



University of Pittsburgh

### Geriatric Medicine Year In Review

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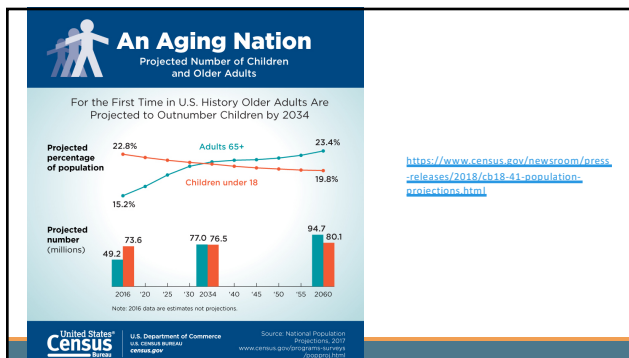


## Speaker Disclosures

- Drs. Rubin and Nace have no relevant financial disclosures.



none



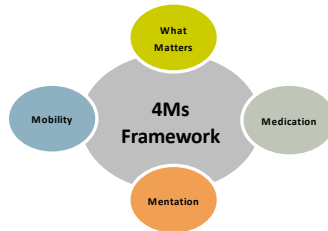
## The 4Ms Framework

Age-Friendly care is the reliable implementation of a set of evidence-based geriatric best practice interventions across four core elements, known as the 4Ms, to all older adults in your system.

The 4Ms	Description
<b>What Matters</b>	Know and align care with each older adult's specific health outcome goals and care preferences including, but not limited to end-of-life care, and across settings of care
<b>Medication</b>	If medication is necessary, use Age-Friendly medications that do not interfere with What Matters to the older adult, Mobility, or Mentation across settings of care
<b>Mentation</b>	Prevent, identify, treat, and manage dementia, depression, and delirium across settings of care
<b>Mobility</b>	Ensure that older adults move safely every day to maintain function and do What Matters

Fulmer T, Mate KS, Berman A. The Age-Friendly Health System imperative. *J Am Geriatr Soc*. 2018 Jan;66(1):22-24. doi: 10.1111/jgs.15076.

## WHAT MATTERS



JAMA Internal Medicine | Original Investigation

## Clinician-Family Communication About Patients' Values and Preferences in Intensive Care Units

Leslie P. Scheunemann, MD, MPH; Natalie C. Erceoff, MPH; Praewpannarai Buddadhumaruk, RN, MS; Shannon S. Carson, MD; Catherine L. Hough, MD; J. Randall Curtis, MD, MPH; Wendy G. Anderson, MD; Jay Steingrub, MD; Bernard Lo, MD; Michael Matthay, MD; Robert M. Arnold, MD; Douglas B. White, MD, MAS

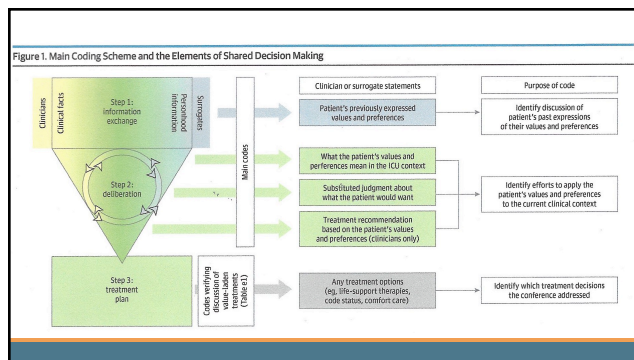
*JAMA Intern Med.* 2019;179(5):676-684.

### Background

- Critically ill ICU patients rely on surrogates (family and friends) to participate with clinicians in shared decision-making (SDM)
- SDM consists of 3 elements:
  - **Information exchange** - clinical status, patient values & preferences
  - **Deliberation** - how to apply patient values to the current situation
  - **Development of a treatment plan** - respects patient preferences
- How often are these 3 elements present in ICU family conferences?

### Methods

- Secondary analysis of a prospective cohort study of meetings between clinicians and surrogate decision-makers for critically ill ICU patients
- 6 academic and community medical centers across U.S. from 2009-2012
- Patients with ARDS with APACHE-II scores >25, predicting at least 50% risk of death
- Transcribed audio recordings of one conference per patient.
- n = 249 recordings
- Quantitative coding of content

