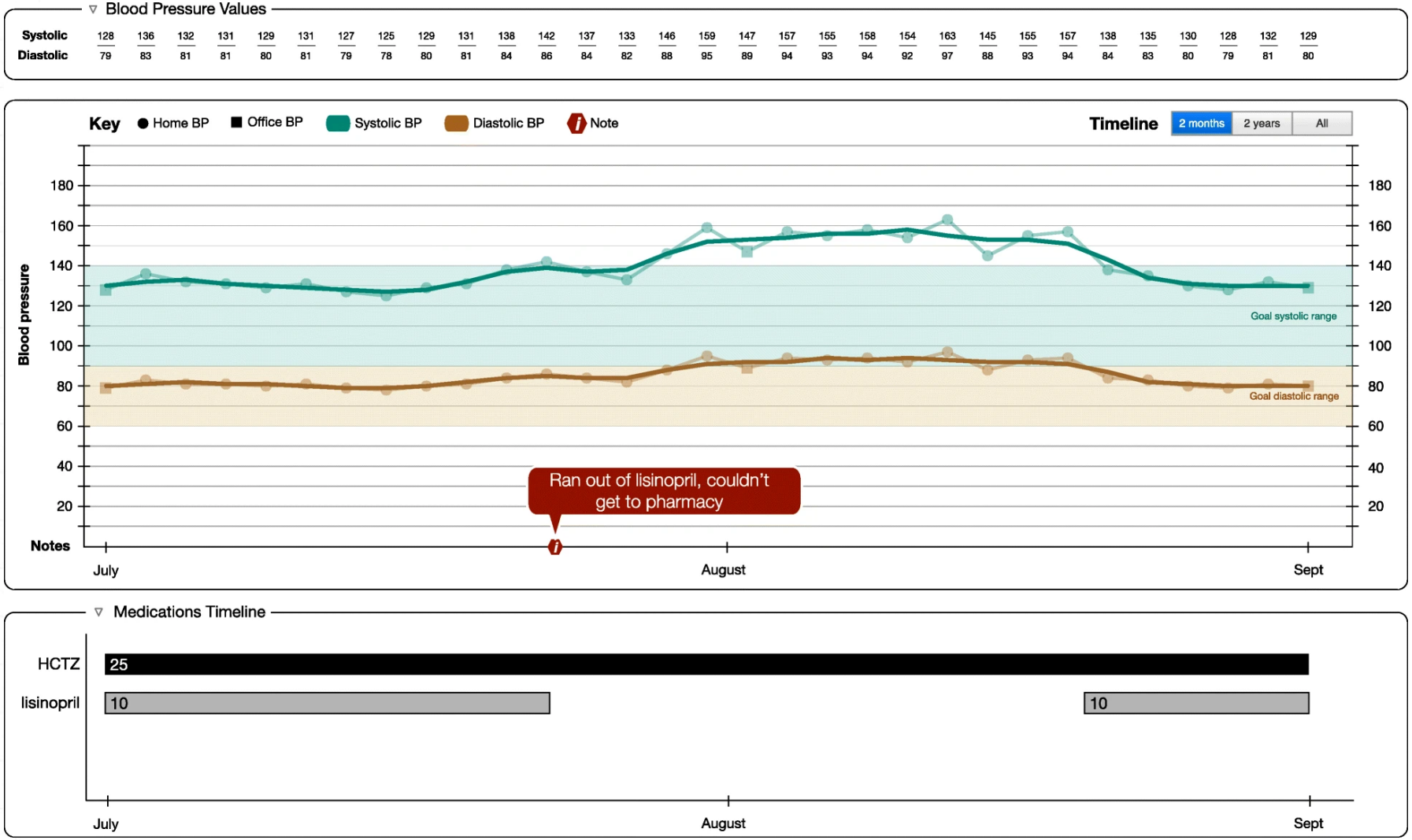
Intuitive Design, Inference



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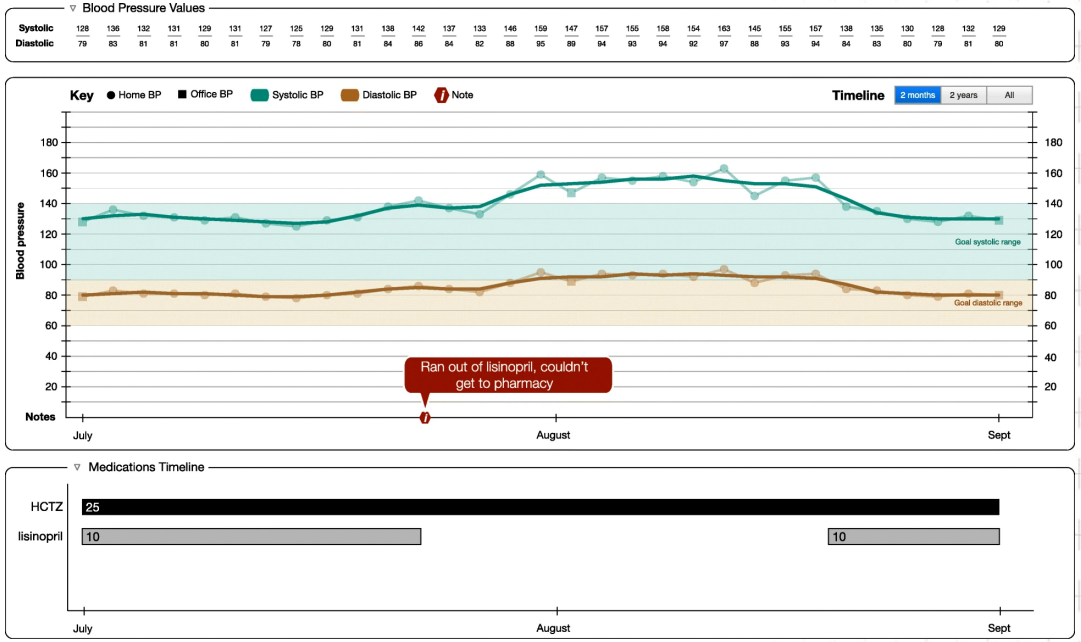
Intuitive Design, Inference

"I mean, it's doing great … [and then this person] quits taking the medication, it's just out of control."

Patient, Design Round 5



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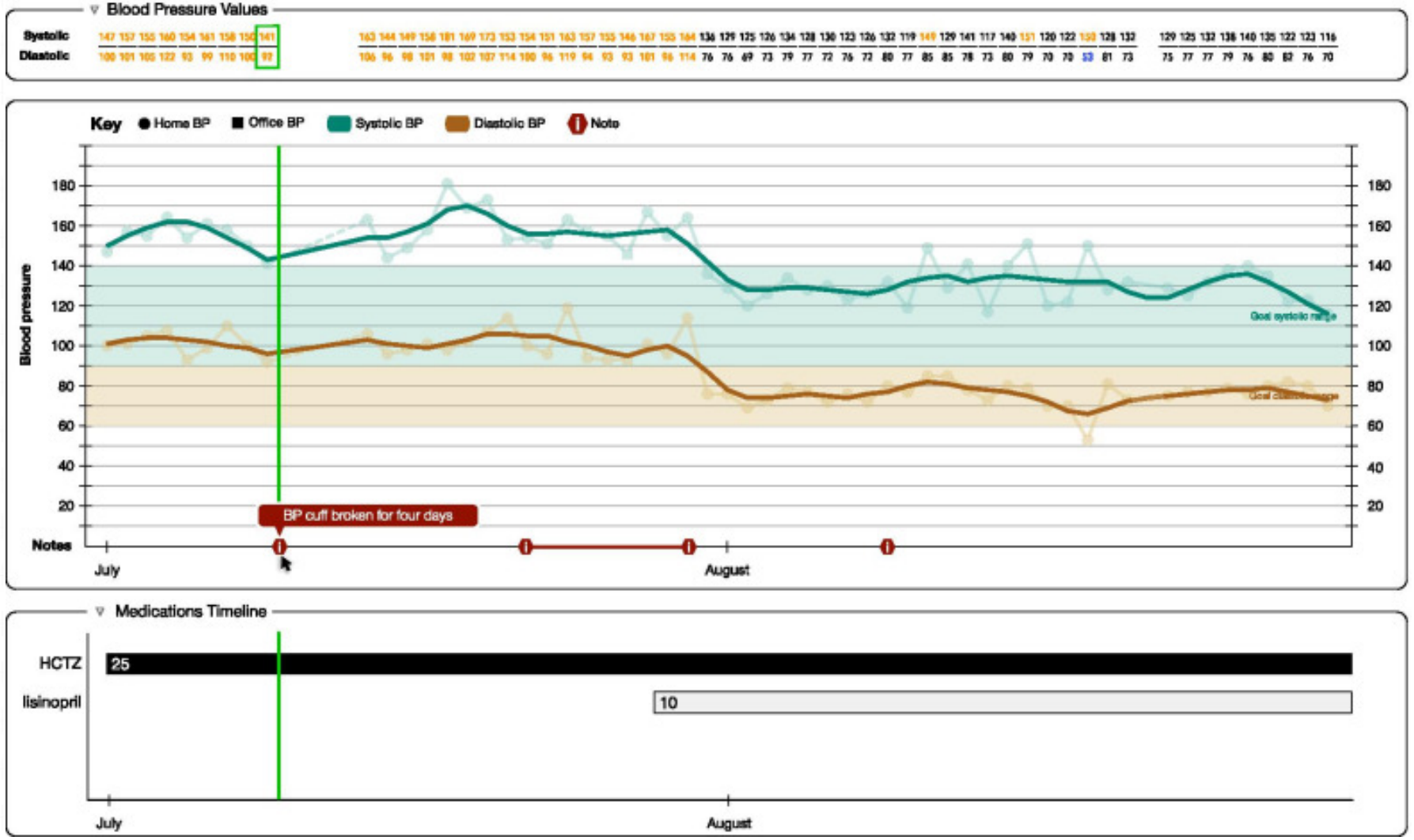
Smoothing Line



