

# Learning Activities and Oversight: Case Studies from Kaiser Permanente

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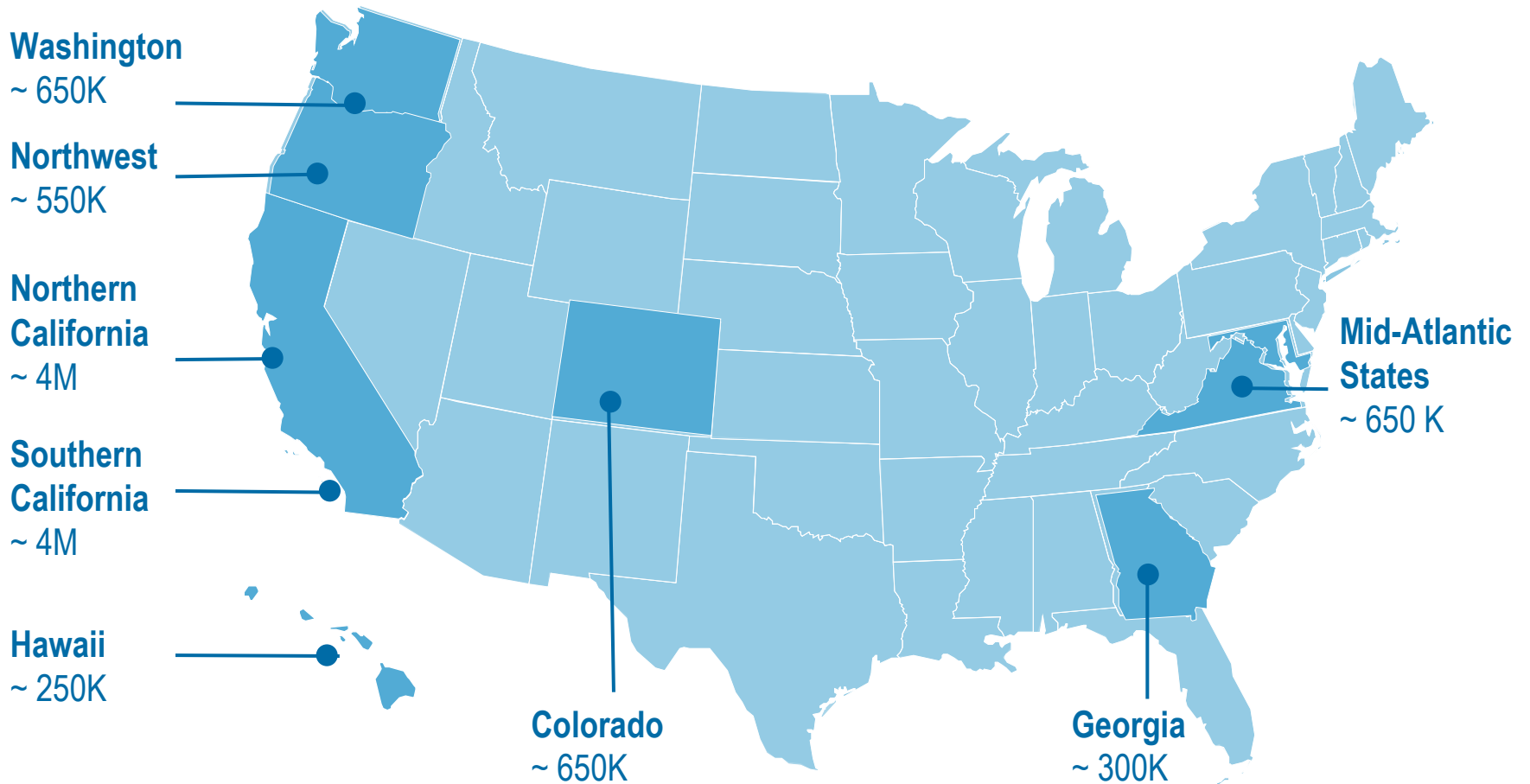
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# Kaiser Permanente is an integrated, learning health care system

11.7M members in 8 regions (3.6% of the U.S. population)



# Kaiser Permanente Northern California holds a stream of learning activities

- 4.1 million patients
- 9,000 physicians
- 21 hospitals
- Fully electronic health record
- Research group with 600 staff



# Research determination process

- Developed by KP's National Compliance in Research Support Program (Eric Garcia)
- In KP Northern California, a physician with research background is the Research Determination Official
  - Receives training and compliance oversight
- Separate from IRB

# Checklist

- Are human subjects involved?
  - Interaction or intervention with people
  - Identifiable private information

If no to both, stop.

If yes to either of these, continue:

# Checklist

- Is it research?
  - Is it a systematic investigation?
    - Has a hypothesis, research question, research methods, or a plan for data analysis
  - Is it designed to contribute to generalizable knowledge?
    - Research design, or “intention”
    - Relevance beyond the population or program

If no to either, it's not human subjects research

# Case study 1: Medication monitoring system



Beth McGlynn

- Feasibility project to test whether KP data can be used to prospectively monitor new medications for previously unknown or uncommon adverse events
- Using weight loss medications as a test case
- Objective: Determine whether KP should develop a system for routinely monitoring drug safety

# Determination re Case study 1: Medication monitoring system

- Evaluation required some back-and-forth
- Are human subjects involved?
  - Involves identifiable private information --> Yes
- Is it research?
  - It is a systematic investigation
  - It is not designed to contribute to generalizable knowledge --> No



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## Not human subjects research



## Case study 2: Outreach for colorectal cancer screening in African-Americans



TR Levin

- Evaluate the effectiveness of tailored media outreach to increase colorectal cancer screening rates in African-American patients
- Usual care = reminder letter, letter with testing kit, robocall, final letter
- Intervention = same and replaced letters with tailored postcards and robocall was tailored
- Notes: Randomized; evaluation is retrospective

# Determination re Case study 2: Outreach for colorectal cancer screening in African-Americans

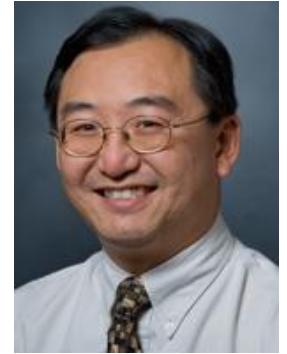


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- Are human subjects involved?
  - Intervention with people --> Yes
- Is it research?
  - It is a systematic investigation
  - It is not designed to contribute to generalizable knowledge --> No

**Not human subjects research**

# Case study 3: Heart failure follow-up research study – informed consent?



Alan Go

- Telephone visit with RN vs. in-person visit with primary care MD for heart failure patients
- Both approaches had been usual care; non-random assignment
- For the study, random assignment at the individual level was planned

## Outcome of Case study 3: Heart failure follow-up research study

- Determined to be human subjects research due to plan to produce generalizable knowledge
- Went to IRB; proposal was revised twice
- Enlisted stakeholders to confirm that both intervention arms were usual care and made the case that care would improve for all
- Five months to approval

**No informed consent was required**

# Lessons learned at Kaiser Permanente

- Ambiguity in regulations can lead to disparate interpretations
  - We often aim to produce generalizable knowledge
- Training is important; calibration is key
- Leave time for iteration
- Experience may improve our efficiency

