Epidemiologia e consumo del farmaco

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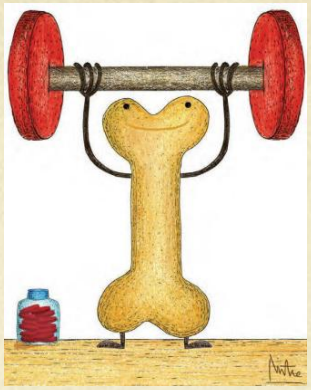
Epidemiologia e consumo del farmaco
Stato vitaminico



Vitamina D	Deficit	Adeguato
Popolazione generale	< 20 ng/ml < 75 nmol/l	20-50 ng/ml 50-125 nmol/l
Popolazione a rischio	< 30 ng/ml < 75 nmol/l	30-50 ng/ml 75-125 nmol/l

Effects of vitamin D supplementation on musculoskeletal health: a systematic review, meta-analysis, and trial sequential analysis

Mark J Bolland, Andrew Grey, Alison Avenell

Methods In this systematic review, random-effects meta-analysis, and trial sequential analysis, we used findings from literature searches in previously published meta-analyses. We updated these findings by searching PubMed, Embase, and Cochrane Central on Sept 14, 2017, and Feb 26, 2018, using the search term "vitamin D" and additional keywords, without any language restrictions. We assessed randomised controlled trials of adults (>18 years) that compared vitamin D with untreated controls, placebo, or lower-dose vitamin D supplements. Trials with multiple interventions (eg, co-administered calcium and vitamin D) were eligible if the study groups differed only by use of vitamin D. We excluded trials of hydroxylated vitamin D analogues. Eligible studies included outcome data for total or hip fractures, falls, or bone mineral density measured at the lumbar spine, total hip, femoral neck, total body, or forearm. We extracted data about participant characteristics, study design, interventions, outcomes, funding sources, and conflicts of interest. The co-primary endpoints were participants with at least one fracture, at least one hip fracture, or at least one fall; we compared data for fractures and falls using relative risks with an intention-to-treat analysis using all available data. The secondary endpoints were the percentage change in bone mineral density from baseline at lumbar spine, total hip, femoral neck, total body, and forearm.

Interpretation Our findings suggest that vitamin D supplementation does not prevent fractures or falls, or have clinically meaningful effects on bone mineral density. There were no differences between the effects of higher and lower doses of vitamin D. There is little justification to use vitamin D supplements to maintain or improve musculoskeletal health. This conclusion should be reflected in clinical guidelines.

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RESEARCH ARTICLE Open Access

Assessment of research waste part 2: wrong study populations- an exemplar of baseline vitamin D status of participants in trials of vitamin D supplementation

Mark J. Bolland[1*], Andrew Grey[1] and Alison Avenell[2]