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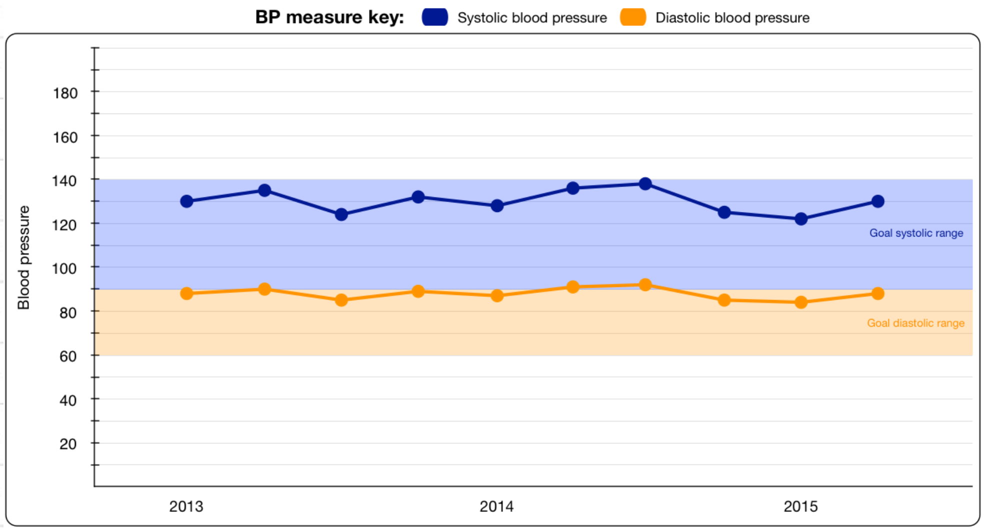
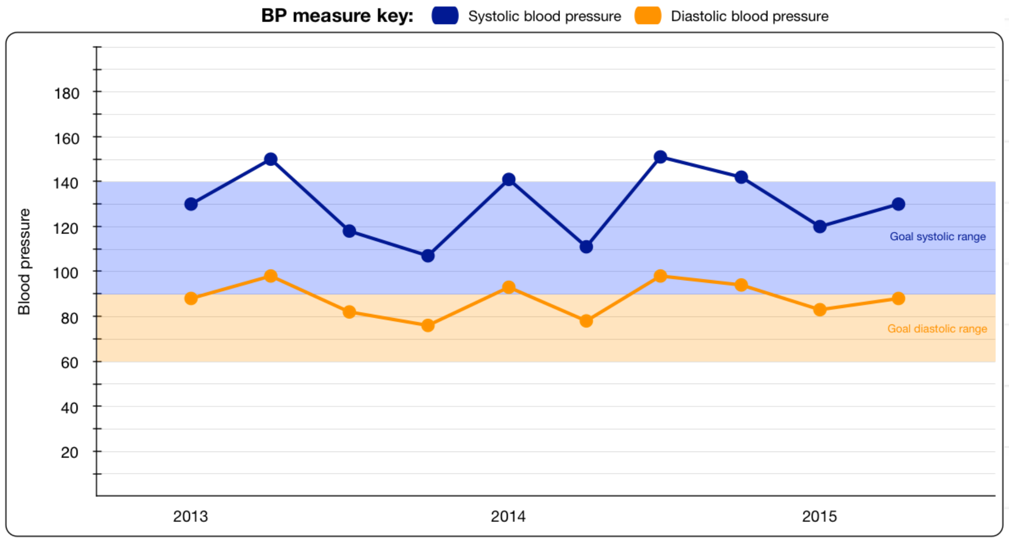
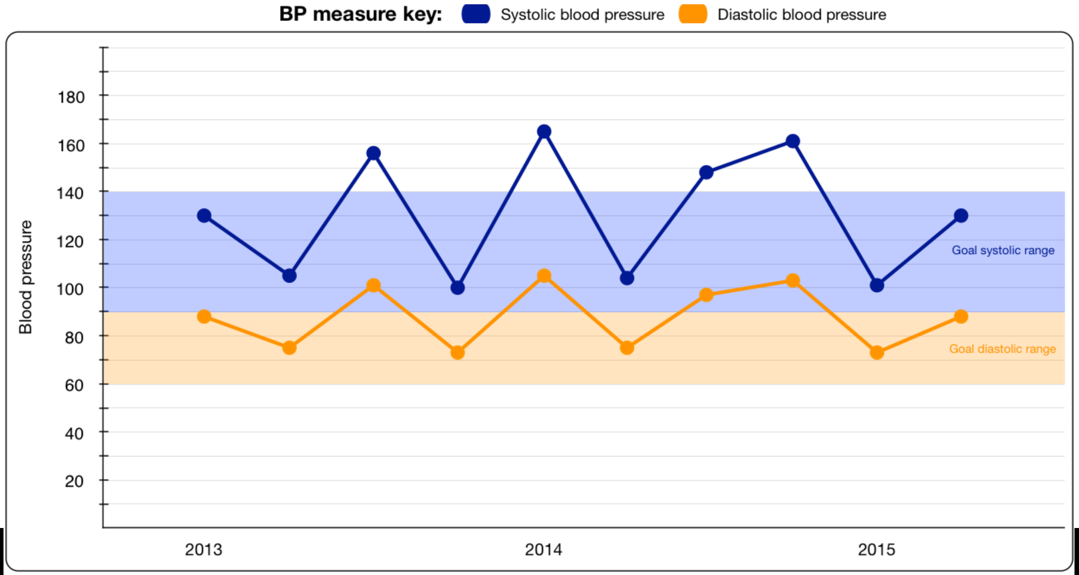
Effect of Variability on Judgment of Control







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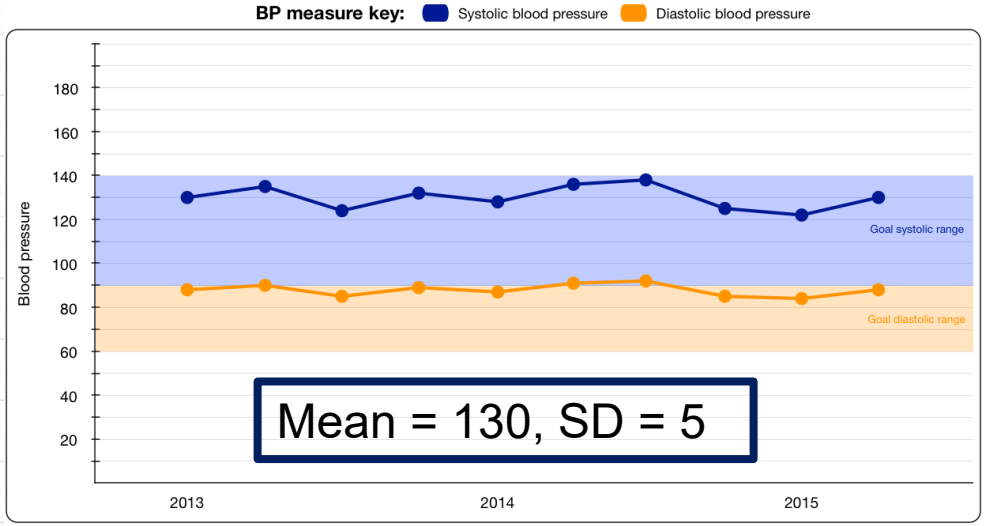
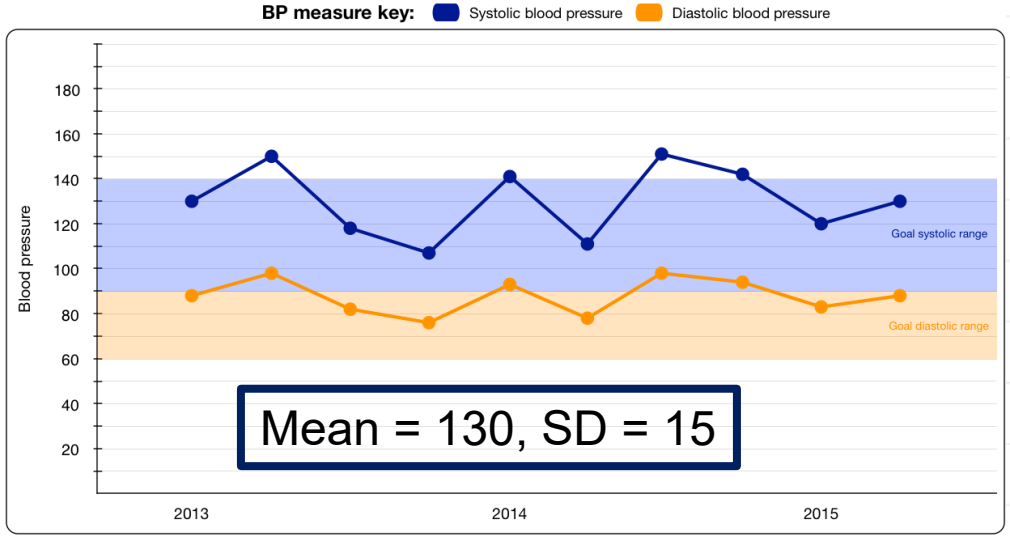
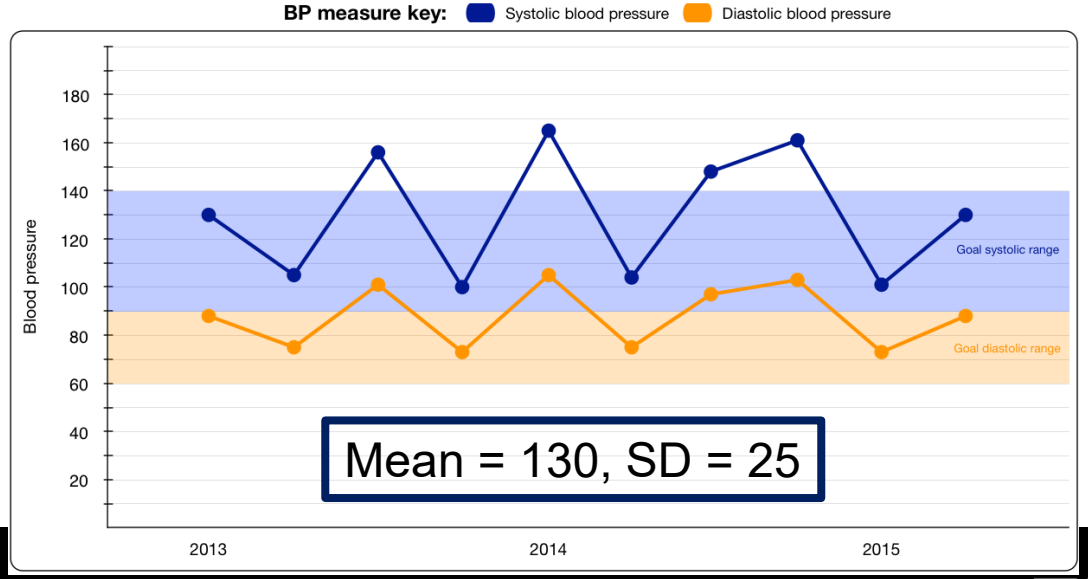
Effect of Variability on Judgment of Control







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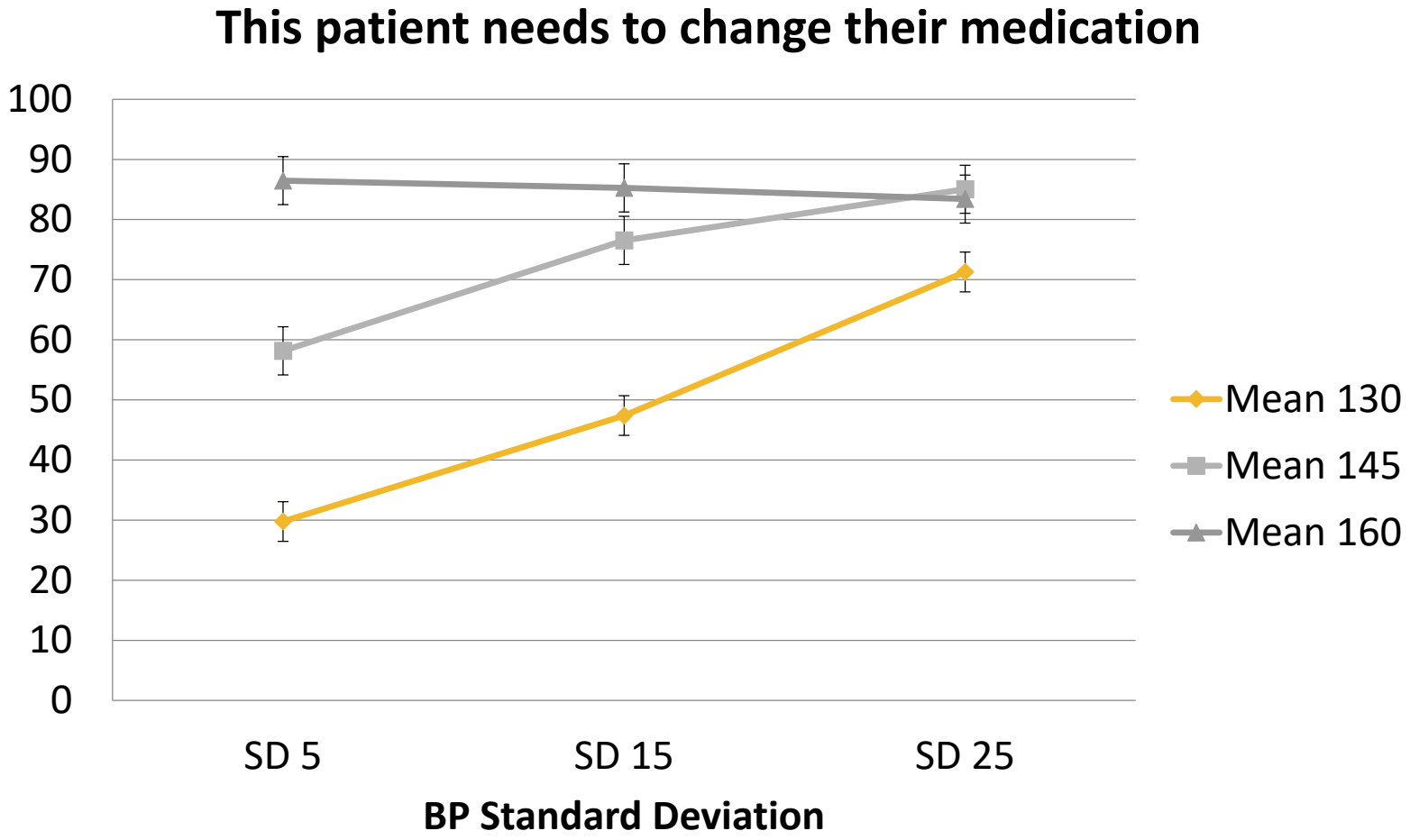