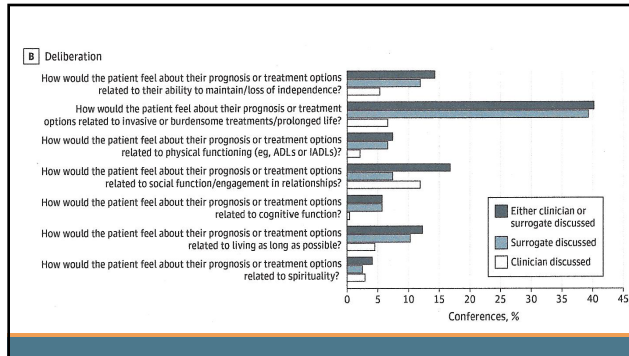
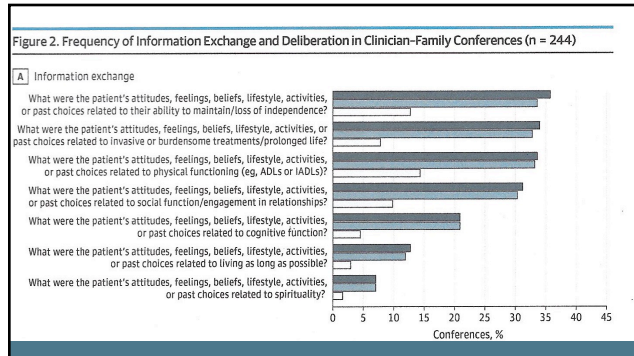


## Results

- Patients: mean age 58, 54.9% male, 74.6% non-Hispanic white
- Died in hospital: 44.3%
- Surrogates: 58% were spouses or children, 47.6% had some college education, 77.6% were religious

### Content of Conferences

Exchanged information	68.4%
Deliberated about values	44.3%
Treatment recommendations incorporating values	8.2%



### Limitations

- Data collected up to 10 years ago; maybe we do a better job now
- Only one conference per patient was recorded; maybe additional conversations had more content.
- Participants knew they were being recorded; maybe they were doing their best, and usual conversations had even less SDM content.

### Conclusions

- Frequent lack of adequate communication about patient values and preferences in critically ill patients, especially concerning an acceptable level of functioning and quality of life
- Treatment plans may not adequately represent patient values and preferences

Scheunemann LP, et al. JAMA Intern Med. 2019;179(5):676-684

JAMA Internal Medicine | Original Investigation

### Association of Patient Priorities–Aligned Decision-Making With Patient Outcomes and Ambulatory Health Care Burden Among Older Adults With Multiple Chronic Conditions A Nonrandomized Clinical Trial

Mary E. Tinetti, MD; Anand D. Naik, MD; Lilian DiIorio, PhD; Darce M. Costello, EdD, MPH, MBA; Jessica Esterson, MPH; Mary Geda, BN, MSN, RN; Jonathan Rosen, MD; Kizzy Hernandez-Bigios, BA; Cynthia Daisy Smith, MD; Gregory M. Ouellet, MD; Gina Kang, MD; Yungah Lee, MD; Caroline Blaum, MD

JAMA Intern Med. 2019;179(12):1688-1697.

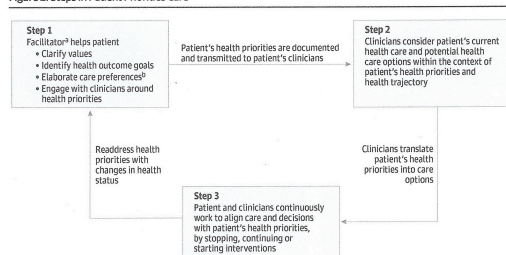
### Methods

- Two similar primary care sites in Connecticut, one providing usual care, and the other PPC
- Eligible patients had >3 chronic conditions and either >10 medications or visits to >2 specialists/year. Exclusions: hospice eligible, dialysis, severe dementia, residence in ECF.
- Nonrandom: physicians selected which patients
- Physicians and staff were trained in PPC and received “modest stipends”
- Enrolled 163 in PPC and 203 in Usual Care



## Patient Priorities Care (PPC)

Figure 2. Steps in Patient Priorities Care



Tinetti, ME et al. JAMA Intern Med. 2019;179(12):1688-1697.

## Primary outcomes

- Patients' perceptions as to whether their health care was collaborative and focused on their goals
- Perceptions of burdensomeness of medical treatments initially and at 6 months
- EHR documentation of shared decision-making
- Medications and self-management tasks started or stopped
- Numbers of tests and procedures performed

## Results

Table 2. Baseline Follow-up Differences in Patient-Reported Outcomes Among Older Adults With MCCs Receiving PPC or UC

Patient-Reported Outcome	Least Squares Mean (SE) <sup>a</sup>		Baseline - Follow-up <sup>b</sup>	
	Patient Priorities Care	Usual Care	Difference (SE)	P Value
Treatment Burden Questionnaire	-12.4 (4.0)	-7.4 (4.0)	-5.0 (2.0)	.01
O-PACIC	-0.2 (0.2)	0.1 (0.2)	-0.06 (0.1)	.60
CollaboRATE	-1.2 (5.3)	2.9 (5.2)	-4.1 (2.8)	.14

No difference in experience of chronic disease care or degree of shared decision-making, but PPC group experienced reduced burden of treatment

