Unanticipated learnings from conducting a pragmatic trial on hypertension control

Shake, Rattle & Roll

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Presentation content

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- About Shake, Rattle & Roll
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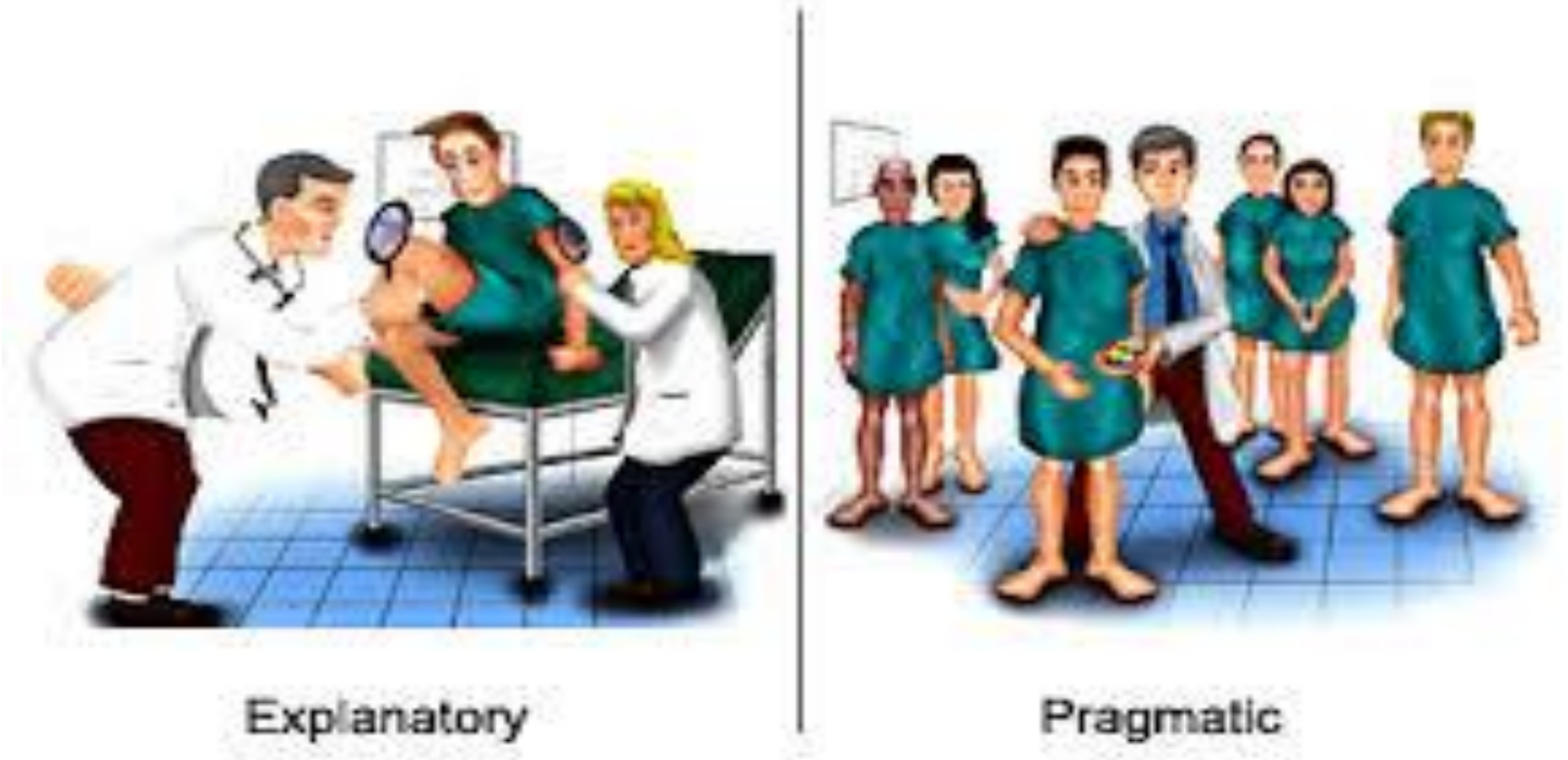
- Lesson 2 – issues with collecting quantitative data
  - Pulling clinical care data directly from EMS
  - Beyond pragmatically driven assessment
- Lesson 3 – “outside” influences on care and study outcomes
  - Effect of “JNC 8” new BP goal recommendation
- Lesson 4 – analytical challenges

Explanatory vs. Pragmatic



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Explanatory vs. Pragmatic Trials

