

Design of an Ongoing Randomized Controlled Trial

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Overview

- Cluster randomized controlled trial
- 3 insurers (Kaiser Permanente Mid-Atlantic States, Medicare FFS, US Family Health Plan/Tricare)
- 3 medical systems (Kaiser Permanent Mid-Atlantic States, Johns Hopkins Community Physicians, Medstar Physician Partners)
- 8 physician practices in the Baltimore/Washington area
- 49 physicians
- 904 participants and 308 caregivers

Selection of Providers

Practice requirements

- Located in the Baltimore/Washington metropolitan area
- At least 2 teams of physicians that could be matched for randomization
- Each team would have no more than 5 physicians and a total panel of 600 patients or more 65+ years of age
- Interested in participating
- Adequate office space for GCN

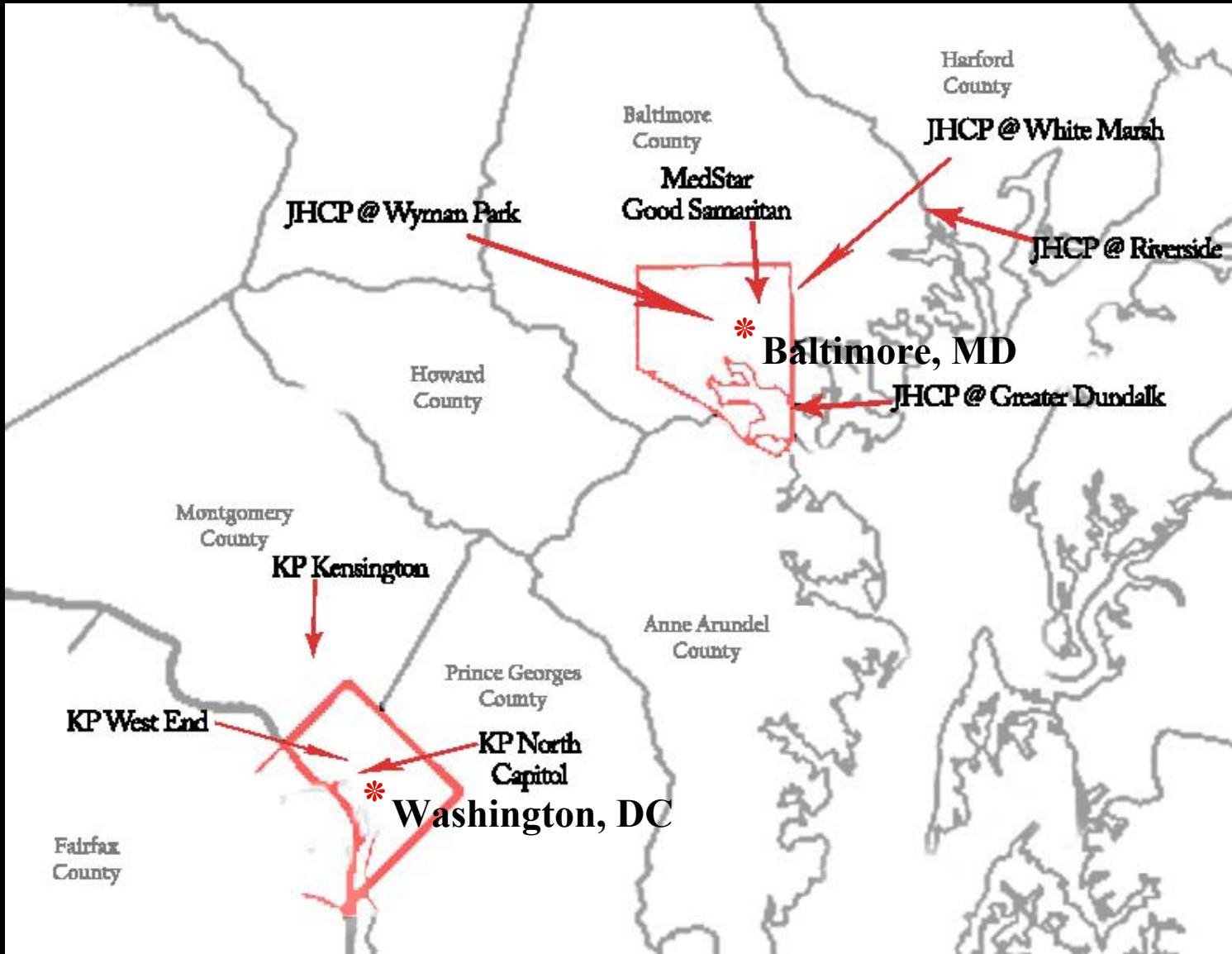
Complex Recruitment

- Not enough practices within one medical system (JHCP) to meet requirements
 - not enough older patients
 - no space for nurse
- Extended study to include Kaiser Permanente and Medstar Physician Partners
- Advantages- enriches study sample; study the effects across multiple systems
- Disadvantages- 3 different IRBs, 3 different insurers

Selection of Providers

	Sites			# of MDs
	Total	Met Eligibility	Selected to Participate	
JHCP	17	9	4	23
Kaiser	14	7	3	20
Medstar	9	1	1	6
Total	40	17	8	49

Physician groups within sites were randomized to either receive Guided Care or Usual Care



Selection of Participants

Inclusion Criteria

- Age 65+
- Patients of a participating physician with at least one visit in preceding 12 months
- Hierarchical Condition Categories (HCC) score of 1.20 (top 25% highest risk)
 - Diagnoses from previous years' insurance claims

