

Convening + Uniting + Transforming

unch earn A forum for researchers and



## **PCC Lunch and Learn**

Tuesday, December 7, 2021 | 12:00 PM - 1:00 PM ET



#### Lunch and Learn Co-chairs and Presenters



Irene Dankwa-Mullan, MD, MPH

Deputy Chief Health Officer, IBM Watson Health



Jack Westfall, MD, MPH

Director, Robert Graham Center



**Mark Ebell, MD** University of Georgia School of Public Health



Frank Moriarty, PhD

Royal College of Surgeons in Ireland



Karen Swietek, PhD

NORC

Medical Homes & Quality of Care for Multiple Chronic Conditions

Karen E. Swietek, PhD MPH December 7, 2021

## Medical homes can improve management of chronic conditions

- In 2018, more than one quarter of adults in the U.S. had at least two chronic conditions
- Multiple chronic conditions are associated with worse health outcomes, higher health care costs, and increased risk of death
- Team-based care, enhanced care coordination, and disease management in the patient-centered medical home (PCMH) model can improve overall quality of care
- Complex patients with multiple chronic conditions may be especially likely to benefit from the PCMH

# We studied the effect of the PCMH on quality of care for patients with multiple chronic conditions

- **Population:** Medicaid enrollees in North Carolina (2008-2010) with 2+ chronic conditions
- **Setting:** Community Care of North Carolina (CCNC)
- Claims-based outcomes: A1C testing, attention for nephropathy, eye examinations, and liver function tests, lipid profiles, angiotensin-converting enzyme inhibitor (ACE) or angiotensin receptor blocker (ARB), short-acting βagonist (SABA) overuse, psychotherapy, assertive community treatment (ACT)
- Methods: Linear probability models with person- and year-level fixed effects

# The PCMH model is an effective way to improve chronic illness care

- Quality-of-care metrics generally improved among patients enrolled in a PCMH for both mental and physical health conditions
- Patients with physical conditions were more likely to receive A1C testing, attention for nephropathy, eye examinations, liver function tests, lipid profiles, and ACE/ARB
- Patients with behavioral health conditions were more likely to receive psychotherapy and ACT
- SABA overuse among those with asthma was an exception to the trend of improved quality metrics

## Further research can tell us more about who benefits from the PCMH and how

- Duration of PCMH enrollment affects outcomes
- Barriers to accessing the PCMH may limit benefits
- Equity is an important consideration; different populations may not benefit equally from the PCMH model



**Study team:** Karen E. Swietek PhD MPH, Marisa Elena Domino PhD, Christopher Beadles MD PhD, Alan R. Ellis PhD MSW, Joel F. Farley PhD, Lexie R. Grove PhD MSPH, Carlos Jackson PhD, C. Annette DuBard MD MPH

## A comparison of contemporary versus older studies of aspirin for primary prevention



Frank Moriarty PhD, MPSI <sup>a</sup> Mark H. Ebell MD, MS<sup>b</sup>

a. School of Pharmacy and Biomolecular Sciences, Royal College of Su

b. College of Public Health, University of Georgia, Athens, USA





**GEORGIA** 

## Background

- 2015 USPSTF guidance based on pre-2000 studies: use low dose aspirin for primary prevention in patients 50-59
  (B) or 60-69 (C) with ≥ 10% 10-year CV event risk.
- Draft 2021 USPSTF guidance incorporating newer studies: shared decision-making for 40-59 with ≥ 10% 10year CV event risk (C); D if 60+ years
- European Society of Cardiology (2016): ""Antiplatelet therapy is not recommended in individuals free from CVD, due to the increased risk of major bleeding."
- Before 2000 hyperlipidemia, hypertension, and diabetes were less well treated, and there was little or no population-based screening for colorectal cancer.
- 4 recent large RCTs give us an opportunity to compare old studies with new data collected in the current context.



