



Journal Club

**12 agosto 2016**

*Aggiornamenti in geriatria*

# Per una corretta prescrizione dei farmaci nell'anziano

**Marco Trabucchi**



**Da decenni la terapia farmacologica dell'anziano è al centro del dibattito clinico. Manca però ancora una base culturale "forte" sulla quale costruire la prassi.**

Marco Trabucchi

# Il vecchio e le medicine

Appunti per affrontare difficoltà psicologiche,  
cliniche, organizzative, economiche



2012

edizioni  
**PANORAMA**  
di Sanità

- **Il progresso continuo**
- **Lo scenario**
- **Inappropriatezza prescrittiva**
- **Il politrattamento**
- **Le linee guida**
- **Il deprescribing**
- **Abuso di oppiacei**

**As in the overall SPRINT cohort, the subgroup of participants aged 75 years or older showed impressive reductions in CVD events and total mortality with intensive as compared with standard therapy. The primary outcome occurred in 102 patients in the intensive treatment group versus 148 in the standard treatment group (hazard ratio, 0.66 [95% CI, 0.51-0.85]), with 73 deaths in the intensive treatment group and 107 in the standard treatment group (hazard ratio, 0.67 [95% CI, 0.49-0.91]).**

(Chobanian AV. JAMA 315 (24): 2669-70, 2016)

**However, the present results have substantial implications for the future of intensive BP therapy in older adults because of this condition's high prevalence, the high absolute risk for cardiovascular disease complications from elevated BP, and the devastating consequences of such events on the independent function of older people.**

(Williamson JD et al. JAMA 315 (24): 2673-82, 2016)

**La farmacoterapia continua a produrre risultati significativi.  
Non deve essere guardata con sospetto né criticata a priori, come viene fatto in alcuni ambienti.**

## **The top 10 causes of death in 2014 were as follows:**

1. Heart disease (23.4% of all deaths)
2. Cancer (22.5%)
3. Chronic lower respiratory diseases (5.6%)
4. Accidents (unintentional injuries; 5.2%)
5. Cerebrovascular diseases (5.1%)
6. Alzheimer's disease (3.6%)
7. Diabetes mellitus (2.9%)
8. Influenza and pneumonia (2.1%)
9. Nephritis, nephrotic syndrome, and nephrosis (1.8%)
10. Intentional self-harm (suicide; 1.6%)



La medicina pratica è costruita come una raccolta di curiosità che si devono organizzare, dopo essere state raccolte ed interpretate, al fine di offrire risposte adeguate. Il medico poco curioso non può essere un bravo medico, per quanto colto o informato; infatti, non è in grado di costruire una cura che è sempre necessariamente fondata sulle informazioni scientifiche e le informazioni del mondo reale, oltre, ovviamente che sulla sua personale cultura ed esperienza. Chi è tentato di restare chiuso nella torre d'avorio delle conoscenze deve invece imparare ad uscire, per cogliere “l'odore delle pecore”; ancora una volta l'insegnamento di Francesco si adatta alle circostanze più diverse, perché un medico che non percepisce “l'odore” delle persone che a lui si affidano resta un estraneo, la cui efficacia terapeutica è limitata (è inutile sottolineare quanto sia importante questo riferimento “carnale” all'odore, il cui significato è spesso anche fisico e non solo psicologico). La *knowledge medicine* è fondata sulla curiosità, oggi per il singolo paziente, ieri, e ancor oggi, per il dato scientifico e per ipotesi culturali coraggiose.

(Trabucchi. In: I farmaci e le sfide di una medicina a misura di paziente, UniversItalia, 2015)

**La complessità come cultura di fondo del nostro tempo apre ad una mentalità “estetica”, che guarda al mondo in modo aperto a qualsiasi evoluzione, e non in modo segmentato, così da arrivare necessariamente ad un risultato ed uno solo. Questa visione deve essere rivolta verso l'esterno della persona (le relazioni), e verso il suo interno (la biologia che produce vita). Anche gli interventi devono essere condotti in questa prospettiva, aprendosi così necessariamente ad una modalità di “*defragmenting care*”. La struttura della persona richiede una risposta unitaria; vi deve essere una “*system care*”, che prende in carico il cittadino ammalato e lo accompagna nel tempo, considerando tutte le possibili origini del bisogno e le risposte in modo complessivo. La dimensione estetica, narrativa, ecc. è quindi premessa irrinunciabile per la clinica, ma anche per l'organizzazione sanitaria. In questa logica è possibile concludere che le reti regolano tutti gli aspetti della salute umana; nei prossimi anni la ricerca sarà impegnata per dare un'interpretazione unitaria di queste intuizioni, in modo che possano pervadere la prassi quotidiana delle cure.**