### Documentation of Shared Decision-Making

PPC	Usual Care
66.3%	0%

Table 3. Changes in Ambulatory Health Care Use in Older Adults With MCCs Receiving PPC or UC

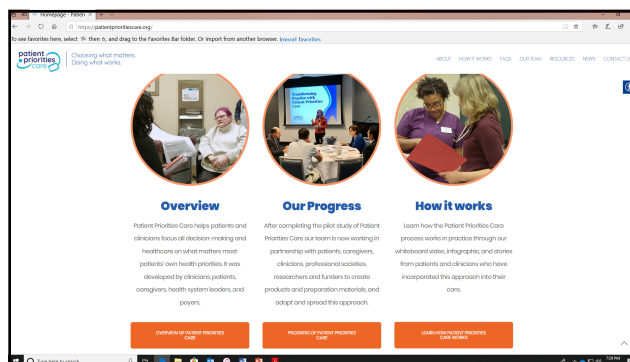
Health Care Use Category	Bivariate Analysis		Odds Ratio (95% CI) <sup>a</sup>	Multivariable Analysis, Odds Ratio (95% CI) <sup>a</sup>
	Weighted N <sup>b</sup>	Usual Care (n = 203)		
Weighted No.	357	362		
<b>Medications</b>				
Any medication				
Added	65.0	58.9	1.15 (0.83-1.58)	0.93 (0.63-1.39)
Stopped	52.0	33.8	2.00 (1.47-2.72)	<b>2.05</b> (1.43-2.95)
Cardiovascular medication <sup>c</sup>				
Added	20.8	15.7	1.33 (0.90-1.96)	1.07 (0.69-1.67)
Stopped	25.9	8.9	3.42 (2.20-5.30)	<b>3.4</b> (2.10-5.60)
Psychotropic medication <sup>c</sup>				
Added	18.7	11.2	1.73 (1.12-2.65)	1.67 (1.02-2.72)
Stopped	11.0	7.0	1.57 (0.92-2.65)	1.66 (0.92-3.01)
Diagnostic/laboratory tests <sup>d</sup>				
Any ordered	80.8	86.4	0.33 (0.20-0.57)	<b>0.35</b> (0.12-0.40)
Any avoided <sup>e</sup>	5.0	3.6	1.37 (0.66-2.86)	1.33 (0.62-2.85)
Referrals/consults <sup>f</sup>				
Any ordered	48.9	44.4	1.09 (0.81-1.49)	1.02 (0.72-1.43)
Any avoided <sup>g</sup>	5.5	2.6	2.08 (0.94-4.62)	1.87 (0.80-4.36)
Procedures <sup>h</sup>				
Any scheduled	29.2	21.5	1.41 (1.00-2.00)	1.37 (0.95-1.98)
Any avoided <sup>i</sup>	12.3	7.1	1.75 (1.04-2.93)	1.49 (0.86-2.57)
Self-management tasks <sup>j</sup>				
Any added	57.5	62.1	0.71 (0.52-0.97)	<b>0.65</b> (0.41-0.84)
Any stopped	6.4	8.6	0.69 (0.39-1.22)	0.59 (0.31-1.11)

Abbreviations: MCCs, multiple chronic conditions; PPC, patient priorities care; UC, usual care.

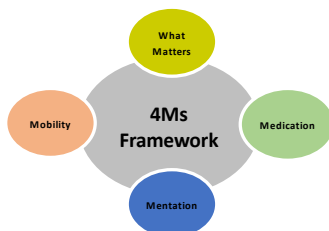
## Conclusions

- Aligning care with what matters to patients can be **operationalized** in the outpatient setting
- Patient Priorities Care is **feasible and acceptable** to patients and to clinicians
- Patients reported **reduced treatment burden**
  - More medications were stopped
  - Reduced self-management tasks
  - Fewer tests performed

Troxell, MD. JAMA Internal Medicine 2019;179(12):1688-1697



## MOBILITY



JAMA Internal Medicine | Original Investigation

## Effect of Exercise Intervention on Functional Decline in Very Elderly Patients During Acute Hospitalization: A Randomized Clinical Trial

Nicolás Martínez-Velilla, PhD, MD; Alvaro Casas-Herrero, PhD, MD; Fabricio Zamboni-Ferraresi, PhD; Mikel López Sáez de Asteasu, MSc; Alejandro Lucia, PhD, MD; Arkaitz Galbete, PhD; Agurte García-Bastán, MD; Javier Alonso-Renedo, MD; Belen González-Glaría, PhD, MD; María Gonzalo-Lázaro, MD; Itziar Apezteguía Iráizoz, PhD, MD; Marta Gutiérrez-Valencia, PharmD; Leocadio Rodríguez-Mañas, PhD, MD; Mikel Izquierdo, PhD

*JAMA Intern Med 2019;179(1):28-36.*

## Background

- Bedrest is hazardous for elderly patients
  - Loss of physical function
  - Decline in cognition
- Hospitalization commonly results in decreased level of function and increased need for extended care, which can persist for months or longer
- Most inpatients spend most of their time in bed
- Frail elderly with multimorbidity receive "gentle" ambulation
- Would a more aggressive exercise intervention prevent some of the hospital-acquired functional decline?

