LE ANALISI SULL'USO DEI FARMACI: METODI ED ESPERIENZE IN ITALIA

Politerapia e interazioni negli anziani: possibili interventi

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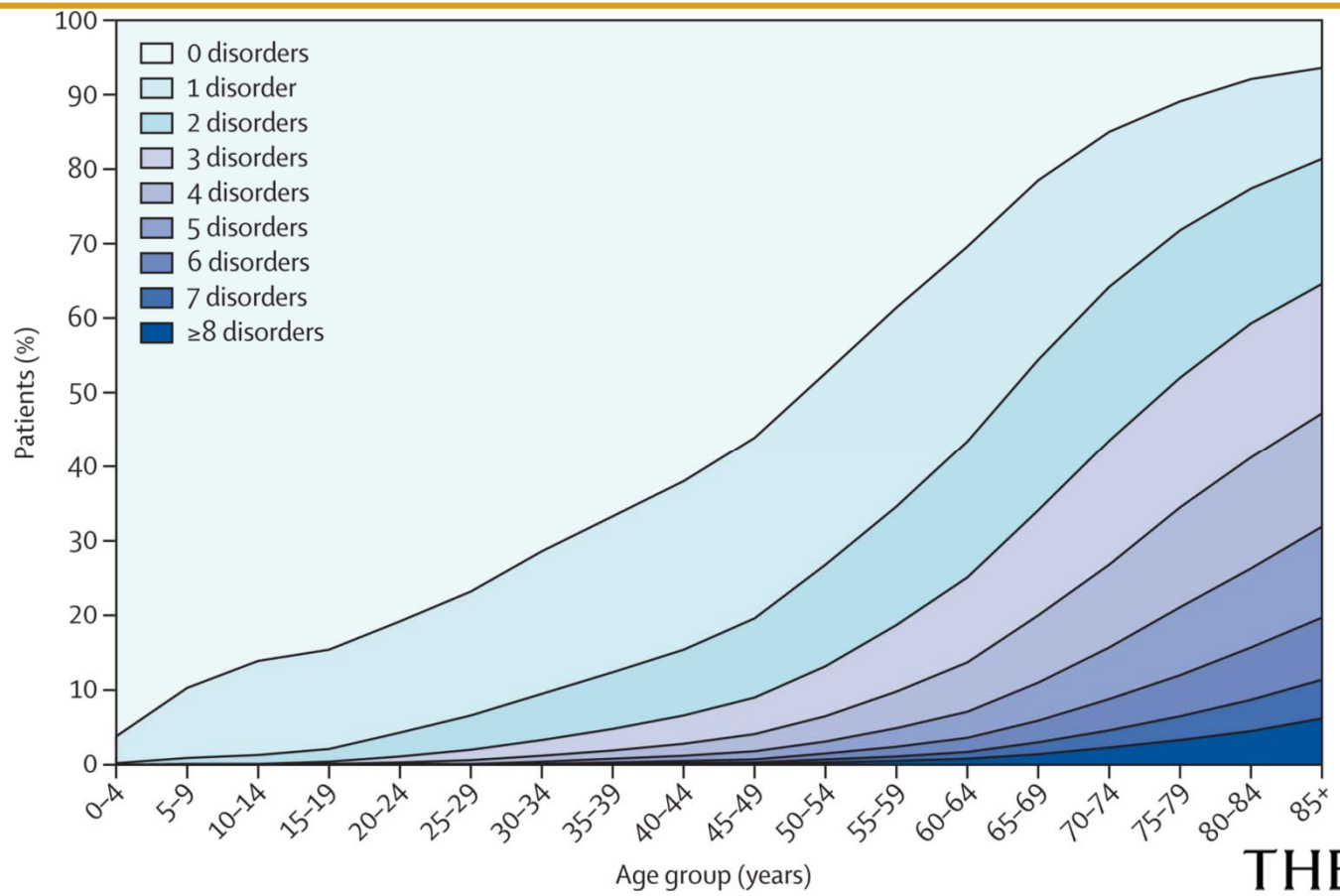
Rome - Italy

Multimorbidity

Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study



UNIVERSITÀ CATTOLICA del Sacro Cuore

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Older adults and polypharmacy

Italy

	All age groups (≥ 65 y) n=12.301.537	**65-74 y n=6.154.421**	**75-84 y n=4.474.887**	**≥85 y n= 1.672.229**
Polypharmacy				
5-9 drugs	6.024.383 (49.0%)	2.681.639 (43.6%)	2.462.378 (55.0%)	880.366 (52.6%)
≥10 drugs	**1.389.591 (11.3%)**	529.506 (8.6%)	629.043 (14.1%)	231.042 (13.8%)

Onder G et al. J Gerontol A Biol Sci Med Sci. 2013

US

… The highest prevalence of medication use was among persons aged at least 65 years, of whom **12% took at least 10 medications**

Kaufman et al. JAMA 2002

Sweden

… mean number of drugs was 7.9 for age group 70-79 y, 9.3 for age group 80-89 y and 9.7 for age group 90 y or older

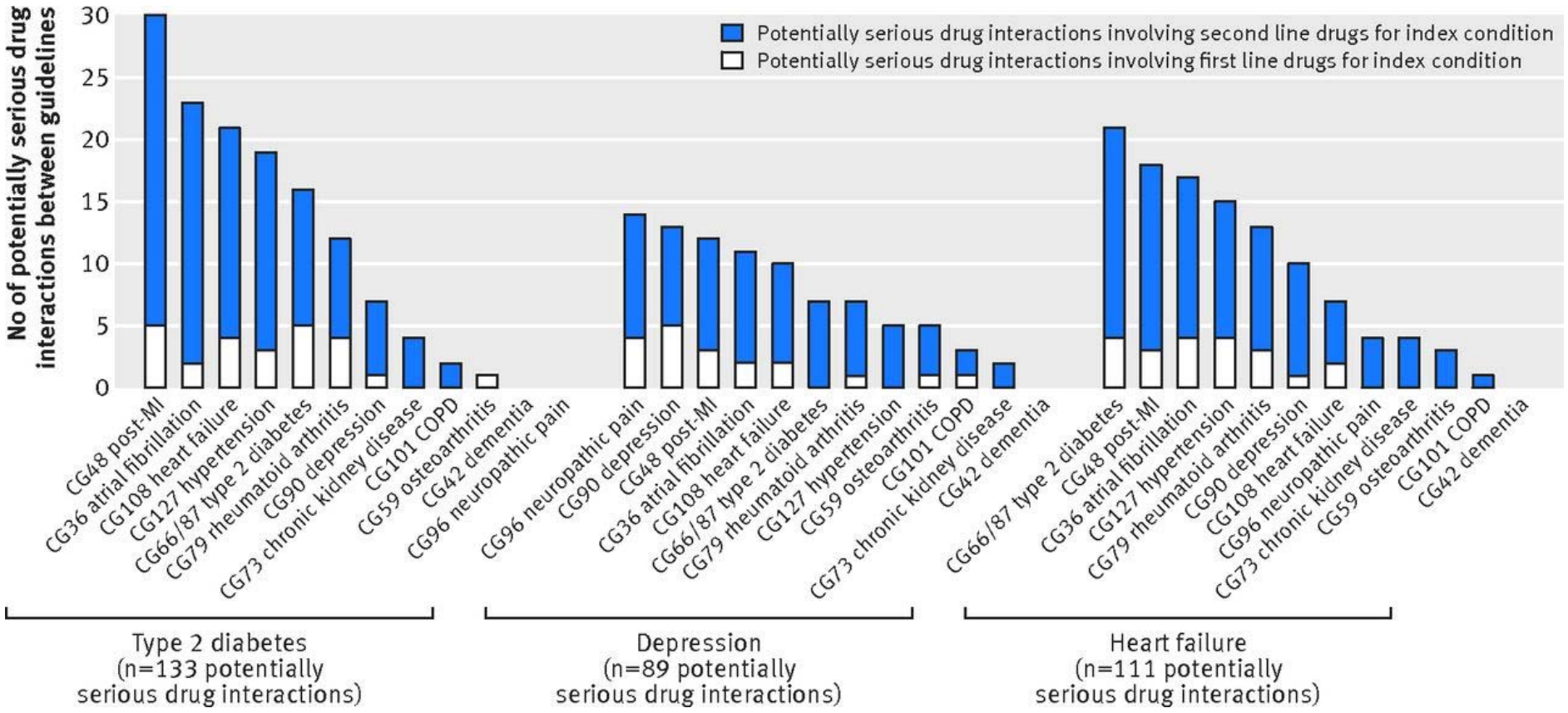
Hovstadius B et al. BMC Clin Pharmacol. 2009