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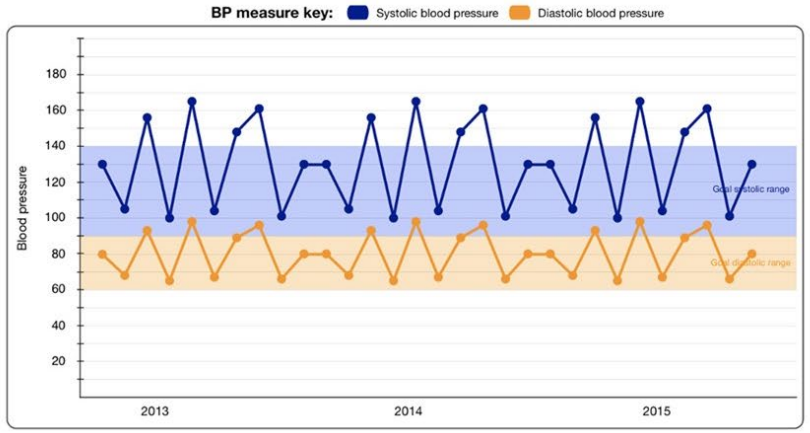
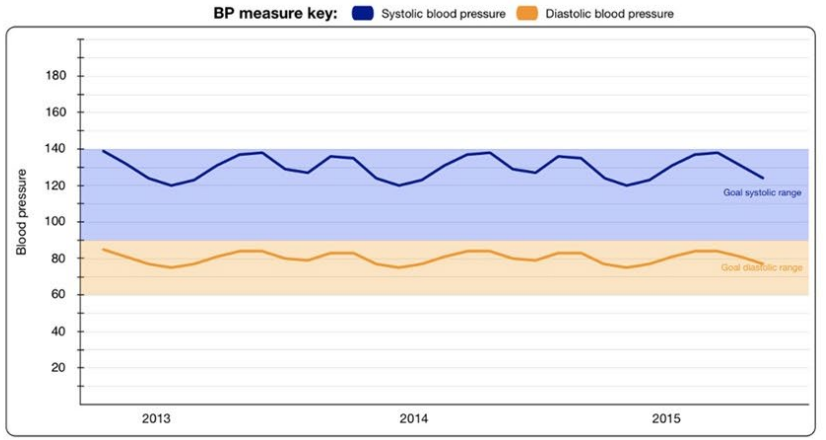
Smoothing the Data





Variability is a potential distraction in judging control

LOWESS Smoothing Algorithm

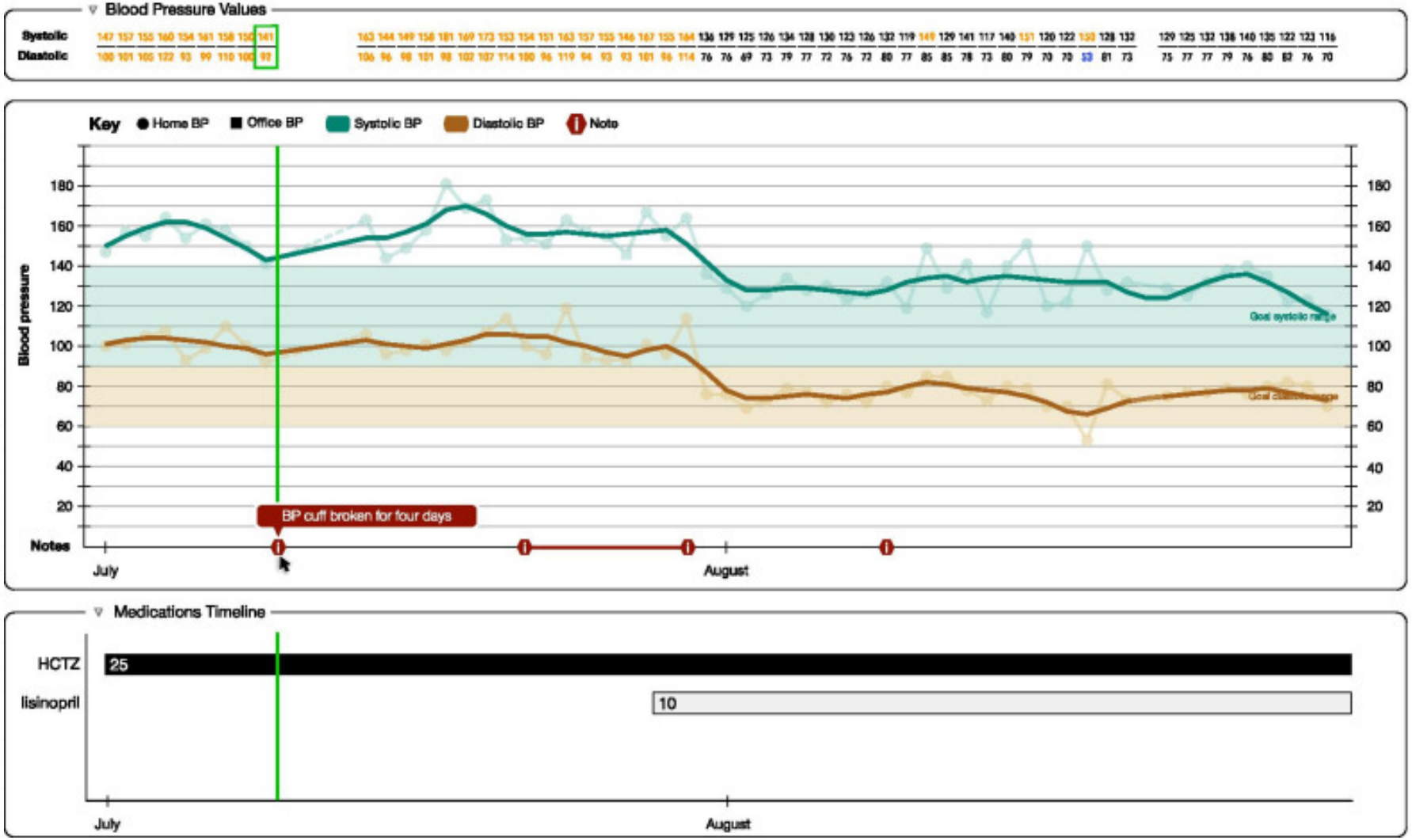
Evidence to value BP mean >> BP variability

Smoothed data acceptable to physicians and patients, many wanted to see both raw and smoothed data

Shaffer VA, Wegier P, Valentine KD, Duan S, Canfield SM, Belden JL Steege LM, Patil SJ, Popescu M, Koopman RJ, Patient judgments about hypertension control: the role of patient numeracy and graph literacy, Journal of the American Medical Informatics Association, 2022.

Hansen TW, Thijs L, Li Y, et al. Prognostic value of reading-to-reading blood pressure variability over 24 hours in 8938 subjects from 11 populations. Hypertension 2010; 55 (4): 1049–57.

Smoothing Line



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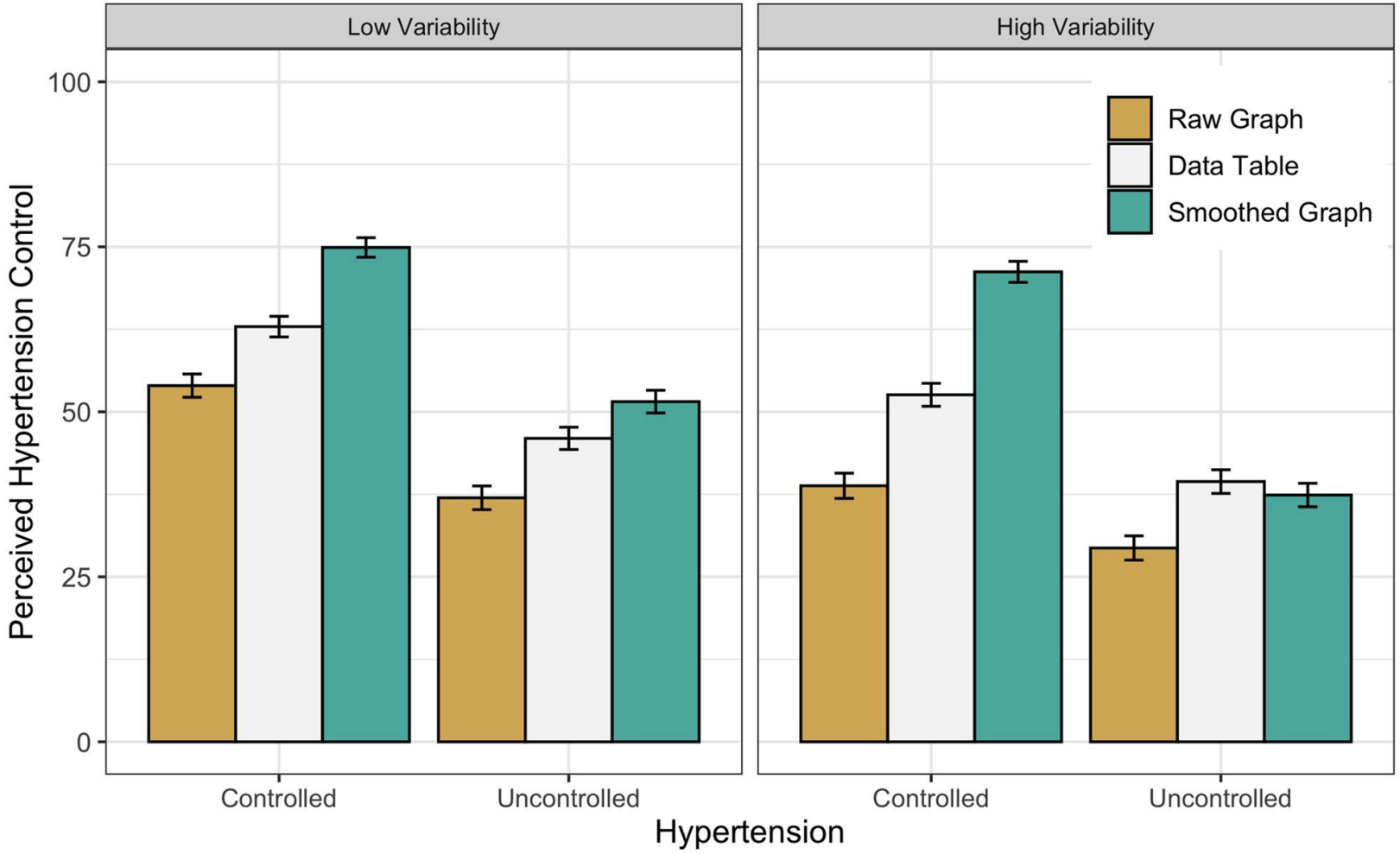
How Much Does Smoothing Data Affect Judgment of Control?