- An explanatory (or efficacy) trial seeks to answer the question "Does an intervention work under *ideal* circumstances?"
  - **A "positive" explanatory trial only meant that the intervention worked under the conditions which the trial was carried out.**
  - **Implementation of trial results in real world setting could often be a challenge.**

- A pragmatic trial seeks to answer the question "Does an intervention work under *real world* conditions?"
  - **Mirroring closely the structure of current care will allow for an easier implementation and dissemination of successful interventions.**

Pragmatic Trials

- Alignment of research questions to those important to stakeholders
- Conducted in everyday clinical practice environment
  - **Capitalized on current system set-up to conduct trial more efficiently**
- Interventions designed with real-world clinical practice in mind
- Study population are those with the greatest need in that clinical care setting
- Collect not just clinical outcomes, but also processes outcome
  - **Health care utilization patterns (visits, adherence to medications or prescription refills…)**
  - **Health care costs**
  - **Patient reported outcomes (satisfaction with study, adherence, challenges to complete intervention, etc)**

Shake, Rattle & Roll

Shake, Rattle & Roll Trial

- A pragmatic, randomized, controlled trial aimed at improving hypertension control in African Americans at Kaiser Oakland

- 3 arms: Usual care, Enhanced arm, and Lifestyle arm
- Shake = shake the salt habit
- Rattle = rattle the intensity of blood pressure control pharmacotherapy
- Roll = roll out the study results in- and outside of Kaiser

Study aims

- **Primary research question**: whether a primary prevention intervention of either diet and lifestyle coaching or an intensive pharmacotherapy protocol is more effective than usual care in improving rates of HTN control in blacks and thereby reducing disparities between black and white.
- **Primary aim**: By implementing either intervention, we will reduce the disparity in hypertension control rates between blacks and whites by 4% at 1 year post-study enrollment.

Randomization

- Total 104 PCPs randomized from OAK Med Center in March 2013
  - **Randomized by panel size of AA patients**
  - **4 PCPs were not randomized because they just joined and had very few AA patients**
- At time of randomization:
  - **Usual Care: Median age = 61 (range 20-86), 70% female**
  - **Enhanced arm: Median age = 63 (range 30-88), 71% female**
  - **Lifestyle arm: Median age = 65 (range 30-87), 64% female**
- Intention to treat
  - **Patient stays in the assigned arm even if changing PCP later**

SRR Inclusion & Exclusion Criteria

- Inclusion
  - Kaiser member with pharmacy benefits
  - Age ≥ 18 years
  - In the Kaiser HTN registry
  - Self-reported race of African American
  - Sufficient understanding of the English language
- Exclusion
  - Non-KP member
  - Age <18
  - Not in the HTN registry
  - Not African American
  - Pregnant women
  - Hospice, SNF or B&C
  - ESRD on dialysis
  - Non-English speaking
  - Dementia

Usual Care

- Kaiser Hypertension Registry
- Outreach program
  - **>50y.o, diabetes, stroke, MI, hypertension**
  - **Panels of patients managed by case managers**
  - **Regular outreach lists of patients not yet at target**
  - **Free blood pressure check visits run by medical assistants and pharmacists**
  - **Evidence-based blood pressure management protocol, “one size fits all”**
  - **PCPs not usually involved**