Community drug data
Drug-drug Interactions

	All age groups (> 65 y) n=12.301.537	**65-74 y n=6.154.421**	**75-84 y n=4.474.887**	**≥85 y n= 1.672.229**
Use of Warfarin + NSAIDs/COX-2 inh. + ASA/antiplatelets	**22.174 (0.2%)**	8.574 (0.1%)	11.135(0.2%)	2.465 (0.1%)
Use of ACE inhibitors/ARB + Aldosterone antagonists + NSAIDS/COX-2 inhibitors	**85.412 (0.7%)**	28.860(0.5%)	40.665(0.9%)	15.887(1.0%)
Use of ≥ 2 drugs that induce QT prolongation	**36.359 (0.3%)**	13.580(0.2%)	15.903(0.4%)	6.876 (0.4%)

Onder G et al. J Gerontol A Biol Sci Med Sci. 2013

Potentially serious drug-drug interactions between drugs recommended by clinical guidelines for 3 index conditions and drugs recommended by each of other 11 other guidelines



Dumbreck et al BMJ 2015

BMJ 2015;350:h1059 doi: 10.1136/bmj.h1059 (Published 11 March 2015)

EDITORIALS

Guidelines, polypharmacy, and drug-drug interactions in patients with multimorbidity

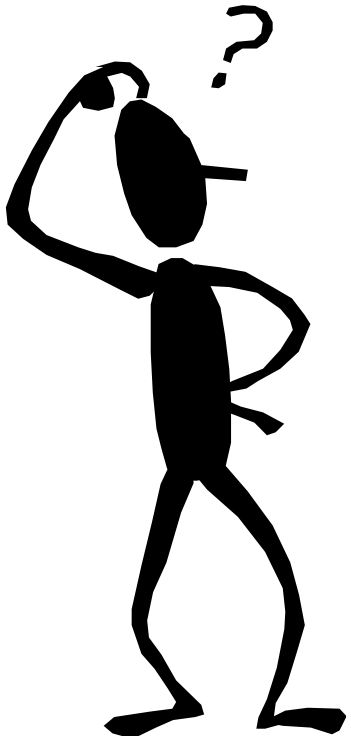
A cascade of failure

Alessandra Marengoni *assistant professor*[1 2], Graziano Onder *assistant professor*[2 3]

One of the biggest challenges in preventing **drug-drug interactions is the substantial gap between theory and clinical practice**. Despite specific regulatory pathways for drug development and marketing, we have so far failed to consider pharmacological agents in a holistic way. **Drugs have a network of effects that go well beyond a single specific drug target, particularly in patients with multimorbidity.**

Strategies

- Screening



Screening
GerontoNET ADR risk score

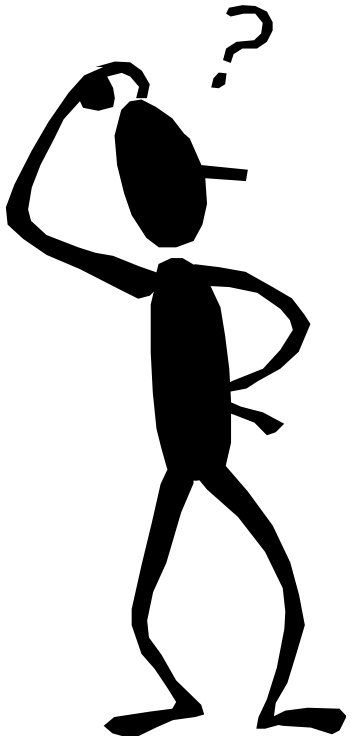
	Any ADR OR	Severe ADR OR	Score
Use of drugs (vs. < 5)			
5-7	1.90	1.58	1
8 or more	4.07	4.09	4
Previous ADR	2.41	2.18	2
≥ 4 diseases	1.36	1.72	1
Heart failure	1.79	1.61	1
Liver disease	1.31	1.32	1
Renal failure	1.21	1.24	1

Onder G et al. Arch Intern Med 2010

ARCHIVES OF INTERNAL MEDICINE

Strategies

- Screening
- Interventions:
    1. Medication review



Medication review hospitalization

Study or sub-category	RR (random) 95% CI	RR (random) 95% CI
Lipton		1.10 [0.90, 1.35]
Smith		1.88 [0.18, 19.77]
Hanlon/Cowper		1.06 [0.74, 1.51]
McMullin		1.20 [0.71, 2.01]
Bond		0.61 [0.44, 0.86]
Bernsten		0.88 [0.77, 1.01]
Krska		0.73 [0.26, 2.06]
Nazareth		0.98 [0.68, 1.42]
Sellors 1		1.02 [0.53, 1.95]
Zermansky		1.25 [0.97, 1.61]
Stowasser		0.84 [0.37, 1.93]
Naunton		0.62 [0.38, 1.02]
Sellors 2		1.36 [0.90, 2.06]
Taylor		0.20 [0.05, 0.83]
Lim		0.97 [0.20, 4.62]
Holland		1.22 [1.01, 1.46]
Lenaghan		1.15 [0.55, 2.38]
Total (95% CI)		0.99 [0.87, 1.14]

Holland R et al Br J Clin Pharmacol 2008

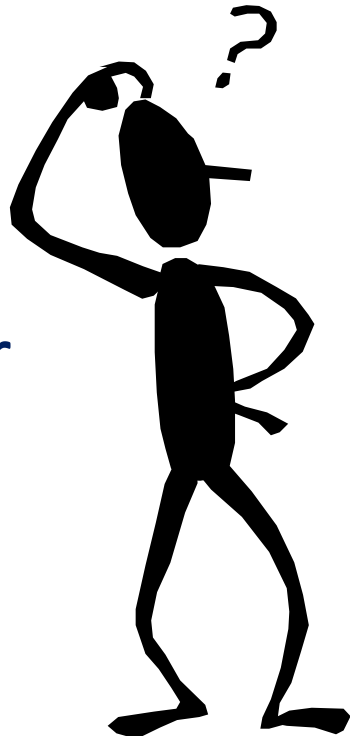
Medication review mortality

Study or sub-category	RR (random) 95% CI	RR (random) 95% CI
Jameson		0.88 [0.06, 13.50]
Begley		4.33 [0.50, 37.66]
Mackie		1.21 [0.68, 2.15]
Smith		0.24 [0.03, 1.99]
Hanlon/Cowper		0.69 [0.27, 1.73]
McMullin		0.60 [0.31, 1.17]
Bond		0.95 [0.66, 1.37]
Carter		1.25 [0.67, 2.35]
Grymonpre		0.96 [0.14, 6.59]
Krska		Not estimable
Nazareth		1.33 [0.82, 2.17]
Sellors 1		1.00 [0.15, 6.89]
Zermansky		0.63 [0.34, 1.18]
Stowasser		0.75 [0.13, 4.40]
Naunton		0.67 [0.17, 2.69]
Sellors 2		1.21 [0.44, 3.32]
Taylor		1.95 [0.18, 20.68]
Bolas		1.48 [0.74, 2.96]
Lim		2.91 [0.12, 70.05]
Sorensen		1.89 [0.54, 6.59]
Holland		0.78 [0.55, 1.10]
Lenaghan		1.13 [0.40, 3.19]
Total (95% CI)		0.96 [0.82, 1.13]