## Methods

- Prospective RCT, single site in Pamplona, Spain on an inpatient ACE unit
- Inclusion criteria:
  - Age > 75
  - Barthel Index score >60 (range 0-100)
  - Able to ambulate, even if only with assistance
- Exclusion criteria:
  - Projected LOS < 6 days
  - Severe dementia
  - Terminal illness
  - Medically unstable (x: hip fracture or acute MI)

## Methods

- Purchased exercise equipment
- Usual care: usual PT referral
- Intervention: two 20-minute sessions/day. AM session with a fitness specialist, tailored for each patient. PM session unsupervised in the exercise room.
- AM sessions included resistance exercises, balance, gait training, following Vivifrail protocols. Adherence for AM sessions 96% and for PM sessions 83%.
- 185 patients in each group, mean age 87.3, with 35% > 90 years.

Supervised AM session using exercise equipment



Unsupervised PM session following protocol  
Leg lifts



Variable <sup>b</sup>	Control Group	Intervention Group	Between-Group Difference (95% CI)	P Value Between Groups
<b>Primary End Point: Change in Functional Capacity</b>				
SPPB scale (balance, gait ability, leg strength)	0.2 (-0.1 to 0.5)	2.4 (2.1 to 2.7)	2.2 (1.7 to 2.6)	<.001
Barthel index (ADLs)	-5.0 (-6.8 to -3.2)	1.9 (0.2 to 3.7)	6.9 (4.4 to 9.5)	<.001
<b>Secondary End Points</b>				
<b>Cognitive status</b>				
MMSE	0.3 (-0.1 to 0.6)	2.1 (1.7 to 2.5)	1.8 (1.3 to 2.3)	<.001
Depression (GDS)	0.7 (0.4 to 0.9)	-1.3 (-1.7 to -1.1)	-2.0 (-2.5 to -1.6)	<.001
QoL (EuroQoL-5D)	-2.2 (-5.8 to 1.3)	11.0 (7.5 to 14.5)	13.2 (8.2 to 18.2)	<.001
Incident delirium (CAM), %	8.3	14.6	OR, 1.9 (0.9 to 4.0)	.12
Handgrip strength, kg	-0.8 (-1.2 to -0.5)	1.5 (1.1 to 1.8)	2.3 (1.8 to 2.8)	<.001

<sup>a</sup>SPPB = Short Physical Performance Battery, score 0-12 (best).

End Point	Control (n = 185)	Intervention (n = 185)	P Value Between Groups
Length of hospital stay, median (IQR), d	8 (4)	8 (4)	.25 <sup>a</sup>
Falls during hospitalization, No./No. (% per group experiencing ≥1 fall)	0/139	4/146 (2.7)	.12 <sup>b</sup>
3-mo Hospital readmission rate (10-person/3-mo), median (IQR)	2.5 (1.8-3.3)	2.4 (1.7-3.2)	.82 <sup>c</sup>
3-mo Mortality, %	9.7	11.9	.62 <sup>d</sup>
<b>Transfer, %</b>			
Home	91.4	92.4	
Institutionalization	1.1	2.2	.55 <sup>b</sup>
Other	7.6	5.4	

## Conclusions

- An individualized multicomponent exercise program reversed the functional decline usually seen with acute hospitalization
- No change in LOS, mortality, or readmission rate
- No increase in adverse events, such as falls

Martinez-Velilla, N et al. JAMA Intern Med 2019;179(1):28-36

## Association Between Mobility Measured During Hospitalization and Functional Outcomes in Older Adults With Acute Myocardial Infarction in the SILVER-AMI Study

Alexandra M. Hajduk, PhD, MPH; Terrence E. Murphy, PhD; Mary E. Geda, BSN, MSN; John A. Dodson, MD, MPH; Sui Tsang, BS; Leila Haghighat, MD, MPhil; Mary E. Tinetti, MD; Thomas M. Gill, MD; Sarwat I. Chaudhry, MD

JAMA Intern Med. 2019;179(12):1669-1677.