Interventions

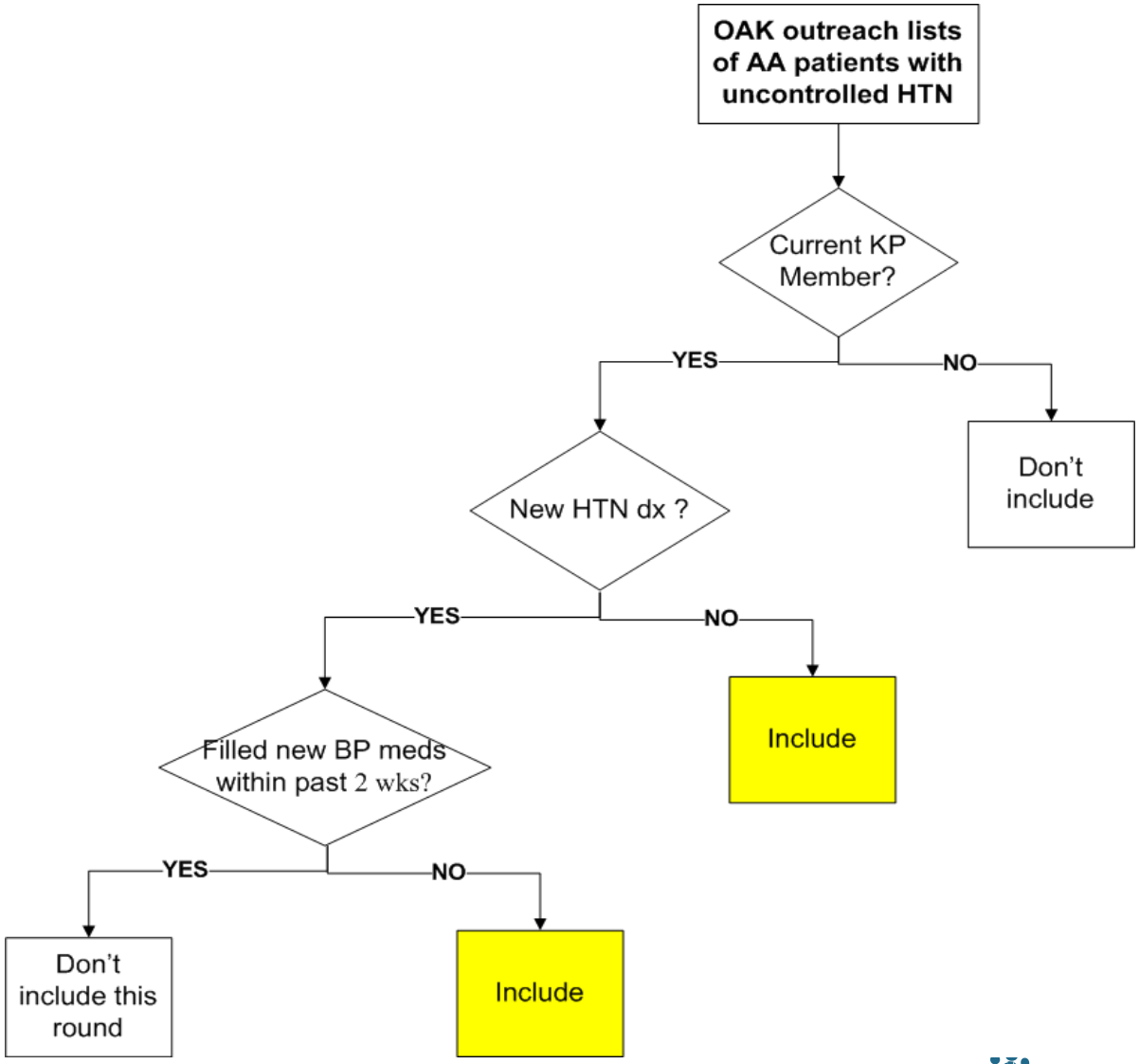
- Enhanced arm:
  - BP check visit scheduled w/in 2 wks of last BP
  - RN face-to-face meeting and/or phone call to discuss barriers & offer resources
  - Consult with clinical pharmacist as appropriate
  - Treatment intensification (esp thiazide)
  - Spironolactone for resistant HTN
- Lifestyle arm:
  - 1st session scheduled at time of consent
  - 4 sessions in the first month
  - 4 sessions in the 2nd & 3rd month
  - Follow-up of individual goals at each session
  - Remainder 8 follow-up sessions over 9 months
  - Group sessions bi-monthly

Shake, Rattle & Roll

Usual Care	Enhanced Monitoring	Lifestyle Coaching
▪ Enrollment began April 2013 ▪ "Intervention" completed April 2015 ▪ No consent required ▪ Reached out only to a random subset for study questionnaires and 24-hr urine Na+ test	▪ Recruitment started in May 2013 ▪ Intervention completed May 2015 ▪ Consent required ▪ Questionnaires and 24-hr urine Na+ test ▪ RN research coord – BP check visits ▪ Pharmacists	▪ Recruitment started in June 2013 ▪ Intervention completed June 2015 ▪ Consent required ▪ Questionnaires and 24-hr urine Na+ test ▪ Health coaches – up to 16 individual sessions

Lesson 1 – Recruitment process
When routine care is “too good”