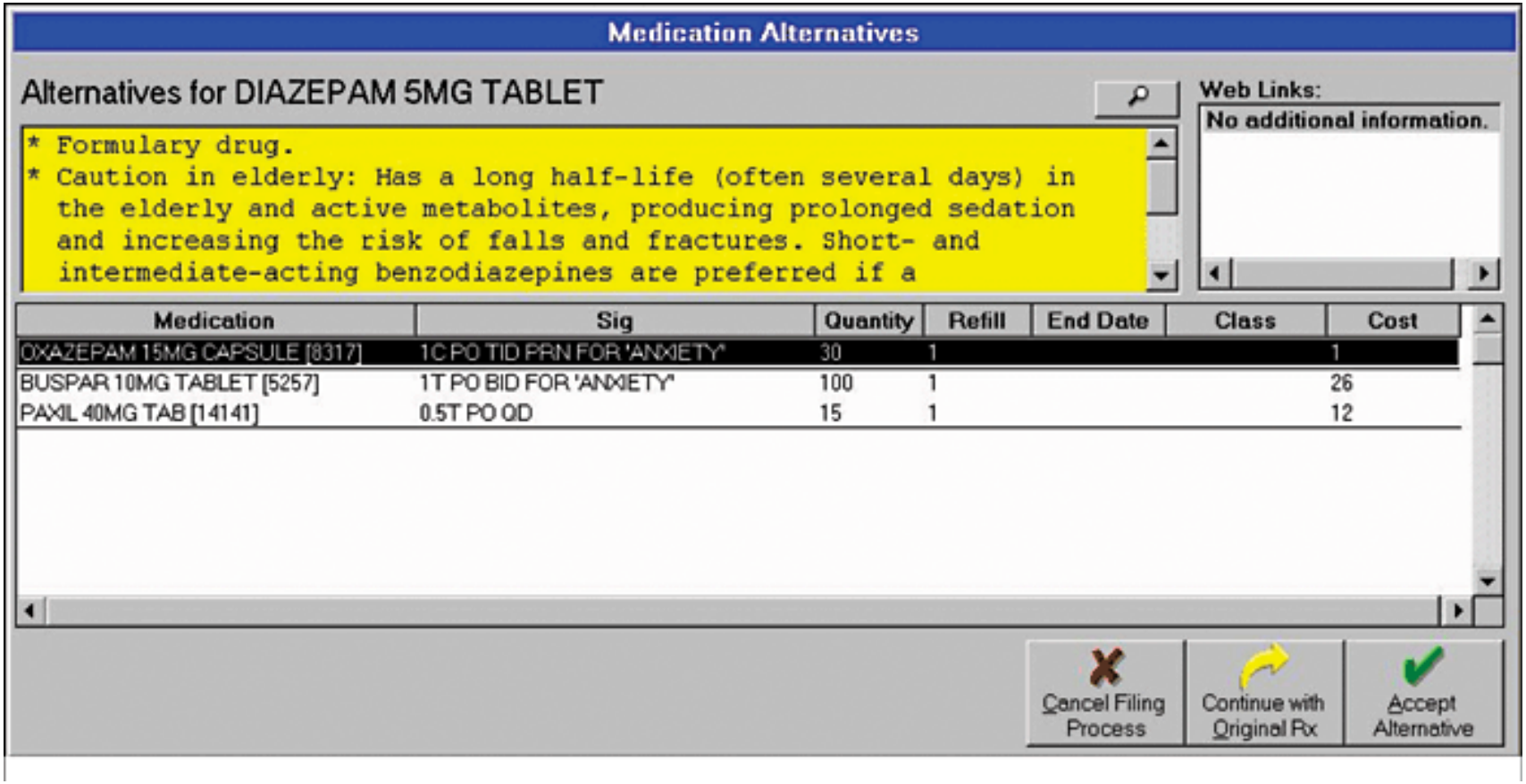
Holland R et al Br J Clin Pharmacol 2008

Strategies

- Screening
- Interventions:
    1. Medication review
    2. Avoid use of un-necessary or inappropriate medications
    3. Computer-based prescribing systems



Example screen shot of an alert for diazepam, a nonpreferred benzodiazepine



Smith et al. Arch Intern Med 2006

ARCHIVES OF INTERNAL MEDICINE

Computerized provider order entry systems (CPOE)

	Intervention Rate/100 residents-years	**Control** Rate/100 residents-years	**RR (95%CI)**
All ADE	10.8	10.4	1.06 (0.92-1.23)
Preventable	4.0	3.9	1.02 (0.81-1.30)
Severe	3.2	3.0	1.07 (0.82-1.40)
Preventable and severe	2.1	1.8	1.15 (0.82-1.61)

Gurwitz J J Am Geriatr Soc 2008

Unintended effects of a CPOE nearly hard-stop alert to prevent a drug interaction: a randomized controlled trial.

Study Month	Unintended Consequences, No.	Nature of Unintended Consequence
1	2	Both were delays in appropriate therapy being administered. The first was a 1-d delay in warfarin administration. Definitely related to the intervention. The second was a failure to prescribe appropriate trimethoprim-sulfamethoxazole prophylaxis for an otherwise critically ill patient. Probably related to the intervention.
2	1	A 3-d delay in initiation of antibiotic therapy recommended by the Infectious Diseases Consultation Service. Probably related to the intervention.
3	1	A 3-d delay in initiation of warfarin therapy (patient receiving alternative anticoagulation). Definitely related to the intervention.
4	None	

Strom BL et al Arch Intern Med 2010

ARCHIVES OF INTERNAL MEDICINE

Computer-based prescribing systems Limitations

1. Lack of evidence on clinical benefits
2. Home-made and not standardized,
3. Different types of tool or algorithms implemented
4. Complexity of older adults not assessed (being mainly focused on pharmacological issues)

SPECIAL ARTICLES

Patient-Centered Care for Older Adults with Multiple Chronic Conditions: A Stepwise Approach from the American Geriatrics Society

American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity*

Guiding Principles:

1. Elicit and incorporate **patient preferences** into medical decision-making for older adults with multimorbidity.

The NEW ENGLAND JOURNAL of MEDICINE

Goal-Oriented Patient Care — An Alternative Health Outcomes Paradigm

David B. Reuben, M.D., and Mary E. Tinetti, M.D.

… focus on a patient's individual health goals within or across a variety of dimensions (e.g., symptoms; physical functional status, including mobility; and social and role functions) and determine how well these goals are being met…

NEJM FREE FULL TEXT Rubern DB NEJM 2012

Goal oriented care

1. Individually desired rather than universally applied health states;
2.It simplifies decision making for patients with multiple conditions by focusing on outcomes that span conditions and aligning treatments toward common goals
3. It prompts patients to articulate which health states are important to them and their relative priority

NEJM FREE FULL TEXT Rubern DB NEJM 2012

Goal oriented care

Comparison of Traditional Disease-Specific and Goal-Oriented Outcomes.*

Measurement Domain	Examples of Diseases	Traditional Outcomes	Goal-Oriented Outcomes
Survival	Cancer, heart failure	Overall, disease-specific, and disease-free survival	None if survival not a high-priority goal; survival until personal milestones are met (e.g., grandchild's wedding)
Biomarkers	Diabetes, COPD	Change in indicators of disease activity (e.g., glycated hemoglobin level, CRP level, and pulmonary-function tests)	None (not a meaningful outcome observed or felt by patient)
Signs and symptoms	Heart failure, COPD, arthritis	Inventory of disease-specific signs and symptoms (e.g., dyspnea, edema, and back pain)	Symptoms that have been identified as important by the patient (e.g., control of dyspnea or pain sufficient to perform an activity such as bowling or walking grandchild to school)
Functional status, including mobility	Cancer, heart failure, COPD	Usually none or disease-specific (e.g., Karnofsky score, NYHA functional classification, and 6-minute walk test)	Ability to complete or compensate for inability to complete specific tasks identified as important by the patient (e.g., ability to get dressed without help)

NEJM FREE FULL TEXT Rubern DB NEJM 2012

Research - Outcomes

Efficacy research

Disease oriented (occurrence of a single disease or exacerbation of a single chronic condition)