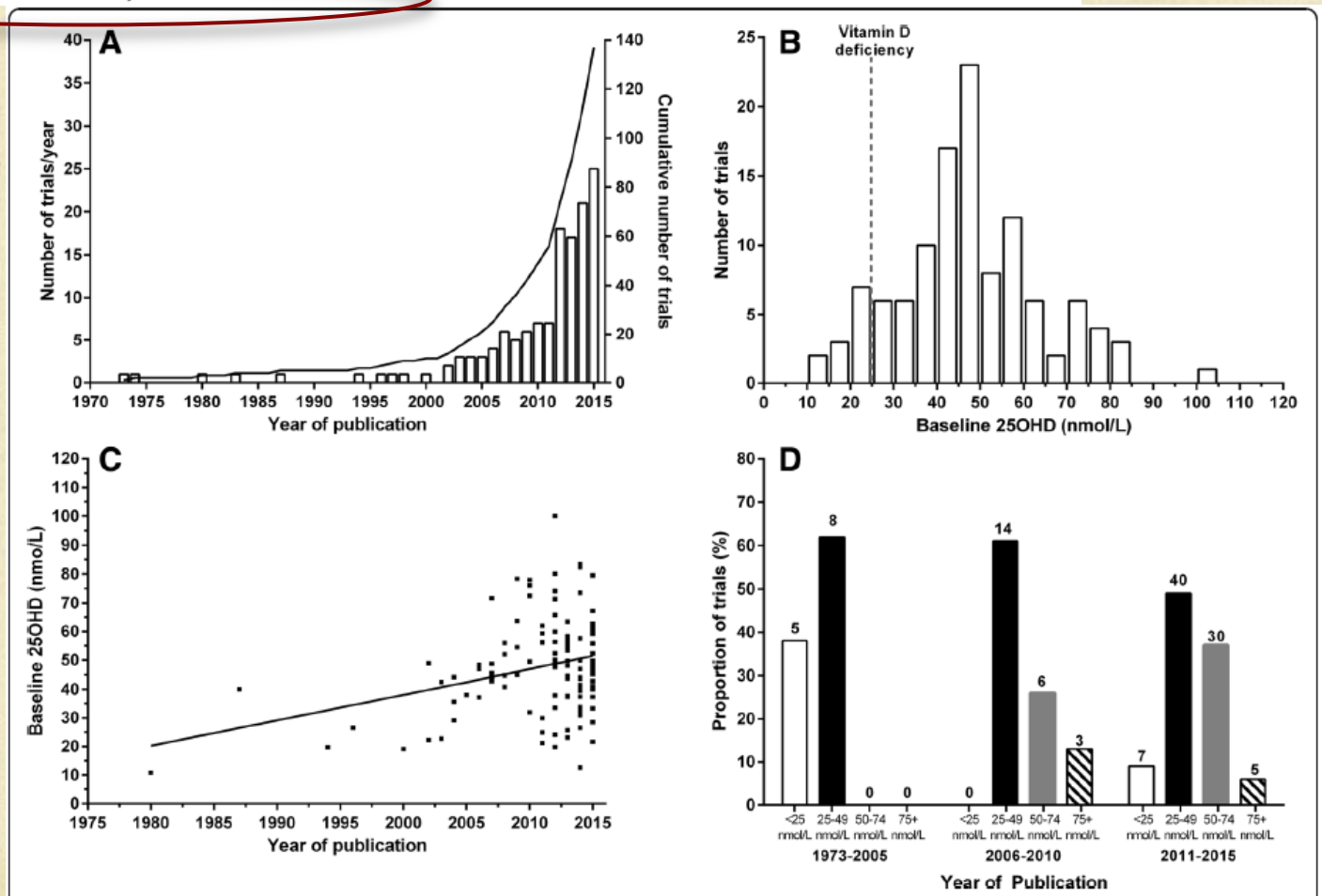

Fig. 1 Panel **a** shows the number of randomized controlled trials (RCTs) of vitamin D with clinical endpoints in the Abstract published over time by year (bars) and cumulatively (line). Panel **b** shows the distribution of mean/median baseline 25-hydroxyvitamin D (25OHD) concentrations in these RCTs. Panel **c** shows the 25OHD concentrations plotted against year of publication with a line of best fit. Panel **d** shows the proportion of trials with mean/median baseline 25OHD < 25, 25–49, 50–74 and ≥ 75 nmol/L by year of publication. Above each bar is the number of trials

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Epidemiologia e Vitamina D

- **Condizioni individuali**

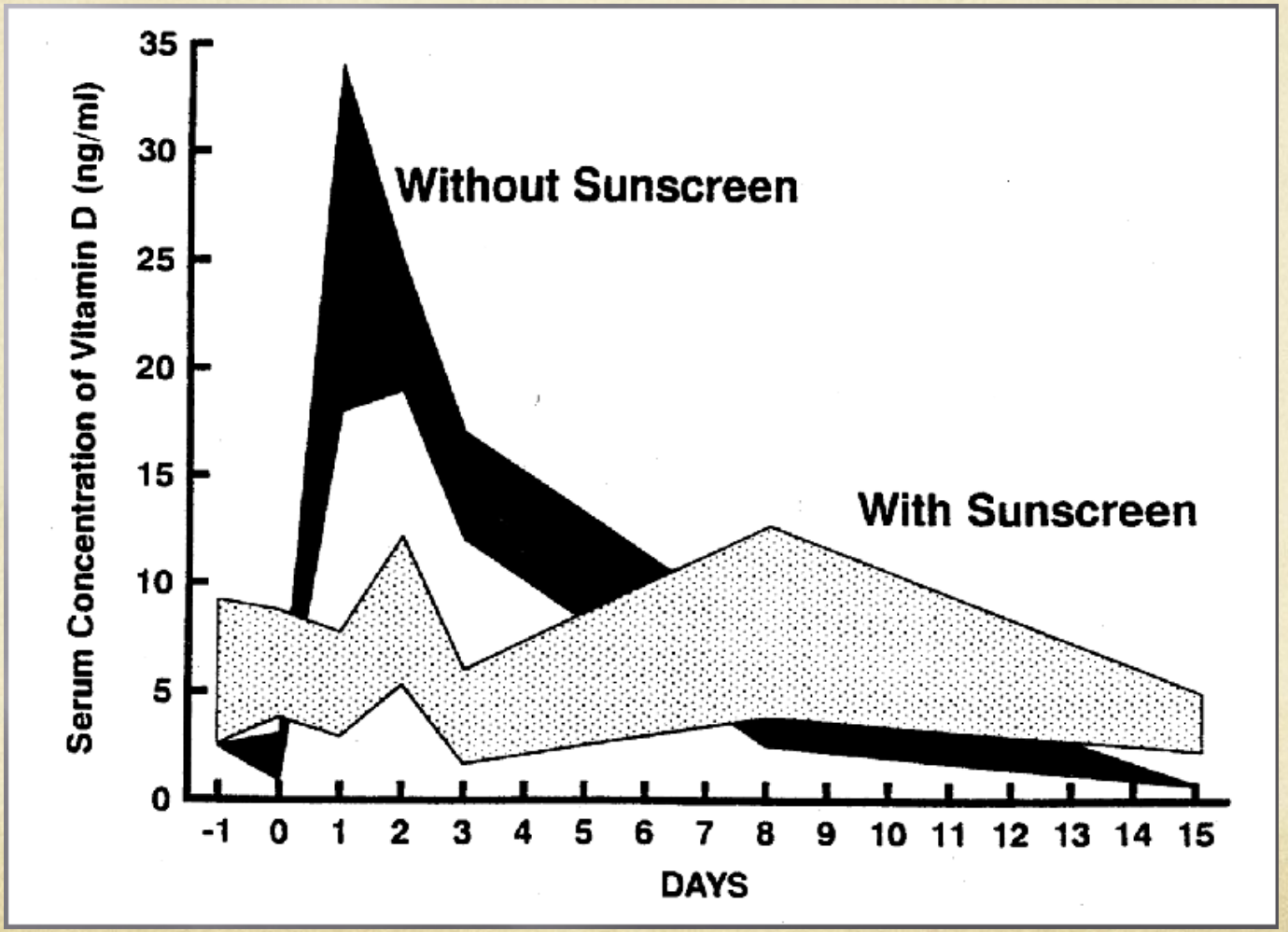
- Età
- Nutrients
- BMI
- Extracellular volume
- DBP concentration and affinity
- Variation between individuals in the half-life of 25(OH)D
- Effect of genetic variation