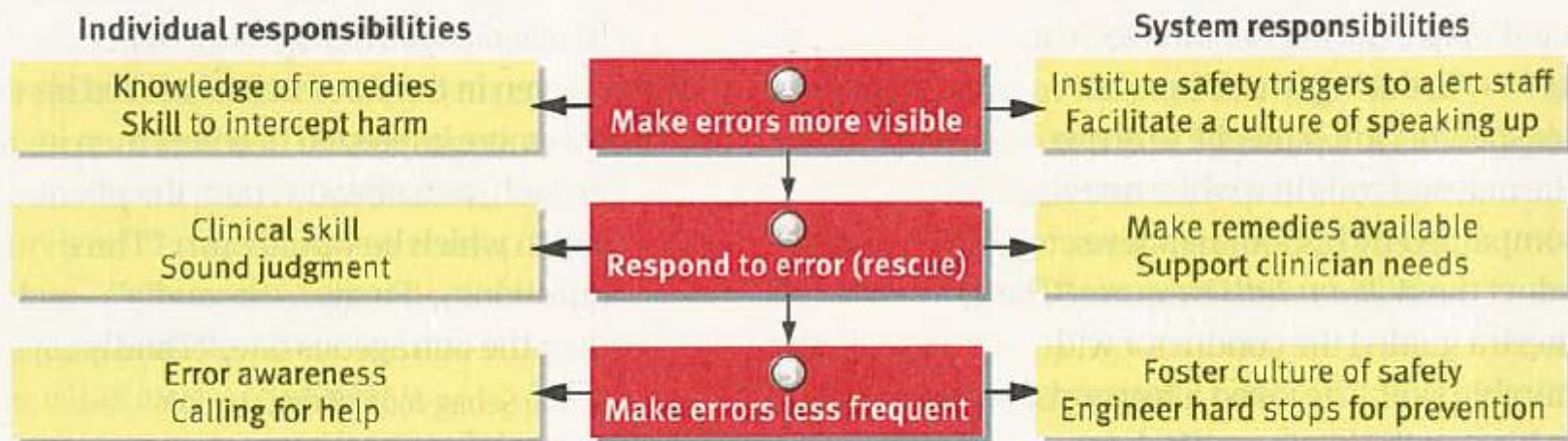
(Trabucchi. In: I farmaci e le sfide di una medicina a misura di paziente, UniversItalia, 2015)



**Alcune problematiche di rilievo:  
prescrizioni errate o inappropriate, polipatologie,  
il ruolo delle linee guida, il deprescribing.**

# Medical error— a leading (but hidden) cause of death

Death certificates and rankings of cause of death in the US don't include medical error. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting



Model for reducing patient harm from individual and system errors in healthcare

# Frequency and cost of potentially inappropriate prescribing for older adults: a cross-sectional study

Steven G. Morgan PhD, Jordan Hunt MA, Jocelyn Rioux BSc, Jeffery Proulx BSc, Deirdre Weymann MA, Cara Tannenbaum MD MSc

## Abstract

**Background:** Many medications pose greater health risks when prescribed for older adults, compared with available pharmacologic and nonpharmacologic alternatives. We sought to quantify the frequency and cost of potentially inappropriate prescribing for older women and men in Canada.

**Methods:** Using data for 2013 from the National Prescription Drug Utilization Information System database, which contains prescription claims from publicly financed drug plans in all provinces except for Quebec, we identified the frequency of prescribing and cost of potentially inappropriate medications dispensed to provincial drug plan enrollees aged 65 years or more. Potentially inappropriate prescriptions were defined with the use of the American Geriatrics Society's 2012 version of the Beers Criteria for potentially inappropriate medication use in older adults.

**Results:** For the 6 provinces with relatively complete data coverage (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario and Prince Edward Island), 37% of older people filled 1 or more prescription meeting the Beers Criteria. A higher proportion of women (42%) than men (31%) filled potentially inappropriate prescriptions. The highest rates of prescribing of potentially inappropriate medications were among women aged 85 or more (47%). Benzodiazepines and other hypnotics were the leading contributors to the overall frequency of and sex differences in prescribing of potentially inappropriate drugs among older adults. We estimated that \$75 per older Canadian, or \$419 million in total, was spent on potentially inappropriate medications outside of hospital settings in 2013.

**Interpretation:** Prescribing of potentially inappropriate medications for older adults is common and costly in Canada, especially for women. Multipronged and well-coordinated strategies to reduce the use and cost of potentially inappropriate drugs would likely generate significant health system savings while simultaneously generating major benefits to patient health.



**Table 1: Proportion of provincial drug plan enrollees aged 65 years or more who filled 1 or more potentially inappropriate prescription\* in 2013, by province, sex and age group**