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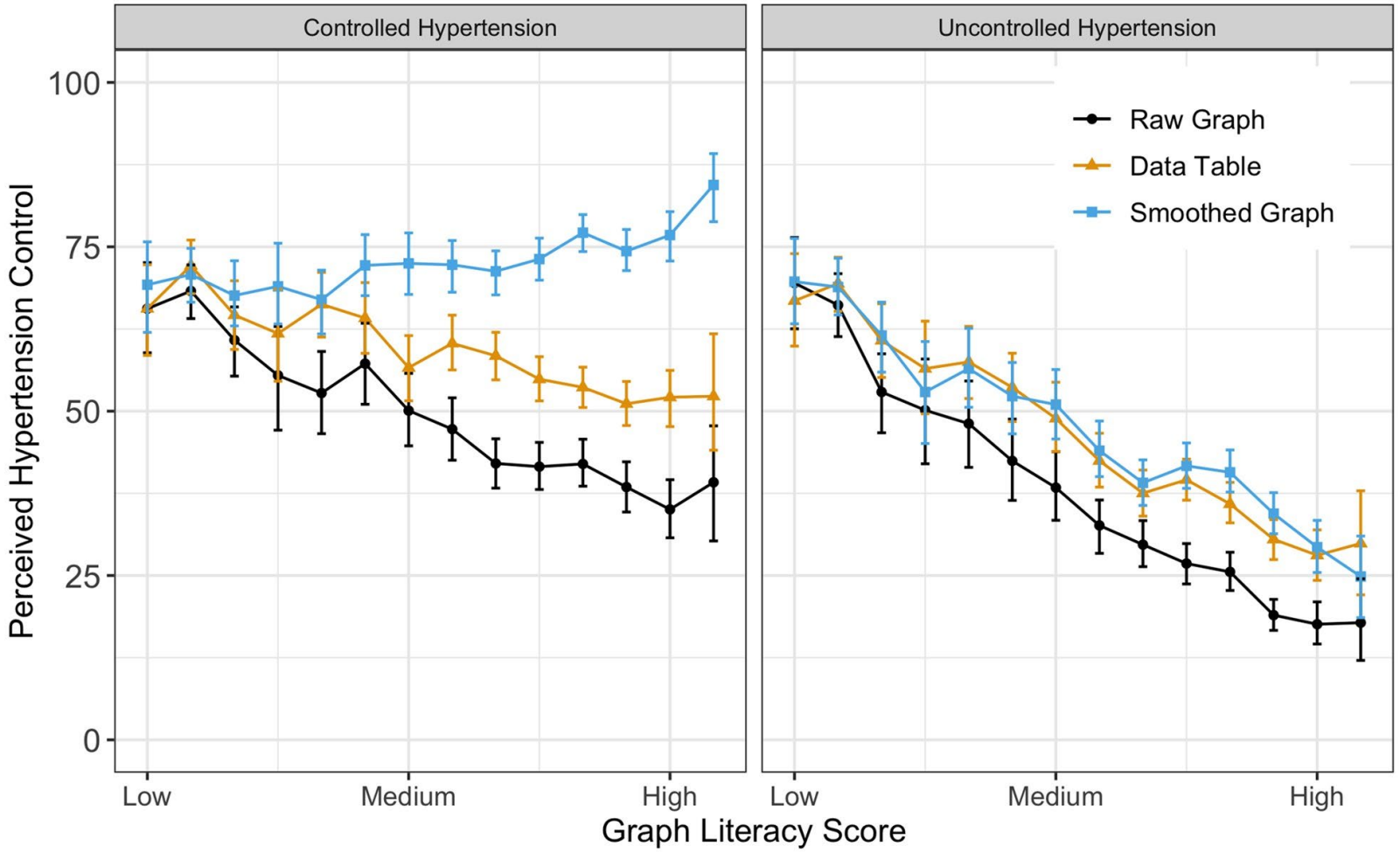
What is the Role of Graph Literacy in Judgments of Control?



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Sensemaking

"Neato … It's really just creating a story where you see what the blood pressure was, when the medicine was started, where it changed."

– Physician, Design Round 4

"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."

– Patient, Design Round 1

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Cohen DJ, Wyte-Lake T, Canfield S, Hall JD, Steege L, Wareg NK, Koopman RJ. Impact of Home Blood Pressure Data Visualization on Hypertension Medical Decision Making in Primary Care. Annals of Family Medicine, July 2022, 20 (4) 305-311

Elevating the Value of Patient-Generated Health Data

Collecting and seeing their data in the EHR gave patients insights into effects of lifestyle on blood pressure

- One patient told his doctor during a visit that this made him quit smoking!

By incorporation patient generated data in to our EHR workflow, we:

- Elevate the importance of these data
- Honor the patient's effort in collecting the data
- Signal the patients role as an active partner and co-decision maker in managing their condition

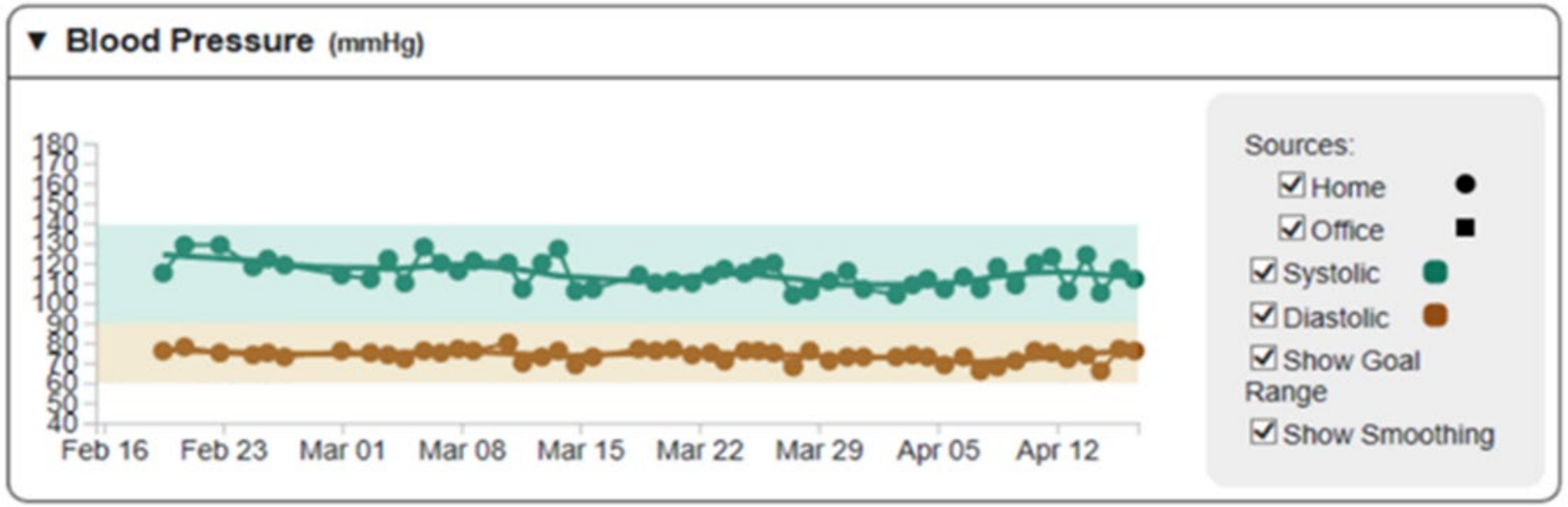
Koopman RJ, Canfield SM, Belden JL, et al. Home blood pressure data visualization for the management of hypertension: designing for patient and physician information needs. BMC Medical Informatics and Decision Making. 2020;20(1):195.

Cohen DJ, Wyte-Lake T, Canfield S, Hall JD, Steege L, Wareg NK, Koopman RJ. Impact of Home Blood Pressure Data Visualization on Hypertension Medical Decision Making in Primary Care. Annals of Family Medicine, July 2022, 20 (4) 305-311

The Ultimate - A Physician-Researcher's Dream!

Pandemic Hypertension Management via Telehealth

April 16, 2020



Telehealth visit with my own patient via zoom

Limitations and Next Steps

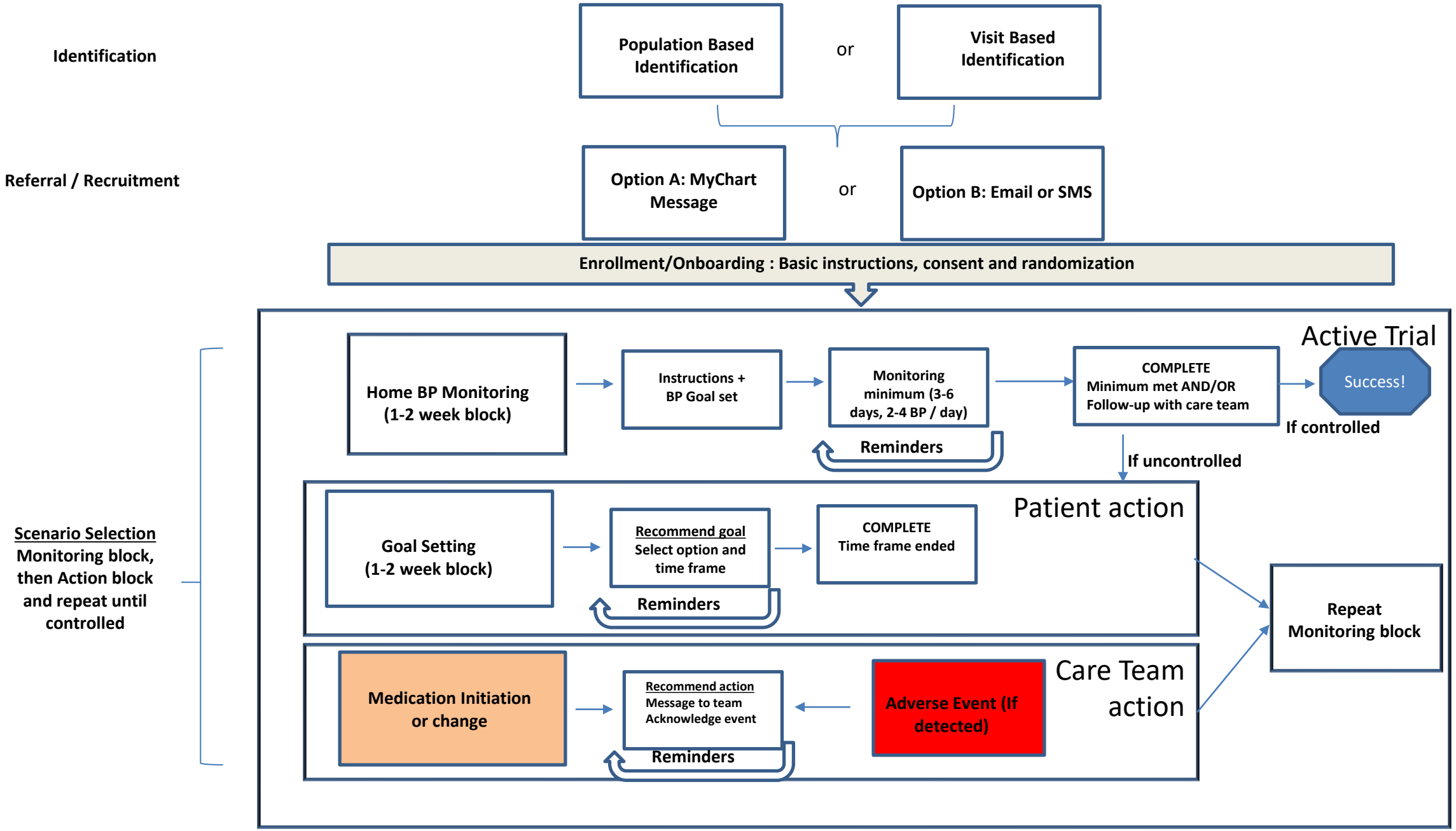
- Clinicians exclusively primary care physicians
  - Follow up focus group with advanced practice nurses and care managers yielded similar results
- Automated upload of patient data
- Determining the flow of home blood pressure data and who manages it
- Logistics of a sustainable practice for using home data in between visits to improve control
- Implemented in EHR but not patient portal