Rating scales/test measures

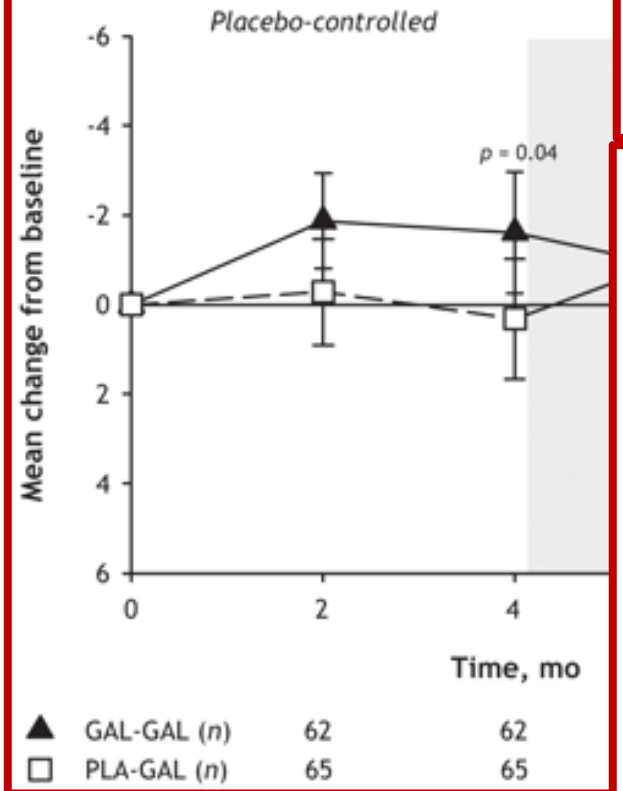
Effectiveness research

Universal health outcomes (symptoms burden, function, health related quality of life, active life expectancy)

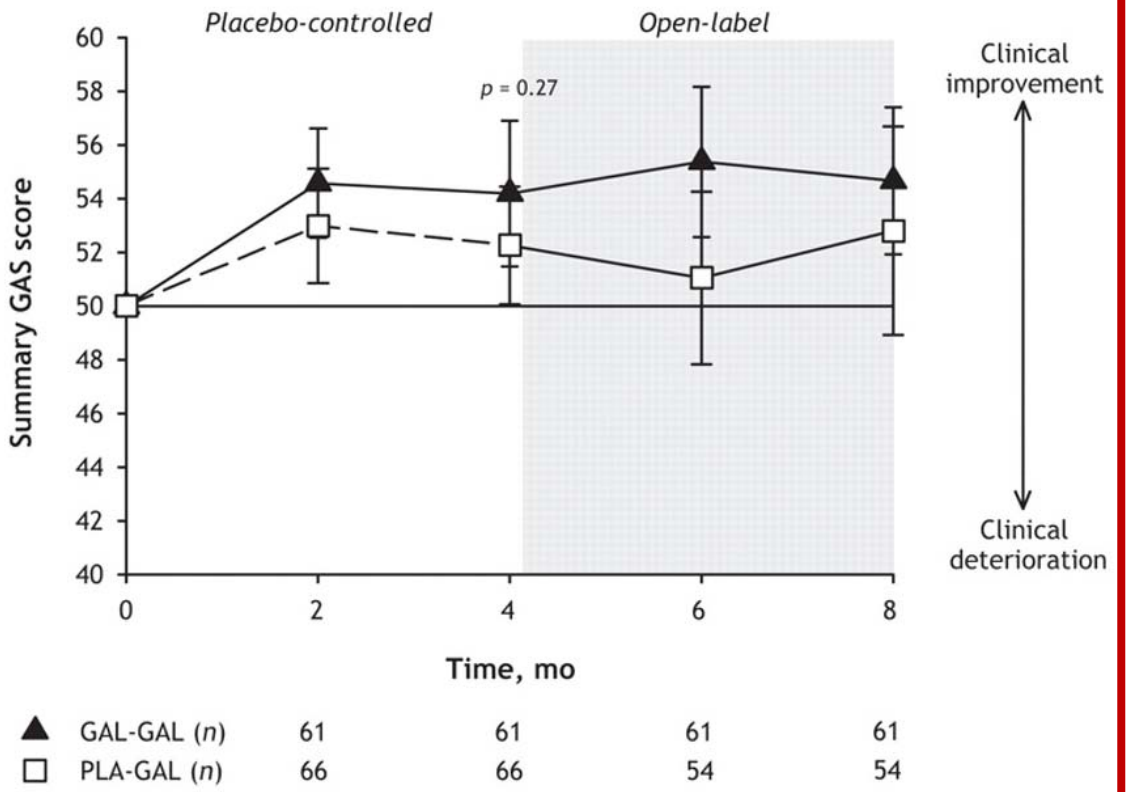
Real-world measure of clinical practice

Goal attainment

Attainment of treatment goals by people with Alzheimer's disease receiving galantamine: a randomized controlled trial



Change in patient-caregiver **Goal Attainment Scaling**



Change in AdasCOG

CMAJ 2013

Develop a common model for multimorbidity management

Delivery system design

- Comprehensive assessment
- Coordinated team
- Individualized care plans
- Case manager

Decision support

- Implementation of EBM
- Team training
- Consultation system

Self management

- Tailor Self-management
- Options for self management
- Shared decision making

Clinical information system

- Electronic patients records
- Exchange patients infos
- Uniform coding
- Patient operated technology

Community resources

- Access community resources
- Involvement of social network

Palmer K et al. Health Policy in press

CHRODIS
ADDRESSING CHRONIC DISEASES AND HEALTHY AGEING ACROSS THE LIFE CYCLE

Develop a common model for multimorbidity management

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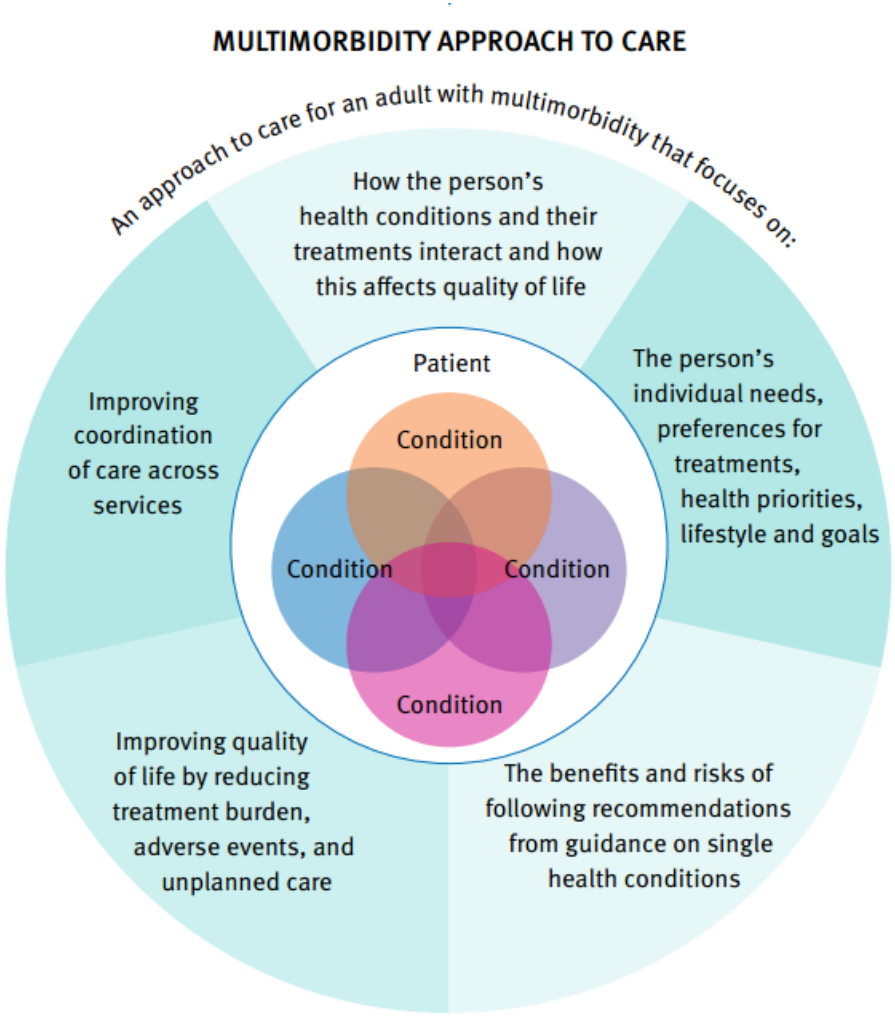
CHRODIS
ADDRESSING CHRONIC DISEASES AND HEALTHY AGEING ACROSS THE LIFE CYCLE

NICE guideline - Multimorbidity



1.5.1 - Focus on the person's **individual needs, preferences for treatments, health priorities, lifestyle and goals**

1.6.3 - Establish disease burden by **talking to people** about how their health problems affect their day-to-day life.