- **Condizioni ambientali**

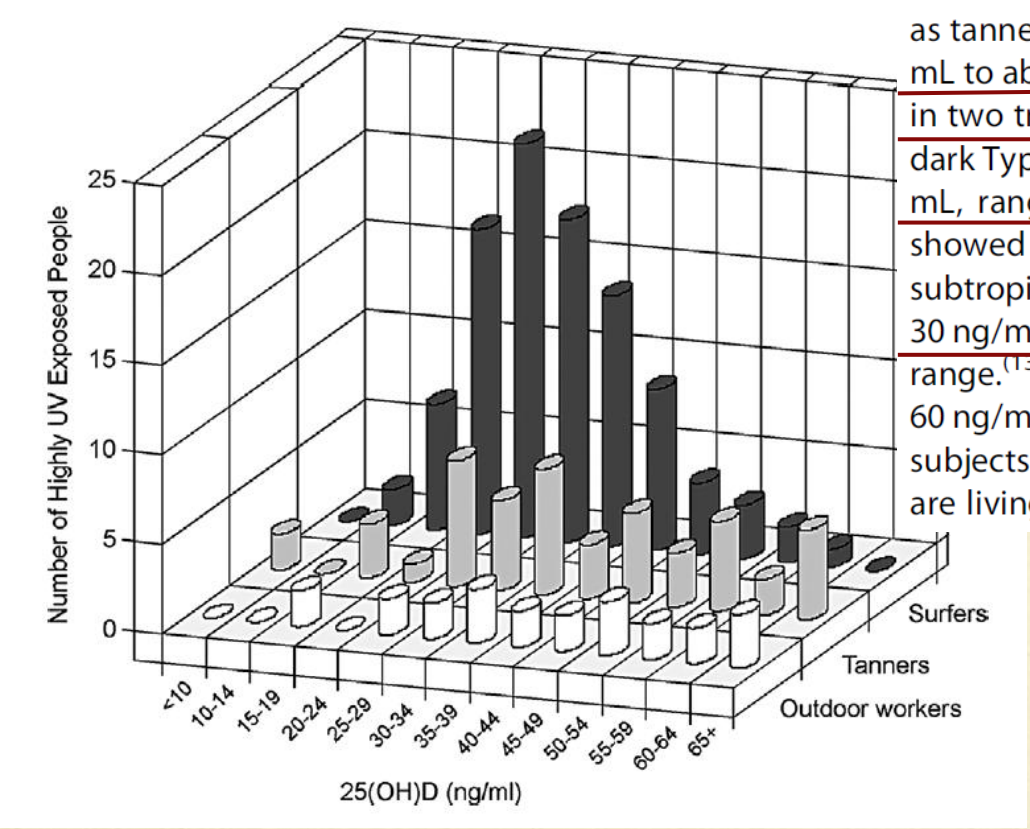
- Sun exposure…
- Season
- Geographic latitude
- Clothing
- Institutionalisation
- Use of sunscreen

(Brannon et al., 2008; Cashman & Kiely, 2011; IOM, 2011)

Epidemiologia e Vitamina D



Epidemiologia e Vitamina D



Serum 25OHD of individuals with high sun-UVB exposure, such as tanners, surfers, and outdoor workers, range between 10 ng/mL to above 65 ng/mL[136] (Fig. 2). Similarly, mean 25OHD levels in two tribes from Tanzania, 2° to 4° South of the equator, with dark Type IV skin, revealed mean 25OHD levels of 44 and 48 ng/mL, ranging from 23 to 68 ng/mL.[137] Finally, a recent study showed that most black subjects living in equatorial or subtropical areas have mean serum 25OHD levels of around 30 ng/mL, with few getting up to the 50-ng/mL to 60-ng/mL range.[138] Therefore, it seems than serum 25OHD levels of 40 to 60 ng/mL are about the maximal levels reached when healthy subjects with a skin pigmentation adapted to their environment are living in natural circumstances.

Fig. 2. Distribution of 25(OH) levels in subjects with high levels of habitual sun exposure. Data from two highly sun exposed groups (surfers and outdoor workers) and from habitual tanners are presented here to estimate the ancestral human "normal" vitamin D status. Recognizing that the studies of outdoor workers and tanners used an assay that overestimated 25OHD, the authors arbitrarily reduced these values by 10%. The mean 25OHD in this group is 36 ng/mL (91 nmol/L) and only 8% of these individuals had a 25OHD below 20 ng/mL (50 nmol/L). Reproduced with permission from Binkley N, Lewiecki EM. Vitamin D and common sense. J Clin Densitom. 2011;14 (2):95–9. (doi: 10.1016/j.jocd.2011.03.006).

