A Clustered-Randomized Stepped-Wedge Pragmatic Trial to Enhance Goals-of-Care Communication for Older Adults with Cancer (ACP-PEACE)

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Why

What

Why We Should Care

People ≥65 Cancer

- Preferences for medical care
- Most have not had goals-of-care conversations
- Patients unaware of their options
- Clinicians unprepared
- Leads to billions of dollars in unwanted (& painful) interventions

ACP DECISIONS

- Short, easy to understand video decision aids activate patients to share in decision making
- Leads to more GOC conversations in small RCTs
- Offers a scalable and rapid strategy to improve GOC

- Communication training for clinicians discussing goals of care in serious illness
- Based on evidence that learning skills requires **practice**, **observation**, and **feedback**
- Documented improvement in conversation quality
- Internationally disseminated “gold standard” program

REFRAME
the situation

EXPECT EMOTION
respond with empathy

MAP
out important values

ALIGN
with the patient & family

PLAN
treatment to uphold values

- Multicenter SW-CRT
- Outcome: GOC documentation
- COVID: 36 to 30 (29) clinics
- Three health systems (A, B & C)
- April 2020– Nov 2022
- Waiver of individual informed consent
- Broadcast notifications

- Eligible patients ≥ 65 with advanced cancer
- No exclusion criteria
- Bundled intervention
- GOC documentation
- NLP

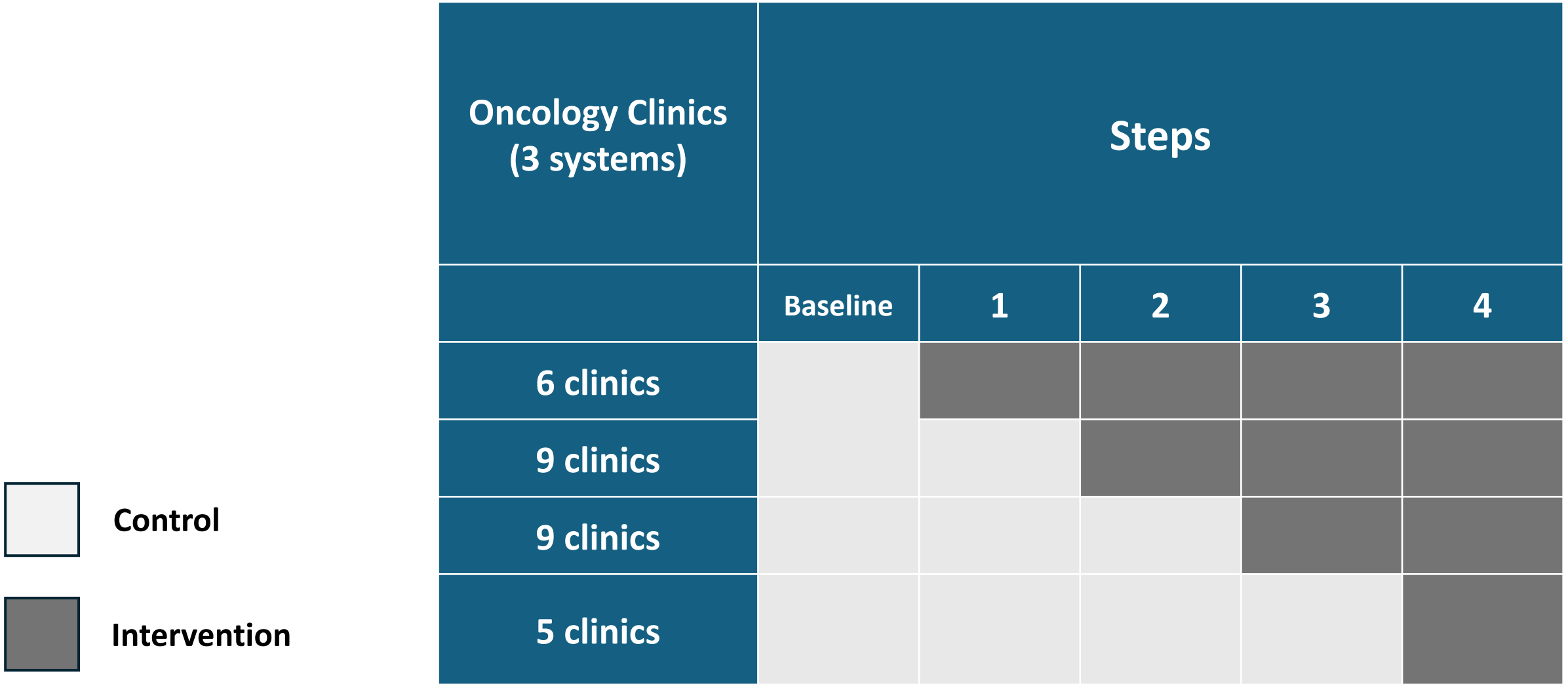
“During goals-of-care discussion with pt and family, pt expressed wish to be home”