## **Methods**

#### Older data from published meta-analyses that recruited patients before 2000

- Anti-Thrombotic Trialists collaboration individual patient meta-analysis for 95,000 patients (1978 – 1998)
- Anti-Thrombotic Trialists collaboration aggregate meta-analysis of 6 studies with 25,000 patients (1978 to 2002)

#### Newer data from 4 studies that recruited patients after 2005

- JPPP, 2014 (Japan, n=14,464; 34% T2DM)
- ASCEND, 2018 (UK, n=14,480; 94% T2DM, 75% statin)
- ARRIVE, 2018 (US & Europe, n=12,546; 0% T2DM, 44% statin)
- ASPREE, 2018 (US & Australia, n=19,114; 11% T2DM, 34% statin)

Performed random effects meta-analysis of 4 new studies with 60,000+ patients and compared that with data from older studies.

All of the above studies randomized moderate to high risk older patients without known heart disease to low dose aspirin or placebo.

Records identified through bridge search (n = 20)

RCTs that began recruitment after 2005 identified from previous metaanalyses (n=4)

Records after duplicates removed (n = 22)

> Records screened (n = 22)

Records excluded (n = 18)

Full-text articles assessed for eligibility (n = 4) Full-text articles excluded (n = 0)

Studies included in qualitative synthesis (n = 4)

Studies included in quantitative synthesis (meta-analysis) (n = 4)

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	
ARRIVE, 2018	•	•	•	•	•	•	•	
ASCEND, 2018	•	•	•	•	•	•	•	

ASPREE, 2018

JPPP, 2014

÷

÷

## **Benefits**

No significant benefit in newer studies for:

- All cause mortality
- CV mortality
- Fatal MI
- Fatal stroke

Small but significant benefit for composite:

 MACE (CV death, non-fatal MI, or nonfatal stroke)

All cause mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 49.6%, $p = 0.114$ ) Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, $p = 0.877$ ) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, $p = 0.673$ )	0.99 (0.80, 1.23) 0.94 (0.86, 1.04) 1.14 (1.01, 1.28) 0.98 (0.84, 1.15)	160/6270 748/7740 558/9525	161/6276	
ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 49.6%, $p = 0.114$ ) Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, $p = 0.877$ ) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 ASCEND, 2018 AS	0.99 (0.80, 1.23) 0.94 (0.86, 1.04) 1.14 (1.01, 1.28) 0.98 (0.84, 1.15)	160/6270 748/7740 558/9525	161/6276	
ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 49.6%, p = 0.114) Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 ASCEND,	0.94 (0.86, 1.04) 1.14 (1.01, 1.28) 0.98 (0.84, 1.15)	748/7740 558/9525		14.37
ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 49.6%, p = 0.114) Cardiovascular mortality ARRIVE, 2018 ASPREE, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE,	1.14 (1.01, 1.28) 0.98 (0.84, 1.15)	558/9525	792/7740	34.53
JPPP, 2014 Subtotal (I-squared = 49.6%, p = 0.114) Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE,	0.98 (0.84, 1.15)		494/9589	29.23
Subtotal (I-squared = 49.6%, p = 0.114) Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2014 ASCEND, 2014 ASCEN	a manage and a second	297/7220	303/7244	21.86
Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2014 ASPREE, 20	1.01 (0.92, 1.12)	1763/30755	1750/30849	100.00
Cardiovascular mortality ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 ASCEND, 2014 ASCEND,	· · · · ·			
ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)				
ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.98 (0.62, 1.52)	38/6270	39/6276	8.80
ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.93 (0.77, 1.12)	210/7740	226/7740	50.92
JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.86 (0.67, 1.11)	109/9525	128/9589	27.10
Subtotal (I-squared = 0.0%, p = 0.877) MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	1.02 (0.71, 1.47)	58/7220	57/7244	13.17
MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.92 (0.81, 1.06)	415/30755	450/30849	100.00
MI (fatal) ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	Contraction (Contraction)			
ARRIVE, 2018 ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)				
ASCEND, 2018 ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.50 (0.20, 1.24)	7/6270	14/6276	6.41
ASPREE, 2018 JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	0.86 (0.66, 1.12)	105/7740	122/7740	78.56
JPPP, 2014 Subtotal (I-squared = 0.0%, p = 0.673)	1.01 (0.48, 2.11)	14/9525	14/9589	9.62
Subtotal (I-squared = 0.0%, p = 0.673)	0.78 (0.29, 2.09)	7/7220	9/7244	5.41
	0.84 (0.67, 1.06)	133/30755	159/30849	100.00
Stroke (fatal, ischemic or hemorrhagic)				
ASCEND, 2018	1.12 (0.70, 1.77)	38/7740	34/7740	43.57
ASPREE, 2018	1.18 (0.72, 1.94)	34/9525	29/9589	39.33
JPPP, 2014	0.56 (0.25, 1.28)	9/7220	16/7244	17.10
Subtotal (I-squared = 20.0%, p = 0.287)	1.02 (0.71, 1.45)	81/24485	79/24573	100.00
Cardiovascular death. non-fatal MI. or non-fatal stroke				
ASPREE, 2018	0.91 (0.80, 1.04)	412/9525	456/9589	30.49
JPPP, 2014	0.94 (0.77, 1.14)	193/7220	207/7244	13.81
ARRIVE, 2018	0.96 (0.79, 1.15)	208/6270	218/6276	14.82
ASCEND, 2018	0.92 (0.83, 1.03)	542/7740	587/7740	40.88
Subtotal (I-squared = $0.0\%$ , p = $0.979$ )	0.93 (0.86, 0.99)	1355/30755	1468/30849	100.00
NOTE: Weights are from random effects analysis				
1 202 1				