1.6.4 - Establish treatment burden by **talking to people** about how treatments for their health problems affect their day-to-day life

1.6.7 - **Encourage people with multimorbidity to clarify what is important to them, including their personal goals, values and priorities**.

SPECIAL ARTICLES

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2. Recognizing the limitations of the evidence base, interpret and apply the medical literature specifically to older adults with multimorbidity.

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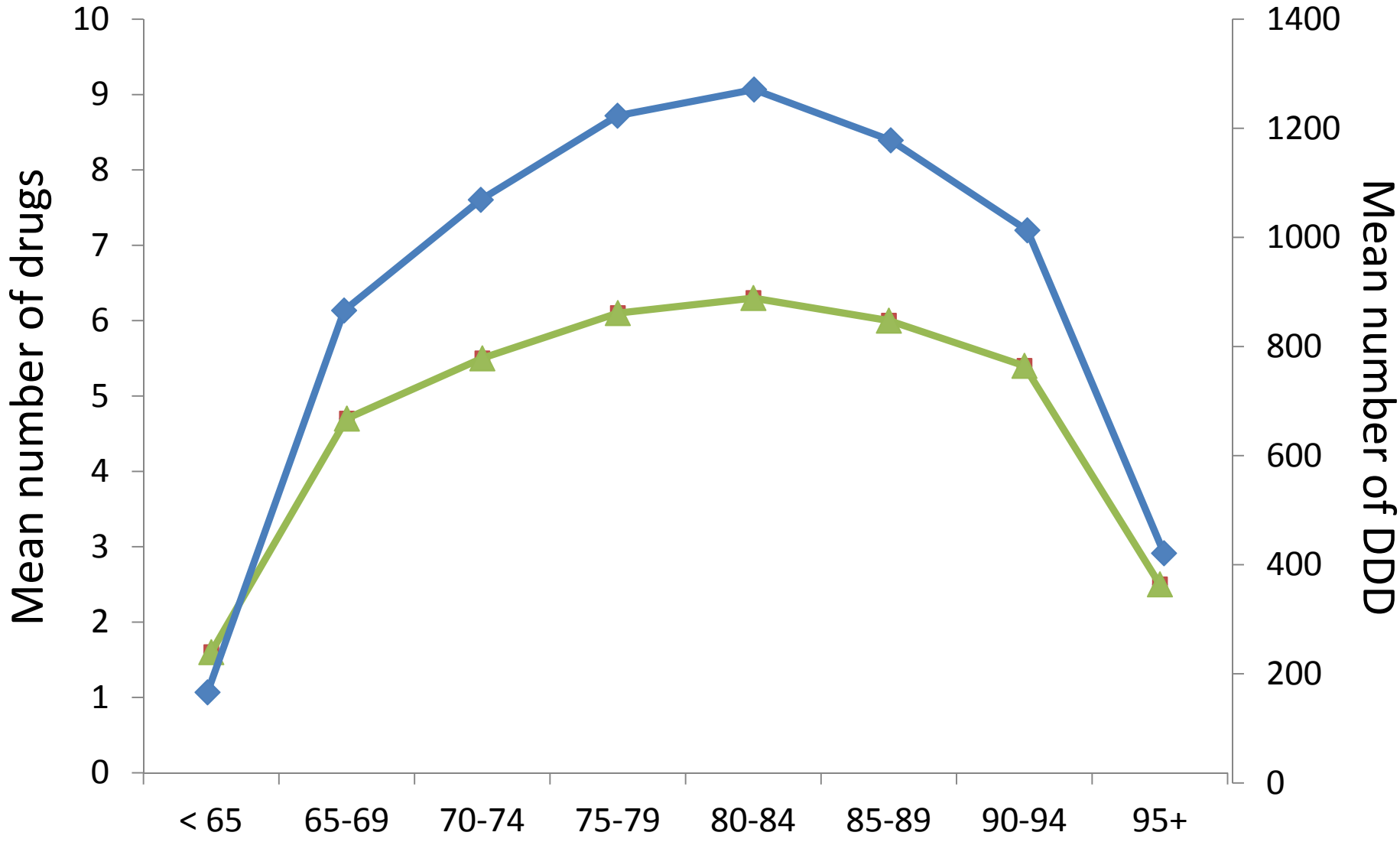
1. Elicit and incorporate patient preferences into medical decision-making for older adults with multimorbidity.
2. Recognizing the limitations of the evidence base, interpret and apply the medical literature specifically to older adults with multimorbidity.
3. Frame clinical management decisions within the context of risks, burdens, benefits, and **prognosis** for older adults with multimorbidity.

Drug use in Italy (n=15,931,642)



Onder G et al. JAMDA 2015

	% medication use in according to age group (years)									
Medication	All	65-69	70-74	75-79	80-84	85-89	90-94	≥94	**65-89**	**≥90**
Proton pump inhibitors	40.9	34.1	39.6	44.5	47.6	47.0	42.2	18.9	41.3	37.3
Platelet aggregation inhibitors	32.8	22.1	30.2	37.1	41.5	42.2	38.7	17.1	32.6	34.1
HMG CoA reductase inhibitors	26.1	24.5	29.2	30.9	28.5	21.6	12.1	2.6	27.4	10.1
Beta blocking agents, selective	19.7	17.3	20.2	22.2	22.6	20.4	15.4	5.0	20.3	13.2
Fluoroquinolones	19.2	17.3	19.3	20.6	21.1	20.4	18.8	9.1	19.5	16.7
ACE inhibitors, plain	17.9	14.5	17.1	19.3	21.1	21.2	19.2	8.3	18.0	16.9
Dihydropyridine derivatives	17.6	13.3	17.1	20.3	21.6	20.2	16.7	6.9	17.8	14.6
Combinations of penicillins	15.9	17.5	16.7	15.8	15.3	14.5	13.3	6.4	16.3	11.9
Angiot. II antagonists and diuretics	14.5	12.7	15.2	16.9	16.5	13.7	10.1	3.4	15.0	8.7
Propionic acid derivatives	14.3	14.0	15.2	15.9	15.1	12.8	10.1	4.1	14.8	8.8
Glucocorticoids	14.2	13.4	14.1	14.9	15.2	14.8	13.7	6.9	14.3	12.3
Sulfonamides, plain	13.9	6.1	9.2	14.1	20.3	25.7	27.6	14.3	13.0	24.8
Angiotensin II antagonists, plain	13.6	12.0	13.8	15.0	15.5	14.5	11.9	4.5	13.9	10.3
Acetic acid derivatives	12.9	12.2	13.6	14.6	14.0	11.9	9.3	3.8	13.3	8.2
Vitamin D and analogues	12.5	11.0	12.8	14.0	14.1	12.6	9.9	3.8	12.7	8.6
Third-generation cephalosporins	11.9	10.1	10.9	12.0	13.4	14.7	16.2	9.9	11.7	14.9
Macrolides	11.0	12.5	11.9	11.1	10.3	9.3	8.5	4.0	11.3	7.5

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Vitamin D and analogues	12.5	11.0	12.8	14.0	14.1	12.6	9.9	3.8	12.7	8.6
Third-generation cephalosporins	**11.9**	**10.1**	**10.9**	**12.0**	**13.4**	**14.7**	**16.2**	**9.9**	**11.7**	**14.9**
Macrolides	11.0	12.5	11.9	11.1	10.3	9.3	8.5	4.0	11.3	7.5

SPECIAL ARTICLES

Patient-Centered Care for Older Adults with Multiple Chronic Conditions: A Stepwise Approach from the American Geriatrics Society

American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity*

Guiding Principles:

4. Consider **patients complexity** and **treatment feasibility** when making clinical management decisions for older adults with multimorbidity.