“The patient indicated that walking with a cane instead of a walker is one of their goals of care”

- Intention to treat analysis
- Intervention period vs. control period
- Open cohort design
- Generalized linear models
- Heterogeneity of intervention effect
- >90% power

Results

Stepped-Wedge Cluster Randomization Design for 29 Clinics in Three Health Care Systems



Patient Characteristics by Intervention Status

- 13,800 unique patients
- Each patient could be assessed more than once in intervention and usual care periods

	All	Usual Care	Intervention
	29,357*	13,603	15,754
Age, years, Mean(SD)	74.5 (6.6)	74.6 (6.7)	74.4 (6.6)
Female, N (%)	14,013 (47.7)	6,729 (49.5)	7,284 (46.2)
Race, N (%)			
American Indian or Alaska Native	62 (0.2)	27 (0.2)	35 (0.2)
Asian	1,035 (3.5)	479 (3.5)	556 (3.5)
Black	3,433 (11.7)	1,455 (10.7)	1,978 (12.6)
Native Hawaiian or Other Pacific Islander	10 (0.0)	3 (0.0)	7 (0.0)
Multi-racial	11 (0.0)	10 (0.1)	1 (0.0)
Other	1,717 (5.8)	836 (6.1)	881 (5.6)
White	22,271 (75.9)	10,441 (76.8)	11,830 (75.1)
Unknown/Missing	818 (2.8)	352 (2.6)	466 (3.0)
Hispanic, N (%)	846 (2.9)	392 (2.9)	454 (2.9)
English, N (%)	28,163 (95.9)	13,067 (96.1)	15,096 (95.8)
Health Care System, N (%)			
A	9,060 (30.9)	3,788 (27.8)	5,272 (33.5)
B	8,439 (28.7)	4,279 (31.5)	4,160 (26.4)
C	11,858 (40.4)	5,536 (40.7)	6,322 (40.1)
Diagnosis type N (%)			
BMT	1,063 (3.6)	164 (1.2)	899 (5.7)
Brain	649 (2.2)	130 (1.0)	519 (3.3)
Breast	1,654 (5.6)	1,001 (7.4)	653 (4.1)
Endocrine	804 (2.7)	430 (3.2)	374 (2.4)
GI	4,071 (13.9)	1,809 (13.3)	2,262 (14.4)
GU	3,567 (12.2)	1,662 (12.2)	1,905 (12.1)
GYN	1,403 (4.8)	916 (6.7)	487 (3.1)
Head and Neck	338 (1.2)	102 (0.7)	236 (1.5)
Leukemia	3,923 (13.4)	3,038 (22.3)	885 (5.6)
Lung	1,780 (6.1)	652 (4.8)	1,128 (7.2)
Lymphoma	2,029 (6.9)	307 (2.3)	1,722 (10.9)
Melanoma	844 (2.9)	491 (3.6)	353 (2.2)
Myeloma	4,036 (13.7)	803 (5.9)	3,233 (20.5)
Neuro-oncology	603 (2.1)	263 (1.9)	340 (2.2)
Sarcoma	1,396 (4.8)	883 (6.5)	513 (3.3)
Thoracic	1,197 (4.1)	952 (7.0)	245 (1.6)

Intervention Fidelity

	Health System A	Health System B	Health System C
Oncologists and APP's Trained (%)	63/63 (100%)	53/60 (88%)	59/91 (65%)
Video decision-aid use (# of viewings)	516	2,564	4,561

ACP Documentation Rate by Intervention Status

	Usual Care N (%)	**Intervention** N (%)	**Adjusted difference** (%)	P-value
ACP documentation	**2,834 (20.8)**	**3,980 (25.3)**	**6.8 (2.8-10.8)**	**<0.001**
Components:				
Goals of Care	2,281 (16.8)	3,377 (21.4)	6.9 (3.4-10.4)	<0.001
Palliative Care	1,287 (9.5)	1,517 (9.6)	0.7 (-0.5-1.9)	0.26
Hospice	724 (5.3)	847 (5.4)	0.3 (-0.4-1.0)	0.39
Limitation of Life-Sustaining Treatments	1,149 (8.4)	1,128 (7.2)	-0.1 (-0.7-0.6)	0.80