Province	Population (%) aged ≥ 65 yr covered by NPDUIS database	Age, yr; no. (%) of enrollees								
		Women				Men				
		65–74	75–84	≥ 85	All ages	65–74	75–84	≥ 85	All ages	Overall
British Columbia	769 993 (89.0)	89 636 (41.5)	57 288 (44.6)	34 735 (50.1)	181 659 (43.9)	58 678 (28.8)	39 299 (34.5)	16 049 (41.2)	114 026 (32.0)	295 685 (38.4)
Alberta	411 322 (91.7)	54 514 (46.5)	34 388 (47.6)	16 304 (47.0)	105 206 (46.9)	33 675 (31.5)	21 163 (35.0)	7 267 (37.0)	62 105 (33.2)	167 311 (40.7)
Saskatchewan	149 505 (93.5)	14 672 (39.4)	11 764 (42.8)	8 762 (46.9)	35 198 (42.2)	9 455 (27.0)	7 166 (32.5)	3 246 (35.9)	19 867 (30.1)	55 065 (36.8)
Manitoba	171 195 (93.8)	19 942 (43.3)	13 606 (44.8)	9 209 (46.3)	42 757 (44.4)	12 905 (30.8)	8 353 (35.0)	3 501 (38.1)	24 759 (33.0)	67 516 (39.4)
Ontario	1 971 856 (95.9)	200 391 (36.7)	152 241 (43.0)	89 780 (46.1)	442 412 (40.4)	128 933 (26.2)	96 492 (33.8)	39 125 (38.9)	264 550 (30.2)	706 962 (35.8)
New Brunswick	73 482 (55.2)	10 650 (55.3)	8 238 (57.3)	5 969 (61.0)	24 857 (57.2)	6 591 (40.6)	4 689 (44.6)	1 690 (50.9)	12 970 (43.1)	37 827 (51.5)
Nova Scotia	112 780 (67.5)	15 000 (47.0)	10 303 (49.0)	6 559 (49.7)	31 862 (48.2)	10 039 (37.3)	6 539 (42.8)	2 013 (45.3)	18 591 (39.9)	50 453 (44.7)
Prince Edward Island	23 051 (91.8)	2 208 (33.6)	1 393 (34.6)	784 (36.8)	4 385 (34.5)	1 324 (21.5)	813 (25.0)	199 (21.9)	2 336 (22.6)	6 721 (29.2)
Newfoundland and Labrador	49 310 (54.9)	7 658 (56.0)	5 787 (58.0)	3 153 (60.1)	16 598 (57.4)	5 383 (48.5)	3 762 (51.8)	1 097 (53.5)	10 242 (50.2)	26 840 (54.4)
All high-data- coverage provinces†	3 496 922 (92.6)	381 363 (39.4)	270 680 (43.9)	159 574 (47.0)	811 617 (42.2)	244 970 (27.7)	173 286 (34.1)	69 387 (38.9)	487 643 (31.0)	1 299 260 (37.2)

Note: NPDUIS = National Prescription Drug Utilization Information System.

\*All prescriptions meeting the Beers Criteria based on drug, dosage and duration.<sup>1</sup>

†Provinces in which at least 85% of the population aged 65 years or more is covered by the NPDUIS database: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario and Prince Edward Island.

**Table 2: Average cost per enrollee of potentially inappropriate prescriptions, by province, sex and age**

Province	Age, yr; average cost, \$*								Overall
	Women				Men				
	65–74	75–84	≥ 85	All ages	65–74	75–84	≥ 85	All ages	
British Columbia	84	83	92	85	64	64	69	65	76
Alberta	101	98	101	100	62	66	71	64	84
Saskatchewan	91	90	92	91	67	68	71	68	81
Manitoba	103	98	91	99	73	76	74	74	88
Ontario	67	82	111	80	55	66	84	62	72
New Brunswick	148	142	162	149	110	109	132	112	134
Nova Scotia	102	100	101	101	88	96	97	91	97
Prince Edward Island	60	58	60	60	37	40	28	37	49
Newfoundland and Labrador	134	129	138	133	122	117	126	121	128
All high-data-coverage provinces	78	85	104	85	59	66	78	63	75

\*Includes public and private shares of total ingredient costs and dispensing fees for eligible prescriptions under provincial drug benefit programs.

(Morgan SG et al. CMAJ Open 2016. DOI:10.9778/cmajo.20150131)

**Table 4: Estimated total cost of potentially inappropriate prescriptions filled by older Canadians in 2013**

Variable	Women	Men	Overall
Estimated average cost per enrollee, \$	84.60	63.40	75.00
National population of age/sex group	3 064 000	2 521 000	5 585 000
Estimated total cost, \$ millions	259	160	419

(Morgan SG et al. CMAJ Open 2016. DOI:10.9778/cmajo.20150131)



## Tre approcci comportamentali per ridurre le prescrizioni inappropriate di antibiotici:

1. le alternative attraverso un sistema telematico che suggeriva trattamenti non antibiotici;
2. la giustificazione responsabile, che chiedeva ai medici di inserire a testo libero nelle cartelle dei pazienti i motivi per cui avevano prescritto gli antibiotici;
3. il confronto tra pari, in cui venivano inviati messaggi di posta elettronica ad altri medici per confrontare i reciproci tassi di prescrizioni inappropriate. E l'analisi dei dati indica che la giustificazione responsabile e il confronto tra pari riducono in modo significativo l'inappropriatezza prescrittiva, mentre le alternative suggerite non hanno effetto.

*Medscape. Jun 21, 2016*

<http://www.medscape.com/viewarticle/864802>

# Effect of Escitalopram on All-Cause Mortality and Hospitalization in Patients With Heart Failure and Depression

## The MOOD-HF Randomized Clinical Trial

Christiane E. Angermann, MD; Götz Gelbrich, PhD; Stefan Störk, MD, PhD; Hilka Gunold, MD; Frank Edelmann, MD; Rolf Wachter, MD; Heribert Schunkert, MD; Tobias Graf, MD; Ingrid Kindermann, MD; Markus Haass, MD; Stephan Blankenberg, MD; Sabine Pankuweit, MD; Christiane Prettin, PhD; Martin Gottwik, MD; Michael Böhm, MD; Hermann Faller, MD, PhD; Jürgen Deckert, MD; Georg Ertl, MD; for the MOOD-HF Study Investigators and Committee Members

**IMPORTANCE** Depression is frequent in patients with heart failure and is associated with adverse clinical outcomes. Long-term efficacy and safety of selective serotonin reuptake inhibitors in these patients are unknown.

**OBJECTIVE** To determine whether 24 months of treatment with escitalopram improves mortality, morbidity, and mood in patients with chronic systolic heart failure and depression.