## Background

- A third of all MI's occur in people > age 75, but prediction models for subsequent outcomes were derived from younger cohorts
- A third of MI survivors experience functional decline over the next 6 months
- Frailty is increasingly recognized as a marker for poor outcomes
- SILVER-AMI is a prospective observational cohort study of 3041 patients > age 75 with acute MI at multiple U.S. hospitals, coordinated at Yale
- Predictive factors included vision, hearing, depression, dementia, falls, weight loss, and functional measures including the Timed Up and Go (TUG) test

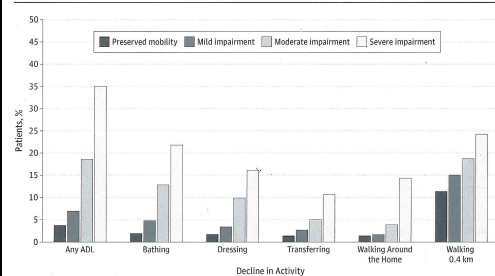
## Methods

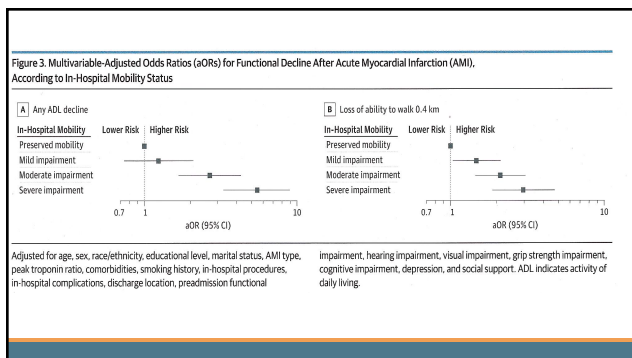
- TUG:
  - Patient arises from a chair, walks 10', turns, walks back to chair, and sits down
  - May use an assistive device
- Scoring
  - < 15 sec = normal (other studies have used a cut point of 10 sec)
  - 15-25 sec = mild impairment
  - > 25 sec = moderate impairment
  - Unable to complete = severe impairment

## Methods

- Phone interview at 6 months to assess ADL status
- Activities of Daily Living (ADL):
  - Bathing, dressing, transferring, ambulating

Figure 2. Percentage of Older Patients With Acute Myocardial Infarction Experiencing Functional Decline at 6 Months After Discharge, According to Mobility Status

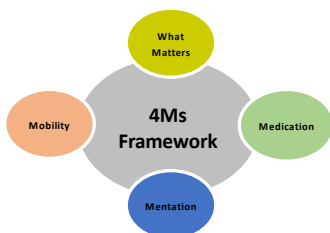




## Conclusions

- Mobility impairment is common among MI patients
- Degree of impairment is predictive of future loss of ADLs, which is mostly What Matters to older patients
- TUG testing is feasible in the acute care setting, and is a surrogate marker for frailty

## MEDICATIONS



### Mr. B

- Mr. B is an 89-year old male admitted for pneumonia.
- PMH includes HTN, DJD, peripheral arterial disease.
- During his admission, his BP hover around 175/74.
- Medications include lisinopril 10 mg daily, amlodipine 5 mg daily.

## In the Older Adult Admitted for Non-Cardiovascular Reasons...

### Should You Adjust BP Medications Prior to Hospital Discharge?

JAMA Internal Medicine | Original Investigation

### Clinical Outcomes After Intensifying Antihypertensive Medication Regimens Among Older Adults at Hospital Discharge

Timothy S. Anderson, MD, MAS, MA; Bocheng Jing, MS; Andrew Auerbach, MD; Charlie M. Wray, DO, MS; Sei Lee, MD; W. John Boscardin, PhD; Kathy Fung, MS; Sarah Ngo, MJS; Molly Silvestrini, BA; Michael A. Steinman, MD

*JAMA Intern Med* 2019;179(11):1528-1536.

doi:10.1001/jamainternmed.2019.3007

## Current State of Knowledge HTN Control in Acute Care

### WHAT WE KNOW

- Outpatient medication regimens are often changed during a hospital admission
- Changes may impact admission related medications or medications for chronic conditions
- HTN medications are frequently changed during an admission

### WHAT WE DON'T

- Does the hospitalization provide an opportunity to improve care by treating previously suboptimal BP control?
- Does adjustment of BP medications in the hospital create harm after discharge?

## Design

- Secondary Analysis
  - Retrospective cohort study (4056 subjects)
  - VA based population
  - Propensity matched cohorts
  - October 2018 – March 2019
- Inclusion Criteria
  - ≥ 65 years
  - History of HTN
  - Admitted for pneumonia, UTI, venous thromboembolism
- Exclusion Criteria
  - A-fib
  - Acute coronary syndrome
  - Acute CVA

## Exposure

- Subjects discharged with intensified HTN regimen
- Matched subjects without intensification of HTN regimen
- Intensification
  - Newly prescribed HTN med
  - Existing HTN med with a 20% increase in dose

