Challenges and Opportunities of Embedding Studies in Real-World Practices in Three PCORI-funded Pragmatic Hypertension Trials

PCORnet BP Control Lab: *Valy Fontil & Madelaine Faulkner, UC San Francisco*
Hyperlink 3: *Karen Margolis & Anna Bergdall, HealthPartners Institute*
BP-Check: *Bev Green & Kelly Ehrlich, Kaiser Permanente Washington Health Research Institute*

Panel discussion moderated by Steve Clauser, PCORI

Introduction & Agenda

1:30-1:35pm: Introduction by Steve Clauser

1:35-1:45pm: Introductions, by each study

1:45-2:30pm: Challenges, Adaptations, and Lessons Learned, by study (approx. 10 minutes each, plus time for 1-2 questions)

2:30-3:00pm: Open discussion

The PCORnet Blood Pressure Control Laboratory

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BP Control Lab: overview

- Rationale:
  - To create a BP Control Lab to enable research and implementation of scalable interventions
- Aims
  - AIM 1: **BP Track** – creation of HTN registry using PCORNet common data model
  - AIM 2: **BP MAP** – Cluster Randomized Control Trial to compare two versions of a hypertension management program developed by the American Medical Association (AMA).
  - AIM 3: **- BP Home—**Direct to participant RCT to compare blue-tooth enabled vs standard BP cuff devices in home BP measurement intervention program

In this discussion, we will focus on Aim 2: **the BP MAP trial**

The BP MAP trial: Improving BP Control by Measuring Accurately, Acting Rapidly, and Partnering with Patients

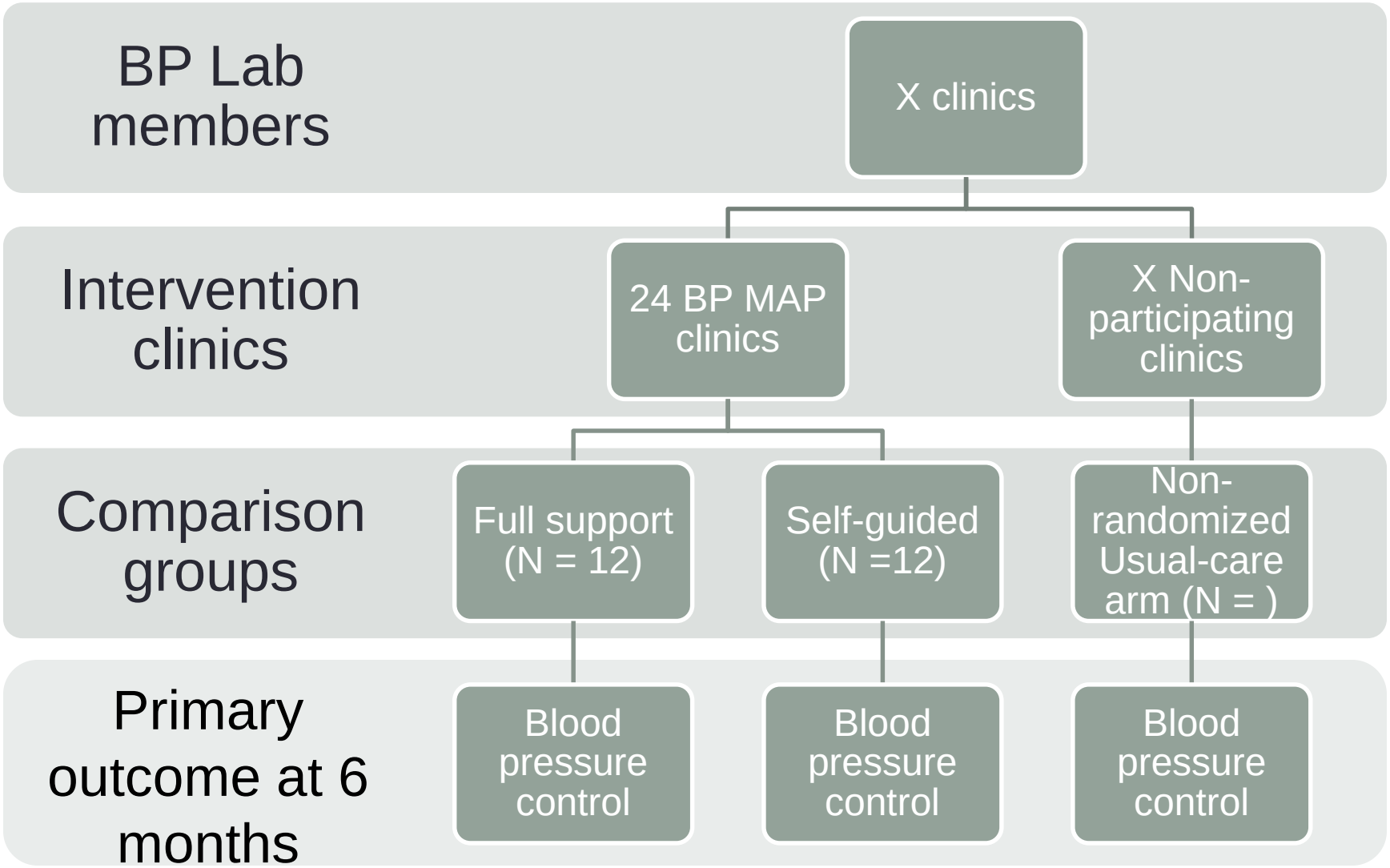
- **Study aim:** Compare the effectiveness of a full-support vs self-guided version of the MAP hypertension program developed by the AMA