**DESIGN, SETTING, AND PARTICIPANTS** The Effects of Selective Serotonin Re-Uptake Inhibition on Morbidity, Mortality, and Mood in Depressed Heart Failure Patients (MOOD-HF) study was a double-blind, placebo-controlled randomized clinical trial conducted at 16 tertiary medical centers in Germany. Between March 2009 and February 2014, patients at outpatient clinics with New York Heart Association class II-IV heart failure and reduced left ventricular ejection fraction (<45%) were screened for depression using the 9-item Patient Health Questionnaire. Patients with suspected depression were then invited to undergo a Structured Clinical Interview based on the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) to establish the diagnosis.

**INTERVENTIONS** Patients were randomized 1:1 to receive escitalopram (10-20 mg) or matching placebo in addition to optimal heart failure therapy. Study duration was 24 months.

**MAIN OUTCOMES AND MEASURES** The composite primary outcome was time to all-cause death or hospitalization. Prespecified secondary outcomes included safety and depression severity at 12 weeks of treatment (including the titration period), which were determined using the 10-item Montgomery-Åsberg Depression Rating Scale (total possible score, 0 to 60; higher scores indicate more severe depression).

**RESULTS** A total of 372 patients (mean age, 62 years; 24% female) were randomized and had taken at least 1 dose of study medication when the data and safety monitoring committee recommended the trial be stopped early. During a median participation time of 18.4 months (n = 185) for the escitalopram group and 18.7 months (n = 187) for the placebo group, the primary outcome of death or hospitalization occurred in 116 (63%) patients and 119 (64%) patients, respectively (hazard ratio, 0.99 [95% CI, 0.76 to 1.27]; P = .92). The mean Montgomery-Åsberg Depression Rating Scale sum score changed from 20.2 at baseline to 11.2 at 12 weeks in the escitalopram group and from 21.4 to 12.5 in the placebo group (between-group difference, -0.9 [95% CI, -2.6 to 0.7]; P = .26). Safety parameters were comparable between groups.

**CONCLUSIONS AND RELEVANCE** In patients with chronic heart failure with reduced ejection fraction and depression, 18 months of treatment with escitalopram compared with placebo did not significantly reduce all-cause mortality or hospitalization, and there was no significant improvement in depression. These findings do not support the use of escitalopram in patients with chronic systolic heart failure and depression.

**TRIAL REGISTRATION** isrctn.com Identifier: ISRCTN33128015

JAMA. 2016;315(24):2683-2693. doi:10.1001/jama.2016.7635

**These observations support the concept of alternative pathophysiological mechanisms for mood disorders in somatic illnesses, with depressive symptoms less responsive or, as in both SADHART-CHF and our study, unresponsive to sertraline or escitalopram.**

**Placebo-controlled trials of antidepressants tended to exclude patients with severe somatic illnesses.**

**These observations suggest that the efficacy results of these studies may not necessarily be transferable to all individuals in whom antidepressants are prescribed in clinical practice.**

(Angermann CE et al. JAMA 315 (24): 2683-93, 2016)



**More recently, Freedland et al demonstrated that integrative cognitive behavior therapy effectively improved depression in a younger population with heart failure, but not self-care and physical functioning.**

**This finding is remarkable in view of the present and previous negative results with SSRI therapy and the Patient-Centered Disease Management for Heart Failure study, in which multidisciplinary patient centered disease management did not improve patient health status; however, mortality was lower and mood improved more in participants who were depressed. Telephone-based collaborative care strategies have been shown to enhance health related quality of life, physical functioning, and mood symptoms in patients with cardiovascular disease and heart failure.**

(Angermann CE et al. JAMA 315 (24): 2683-93, 2016)

**IMPORTANCE** Prescription and over-the-counter medicines and dietary supplements are commonly used, alone and together, among older adults. However, the effect of recent regulatory and market forces on these patterns is not known.

**OBJECTIVES** To characterize changes in the prevalence of medication use, including concurrent use of prescription and over-the-counter medications and dietary supplements, and to quantify the frequency and types of potential major drug-drug interactions.

**DESIGN, SETTING, AND PARTICIPANTS** Descriptive analyses of a longitudinal, nationally representative sample of community-dwelling older adults 62 to 85 years old. In-home interviews with direct medication inspection were conducted in 2005-2006 and again in 2010-2011. The dates of the analysis were March to November 2015. We defined medication use as the use of at least 1 prescription or over-the-counter medication or dietary supplement at least daily or weekly and defined concurrent use as the regular use of at least 2 medications. We used Micromedex to identify potential major drug-drug interactions.

**MAIN OUTCOMES AND MEASURES** Population estimates of the prevalence of medication use (in aggregate and by therapeutic class), concurrent use, and major drug-drug interactions.

**RESULTS** The study cohort comprised 2351 participants in 2005-2006 and 2206 in 2010-2011. Their mean age was 70.9 years in 2005-2006 and 71.4 years in 2010-2011. Fifty-three percent of participants were female in 2005-2006, and 51.6% were female in 2010-2011. The use of at least 1 prescription medication slightly increased from 84.1% in 2005-2006 to 87.7% in 2010-2011 ( $P = .003$ ). Concurrent use of at least 5 prescription medications increased from 30.6% to 35.8% ( $P = .02$ ). While the use of over-the-counter medications declined from 44.4% to 37.9%, the use of dietary supplements increased from 51.8% to 63.7% ( $P < .001$  for both). There were clinically significant increases in the use of statins (33.8% to 46.2%), antiplatelets (32.8% to 43.0%), and omega-3 fish oils (4.7% to 18.6%) ( $P < .05$  for all). In 2010-2011, approximately 15.1% of older adults were at risk for a potential major drug-drug interaction compared with an estimated 8.4% in 2005-2006 ( $P < .001$ ). Most of these interacting regimens involved medications and dietary supplements increasingly used in 2010-2011.