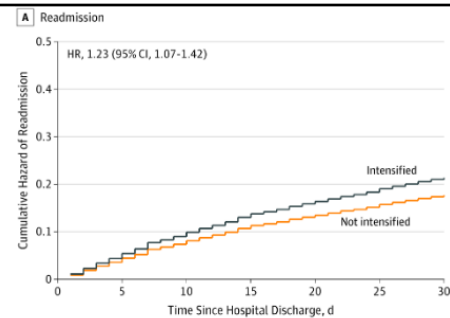
## Outcome Measures

- **Primary Outcomes**
  - All cause admissions within 30 days
  - Medication related serious adverse events (SAE)\* within 30 days
  - Cardiovascular events within 1 year
- **Secondary Outcomes**
  - All cause readmissions within 1 year
  - SAE within 1 year
  - Cardiovascular events within 30 days

\*SAE – required ED visit or admission

## Results

Outcome	Intensified Regimen	Not Intensified	Hazard Ratio	NNH
Hospital Readmissions - 30 day	434 (21.4%)	358 (17.7%)	1.23 (1.07-1.42)	27
SAE - 30 day	91.5 (4.5%)	62 (3.1%)	1.41 (1.06-1.88)	63
Cardiovascular Events - 1 year	280 (13.8%)	242 (11.9%)	1.18 (0.99-1.40)	NA
Mortality – 30 day	84 (4.1%)	101 (5.0%)	0.84 (0.62-1.12)	NA
Cardiovascular Events – 30 day	72 (3.6%)	44 (2.2%)	1.65 (1.13-2.40)	72
Mortality – 1 year	477 (22.0%)	519 (25.6%)	0.91 (0.80-1.3)	NA
Readmission – 1 year	1210 (59.7%)	1161 (57.2%)	1.07 (0.99-1.16)	NA
SAE – 1 year	413 (20.4%)	376 (18.5%)	1.12 (0.97-1.28)	NA





## Conclusions

- Intensification of HTN regimens at discharge should be avoided
  - Increases risk of readmission and SAE within 30 days of discharge.
  - Does not improve long-term BP control
  - Does not reduce cardiovascular events
- If there is a compelling reason to adjust HTN meds -
  - *Direct communication with receiving provider*
  - *Clear plan for prompt follow-up reassessment*

## Mrs. S

- Mrs. S is a 90-year old female with stage VI Alzheimer's Disease, breast cancer, CAD, and remote urosepsis.
- She presents with decreased mental status, increased lethargy and functional decline. No fever, hypotension, or urinary symptoms.
- A nurse requests a urine specimen.

**SHOULD YOU OBTAIN A URINE CULTURE?  
IF POSITIVE HOW WOULD YOU TREAT?**

Original Study

### The Improving Outcomes of UTI Management in Long-Term Care Project (IOU) Consensus Guidelines for the Diagnosis of Uncomplicated Cystitis in Nursing Home Residents

David A. Nace MD<sup>a,\*</sup>, Subashan K. Perera PhD<sup>a,b</sup>, Joseph T. Hanlon PharmD<sup>a</sup>, Stacey Saracco RN<sup>a</sup>, Gulsum Anderson PhD<sup>a</sup>, Steven J. Schweton MSN<sup>c</sup>, Michele Klein-Fedyshin MSLS<sup>d</sup>, Charles B. Wessel MSLS<sup>d</sup>, Mary Mulligan RN<sup>e</sup>, Paul J. Drinka MD<sup>f</sup>, Christopher J. Crnich MD<sup>a,b</sup>

*J Am Med Dir Assoc 2018;19:765-769*

DOI: <https://doi.org/10.1016/j.jamda.2018.05.030>

### The IOU Consensus Recommendations for Empirical Therapy of Cystitis in Nursing Home Residents

Joseph T. Hanlon, PharmD, MS, AGSF,<sup>a,†§</sup> Subashan Perera, PhD,<sup>a,\*§</sup> Paul J. Drinka, MD, AGSF,<sup>‡</sup> Christopher J. Crnich, MD, MS,<sup>a,\*†‡</sup> Steven J. Schweton, RN, MPH, MSN,<sup>‡‡</sup> Michele Klein-Fedyshin, RN, MSLS,<sup>§§</sup> Charles B. Wessel, MSLS,<sup>§§</sup> Stacey Saracco, RN,<sup>a</sup> Gulsum Anderson, PhD,<sup>a</sup> Mary Mulligan, RN,<sup>¶¶</sup> and David A. Nace, MD, MPH<sup>a</sup> ●

*J Am Geriatr Soc 67:539–545, 2019.*

DOI: [10.1111/jgs.15726](https://doi.org/10.1111/jgs.15726)