Concerns about older persons' ability to adhere to complex medication regimens

Concern	Representative Quotation
Historical evidence of inability to adhere	Also I factor in adherence to even a basic treatment. If they cannot manage a basic treatment, the one I am giving them, I am not going to complicate it further by adding something to get to the goal range.
Difficulty understanding medications	Whenever [patients] are confused about what medications they are on that suggests a problem. When they can not tell you what the medications either by name or description, and they are confused about when they are supposed to take them
Availability of social support	Often what you are doing is assessing someone's personality and their abilities to integrate complicated information and goals and if you have a patient who is limited you are obviously not going to push the meds nearly as hard unless there is somebody else in the picture who can administer them.
	I look at their functioning as a whole and also whether or not they live alone, their support system, have help.

Fried, T. R. et al. Arch Intern Med 2010 ARCHIVES OF INTERNAL MEDICINE

SPECIAL ARTICLES

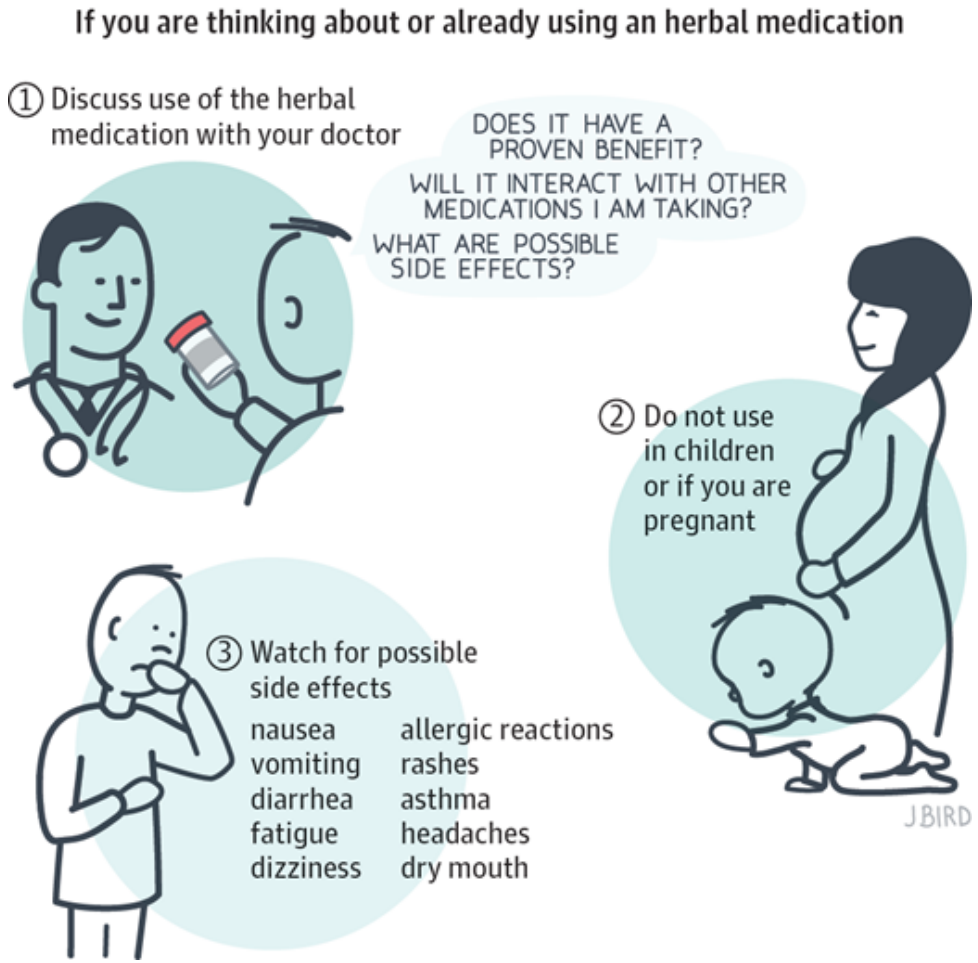
Patient-Centered Care for Older Adults with Multiple Chronic Conditions: A Stepwise Approach from the American Geriatrics Society

American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity*

Guiding Principles:

4. Consider treatment complexity and feasibility when making clinical management decisions for older adults with multimorbidity.
5. Use strategies for choosing **therapies that optimize benefit, minimize harm, and enhance quality of life** for older adults with multimorbidity.

Avoid un-necessary drugs
Herbal medications



Herbal meds:

- Not regulated
- No proofs of safety and efficacy
- Contamination
- Concentration (?)
- Side effects

Onder G et al. JACC 2017

Onder G et al. JAMA 2016

Prescribing

Disease → Drug treatment

Disease
+
Patient

- Functional status
- Cognitive status
- Life expectancy
- Quality of life
- Patient preferences

→ Appropriate drug treatment

Conclusions

1. Polypharmacy is common
2. Lack of rules on treatment of complex older adults
3. Patient preferences should be included in the prescribing process
4. CGA and management is a valuable instrument to improve quality of prescribing and reduce polypharmacy

AGE 0-4	4-12	12-18	18-24	24-38	38-65	65 ——
AMOXICLIN	RITALIN	APPETITE SUPPRESSANTS	NO-DOZ	PROZAC	ZANTAC	EVERYTHING ELSE

Statins in primary prevention

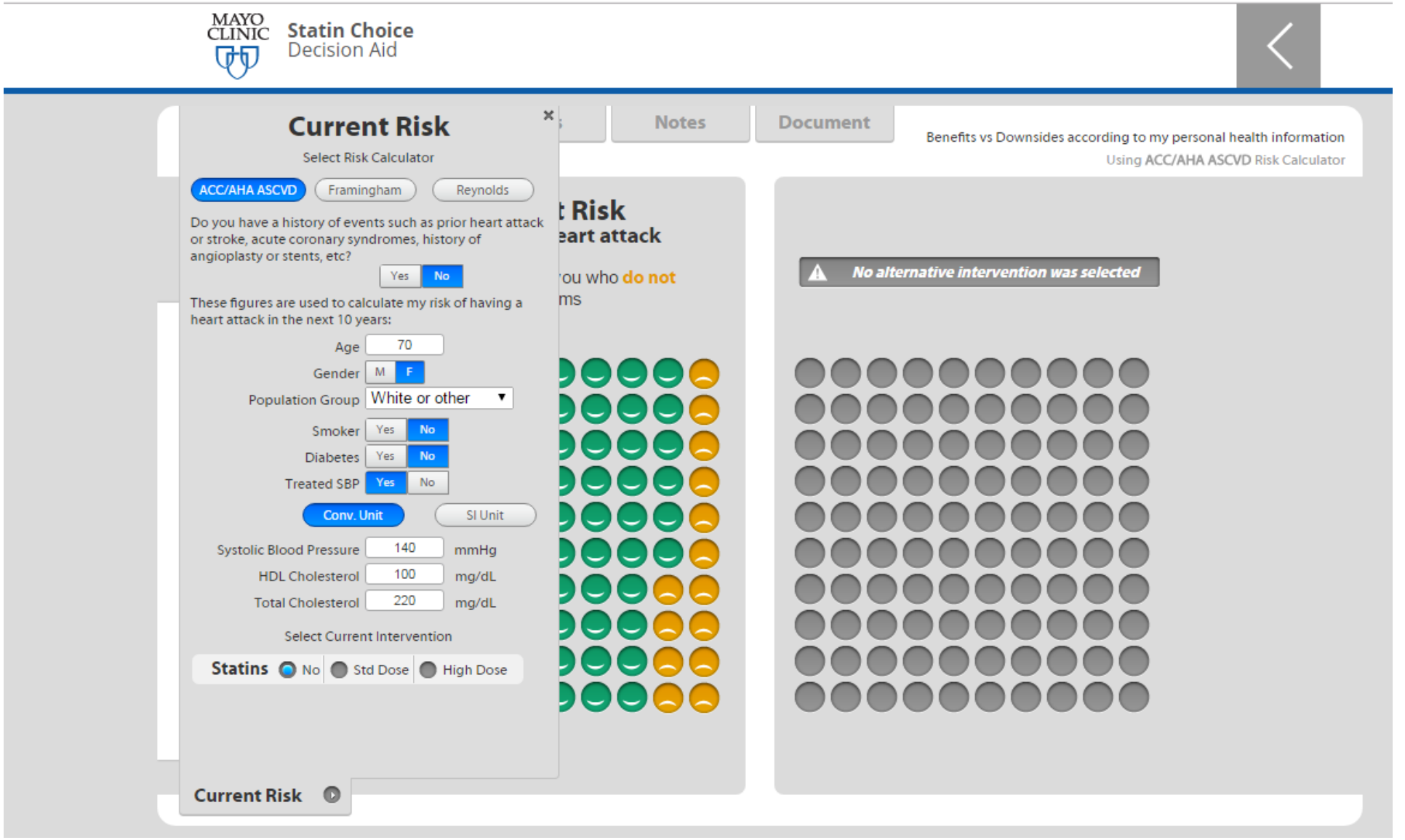
US Preventive Services Task Force (USPSTF) recommendation statement on statins for prevention of cardiovascular disease:

- initiating use of low- to moderate-dose statins in adults aged 40 to 75 years without a history of CVD who have 1 or more CVD risk factors and a calculated 10-year CVD event risk of 10% or greater **(B recommendation)** or 7.5% to 10% **(C recommendation).**

- absolute benefit for use of statins of 0.40% for all-cause mortality and 0.43% for cardiovascular mortality

JAMA. 2016;316(19):1997-2007.

Statins in primary prevention



https://statindecisionaid.mayoclinic.org/

MAYO CLINIC **Statin Choice**
Decision Aid

Current Risk | Intervention | Issues | Notes

3. View Issues

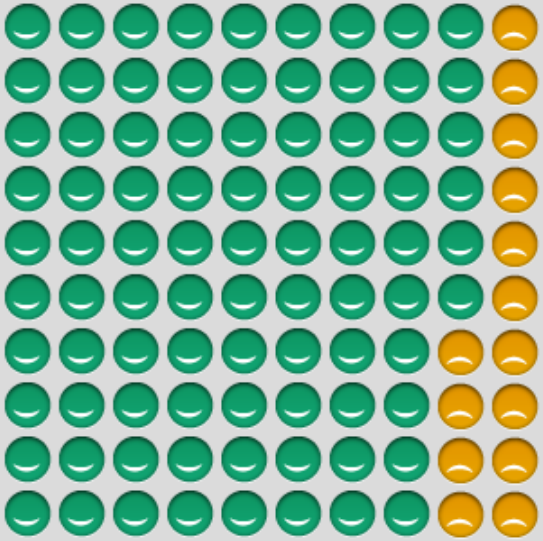
Current Risk
of having a heart attack

Risk for 100 people like you who **do not** medicate for heart problems

Over 10 years

14 people will have a heart attack

86 people will have no heart attack



MAYO CLINIC **Statin Choice**
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Current Risk | Intervention | Issues | Notes | Document

Benefits vs Downsides according to my personal health information
Using ACC/AHA ASCVD Risk Calculator

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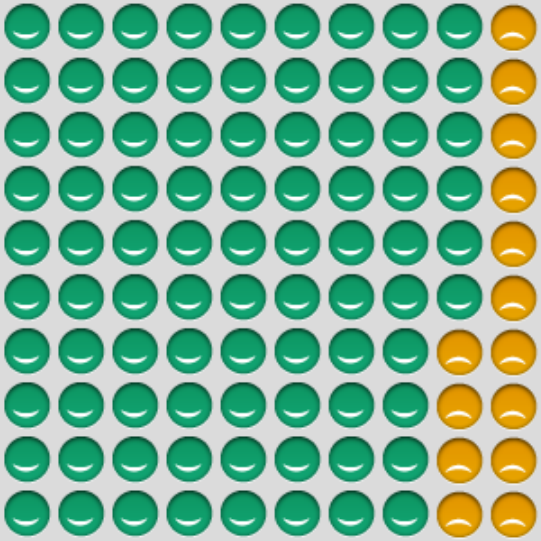


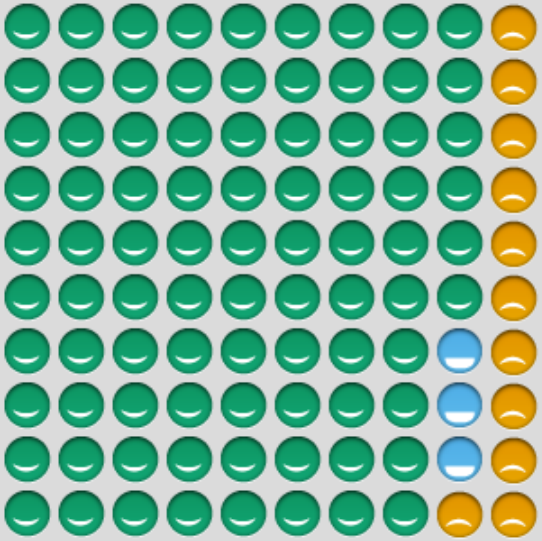
Over 10 years

14 people will have a heart attack

86 people will have no heart attack

Future Risk
of having a heart attack

Risk for 100 people like you who do take **standard dose statins**



Over 10 years

11 people will have a heart attack

86 people will have no heart attack

3 people will be saved from a heart attack by taking medicine

MAYO CLINIC **Statin Choice** Decision Aid

Current Risk | Intervention | Issues | Notes | Document

Benefits vs Downsides according to my personal health information

Using ACC/AHA ASCVD Risk Calculator

Current Risk of having a heart attack

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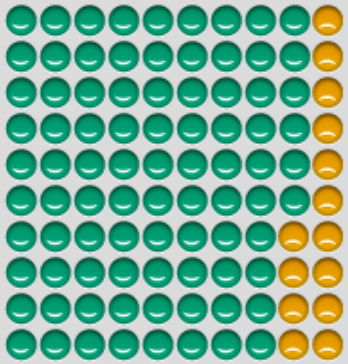


Over 10 years
14 people will have a heart attack
86 people will have no heart attack

Cost

Standard dose statins
about $4/month

Daily Routine

Standard dose statins
One pill once a day

Other Benefits

Standard dose statins
The use of statins reduces your stroke risk by about one fifth.

Side Effects

Standard dose statins

Common side effects
nausea, diarrhea, constipation
(most patients can tolerate);

Muscle aching/stiffness
5 in 100 patients
(some need to stop statins because of this);

Liver blood test goes up
(no pain, no permanent liver damage):
2 in 100 patients
(some need to stop statins because of this);

Muscle and kidney damage
1 in 20,000 patients
(requires patients to stop statins).

Future Risk of having a heart attack

Risk for 100 people like you who do take standard dose statins

Over 10 years
11 people will have a heart attack
86 people will have no heart attack
3 people will be saved from a heart attack by taking medicine