**CONCLUSIONS AND RELEVANCE** In this study, the use of prescription medications and dietary supplements, and concurrent use of interacting medications, has increased since 2005, with 15% of older adults potentially at risk for a major drug-drug interaction. Improving safety with the use of multiple medications has the potential to reduce preventable adverse drug events associated with medications commonly used among older adults.

Original Investigation

## Changes in Prescription and Over-the-Counter Medication and Dietary Supplement Use Among Older Adults in the United States, 2005 vs 2011

Dima M. Qato, PharmD, MPH, PhD; Jocelyn Wilder, MPH; L. Philip Schumm, MA; Victoria Gillet, BS; G. Caleb Alexander, MD, MS

*JAMA Intern Med.* doi:10.1001/jamainternmed.2015.8581  
Published online March 21, 2016.



# Polypharmacy in the Aging Patient

## A Review of Glycemic Control in Older Adults With Type 2 Diabetes

Kasia J. Lipska, MD, MHS; Harlan Krumholz, MD, SM; Tacara Soones, MD, MPH; Sei J. Lee, MD, MAS

**IMPORTANCE** There is substantial uncertainty about optimal glycemic control in older adults with type 2 diabetes mellitus.

**OBSERVATIONS** Four large randomized clinical trials (RCTs), ranging in size from 1791 to 11 440 patients, provide the majority of the evidence used to guide diabetes therapy. Most RCTs of intensive vs standard glycemic control excluded adults older than 80 years, used surrogate end points to evaluate microvascular outcomes and provided limited data on which subgroups are most likely to benefit or be harmed by specific therapies. Available data from randomized clinical trials suggest that intensive glycemic control does not reduce major macrovascular events in older adults for at least 10 years. Furthermore, intensive glycemic control does not lead to improved patient-centered microvascular outcomes for at least 8 years. Data from randomized clinical trials consistently suggest that intensive glycemic control immediately increases the risk of severe hypoglycemia 1.5- to 3-fold. Based on these data and observational studies, for the majority of adults older than 65 years, the harms associated with a hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) target lower than 7.5% or higher than 9% are likely to outweigh the benefits. However, the optimal target depends on patient factors, medications used to reach the target, life expectancy, and patient preferences about treatment. If only medications with low treatment burden and hypoglycemia risk (such as metformin) are required, a lower HbA<sub>1c</sub> target may be appropriate. If patients strongly prefer to avoid injections or frequent fingerstick monitoring, a higher HbA<sub>1c</sub> target that obviates the need for insulin may be appropriate.

**CONCLUSIONS AND RELEVANCE** High-quality evidence about glycemic treatment in older adults is lacking. Optimal decisions need to be made collaboratively with patients, incorporating the likelihood of benefits and harms and patient preferences about treatment and treatment burden. For the majority of older adults, an HbA<sub>1c</sub> target between 7.5% and 9% will maximize benefits and minimize harms.

**Insulin resistance and impaired beta-cell function both contribute to the pathogenesis of type 2 diabetes in older adults.**

**Aging is associated with accumulation of fat in muscle and liver tissues and reduced rates of mitochondrial activity in muscle and brain, contributing to insulin resistance.**

**Along with these changes, aging is associated with defects in insulin secretion, which further contribute to hyperglycemia and type 2 diabetes.**

(Lipska KJ et al, JAMA 315(10): 1034-1045, 2016)

**In adults older than 70 years, the nonfatal diabetes complications with the highest incidence rates include congestive heart failure, coronary artery disease, and cerebrovascular disease.**

**However, among older patients with duration of diabetes of 10 years or more, rates of acute hypoglycemic events and eye disease slightly exceed rates of cerebrovascular disease and approximate those of coronary artery disease.**

**Therefore, both the risk of diabetes complications and the risk of therapy resulting in hypoglycemia become critically important to consider when setting therapeutic goals.**

(Lipska KJ et al, JAMA 315(10): 1034-1045, 2016)



**The goals of treatment of type 2 diabetes are to improve symptoms (if present), reduce the risk of acute and chronic diabetes complications, and minimize harms and burdens of therapy.**

**Glycemic control has been the central focus of diabetes care for decades and is the primary subject of this review.**

**Randomized trials have shown that intensive glycemic control may lower the risk of some long-term complications (ie, microvascular disease) but increase the risk of harm (ie, hypoglycemia).**

(Lipska KJ et al, JAMA 315(10): 1034-1045, 2016)

# Conclusions

Although there are major gaps in the evidence base on how best to care for older adults with diabetes, 4 evidence-informed steps can help clinicians and patients make individualized treatment decisions. Patient-centered decisions start with a strong partnership between the clinician and the patient. The first and second steps include assessments of potential benefits and harms of intensive glycemic control. Estimation of life expectancy can be useful to determine whether long-term benefits of intensive glycemic control are possible. The need for insulin (or other type of therapy), duration of diabetes, and cognitive impairment can be used to determine the likelihood of harms associated with treatment. In the third step, patient preferences should play a major role in determining the appropriate glycemic target. Fourth, polypharmacy should be minimized. If a glycemic target cannot be easily achieved, the most appropriate course may be to modify the glycemic target rather than intensify treatment.