- **Study design:** Pragmatic cluster randomized controlled trial
  - Full support
  - Self-guided

- **Study subjects:** 24 clinics
  - 4 health systems in Louisiana, Oregon, and Washington

- **Primary outcome**: change in clinic-level % BP control

Study design



The BP MAP trial

Intervention: Measure Accurately, **A**ct Rapidly, and **P**artner with patients and communities (MAP) program

Training models

Features	Full support	Self-guided
Evidence-based program	X	X
In-person training	X	
Digital module for on-demand training	X	X
Webinars (recorded)	X	X
Email support	X	X
Telephonic support for PCF/Site Champion	X	
"Office hours" monthly collaborative telephone calls, Q&A with clinical teams	X	

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Hyperlink 3

Patient Centered Outcomes Research Institute IHS-1507-31146

Karen Margolis, MD, MPH – Principal Investigator

Anna Bergdall, MPH – Project Manager

Amy Kodet, MPP – Project Manger

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Objective

- To directly compare two models of team-based care for uncontrolled hypertension
  - Best practice clinic-based care (similar to KPNC and KPSC)
  - Home BP telemonitoring plus pharmacist care (previous Hyperlink 1 trial)

- Aim 1: Effects on SBP and patient-reported outcomes
- Aim 2: Evaluates implementation in a large health system

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Hyperlink 3

Design: Cluster-randomized trial

Setting

- 21 primary health care clinics in Minneapolis/St. Paul metro area and nearby suburban and rural communities
- All clinics have a Medication Therapy Management (MTM) Pharmacist onsite with collaborative practice agreement

Target population

- Adults (18-85) with hypertension diagnosis and BP ≥150/95 mmHg at two consecutive office encounters
- Excluded: pregnancy, end stage renal disease, hospice/nursing home residence
- Patients must be “plugged in” with primary care – seen PCP in last 12 months, at PCP’s clinic today

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Interventions

Best Practice Clinic Care

- Automated oscillometric clinic BP measurement
- Physician-MA/LPN dyad supported by hypertension registry, RN protocol, and automated follow-up reminders for elevated BP
- Face-to-face clinic visits, nurse BP checks
- Option for any other referrals as usual

Telehealth Care

Based on previous RCT with -10/-6 mm Hg ↓BP compared to usual care

Best Practice Care components, PLUS:

- Free home BP telemonitor, phone visits by MTM
- MTM uses existing HP hypertension protocol
- Home BPs available to care team in Epic flowsheet