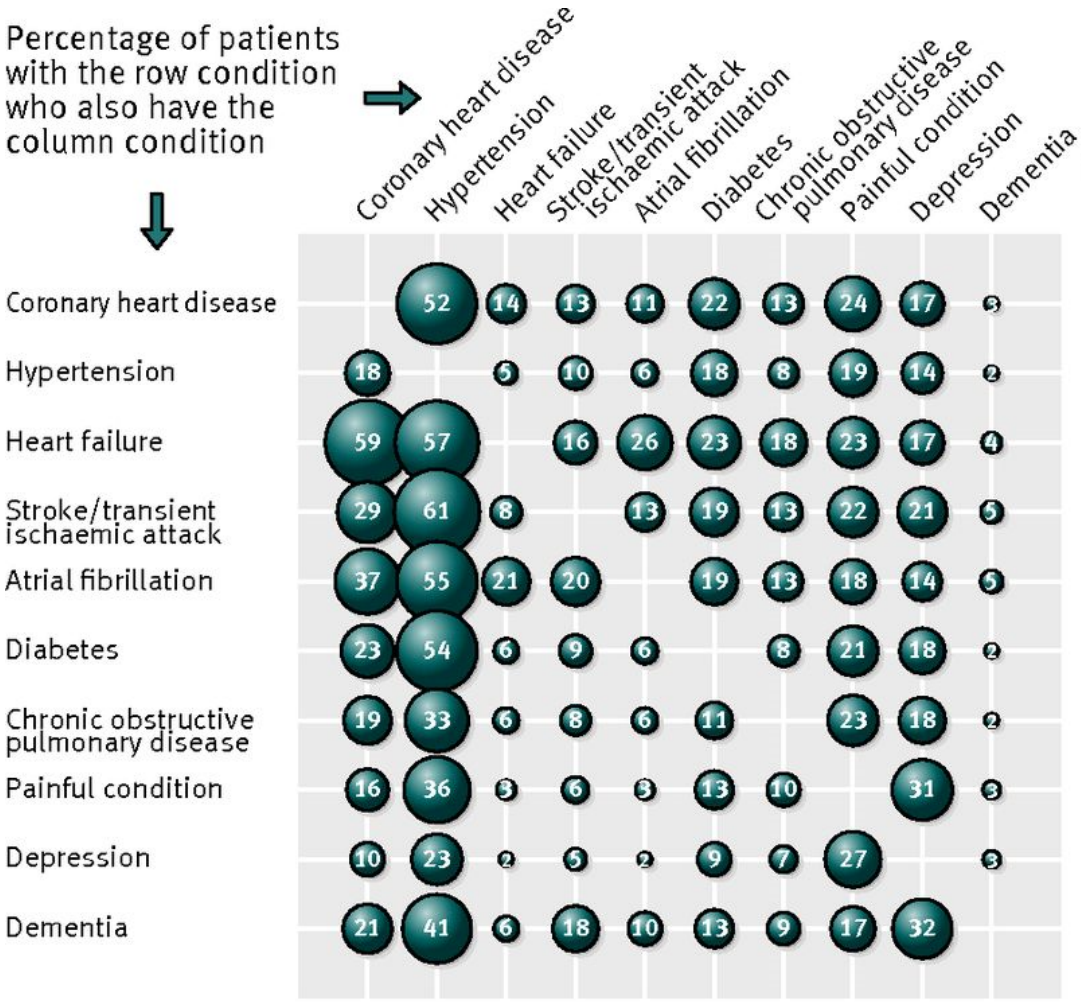
Statins in primary prevention

US Preventive Services Task Force (USPSTF) recommendation statement on statins for prevention of cardiovascular disease:

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of initiating statin use in adults 76 years and older (I statement).

JAMA. 2016;316(19):1997-2007.

Comorbidity of 10 common conditions



	Percentage who only have the row condition*	Mean No of conditions in people aged <65 years with row condition	Mean No of conditions in people aged ≥65 years with row condition
Coronary heart disease	8.8	3.4	4.4
Hypertension	21.9	2.5	3.6
Heart failure	2.8	3.9	5.6
Stroke/transient ischaemic attack	6.0	3.6	4.8
Atrial fibrillation	6.5	3.3	5.0
Diabetes	17.6	2.9	6.5
Chronic obstructive pulmonary disease	14.3	2.8	4.5
Painful condition	12.7	3.1	4.3
Depression	25.4	2.6	4.9
Dementia	5.3	4.1	4.6

* Percentage who do not have one of 39 other conditions in the full count

Guthrie B et al. BMJ 2012;345:bmj.e6341

BMJ

Shared decision making

… Health care professionals should include the patient (and, where relevant, their family) in making decisions about their care and treatment, including identifying their **individual needs as well as deciding on future goals and outcomes to aim for**.

…**Individualized care plans should be constructed that represent these shared desires and decisions** …

This is relevant to **multimorbidity patients** as they often have complex care needs that need careful consideration of potential negative outcomes, including loss of physical functioning, depression, and reduced quality of life.

Palmer K et al. Health Policy in press

JOURNAL OF PALLIATIVE MEDICINE
Volume 11, Number 5, 2008

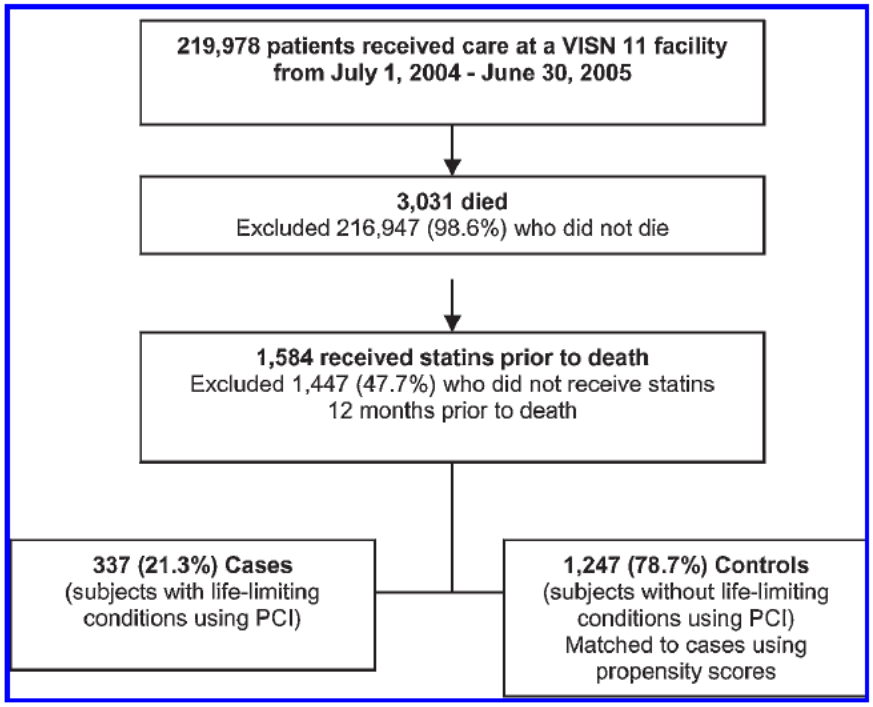
DOI: 10.1089/jpm.2007.0215

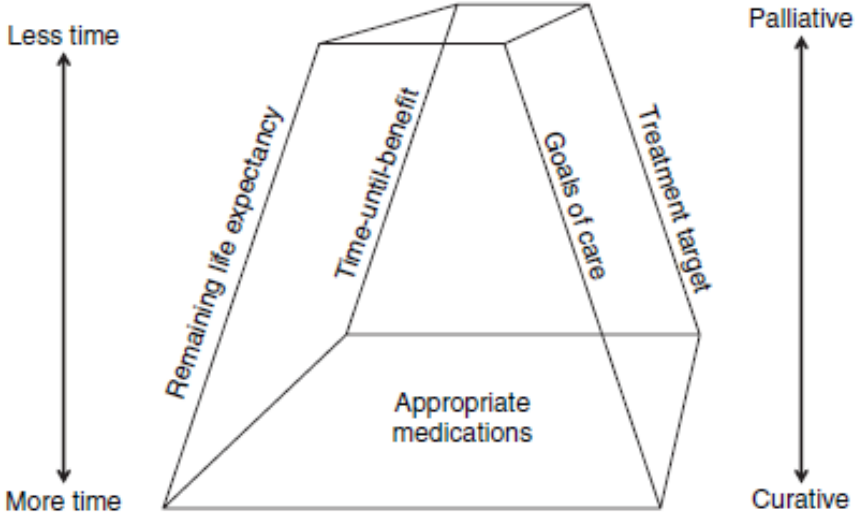
Brief Reports

Statins in the Last Six Months of Life: A Recognizable, Life-Limiting Condition Does Not Decrease their Use

MARIA J. SILVEIRA, M.D., M.A., M.P.H.,[1,2] ANAMARIA SEGNINI KAZANIS, M.A., M.A.,[1] and MATTHEW P. SHEVRIN, B.A.[1]

In conclusion, we find that statins are prescribed frequently in the last year of life for patients carrying recognizable, life-limiting conditions and that the patient's diagnosis does not appear to affect prescribing patterns. The small amount of discontinuation we did observe in the last 6 months of life occurs for reasons we have yet to understand. Still, our findings highlight an area for discussion as a specialty and potential intervention in the future.





Holmes, Clin Pharmacol Ther 2009