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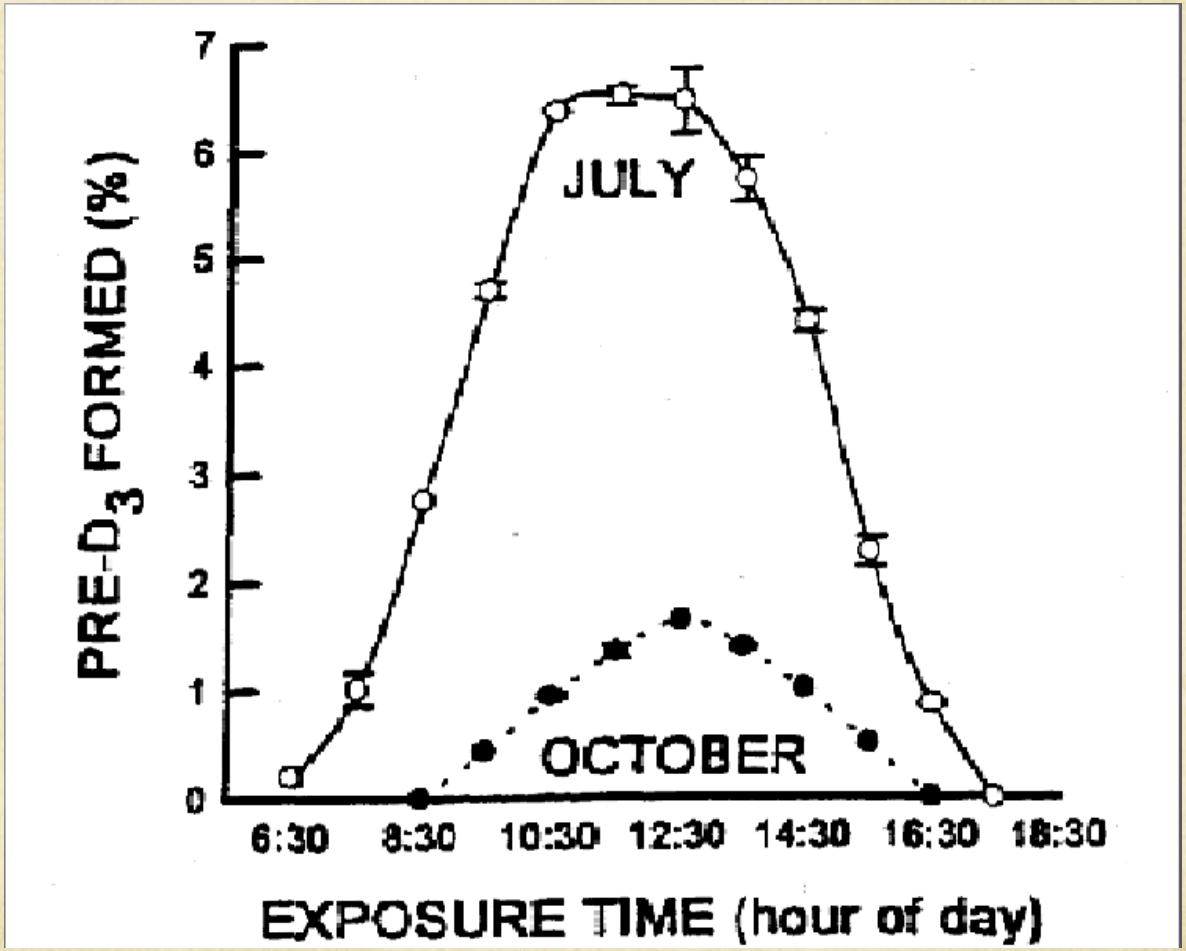
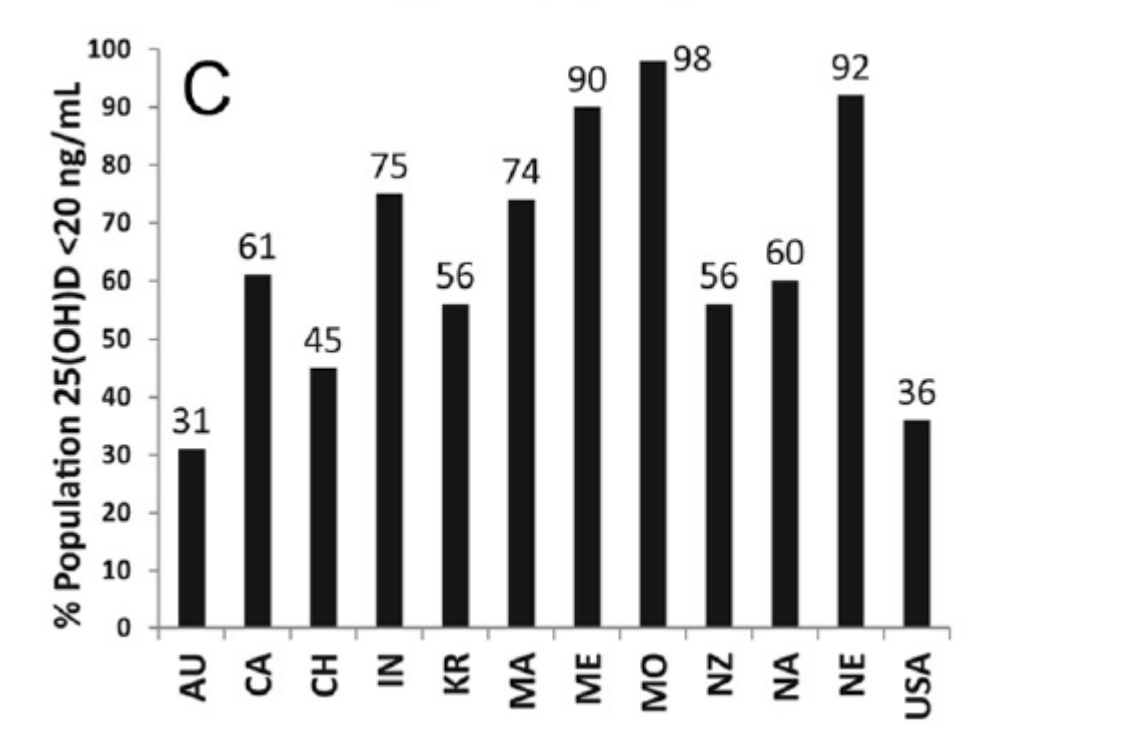
Epidemiologia e Vitamina D