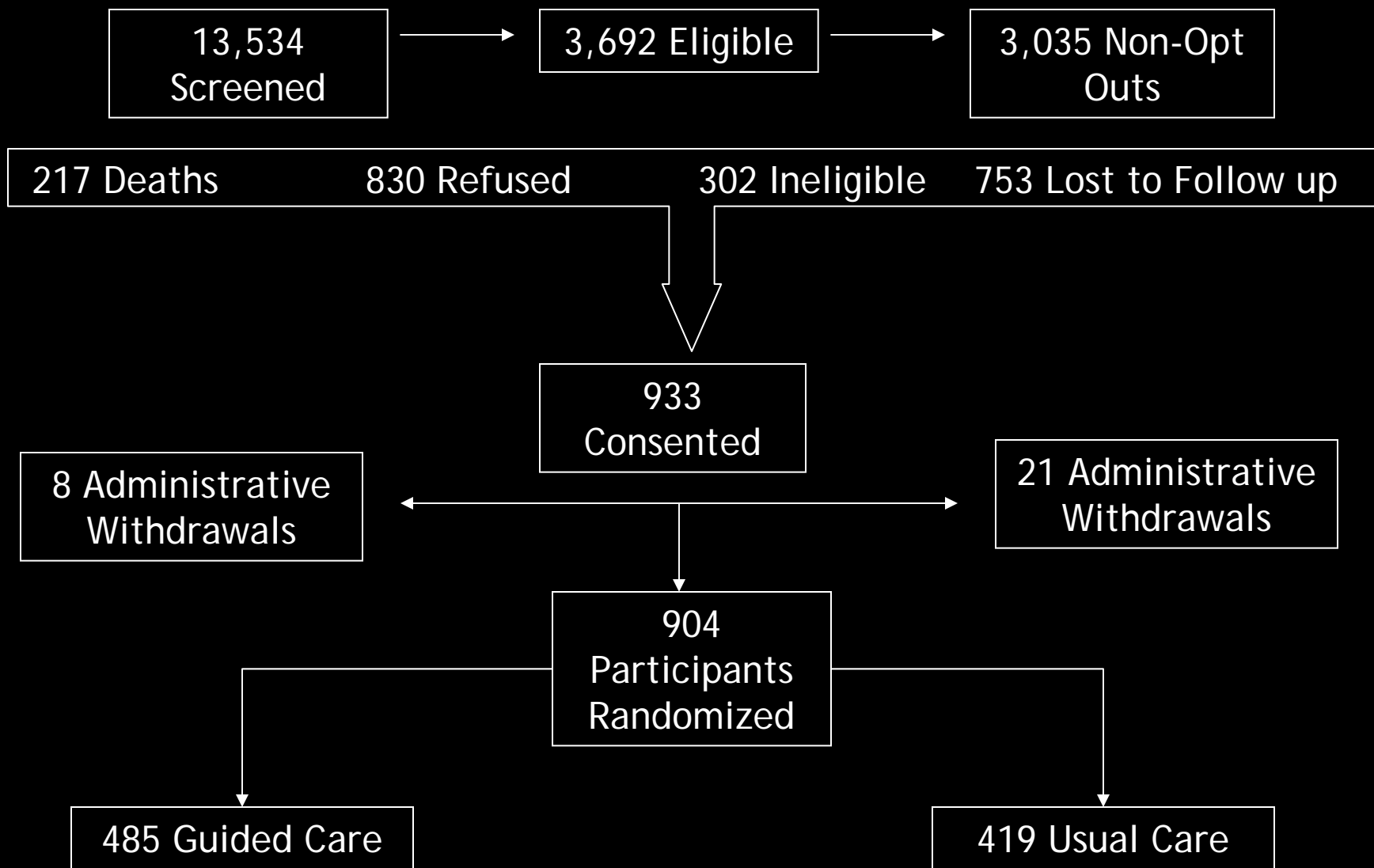
Selection of Participants

Exclusion Criteria

- Have cognitive impairment with no legal representative
- Would be unable to participate in the baseline or follow-up interviews (e.g., because of communication barrier, inability to be contacted by telephone, or plans for extended travel out of the area)
- Non-English speaking

Recruiting Participants

- Nurse case load of 50-60 patients
- Target recruitment of 65+ participants at each site to enable replenishment during the first year of the study
- Three waves of recruitment
 - Lower the HCC threshold in one insurer to include adequate number of patients
 - Differential consent rates across sites
 - Attrition



Identifying Caregivers

- Identified during patient baseline interview
- Relatives or unpaid friends who assist patients with health related tasks regardless of intensity or specific types of assistance provided
- Of the 449 caregivers identified, 68.6% (308) were consented to participate in the study

Patient Outcomes

Physical and Mental Health

- SF36 physical and mental component

Quality and Satisfaction with Care

- Patient Assessment of Chronic Illness Care (PACIC)
- Primary Care Assessment Survey (PCAS)

Health Care Utilization

- Claims and encounter data from all 3 insurers

Caregiver Outcomes

Caregiver burden, cost, health and satisfaction with care

- Modified Caregiver Strain Index (CSI)
- EUROQOL
- Work Productivity and Activity Impairment (WPAI)
- Center for Epi Studies Depression Scale (CES-D)
- Modified PACIC

Physician Outcomes & Practice Environment

Physician satisfaction with care provided to older, chronically ill patients

- Managing and coordinating care
- Primary Care Assessment Tool (PCAT)