Identification of AA with uncontrolled HTN



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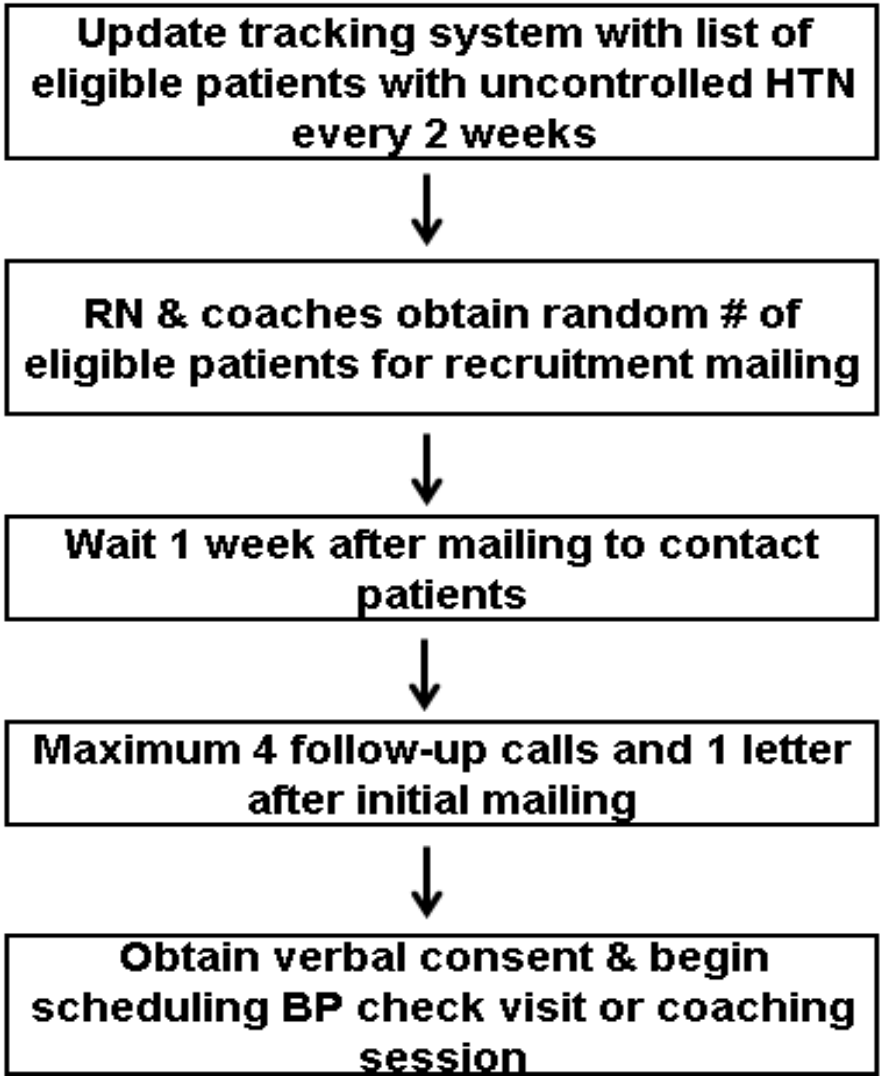
Recruitment workflow



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Enrollment report (as of 6/1/15)

	Usual Care	Enhanced	Lifestyle
Participants with high BP – ever	3599	3940	3475
Participants contacted	n/a	794	685
Participants enrolled	731	349	304
Unable to reach	n/a	272 (34%)	215 (31%)
If reached, consented	n/a	349/522 (67%)	304/470 (65%)
If reached, declined -- No EMR	n/a	93 (18%) 67 (72%)	110 (20%) 55 (50%)

Enhanced – recruitment & initial BP reading

- Average # of calls to recruit =1.9
- Range = 1 – 5
- Median = 1

- # with a BP reading recorded between study identification and enrollment call = 304
- 91 / 304 (30%) of above # with high BP closest to recruitment mailing date

Lifestyle – recruitment & initial BP reading

- Average # of calls to recruit = 2.03 calls
- Range = 1-7 calls

- # with a BP reading recorded between study identification and enrollment/call = 191
- 70/191 (36.6%) of above # with high BP closest to recruitment mailing date

Next time around…

- Shorten the time between mail out and actual recruitment call
  - IRB issues
  - Staff time
- Consider requiring more than one “uncontrolled BP reading” before a patient becomes eligible for recruitment