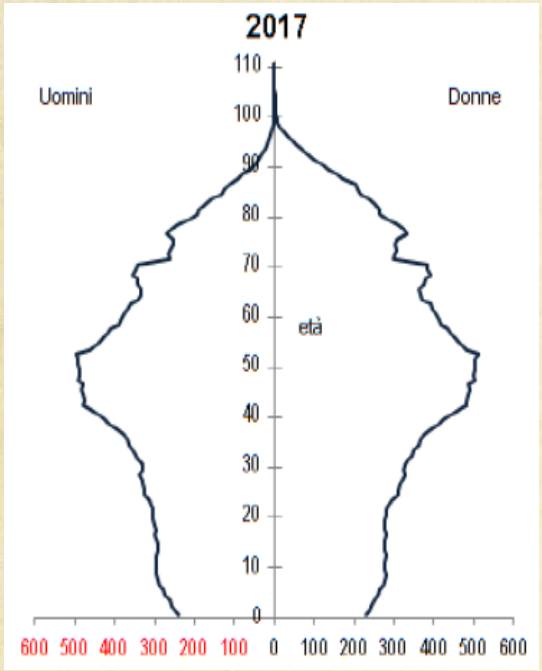


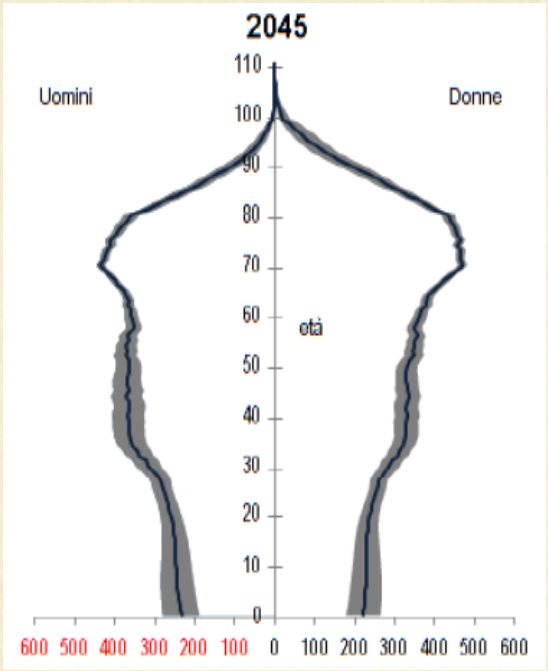
Epidemiologia e Vitamina D

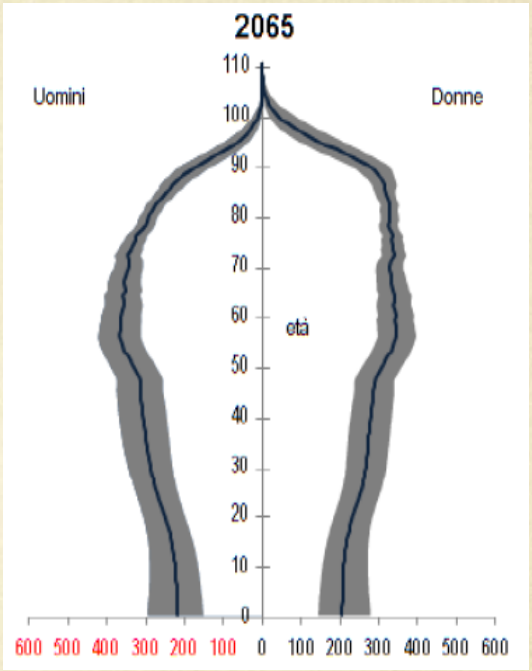


980–983, 2004 (46), with permission. © Elsevier.]. C, Reported incidence of vitamin D deficiency defined as a 25(OH)D $<$ 20 ng/mL around the globe including Australia (AU), Canada (CA), China (CH), India (IN), Korea (KR), Malaysia (MA), Middle East (ME), Mongolia (MO), New Zealand (NZ), North Africa (NA), Northern Europe (NE), United States (USA).