Recruitment

- Electronic Health Record alert during primary care office encounters for eligible patients

- Alert advises hypertension follow-up visit within 2 weeks.
  - Best Practice: referral for Nurse BP Check
  - Telehealth care: referral for MTM visit

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Outcomes

Primary Outcome: Change in Systolic BP at 12 months from EHR

Secondary Outcomes: Patient Reported Outcomes from surveys at baseline, 6, 12, 24 months

- Medication side effects, use of home monitoring, satisfaction with care, self-efficacy and confidence

Other Outcomes:

- Cardiovascular biomedical outcomes from EHR data
- Hypertension care process measures
  - Repeat BP measurement, recognition and action on uncontrolled BP
  - Follow-up visit completion
  - Intervention engagement and treatment components

Ongoing mixed methods evaluation work following RE-AIM model from patient, clinician, clinic, and system perspectives.

Blood Pressure Checks and Hypertension Diagnosis
BP-CHECK

Patient Centered Outcomes Research Institute CER-1511-32979

Bev Green, MD, MPH – Principal Investigator
Kelly Ehrlich, MS – Project Manager

BP Checks and Diagnosing Hypertension – BP CHECK

Patient Centered Outcomes Research Institute CER-1511-32979

- US Preventive Services Task Force and ACC/AHA hypertension guidelines recommend out of office blood pressure (BP) monitoring prior to making a new diagnosis of hypertension:

  The preferred method is 24-hr ambulatory BP monitoring – but home BPs are an option. There is lack of knowledge on whether kiosk BPs could also be used.

- **BP-CHECK** is a randomized controlled diagnostic trial comparing 3 methods for diagnosing hypertension (clinic, home, and kiosk BPs) to 24-hr ambulatory BP monitoring (the reference standard)

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BP–CHECK is being conducted within the Healthcare Delivery System

- We use EHR data to identify patients:
  - ❑ Aged 18-85
  - ❑ Last visit with a high BP
  - ❑ No diagnosis of hypertension
  - ❑ Not on hypertension medications
  - ❑ Excluded those with atrial fibrillation/arrhythmias, pregnant
- Patients received an invitation letter, called, and invited to come to their own clinic for a research screening visit.
- If BP was high on each of 2 measurements (either systolic or diastolic BP) and consent they and randomized

Randomized 3-Arm Diagnostic Trial
BPs and Patient Self-Reported Data Collected at 4 Visits

Visit 1 - Randomized to 1 of 3 Diagnostic Groups		
Arm 1 - Clinic BPs	**Arm 2 - Home BPs**	**Arm 3 - Kiosk BPs**
• Asked to make an appointment (or walk in visit) for a BP check	• Received a home BP monitor and training • Asked to measure BP twice a day (2 BPs each time) for 5 days.	• Received smart card for collecting BPs, and kiosk training • Asked to use the BP kiosk at their clinic or a local drug store on3 separate days (3 measurements each time)
• BPs collected from the EHR	• BPs collected from the home BP monitor (downloaded at visit 2)	• BPs collected in the cloud
Visit 2 - Returned to clinic after 3 weeks all asked to complete 24 hour ambulatory BP monitor monitoring		
Visit 3 (next day) 24 – hour BP monitor test BP data downloaded Patient and their physician received the results		
Visit 4 at 6 months		

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BP-CHECK Outcomes

- **Primary outcome**: accuracy and acceptability of each method compared to ambulatory BP monitoring.
- **Secondary outcomes** include whether a clinician made a diagnosis that was congruent with the ambulatory BP results and BP control 6 months after randomization.
- **Mixed methods** (provider surveys and interviews) used to understand patient and provider knowledge, attitudes, and beliefs about BP measurement and feasibility of integrating different methods for diagnosing hypertension into routine care.

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Challenges, Adaptations, & Lessons Learned

- Hyperlink 3
- BP Check
- PCORnet BP Control Lab

1-2 questions after each, discussion to follow

Open Discussion

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