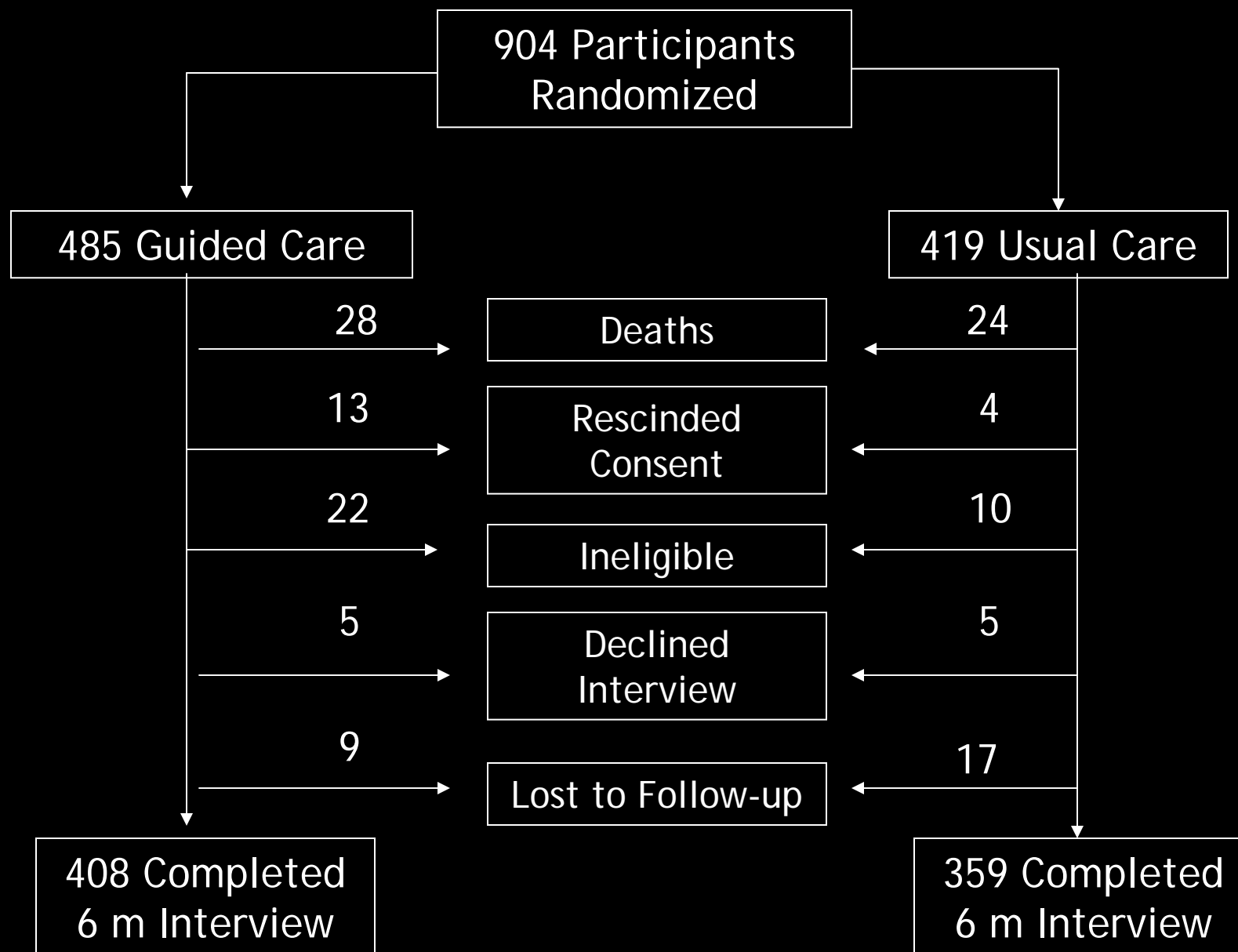
Practice Environment

- Characterize infrastructure at each site

Data Collection

	Completed Data Collection	Future Data Collection
Patient/Caregiver	BL interview 6 month interview	18 month interview (6/08)
Physician & Practice Staff	BL survey 1 yr PCP survey	2 yr practice staff & PCP survey
Claims	-----	6 month (thru 6/07) 18 month (thru 6/08)

6 Month Follow-up



Baseline Socio-Demographics

	Guided Care (n=485)	Usual Care (n=419)
Age, mean yr (range)	77.2 (66-106)	78.1 (66-96)
% female	54.2	55.4
% Minority	48.9	51.1
% Married	46.0	48.5
Education (% 12+ yrs)	46.4	43.4
% with just enough or not enough money left over at the end of the month	42.1	48.9
Insurance		
FFS Medicare	31.7	36.5
MO 1	26.2	16.0
MO 2	42.1	47.5

Baseline Health Status and Function

	Guided Care (n=485)	Usual Care (n=419)
HCC score, mean (95% CI)	2.1 (2.0, 2.1)	2.0 (1.9, 2.0)
% rated health as fair or poor	39.8	46.8
Self-reported conditions, mean (out of 14)	4.3	4.3
SF36 score, mean (95% CI)		
Physical component	38.7 (38.3, 39.1)	38.1 (37.6, 38.5)
Mental Component	50.3 (49.8, 50.7)	48.7 (48.2, 49.2)
Difficulty with 1+ ADL (%)	30.9	29.3
Difficulty with 2+ IADL (%)	19.6	27.6
Cognition, mean SPMS	9.1	9.0