## Current State of Knowledge Cystitis Treatment

### WHAT WE KNOW

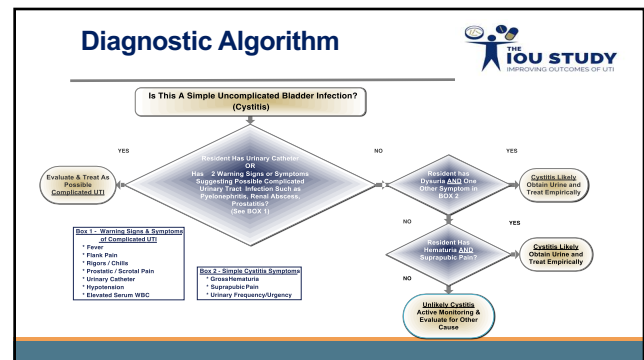
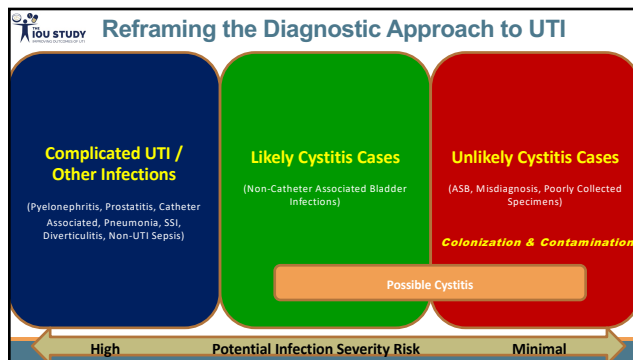
- Uncomplicated cystitis is the most common type of UTI
- Diagnostic and treatment guidelines lump all types of UTI together
- Most diagnostic errors involve distinguishing uncomplicated cystitis from asymptomatic bacteriuria.

### WHAT WE DON'T

- There are no guidelines specific to the diagnosis & treatment of uncomplicated cystitis in frail older adults

## Methods

- Guideline Development
  - Literature review
    - English language, 1980 to 2016
    - Diagnosis (1219 potential articles) & Treatment (462 potential articles)
  - Survey Development
  - Delphi process
- Implementation Intervention



Empiric Initial Treatment	
Nitrofurantoin in those with eCrClr >30ml/min OR Trimethoprim-sulfamethoxazole in those with eCrClr > 15ml/min OR Ciprofloxacin or Fosfomycin <b>ONLY</b> if eCrClr < 15ml/min	
Recommended Dosing for Different Levels of Renal Function	
Estimated CrClr	Maximum Dosing for Anti-infective
>30ml/min	Nitrofurantoin 100mg twice daily Or Trimethoprim-Sulfamethoxazole 160mg/800mg (one double strength) twice daily
15-30ml/min	Trimethoprim-sulfamethoxazole 80mg/400mg (one single strength) twice daily
<15ml/min	<b>AVOID → Nitrofurantoin</b> Ciprofloxacin 250mg twice daily Fosfomycin 3gm once
<b>AVOID → Nitrofurantoin &amp; Trimethoprim-Sulfamethoxazole</b>	
Drug-Drug Interactions to Avoid	
Interacting Anti-infective	Affected Medications
Ciprofloxacin	Theophylline, Ticagrelor, Warfarin
Trimethoprim-sulfamethoxazole	Methotrexate, Phenytoin, Probenecid, Warfarin
Maximum Duration of Anti-infective Treatment Except for Fosfomycin	
Gender	Number of Days
Women	7
Men	7

Hanlon JT, Perera S, Drinka PJ, Crnich CJ, Schween SJ, Klein-Fedyshin M, Wessel CB, Saracco S, Anderson G, Mulligan M, Nace DA.  
 J Am Geriatr Soc 2018 Dec 24. doi: 10.1111/jgs.15726



**Treatment of Uncomplicated Bladder Infection (Cystitis) In Nursing Home Residents ≥ 65 Years Without a Urinary Catheter**

Empiric Treatment Recommendations Uncomplicated Cystitis	
Recommended Dosing for Different Levels of Renal Function	
Estimated CrClr	Maximum Dosing for Anti-infective
>30ml/min	Nitrofurantoin 100mg twice daily Or Trimethoprim-Sulfamethoxazole 160mg/800mg (one double strength) twice daily
15-30ml/min	Trimethoprim-sulfamethoxazole 80mg/400mg (one single strength) twice daily
<15ml/min	<b>AVOID → Nitrofurantoin</b> Ciprofloxacin 250mg twice daily Fosfomycin 3gm once
<b>AVOID → Nitrofurantoin &amp; Trimethoprim-Sulfamethoxazole</b>	
Clinicians should be mindful of local resistance patterns & prior patient culture results	

## IOU Study Toolkit

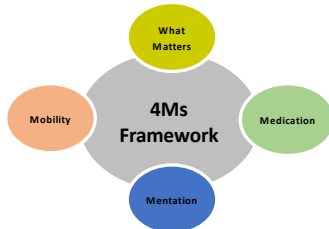
- AMDA website
- Free Toolkit Download  
<https://paltc.org/content/iou-toolkit>



## Comments

- These guidelines are for **empiric treatment** pending culture results
- The guidelines apply to **uncomplicated bladder infections**, not pyelonephritis, prostatitis, CAUTI, etc.
- **Local resistance patterns & patient history** should be considered
- **Fluoroquinolones should be avoided** unless there is no alternative option

## MENTATION



### Mrs. K

- Mrs. K is a 76-year old female.
- Mother was diagnosed w/Alzheimer's Disease at age 82.
- Mrs. K has mild cognitive impairment (MOCA = 28/30).
- She is very worried about getting dementia.
- She brings you information about a potential new treatment.
- You don't want to look like a fool, but...