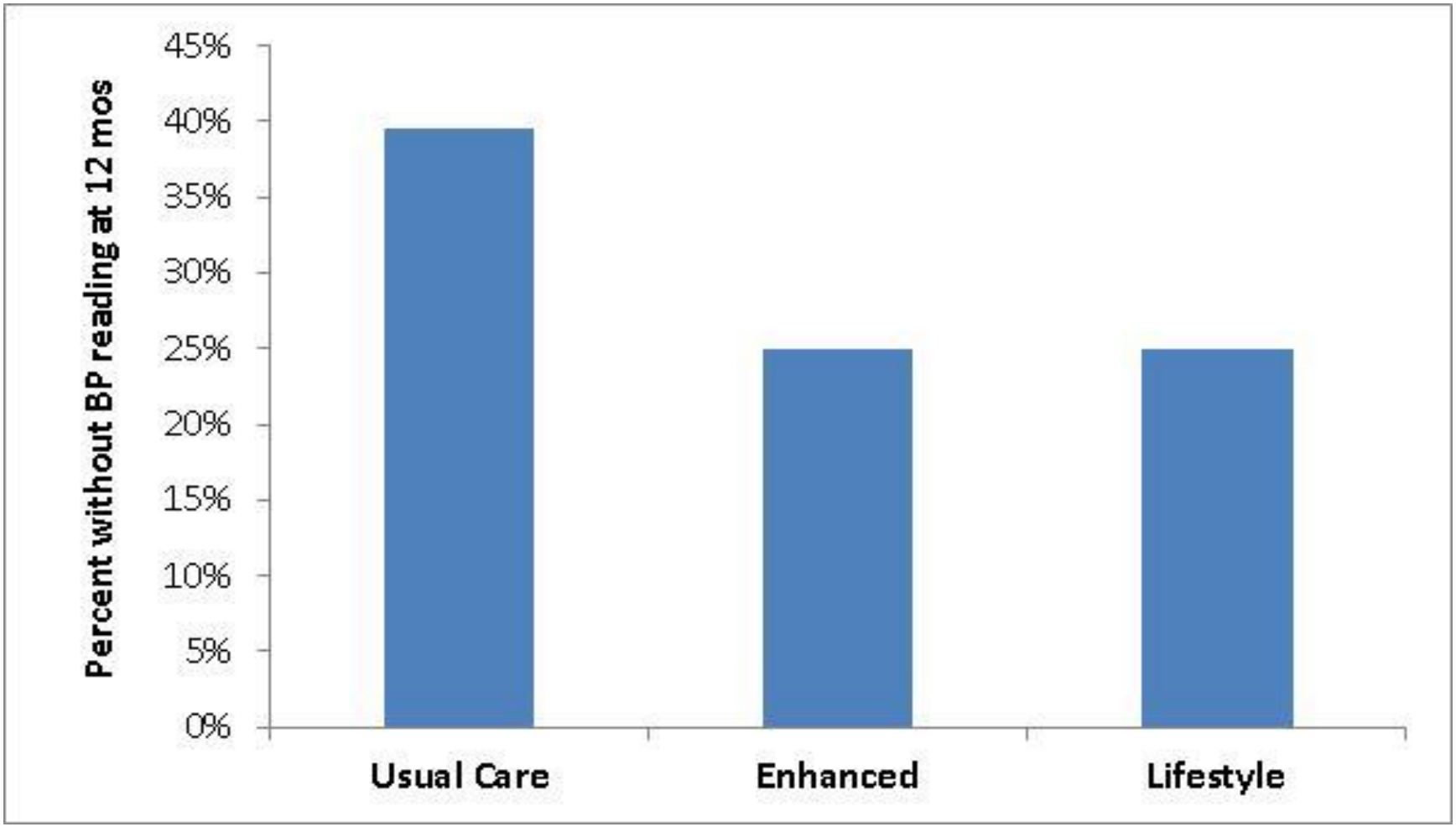
Lesson 2 – Issues with collecting quantitative data

Lesson 2 – issues with collecting quantitative data

- Pulling clinical care data directly from electronic medical record system
  - **Blood pressure data stored in multiple different "tables"**
  - **Clinical care versus research databases**

- Next time around…
- Beyond pragmatically driven assessment
  - **Need to ensure adequacy of primary outcome data**
  - **The need to include blood pressure measurements at certain key time points**

Percent of participants with no BP readings at 12 ± 3 months



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Lesson 3 – “Outside” influences on care and study outcomes