Part 2

Refining the COACH app for clinician and patient preferred workflows

COACH

Collaborative Oriented Approach to Controlling High Blood Pressure


Identification
Population Based Identification
or
Visit Based Identification
Referral / Recruitment
Option A: MyChart Message
or
Option B: Email or SMS
Enrollment/Onboarding : Basic instructions, consent and randomization
Active Trial
Home BP Monitoring (1-2 week block)
Instructions + BP Goal set
Monitoring minimum (3-6 days, 2-4 BP / day)
Reminders
COMPLETE
Minimum met AND/OR
Follow-up with care team
Success!
If controlled
If uncontrolled
Patient action
Goal Setting (1-2 week block)
Recommend goal
Select option and time frame
Reminders
COMPLETE
Time frame ended
Care Team action
Medication Initiation or change
Recommend action
Message to team
Acknowledge event
Reminders
Adverse Event (If detected)
Repeat Monitoring block
Scenario Selection
Monitoring block, then Action block and repeat until controlled

Evaluating and Refining

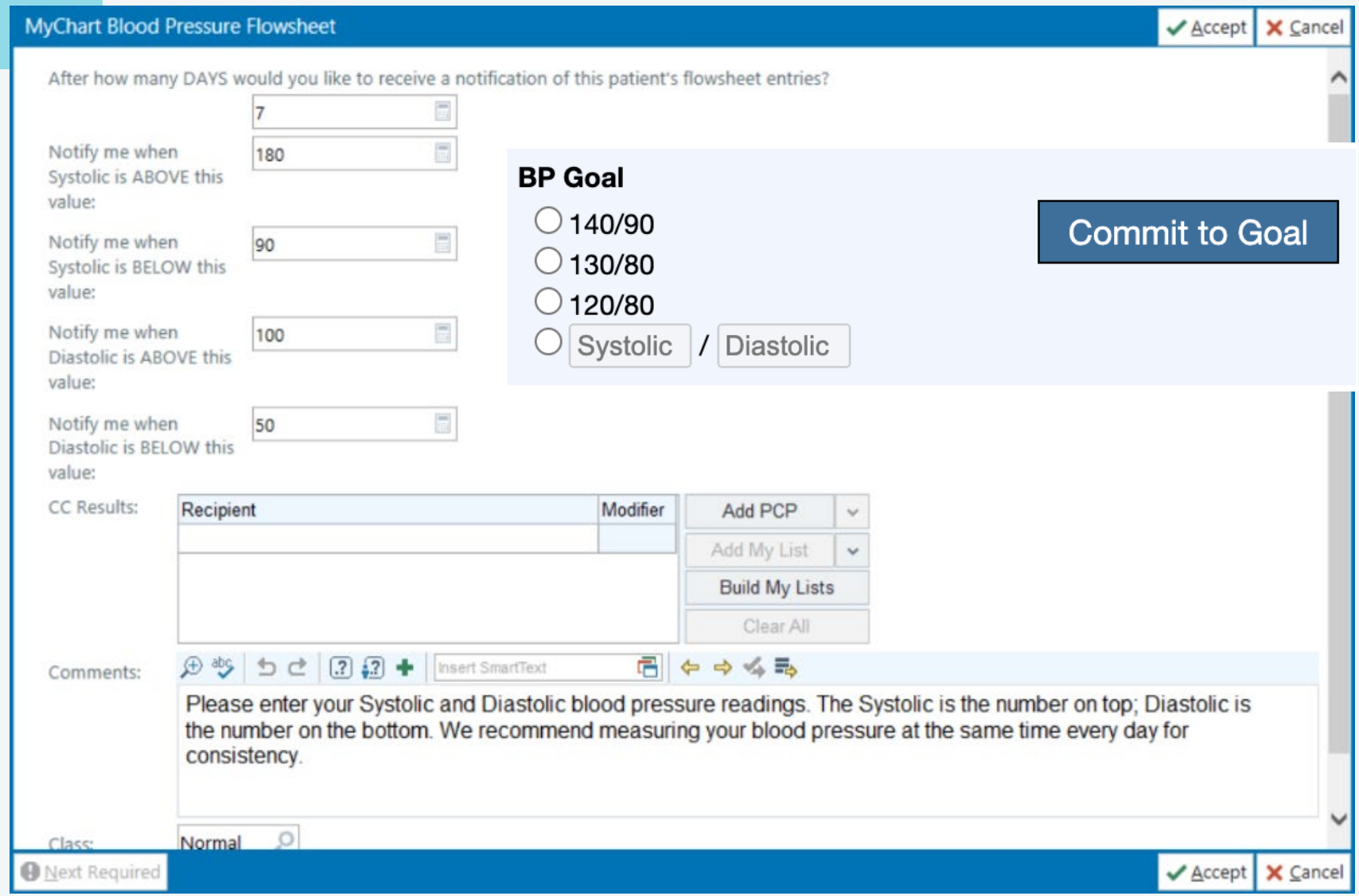
Site visits at Missouri, OHSU, and Vanderbilt

- 3 Patient Focus Groups, 1 at Each Site
  - n = 17 patients with hypertension, portal users
- Clinic Visits with Observation and Interviews
- Interviews with Institutional Leaders
  - n = 9 clinics visited (3 at each site)
  - n = 72 interviews with personnel and leaders

“I was just wondering, does this have, I mean, I know myself when I need to notify the physician or something, but is there something on here that tells someone that its too high or they should be calling somebody?”

- patient from MU focus group

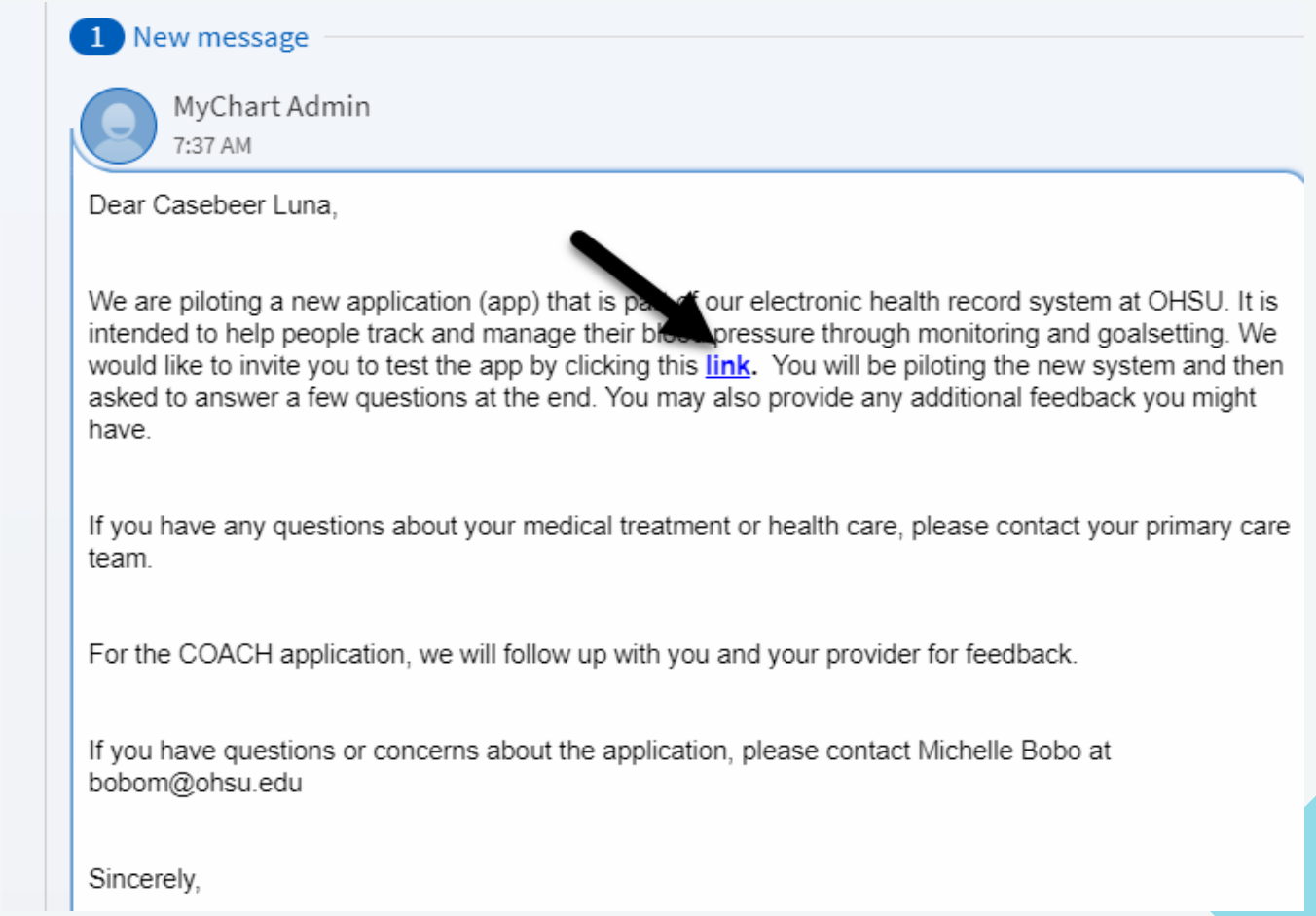
Set Goals and Parameters



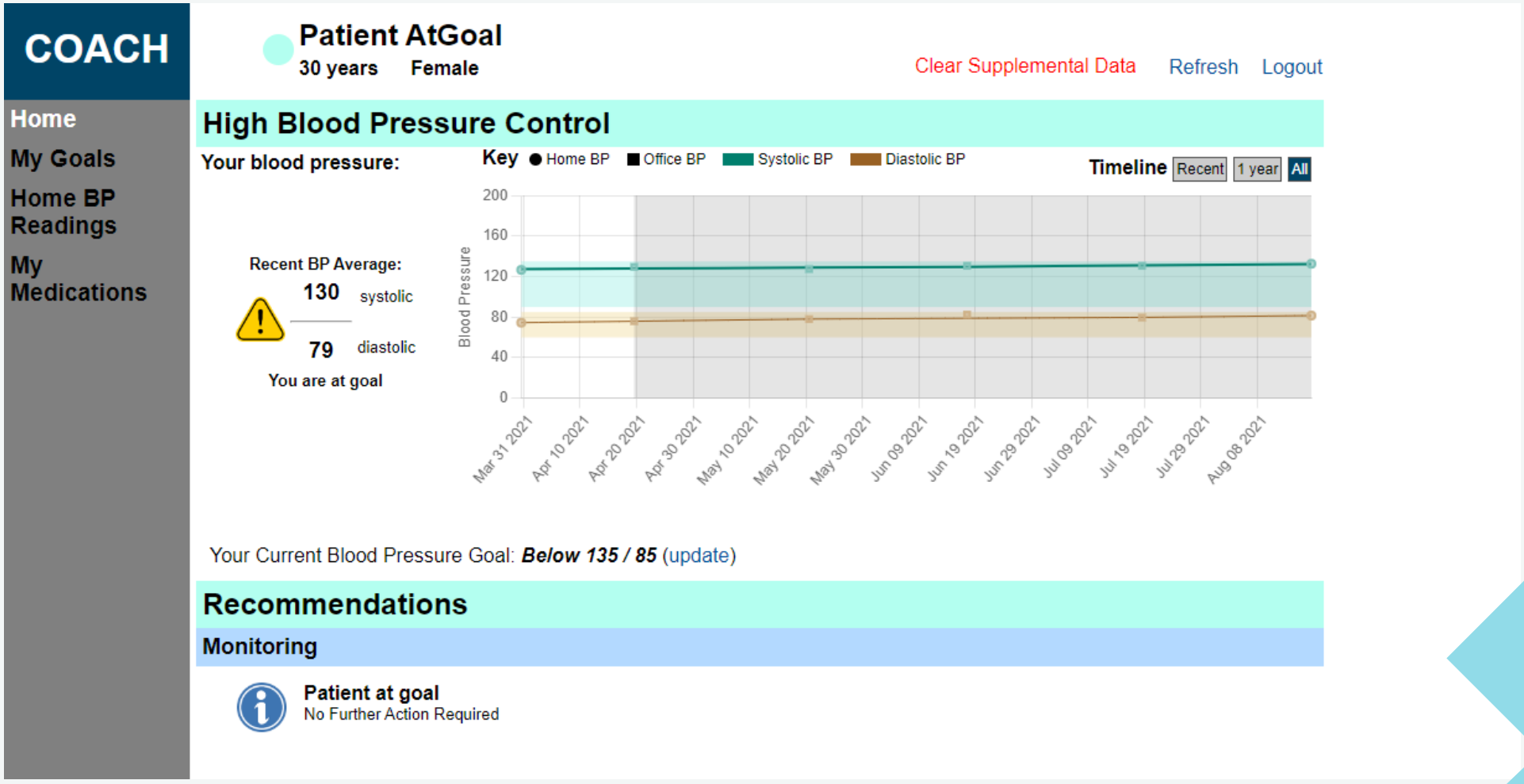
Changed “number of days” to “12 home blood pressures” within a month based on evidence