### Harms

Similar harms as in older studies:

- Intracranial hemorrhage: RR 1.4 (1.2-1.8)
- Major hemorrhage: RR 1.4 (1.2-1.5)
- Hemorrhagic stroke: RR 1.2 (0.9-1.6)

			Events,	Events,	%
StudyYear		RR (95% CI)	Treatment	Control	Weigh
Intracranial hemorrhage					
ASCEND, 2018	•	1.22 (0.83, 1.81)	55/7740	45/7740	31.88
ASPREE, 2018	· · · · ·	1.50 (1.11, 2.01)	107/9525	72/9589	55.58
JPPP, 2014	•	1.87 (1.00, 3.50)	28/7220	15/7244	12.53
Subtotal (I-squared = 0.0%, p = 0.494)	$\bigcirc$	1.44 (1.16, 1.80)	190/24485	132/24573	100.0
Major hemorrhage					
ARRIVE, 2018	*	1.50 (0.83, 2.72)	27/6270	18/6276	3.16
ASCEND, 2018		1.28 (1.09, 1.51)	314/7740	245/7740	40.95
ASPREE, 2018	_ <b>- -</b>	1.37 (1.17, 1.60)	361/9525	265/9589	45.22
JPPP, 2014	•	1.76 (1.27, 2.43)	100/7220	57/7244	10.67
Subtotal (I-squared = 0.9%, p = 0.387)	$\diamond$	1.37 (1.24, 1.53)	802/30755	585/30849	100.00
Stroke (fatal or non-fatal, hemorrhagic)					
ARRIVE, 2018		0.73 (0.29, 1.81)	8/6270	11/6276	9.78
ASCEND, 2018		0.96 (0.56, 1.66)	25/7740	26/7740	24.66
ASPREE, 2018	•	1.32 (0.87, 2.02)	50/9525	38/9589	38.28
JPPP, 2014	•	1.66 (0.99, 2.78)	38/7220	23/7244	27.29
Subtotal (I-squared = 13.0%, p = 0.327)	$\bigcirc$	1.23 (0.92, 1.64)	121/30755	98/30849	100.0
NOTE: Weights are from random effects analysis					
І .285	       1   3.5	5			
Better with asnirin	Worse with aspir	in			

-

-

01

## **Cancer incidence and mortality in newer studies**

For cancer outcomes, trends toward:

- greater incidence: RR 1.11 (0.92-1.34)
- greater mortality: RR 1.06 (0.99 – 1.14)