JAMA New BP Goal

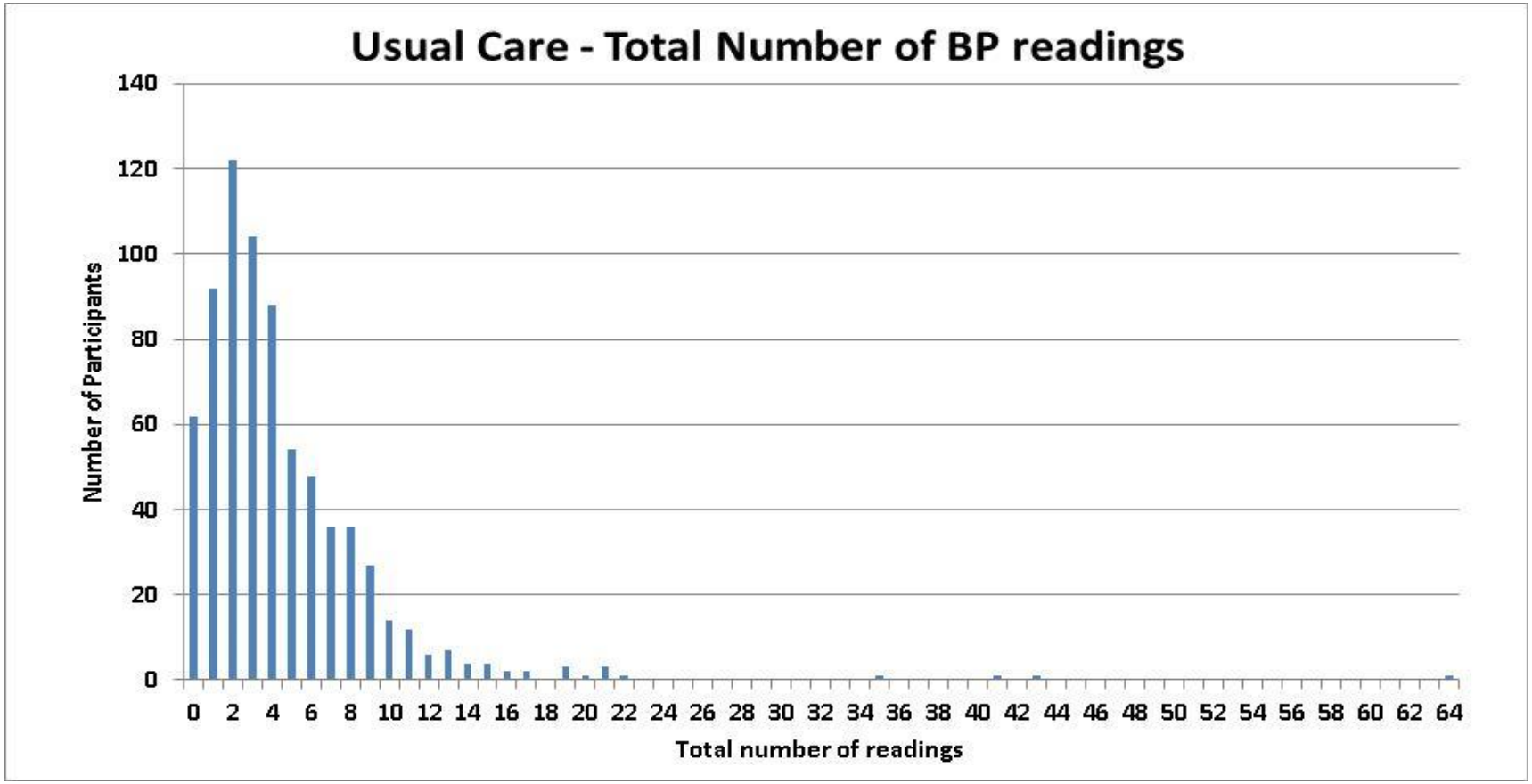
- <150/90 for those age >60 with HTN, and no DM or CKD
- Region-wide adoption of JNC 8 guidelines approved by Board of Directors on March 20, 2014.
- 2014 KPNC Hypertension Clinical Practice Guideline updated to include new BP recommendations
- How will this affect Shake, Rattle & Roll?
  - Not likely to have an effect on prescribing habits during SRR, but less outreach efforts for those meeting the new BP goal
  - Will need to consider analyses with both the "old" BP goal of 140/90 and the "new" BP goal

Lesson 4 – Analytical challenges

Analytical Challenges

- # of coaching sessions in Lifestyle arm >> # of BP check visits with RN & pharmacists in Enhanced arm
- The in- and out-flux of those with BP “under controlled” and “out of control”
- Different number of BP measurements recorded per participant

Usual Care – BP readings during intervention year



- Median total # of BP readings/patient = 3
- Range of total # of BP readings/patient = 0 - 64