Initiating COACH

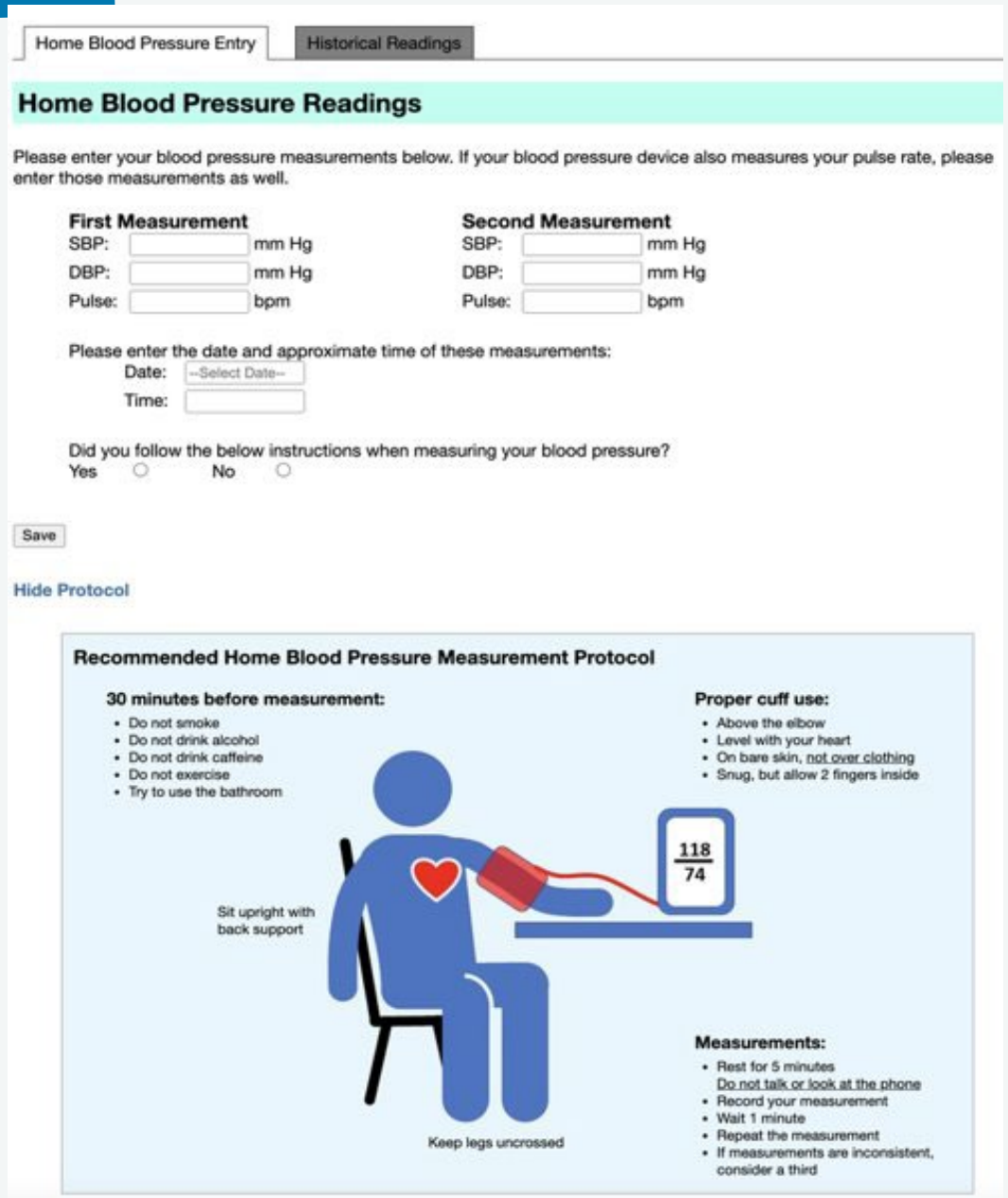
- Send a portal message to patient
  - Enter subject of message
  - Use SmartPhrase CoachInvite
  - Patient will receive a MyChart message with the invite and the link. This link will take the patient directly into Coach.



MyChart Patient Home Screen

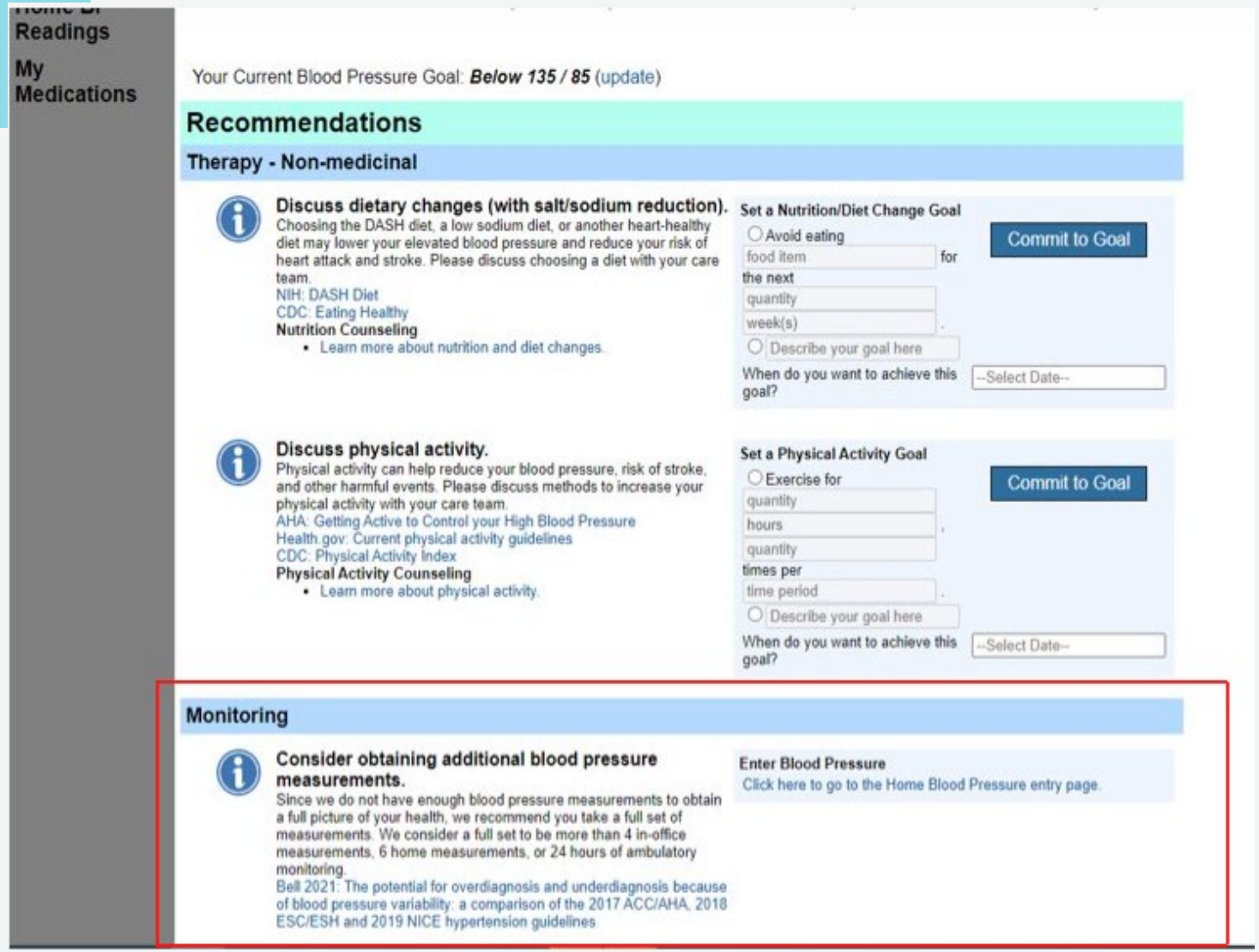


Home BPs Protocol



- Appreciated the instructions
- Wanted to know more about schedule for readings
- Not interested in the slightest in being reminded daily to measure BP
- Autofill date and time, but ability to edit
- Want to share context of why they didn't follow the directions