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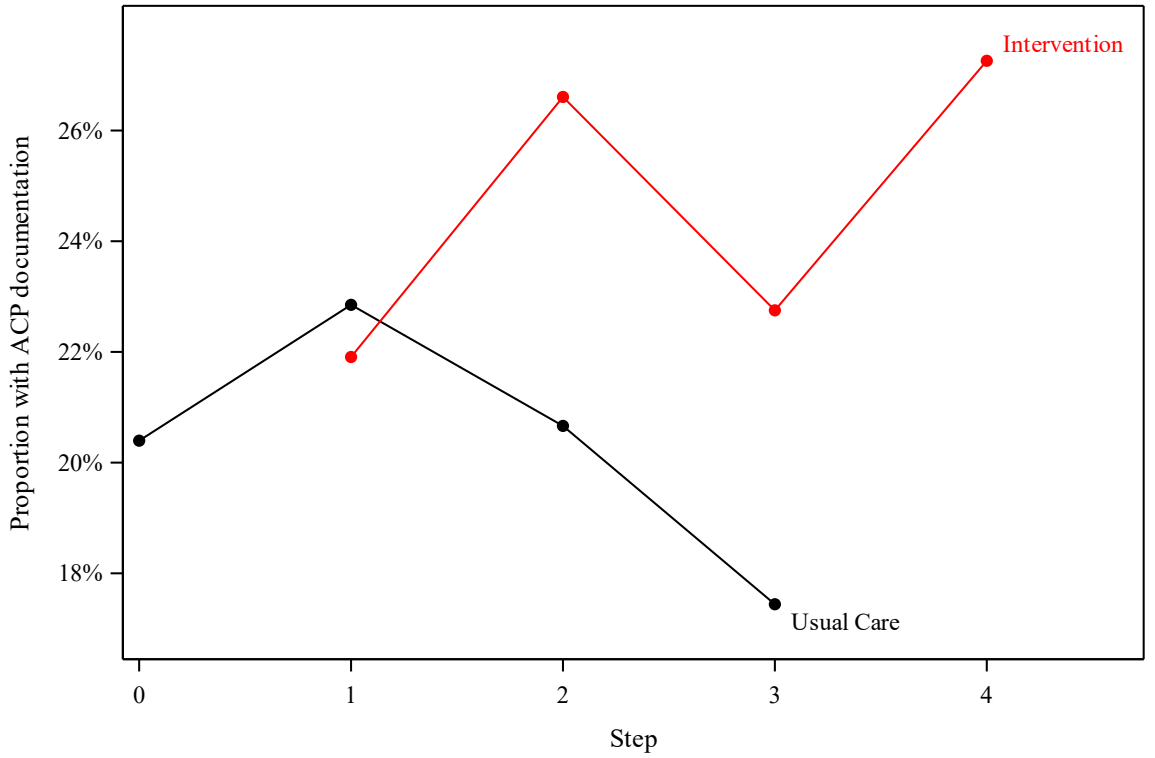
ACP documentation by six-month step for the intervention and control periods



Heterogeneity of Treatment Effect by Health Care System

	Usual Care		Intervention		P=0.061
	N	%	N	%	
Health Care System A	1,238/3,788	32.7%	1,333/5,272	25.3%	-7.4%
Health Care System B	967/4,279	22.6%	1,403/4,160	33.7%	11.1%
Health Care System C	629/5,536	11.4%	1,244/6,322	19.7%	8.3%

Right Target?

- GOC conversation
- Goal-aligned medical care (goal concordance)

Sustainability: A Tale of Three Health Systems

- HCS A
  - Clinician burnout
  - Clinical champion left
  - Clinic left
  - Difficult to f/up
  - *Lack of front-line representation
  - *Systemic issues
- HCS B
  - Clinical champion relocated
  - Still using intervention but not broadly
  - *Loss of interest over time
- HCS C
  - Least academic
  - Frontline staff
  - Constant C-Suite Presence


ACP
PEACE
Promoting Effective & Aligned
Communication in the Elderly

ACP COVID

Communicating with Outpatients for Vital Informed Decisions

VIDEO-PCE

Videos Images about Decisions for
Ethical Outcomes with **Palliative Care Educators**


Pragmatic Clinical Trials Are Having a Moment…
Making Pragmatic Clinical Trials More Pragmatic…


The shackles of
p values…

UG3/UH3
Fit for purpose?

- 5 years of planning (2018!)
- 1 year start-up time
- Cost savings not explicit
- Interim analyses not required

Healthcare in the U.S.

- The only constant is change
- Two-year trials
- Cost savings must be explicit
- Interim analyses required
- Competitive advantage
- Not for the faint-hearted

Thank you!

- NIA
- Marcel Salive, MD, MPH
- Yuchiao Chang, PhD
- Healthcare Systems A, B & C
- The Pragmatic Trials Collaboratory Cores
- The U.S. Taxpayer

References

Making Pragmatic Clinical Trials More Pragmatic

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