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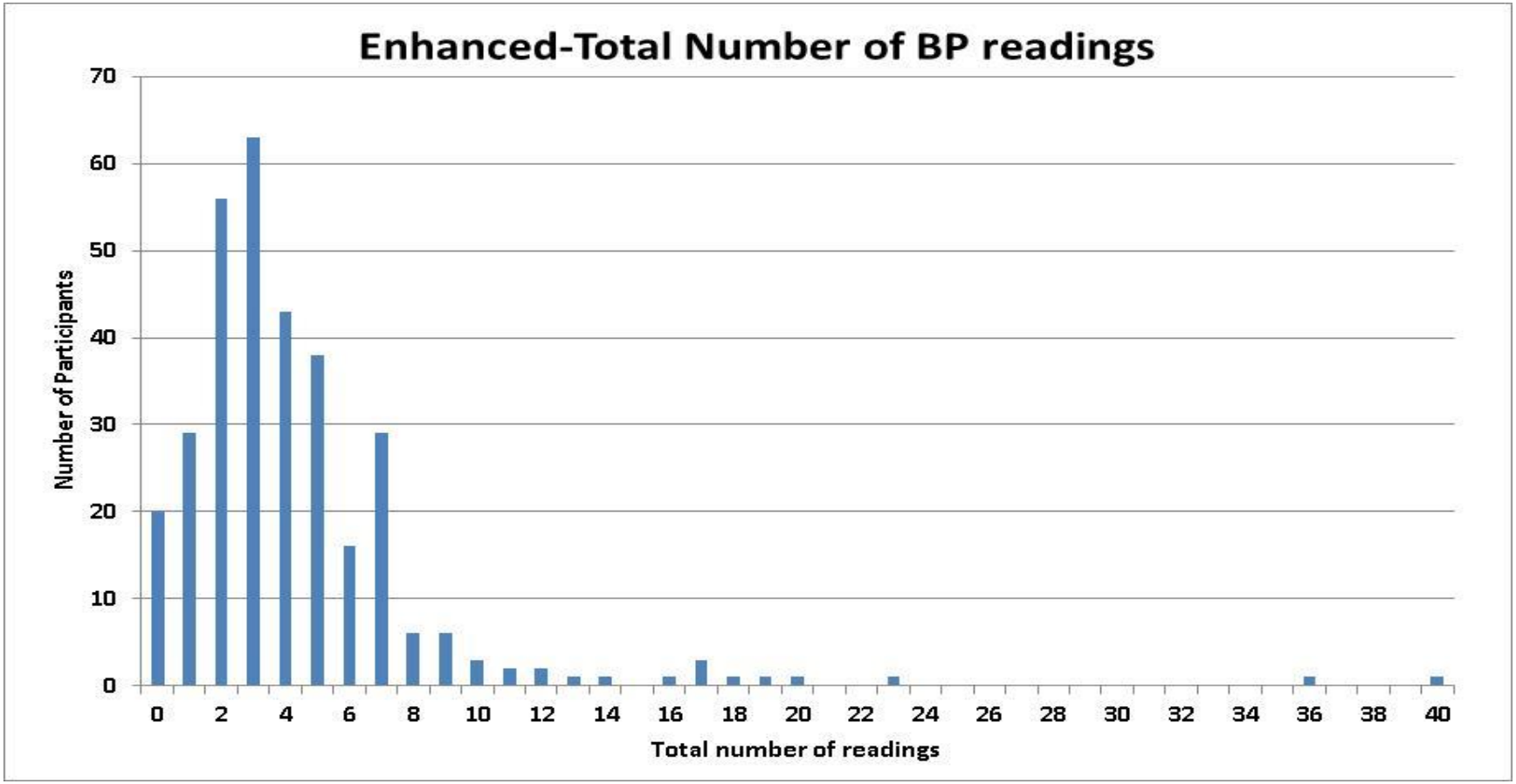
Enhanced– BP readings during intervention year



- Median total # of BP readings/patient = 3
- Range of total # of BP readings/patient = 0 - 40