Remember, older studies showed benefit



## **Comparison of old and new studies**

	Older Studies <sup>3,5</sup>	Most Recent Studies	
Outcome		13,14,15,16,17,18	
Major Adverse Cardiovascular Events *	0.89 (0.83, 0.95)	0.93 (0.86, 0.99)	
Mortality Outcomes			
All-cause mortality	0.95 (0.89, 1.01)	1.01 (0.92, 1.12)	
Cardiovascular mortality	0.97 (0.87, 1.09)	0.92 (0.81, 1.06)	
Fatal myocardial infarction	0.95 (0.82, 1.09)	0.84 (0.67, 1.06)	
Fatal stroke	1.21 (0.93, 1.59)	1.02 (0.71, 1.45)	
Bleeding Outcomes			
Intracranial hemorrhage	NR	1.44 (1.16, 1.80)	
Major hemorrhage	1.53 (1.29, 1.81)	1.37 (1.24, 1.53)	
Stroke (any hemorrhagic)	1.30 (0.99, 1.72)	1.23 (0.92, 1.64)	
Cancer Outcomes			
Cancer death	0.79 (0.68, <u>0.92)**</u>	1.11 (0.92, 1.34)	
Cancer incidence	NR	1.06 (0.99, 1.14)	

### **Comparison of old and new studies**

	Older Studies <sup>3,5</sup>	Most Recent Studies
Outcome		13,14,15,16,17,18
Stroke Outcomes		
Stroke (any)	0.96 (0.86, 1.07)	0.96 (0.86, 1.07)
Stroke (any fatal)	1.21 (0.93, 1.59)	1.02 (0.71, 1.45)
Stroke (any non-fatal)	0.93 (0.83, 1.04)	0.93 (0.82, 1.05)
Stroke (any hemorrhagic)	1.30 (0.99, 1.72)	1.23 (0.92, 1.64)
Stroke (fatal hemorrhagic)	1.73 (1.11, 2.72)	1.06 (0.66, 1.70)
Stroke (non-fatal hemorrhagic)	1.09 (0.76, 1.55)	1.39 (0.80, 2.42)
Stroke (any ischemic)	0.86 (0.74, 1.00)	0.86 (0.75, 0.98)
Stroke (fatal ischemic)	0.83 (0.48, 1.42)	0.98 (0.56, 1.72)
Stroke (non-fatal ischemic)	0.87 (0.74, 1.01)	0.88 (0.77, 1.00)
Myocardial Infarction Outcomes		
Any myocardial infarction	0.94 (0.88, 1.03)	0.88 (0.77, 1.00)
Fatal myocardial infarction	0.95 (0.82, 1.09)	0.84 (0.67, 1.06)
Non-fatal myocardial infarction	0.79 (0.71, 0.88)	0.90 (0.76, 1.06)

## **Clinical application of the results**

					Events / 1000	
					persons/5 yea	
	Rate in	Rate in	ARR or ARI	NNT or NNH	Aspirin	Control
	controls	aspirin				
MACE (CV death, MI or	4.76%	4.43%	ARR = 0.33%	NNT = 303	44	48
stroke)						
Any ischemic stroke	1.81%	1.56%	ARR = 0.25%	NNT = 400	16	18
Intracranial	0.54%	0.78%	ARI = 0.24%	NNH = 417	8	5
hemorrhage						
Major hemorrhage	1.90%	2.60%	ARI = 0.70%	NNH = 143	26	19

For every 1200 persons taking aspirin for primary prevention for 5 years, there will be: 4 fewer MACEs and 3 fewer ischemic strokes, but 3 more intracranial hemorrhages and 8 more major bleeding events.

## **Key conclusions**

- Harms of aspirin use were consistent between old and new studies
- There is no longer any reduction in cancer incidence or mortality
- Consistent decrease in ischemic stroke, although small
- No longer any reduction in non-fatal MI
- On balance, aspirin can no longer be recommended for primary prevention of cancer or CV disease