Epidemiologia e consumo del farmaco

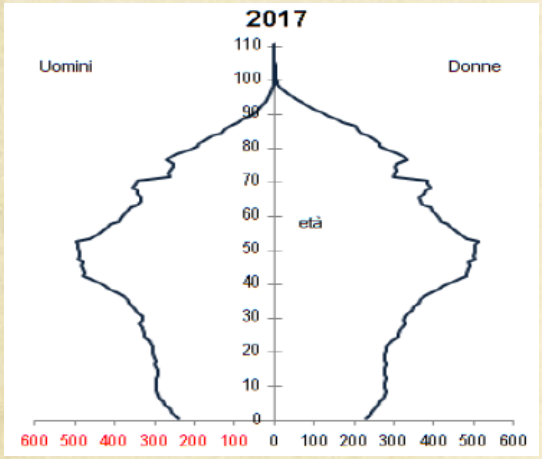


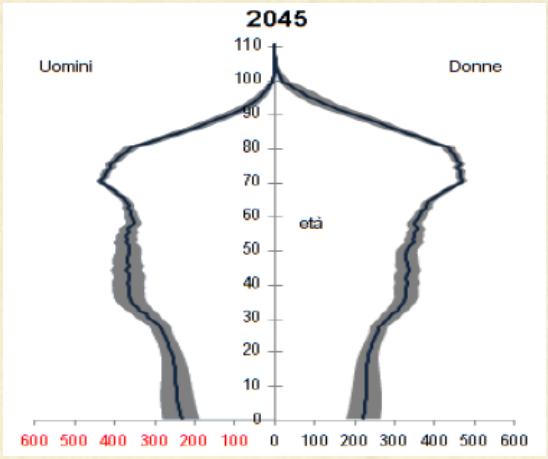


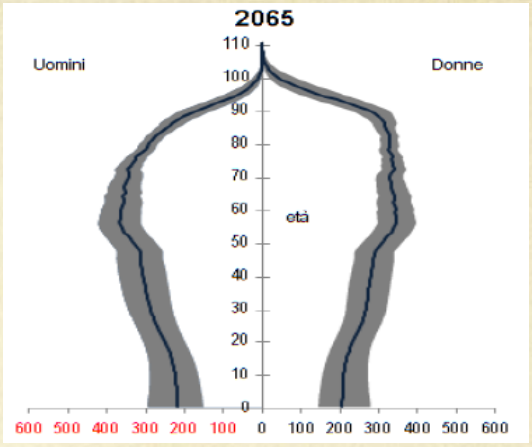


ISTAT –Report Il futuro demografico del paese. 3 maggio 2018

Epidemiologia e consumo del farmaco







ISTAT –Report Il futuro demografico del paese. 3 maggio 2018

In Italia

- Pantoprazolo, **colecalciferolo**, atorvastatina e amoxicillina in associazione con acido clavulanico rappresentano i primi principi attivi a brevetto scaduto in termini di spesa convenzionata.

- Il pantoprazolo e il **colecalciferolo** rappresentano le molecole che si associano alla più alta spesa pro capite (4,59 e 3,86 euro pro capite, rispettivamente) e rappresentano, insieme, la principale voce di costo della spesa farmaceutica convenzionata dei farmaci per l'apparato gastrointestinale (25,8%)

- il **colecalciferolo**, invece, passa dal terzo al quarto posto, in termini di spesa, e dal venticinquesimo al sedicesimo posto, in termini di consumo; inoltre questa molecola compare al quarto posto dei primi 30 principi attivi a maggiore variazione di spesa convenzionata rispetto all'anno precedente (+26,0%)

OSMED
L'uso dei Farmaci in Italia
Rapporto Nazionale. Anno 2017

In Italia

Tabella 2.8 Primi trenta principi attivi per spesa convenzionata di classe A-SSN: confronto 2017-2016

ATC	Principio attivo	Spesa (milioni)	%*	Spesa lorda pro capite	Rango 2017	Rango 2016
A	pantoprazolo	277,9	2,7	4,59	1	1
C	rosuvastatina	244,8	2,3	4,04	2	2
C	atorvastatina	234,5	2,3	3,87	3	3
A	colecalciferolo	233,9	2,2	3,86	4	6
C	ezetimibe/simvastatina	186,8	1,8	3,08	5	8
A	lansoprazolo	180,4	1,7	2,98	6	4
J	amoxicillina/acido clavulanico	173,7	1,7	2,87	7	7
A	omeprazolo	163,5	1,6	2,70	8	9
R	salmeterolo/fluticasone	161,3	1,5	2,66	9	5
A	esomeprazolo	149,2	1,4	2,46	10	11

OSMED
L'uso dei Farmaci in Italia
Rapporto Nazionale. Anno 2017

Dati di consumo in RER
8 mesi 18/17

Consumi territoriale: var 18/17 (%)

Descrizione	RER	PC	PR	RE	MO	BO	IM	FE	RA	FO	CS	RN	ROMAGNA
A11CC - VITAMINA D E ANALOGHI	9,4	30,4	17,2	6,3	3,9	12,6	17,1	6,4	5,0	2,5	4,4	8,4	5,9
A11CC02 - DIIDROTACHISTEROLO	-75,0					-75,0							
A11CC03 - ALFACALCIDOLO	-6,9	-18,5	-4,7	-16,6	-7,2	-5,9	0,5	-6,9	-6,0	-6,9	-5,5	12,7	0,7
A11CC04 - CALCITRIOLO	-2,4	-4,4	-1,3	0,5	0,2	-5,1	-4,9	-6,3	-5,2	4,0	-1,4	-3,4	-1,9
A11CC05 - COLECALCIFEROLO	7,7	19,8	14,7	4,0	2,8	12,7	20,2	1,9	6,0	1,4	5,3	8,2	6,2
A11CC06 - CALCIFEDIOLO	406,6	1133,5	335,9	513,5	199,9	292,1	96,0	646,2	80,4	318,1	-6,3	212,8	141,9

Fonte: Regione Emilia-Romagna Flussi farmaceutica territoriale

Dati di spesa RER e AUSL Bologna 8 mesi 18/17

	RER 8 mesi 2018 (€)	8 mesi 18vs17 (%)	AUSL BO 8 mesi 2018 (€)	8 mesi 18vs17
Colecalciferolo	9.399.505	3,1	2.261.791	0,1