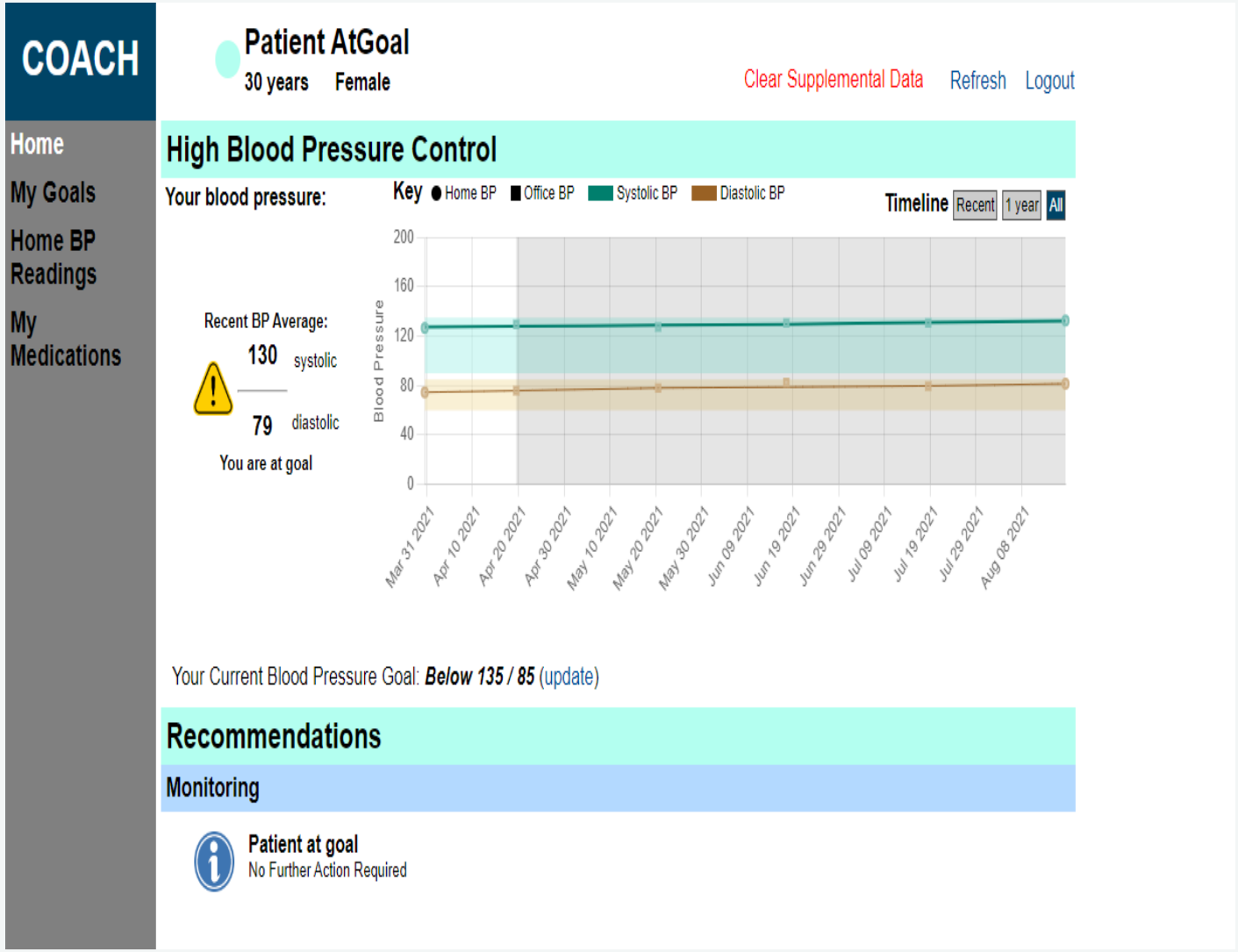
Additional BPs



Want feedback about individual BPs immediately, even before reach goal of 12 BPs

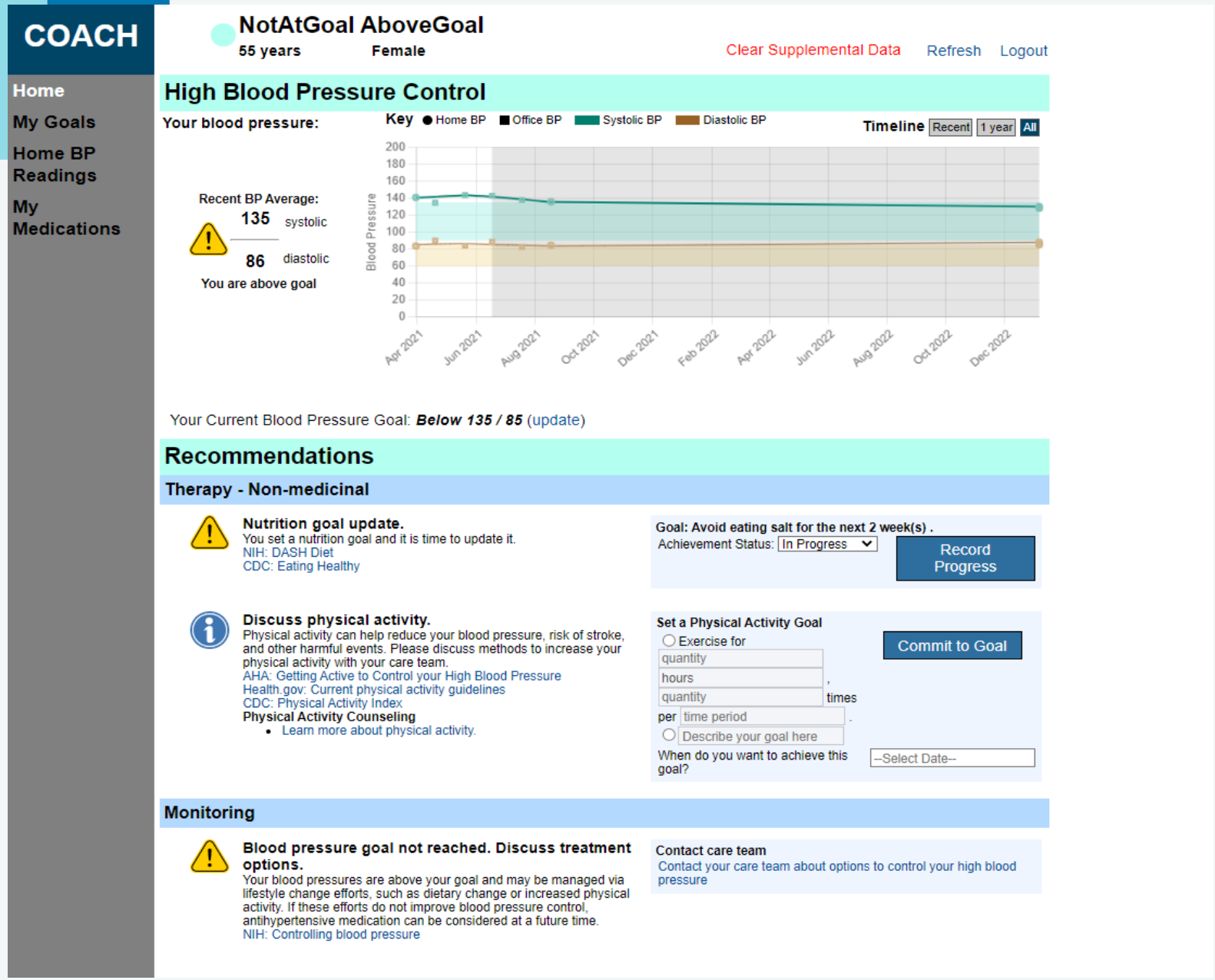
Want to be “warned” if reading is high

BP in Goal Range



- "Do I need to do anything because it says 'you're at goal and everything is just hunky dory?'"
- Patient or care team to set the goal range?

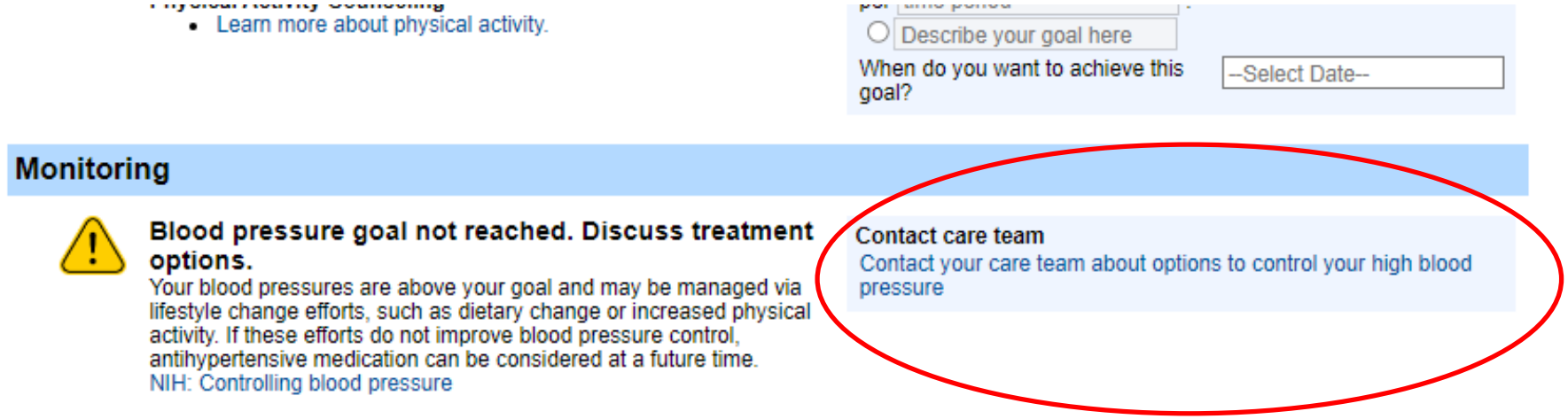
BP Not in Goal Range



Be more directive with recommendations

“I don’t know. Am I supposed to contact the care team or am I not? Or am I supposed to do those things on my own? … Am I supposed to increase my walking?”

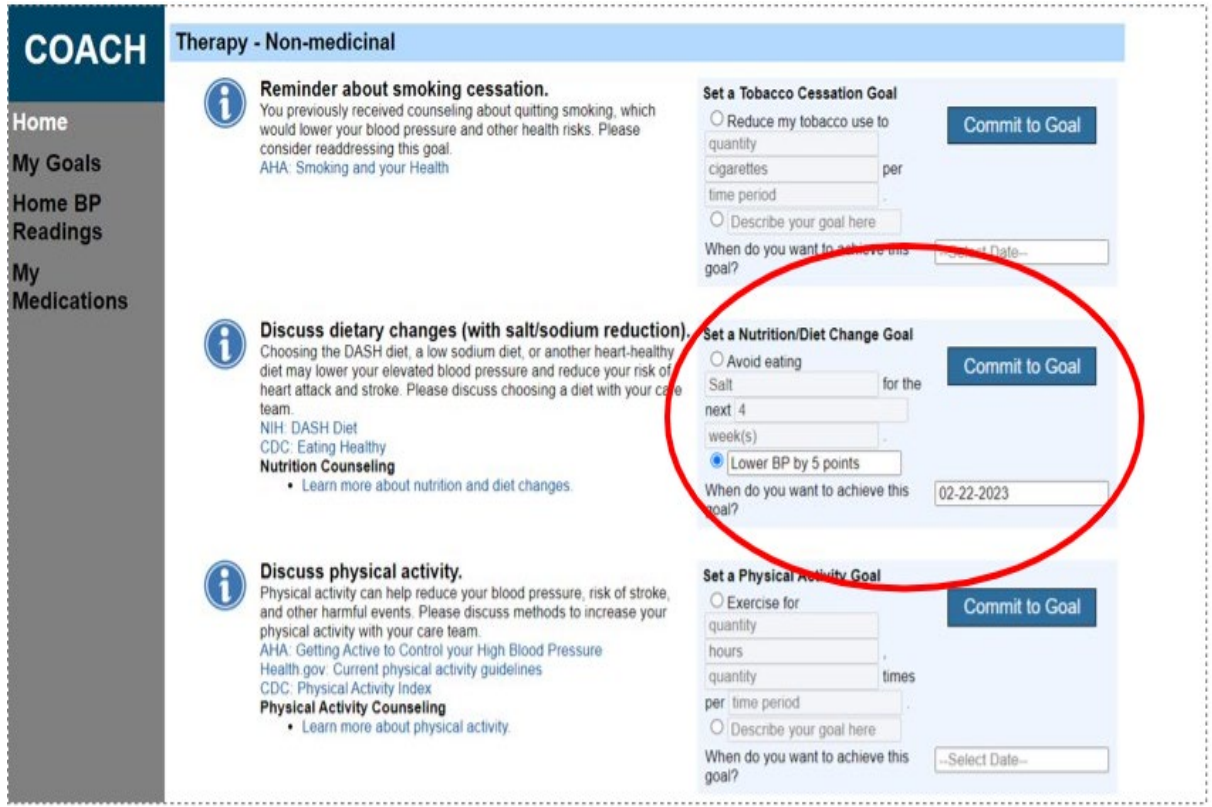
BP Not in Goal Range



Message to care team

- Pre-written
- Include their average
- Patient able to edit

Lifestyle



- Suggest what their goal should be
  - Maybe auto-populate a standard goal and then they can edit
- Lifestyle changes
  - “I think I would go with it for a while and then I would revert back.”
- Goals should be realistic and achievable – incremental wins, make progress

Other Thoughts from Patients

- Use COACH data to inform a pre-visit questionnaire or instructions
- Introduce COACH by going over with the patient during a visit, maybe give an info flyer
- Bluetooth upload
  - Accuracy
  - Reduce patient burden