(Lipska KJ et al, JAMA 315(10): 1034-1045, 2016)



## **Alcuni problemi pratici**

# Research

## Safe to crush? A pilot study into solid dosage form modification in aged care



*Nicole Mercovich, Greg J Kyle and Mark Naunton*

**Aims:** *To observe medication solid dosage form modification in aged care facilities (ACFs), and assess staff levels of self-perceived knowledge of medication modification and the types of resources available to them.*

**Method:** *Observation of medication rounds in a convenience sample of Australian Capital Territory ACFs and assessment of staff knowledge of dosage form modification and available resources.*

**Results:** *From 160 observations across six medication rounds, 29 residents had a total of 75 medications modified by the nursing staff prior to administration, with 32% of these instances identified as inappropriate. The methods used for crushing and administration resulted in drug mixing, spillage and incomplete dosing. The staff reported adequate resources; however, a lack of knowledge on how to locate and use these resources was evident.*

**Conclusions:** *Improved staff training on how to use available resources is needed to reduce the observed high incidence of inappropriate medication crushing.*

**Key words:** *aged care, altered pharmacokinetics, dosage form modification, dysphagia, medication administration.*



## Physicians and Nurses Have Similar Prescribing Habits

Nurse practitioners who have the authority to prescribe controlled substances in the form of mental health drugs have prescribing patterns similar to physicians, new research shows. "This demonstrates that nurse practitioners who have had unrestricted authority for prescribing controlled substances do not prescribe them in greater quantity or differently than their peers," said Tracy Klein, from the Washington State University College of Nursing in Spokane.

Dr Klein and her colleagues assessed the prescribing patterns of generalists (family, pediatrics) and specialists (psychiatry) who treated Medicaid patients in Oregon with attention-deficit and hyperactivity disorder (ADHD) in 2012.

## **L'insostenibile costo dei farmaci, innovativi e non. Le ricette *made in Usa* per affrontare il problema**

Contenere la spesa dei farmaci, per rendere l'innovazione, ma anche i vecchi farmaci, disponibili a molti se non a tutti. Negli Usa ci si sta provando, sensibilizzando i medici prescrittori alla valutazione del costo-efficacia ma anche chiedendo per legge alle aziende di rendere trasparenti i loro investimenti in ricerca e sviluppo, così da poter valutare se il prezzo richiesto per un determinato farmaco sia ragionevole o gonfiato in maniera immotivata.

Il costo dei farmaci innovativi è un argomento spinoso e controverso in tutto il mondo. Da una parte l'esigenza etica di renderli disponibili a quanti ne hanno bisogno; dall'altra la questione della sostenibilità, a fronte di *budget* sanitari non adeguati a reggere l'impatto di queste spese. Gli Stati Uniti stanno cercando delle possibili soluzioni, certamente non facili, ma di certo interessanti come spunto di riflessione.



**“Guidelines, not tramlines”,  
guideline producers need to resist the  
temptation to tell clinicians and patients  
what to do.**

(McCartney M et al, BMJ 353:360-1, 2016)

## **Box 1 | Problems with applying population based evidence**

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- Randomised trials often exclude patients with comorbidities
- Guidelines describe the evidence for single conditions; real patients often have several comorbidities
- Individual patients may have different values and preferences from their clinician and the people creating the evidence
- Guidelines may not cover aspects of care important to patients
- Guidelines may make recommendations, quite often based solely on expert opinion, when individual patients would make a different choice
- Risks, benefits, and downsides of management options may be viewed differently at the level of the population than from the perspective of an individual
- Shared decision making is not clearly enabled in contemporary practice



## Box 2 | Suggested actions to improve evidence informed, individualised decisions

- The patient as a whole should matter more than their individual conditions
- Limitations of the evidence should be explicitly stated. Can guidelines safely be applied to people with frailty or who are very old? Are women and people from ethnic minorities adequately represented in the underlying trials?
- Key evidence from guideline writers should be summarised using visual representations of benefits and risks, or numbers needed to treat and harm
- Guidelines should be written assuming that patients will wish to make choices and give information in a way that highlights what choices fit better with different preferences (eg, fewer blood tests, less medication)
- Patient decision aids should be published in tandem with guidelines, but better research is required into how to provide information about choices
- Chronic disease management “courses” sharing current practice should be developed by patients and professionals and then evaluated
- Clinicians and patients should be encouraged to make decisions according to both the evidence and patient preference
- The negative effect of guidelines on the quality of care for individuals requires evaluation. Guidelines should be created for and evaluated in real world conditions

(McCartney M et al, BMJ 353:360-1, 2016)

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# Too much medicine in older people? Deprescribing through shared decision making

**Jansen and colleagues** explore the role of shared decision making in tackling inappropriate polypharmacy in older adults