Fonte: Regione Emilia-Romagna Flussi farmaceutica convenzionata

COLECALCIFEROLO
Formulazioni

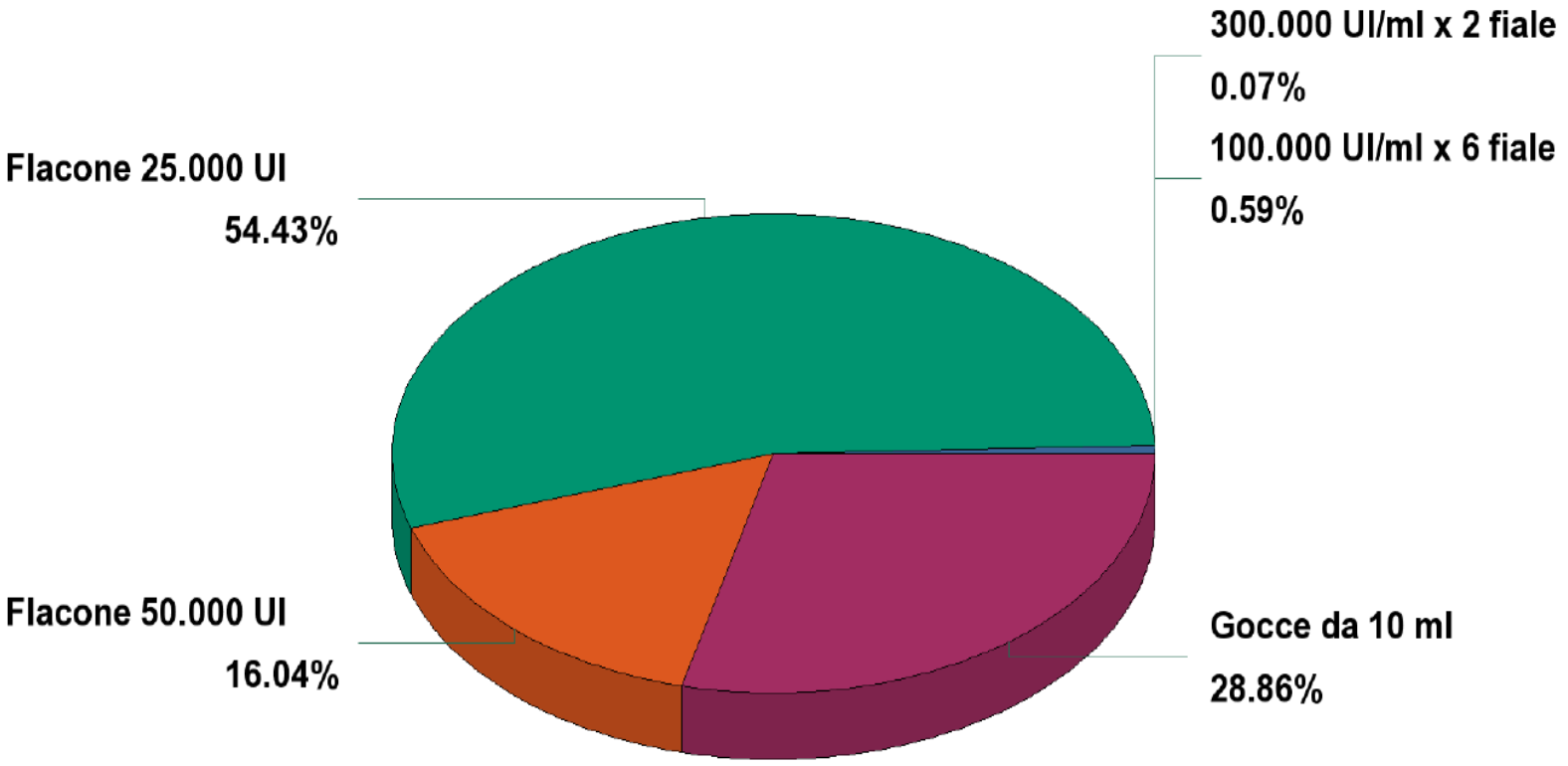
Tabella riepilogativa luglio 2017 - giugno 2018			
Formulazione	Importo Lordo	DDD dosi	Costo/DDD
Flacone 25.000 UI	1.635.142	913.528	1,79
Gocce da 10 ml	866.980	1.704.060	0,51
Flacone 50.000 UI	481.869	305.740	1,58
100.000 UI/ml x 6 fiale im e os	17.748	266.220	0,07
300.000 UI/ml x 2 fiale im e os	2.125	36.420	0,06
Totale	**3.003.863**	**3.225.968**	**0,93**

COLECALCIFEROLO

Dati: AUSL Bologna

	2017 S2					2018 S1				
Tipologia Formulazione	Importo lordo		DDD dosi		Costo/DDD	Importo lordo		DDD dosi		Costo/DDD
monodose	999.224	72,1%	704.888	48,2%	1,42	1.137.659	70,3%	817.020	46,4%	1,39
multidose	387.130	27,9%	758.860	51,8%	0,51	479.850	29,7%	945.200	53,6%	0,51
Totale	**1.386.354**	**100%**	**1.463.748**	**100%**	**0,95**	**1.617.509**	**100%**	**1.762.220**	**100%**	**0,92**

COLECALCIFEROLO
Dati di spesa: AUSL Bologna



ESTRAZIONE LUG-SET 2018

Reparto	Multidose	Monodose+Multidose	% Prescrizioni di Colecalciferolo Multidose
OB - PNEU	2	2	**100%**
BAZ - MED	3	6	**50%**
BEN - GER	7	7	**100%**
BEN - MED	1	3	**33%**
BUD - MED	31	33	**94%**
LOI - MED	9	9	**100%**
POR - MED	13	14	**93%**
SGP - MED	2	2	**100%**
VER - MED	2	2	**100%**
OM - GER	12	13	**92%**
OM - MED A - VASCOLARE	8	10	**80%**
OM - MED A - CARDIO-RENALE	1	1	**100%**
OM - MED A - PERI-CHIRURGICA	11	12	**92%**
OM - MED B	4	5	**80%**
OM - MED C	16	17	**94%**
OM - MED D	4	6	**67%**
OM - SU- GER	2	2	**100%**
TOTALE	128	144	**89%**

L'associazione

ACIDO ALENDRONICO E COLECALCIFEROLO

- In alcune preparazioni orali la Vit.D3 è associata all'alendronato.
- L'appropriatezza di quest'ultima associazione è discutibile essendo opposte le condizioni ottimali di assorbimento: a digiuno per l'alendronato, durante i pasti per la Vit.D.