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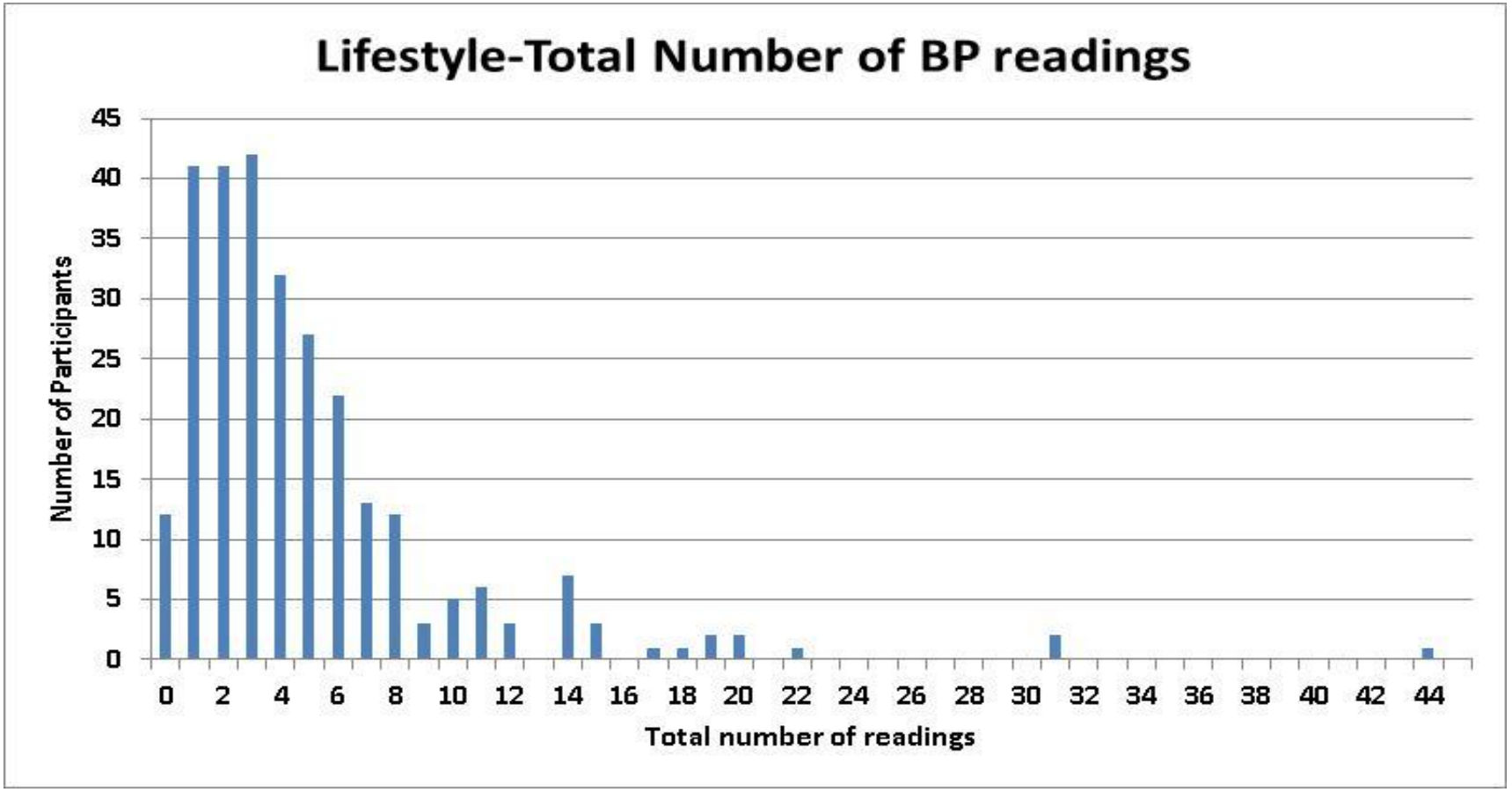
Lifestyle – BP readings during intervention year



- Median total # of BP readings/patient = 4
- Range of total # of BP readings/patient = 0 - 44

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In Summary: Conducting Pragmatic Trials

- Could be more efficient and cost-effective to carry out than traditional RCTs
  - **Utilization of existing infrastructure, clinical care systems and EMR to identify and enroll participants, and to collect follow-up data**
  - **Need a "real" run-in period to test for unanticipated issues**
- Could be more complicated than traditional RCTs
  - **Need to ensure adequate collection of outcome data**
  - **Shortest duration of intervention possible in order to minimize potential changes in clinical care**

In the end…

- Conducting a pragmatic trial within a health care system is challenging but possible.
- Close collaboration with patients, and everyone in clinical care (PCPs, clinic managers, medical assistants, pharmacists) as well as regional champions and leaders is critical.
- Adequate time is needed for setting up tracking system, data collection processes, and testing these operations within the health care system.
- Combining a pragmatic trial design with an integrated health care system like Kaiser and its extensive EMR system offers the opportunity not just to evaluate effectiveness of the interventions but also to explore how things work.

Thank you!!!

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