Jesse Jansen *senior research fellow*<sup>1 2</sup>, Vasi Naganathan *geriatrician and associate professor*<sup>3</sup>, Stacy M Carter *associate professor*<sup>4</sup>, Andrew J McLachlan *professor of pharmacy*<sup>3 5</sup>, Brooke Nickel *PhD candidate*<sup>1 2</sup>, Les Irwig *professor of epidemiology*<sup>1</sup>, Carissa Bonner *senior research officer*<sup>1 2</sup>, Jenny Doust *GP and professor of clinical epidemiology*<sup>6</sup>, Jim Colvin *health consumer representative*<sup>7</sup>, Aine Heaney *manager program design at NPS MedicineWise*<sup>8</sup>, Robin Turner *biostatistician*<sup>9</sup>, Kirsten McCaffery *professorial research fellow*<sup>1 2</sup>

*BMJ* 2016;353:i2893 doi: 10.1136/bmj.i2893 (Published 3 June 2016)

**Clinicians may be reluctant to initiate discussions about deprescribing with older people, believing that they value medicines highly.**

(Jansen J et al, BMJ 353: 431-3, 2016)

## Key messages

Deprescribing is a process of planned and supervised tapering or ceasing of inappropriate medicines

Shared decision making should be an integral part of the deprescribing process

Many factors affect this process, including trust in clinicians' advice, contradictory patient attitudes about medication, cognitive biases that lead to a preference for the status quo and positive information, and information processing difficulties

There is uncertainty about the effect of risk communication and preference elicitation tools in older people

Older people's preferences for discussing life expectancy and quality of life vary widely, but even those who wish to delegate their decisions still appreciate discussion of options

(Jansen J et al, BMJ 353: 431-3, 2016)

# Cognitive biases

A well recognised cognitive bias is status quo bias: a preference for continuing with the status quo, especially if it has been the default for many years. A related concept in the medical literature is clinical or therapeutic inertia: “recognition of the problem, but failure to act.” Omission bias—being more willing to risk harms arising from inaction than from action—is another well recognised problem. Paradoxically, once people are taking a medicine, continuing it unchanged is perceived as inaction, while ceasing it is perceived to be an action. Patient resistance to change (as perceived by the clinician) was the most commonly expressed barrier in a recent systematic review of qualitative studies on this topic.

Patients may presume medicines are important if they have been taking them for many years. The language used by clinicians when starting a medicine can be very important. For example, if patients have been told that they would need the medicines for the “rest of their lives,” discussion of possible discontinuation can make them anxious.

**I cognitive biases sono una testimonianza della fragilità “scientifica” della terapia farmacologica, i cui risultati si ottengono attraverso percorsi talvolta casuali.**

# **Il capitolo dolente dell'abuso degli oppioidi indotto dal trattamento inappropriato del dolore.**

## Self-medicating in the opioid crisis

On June 7, the US Food and Drug Administration released a drug safety notice about loperamide, an anti-diarrhoea medicine sold over the counter and under prescription. The drug is being used as a cheap and legally-available high, and to reduce the symptoms of opioid withdrawal. A standard dose for the medicine is 8 mg per day in divided doses, but opioid users have been taking massive doses of the drug, as much as 300 mg or more daily for weeks at a time. Taken in such high quantities, overdoses of loperamide can cause severe heart problems like ventricular arrhythmias, cardiac arrest, and death. Although the number of reported cases is currently small, standard toxicology screenings do not look for loperamide, and it is possible that the rate of loperamide abuse is under-reported.

**(Lancet 387 (10037): 2480, 2016)**



Using data from nearly half a million respondents to the annual National Survey on Drug Use and Health (NSDUH), the authors found that overall trends in self-reported nonmedical use of prescription opioids decreased from 5.4% to 4.9% over an 11-year period, including a decline in new users of opioids, from 1% in 2003 to 0.6% in 2013. Although this overall finding of a reduction in nonmedical use of prescription opioids is encouraging, the study also reported increases in the prevalence of prescription opioid use disorders (abuse and addiction) and increases in the prevalence of opioid-associated mortality, using data from the National Vital Statistics System's Multiple Cause of Death Files. The authors also reported an increased prevalence of frequent opioid use (>100 days/year) and highly frequent use (>200 days/year), as well as a greater prevalence of prescription opioid use disorders in patients with major depressive episodes (MDEs) than in patients without them. The findings of Han et al suggest that more patients are experiencing an inexorable progression from initial opioid use to frequent use, highly frequent use, or an opioid use disorder.

(Nelson LS et al, JAMA 314(14):1453-4, 2015)

**Prescribing of opioid analgesics, particularly for chronic pain, appears to be a main factor in the majority of nonmedical use. Based on other data available in the NSDUH, prescribers are, directly or indirectly, the source of most misused opioids. An estimated 53% of nonmedical users reported obtaining prescription opioids from a friend or relative, 81% of whom received their drug from a physician. It is unclear whether these prescriptions were issued for therapeutic purposes or originated from unscrupulous prescribers (ie, “pill mills”); regardless, the source of opioid use and misuse is often a seemingly legitimate prescription.**

(Nelson LS et al, JAMA 314(14):1453-4, 2015)

**There is little evidence for long-term benefit from opioid therapy for most types of chronic pain. It remains unclear why this practice of opioid prescribing continues despite recommendations to the contrary. New opioid medications, many of them with tamper-resistant formulations, continue to be marketed despite the lack of evidence that these preparations reduce the risk of addiction. More than 10% of patients who initiate treatment with opioids will likely progress to chronic use, defined as ongoing treatment for more than 3 months. Nearly all patients treated with long-term opioid therapy develop tolerance and dependence to varying degrees, about 25% become nonmedical users, and 10% develop features suggestive of addiction. These are sobering percentages in light of the millions of patients prescribed these drugs every year. Consequently, for the many patients who need treatment for addiction or complications of substance misuse, there are often significant barriers to obtaining care.**