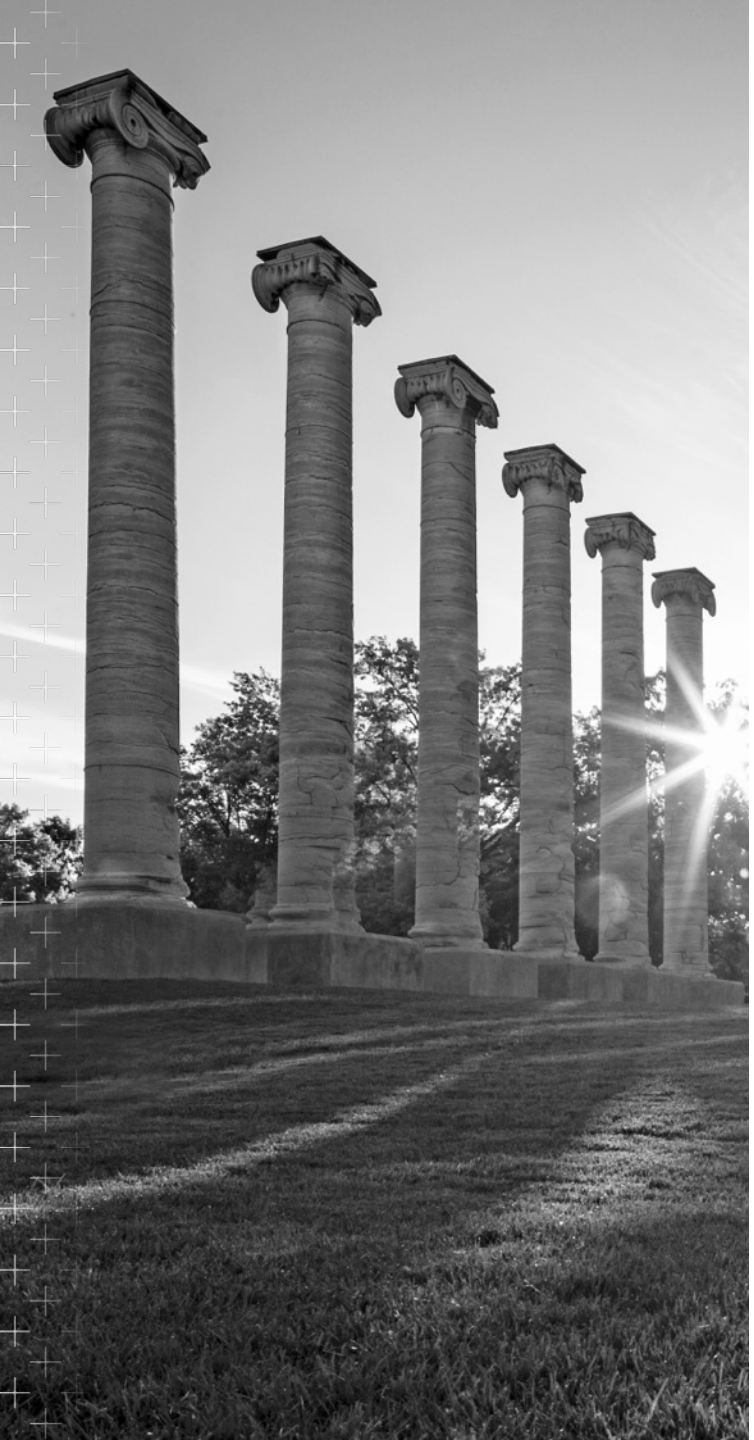
Other Thoughts from Patients

“I definitely think when you change your medication because that’s what I’m in right now. And it scared me to death because my blood pressure was in control for a very long time. And then I changed medications and now it’s really high and I’m thinking, okay, you know, what can I do? And I would like to be more in touch with my care team.”

Part 3

Designing a Pragmatic Trial of COACH

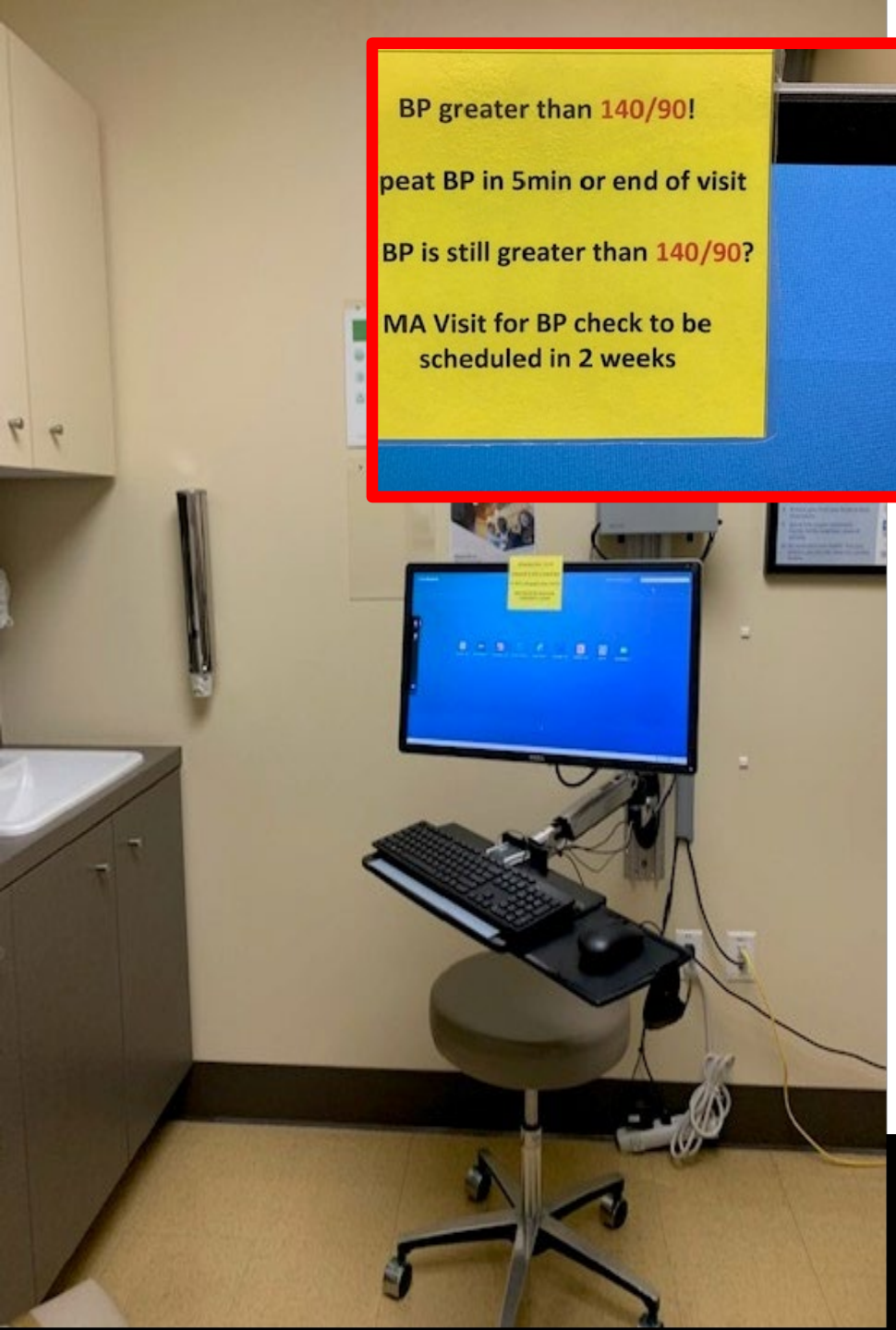
University of Missouri



Design of the COACH Trial

- 550 adult primary care patients with uncontrolled hypertension who are portal users
- Across 3 sites – U Missouri, OHSU, Vanderbilt
- Across 2 EHR Platforms – EPIC and Oracle
- Primary Outcome: Blood pressure control at 6 months
- Secondary Outcomes, informed by RE-AIM and Social Cognitive Theory
  - BP reduction at 6 months
  - Adverse events
  - Adherence to home BP monitoring
  - Enrolled patients similarity to eligible population
  - Perceived risk, perceived control, behavioral intention
  - Number of home BPs entered
  - Number of portal messages
  - Implementation barriers
  - Use of COACH beyond trial

University of Missouri



CFIR-based pre-implementation analysis

Consolidated Framework for Implementation Research

Understanding preferred workflows and concerns for patients and physicians.

"This is a great design, but how much is it going to increase workload for me and my staff"

– physician at site visit (very common theme for almost all staff)

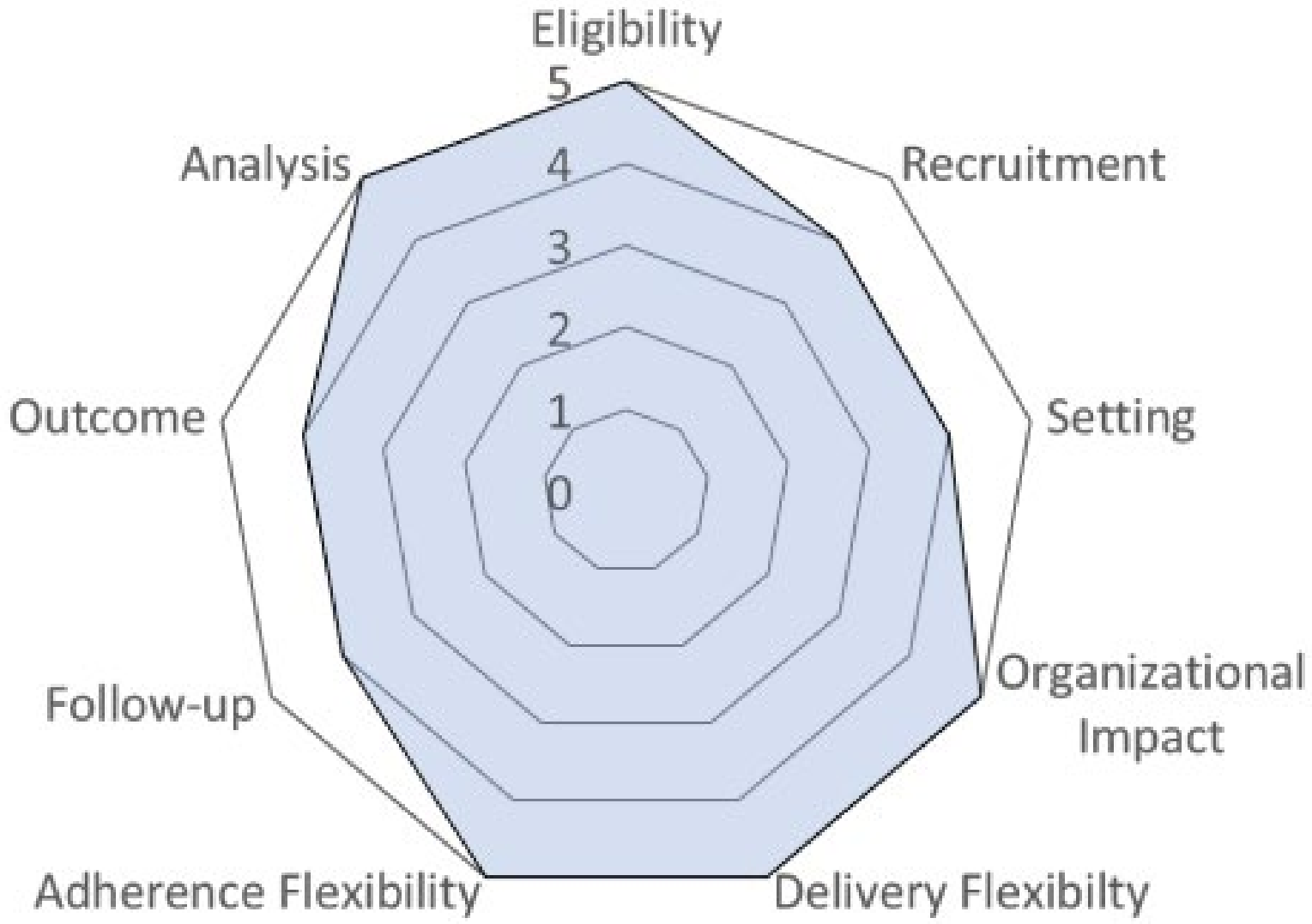
Pragmatic Trial Decisions

PRECIS-2 Scores

Compare suggestion to Collect home BP and link to COACH

to

COACH with affectively enhanced reminders and goal setting



Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. BMJ. 2015;350:h2147.

Pragmatic Trial Decisions

Eligibility (4) All primary care patients with high blood pressure who use patient portal

Recruitment (4) Alert during visit for those with high blood pressure, order for home monitoring. Will also use less pragmatic registry-based enrollment based on site preferences and resources

Setting (4) Primary care clinics at the 3 sites.

Organizational Impact (5) No additional staff or change from usual care processes, should make usual care more efficient for care teams and patients.

Informed by PRECIS-2

Flexible delivery for the practice (5) Care processes based on decision of what is best for patient.

Flexible Adherence for the patient (5) Standard practice for home BP monitoring, intent to treat analysis

Follow Up (4) Six month follow up

Measurement (4) Clinical and messaging measures gathered from the EHR. Self efficacy measures that are not part of usual care.

Analysis plan and Sample Size (5) Intent-to-treat analysis, a fully pragmatic approach that will translate to real-world implementation.

University of Missouri

Questions and Discussion

COACH Trial

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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