**YOU CAN'T EVEN PRONOUNCE THE DRUG'S NAME**

FIRST OPINION

### Aducanumab: the beginning of the end of Alzheimer's disease?

By JASON KARLAWISH / DECEMBER 6, 2019



STAT

<https://www.statnews.com/2019/12/06/aducanumab-the-beginning-of-the-end-of-alzheimers-disease/>

### THE LANCET Neurology

Volume 19, Issue 2, February 2020, Pages 111-112



In Context

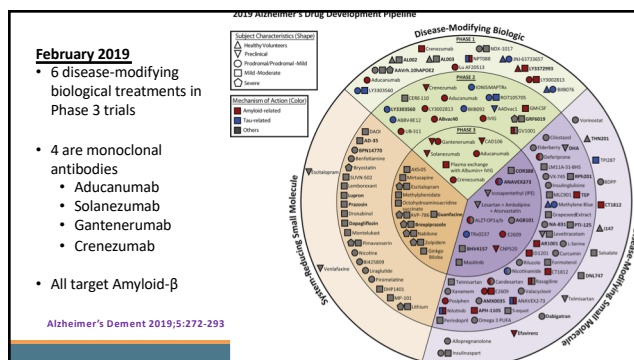
### A resurrection of aducanumab for Alzheimer's disease

Lon Schneider

Show more

[https://doi.org/10.1016/S1474-4422\(19\)30480-6](https://doi.org/10.1016/S1474-4422(19)30480-6)

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## Aducanumab

- 2015** – Two Phase 3 trials (EMERGE and ENGAGE)
  - Cut point = December 2018
  - Population = All with 18 months follow-up (half total enrolled)
  - Analysis Finding = Little chance of tx efficacy
- March 2019** – both trials discontinued

## Aducanumab

- December 2018 to March 2019** - Reanalysis
  - Additional 318 subjects completed 18 months
- June 2015** – FDA meeting
  - Primary & secondary outcomes met in high dose arm
    - 23% reduction in CDR-SB
    - 27% reduction on ADAS-Cog-13
    - 40% improvement on ADCS-ADL-MCI
  - BUT – only in EMERGE – not in ENGAGE
- December 2019** – FDA licensure application

## Aducanumab – To Be or Not to Be?

- | POSSIBLY                          | POSSIBLY NOT   |
|-----------------------------------|--|
| First in class drug               | Data not publically available  |
| First disease-modifier            | EMERGE vs ENGAGE results   |
| Suggestion of benefit             | Differences modest and possibly not meaningful                         |
| Devastating disease               | All prior amyloid-directed therapies have been a bust – correct model? |
| Large societal impact             | Side effects (ARIA <sup>a</sup> )                                      |
| No effective treatment at present | Societal Impact  |

<sup>a</sup>ARIA = Amyloid-related imaging abnormalities





Alzheimer's & Dementia: Translational Research & Clinical Interventions 5 (2019) 272-293

**Featured Article**

**Alzheimer's disease drug development pipeline: 2019**

Jeffrey Cummings<sup>a,b,\*</sup>, Garam Lee<sup>b</sup>, Aaron Ritter<sup>c</sup>, Marwan Sabbagh<sup>b</sup>, Kate Zhong<sup>c</sup>

<sup>a</sup>Department of Brain Health, University of Nevada, Las Vegas (UNLV), School of Integrated Health Sciences, Las Vegas, NV, USA  
<sup>b</sup>Cleveland Clinic Las Vegas Center for Brain Health, Las Vegas, NV, USA  
<sup>c</sup>CNS Innovations, Henderson, NV, USA

<https://doi.org/10.1016/j.trci.2019.05.008>

**Review**

**Anti-Amyloid- $\beta$  Monoclonal Antibodies for Alzheimer's Disease: Pitfalls and Promise**

Christopher H. van Dyck [Biological Psychiatry 2018;83:311-319.](https://doi.org/10.1016/j.biopsych.2017.08.010)  
<http://dx.doi.org/10.1016/j.biopsych.2017.08.010>

**Aducanumab Phase 3 Topline Results  
EMERGE and ENGAGE Trials**

<http://investors.biogen.com/static-files/ddd45672-9c7e-4c99-8a06-3b557697c06f>

**Questions?**

**Thank You!**

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