(Nelson LS et al, JAMA 314(14):1453-4, 2015)

**What is really needed is a sea change within the medical profession itself. We should be educating and training our medical students and residents about the risks and limited benefits of opioids in treating pain. All medical professional organizations should back mandated education about safe opioid treatment as a prerequisite for licensure and prescribing. At present, the American Academy of Family Physicians opposes such a measure because it could limit patient access to pain treatment with opioids, which I think is misguided. Don't we want family doctors, who are significant prescribers of opioids, to learn about their limitations and dangers?**

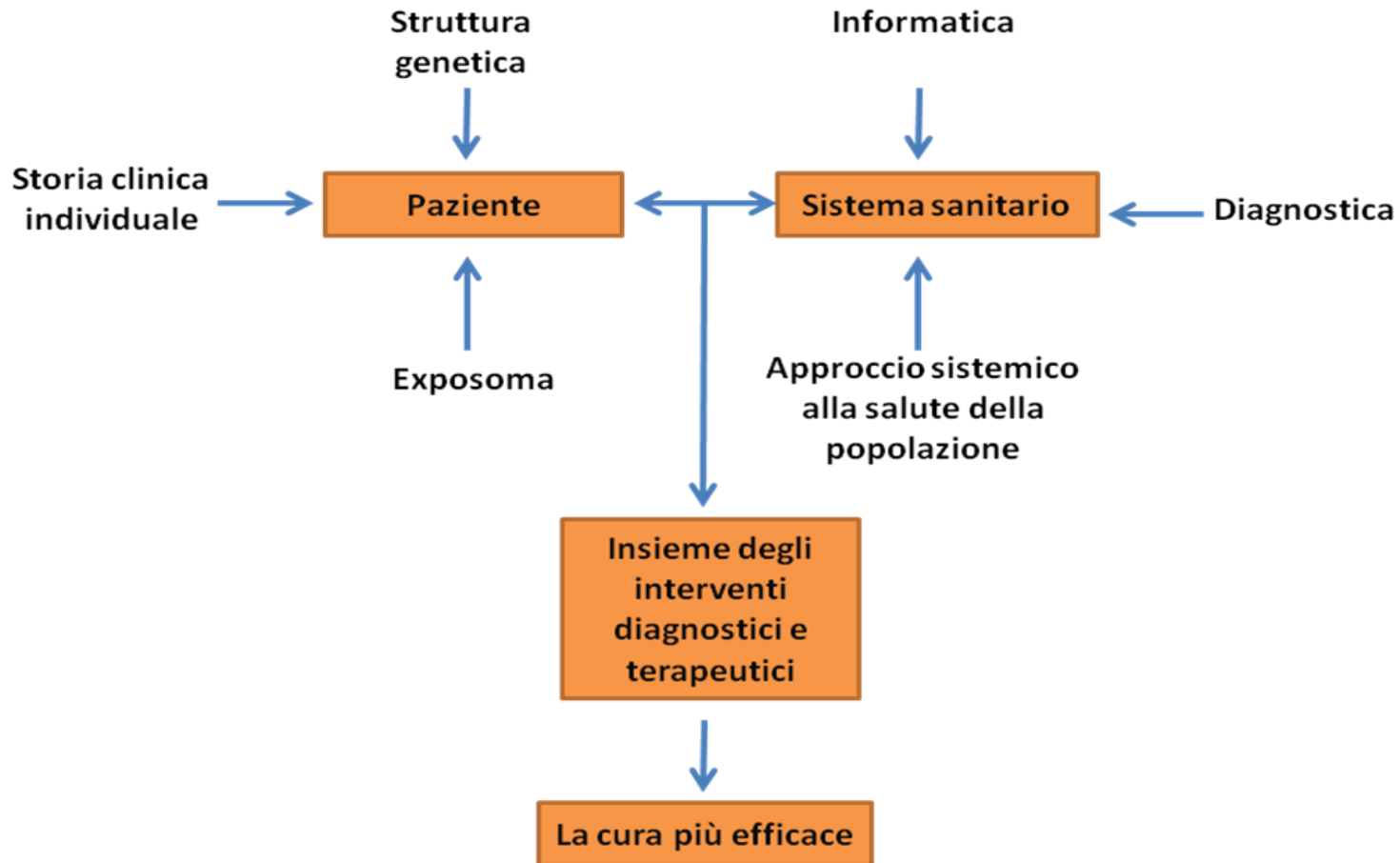
**It is physicians who, in large part, unleashed the current opioid epidemic with their promiscuous use of these drugs; we have a large responsibility to end it.**

(Friedman RA, New York Times, November 7, 2015)

**Come è possibile che in USA vi siano comportamenti prescrittivi così errati ma così diffusi?**

**... la storia della prescrizione farmacologica non finisce mai ... in tutte le età della vita.**

# La medicina su nuove basi



**La medicina si fonda sulla conoscenza del paziente (genetica, storia, ambiente), che si incontra con la struttura del sistema sanitario (servizi diagnostici e terapeutici, data base, salute della popolazione). Questo incontro produce risultato di salute per la popolazione e per ogni singolo individuo, attraverso una serie di interventi formalizzati.**