	RER 8 mesi 2018 (€)	8 mesi 18vs17 (%)	AUSL BO 8 mesi 2018 (€)	8 mesi 18vs17
ACIDO ALENDRONICO E COLECALCIFEROLO	905.206	-25,5	180.516	-30,3

Conclusioni

- Il contesto attuale:
  - Costante crescita della richiesta di servizi
  - Invecchiamento della popolazione
  - Aumento delle patologie croniche, sviluppo di nuove tecnologie/progresso scientifico (farmaci sempre più costosi)
- e di progressiva riduzione delle risorse a disposizione

.....

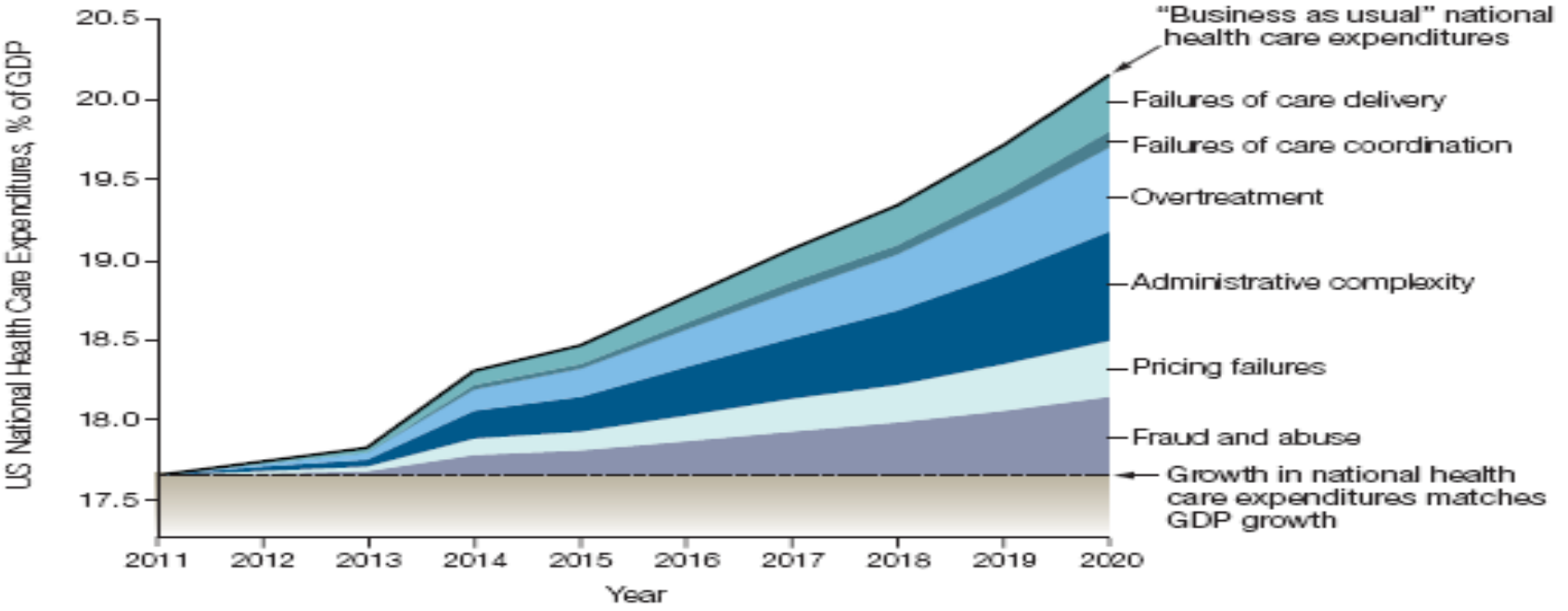
Eliminating Waste in US Health Care

Donald M. Berwick, MD, MPP
Andrew D. Hackbarth, MPhil

JAMA. 2012;307(14):1513-1516

Il Modello **dei** cunei

Figure. Proposed "Wedges" Model for US Health Care, With Theoretical Spending Reduction Targets for 6 Categories of Waste



The "wedges" model for US health care follows the approach based on the model by Pacala and Socolow.[9] The solid black "business as usual" line depicts a current projection of health care spending, which is estimated to grow faster than the gross domestic product (GDP), increasing the percentage of GDP spent on health care; the dashed line depicts a more sustainable level of health care spending growth that matches GDP growth, fixing the percentage of GDP spent on health care at 2011 levels. Between these lines lies the "stabilization triangle"—the reduction in national health care expenditures needed to close the gap. The 6 colored regions filling the triangle show one possible set of spending reduction targets; each region represents health care expenditures as a percentage of GDP that could be eliminated by reduction of spending in that waste category over time.

Eliminating Waste in US Health Care

Donald M. Berwick, MD, MPP
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JAMA. 2012;307(14):1513-1516

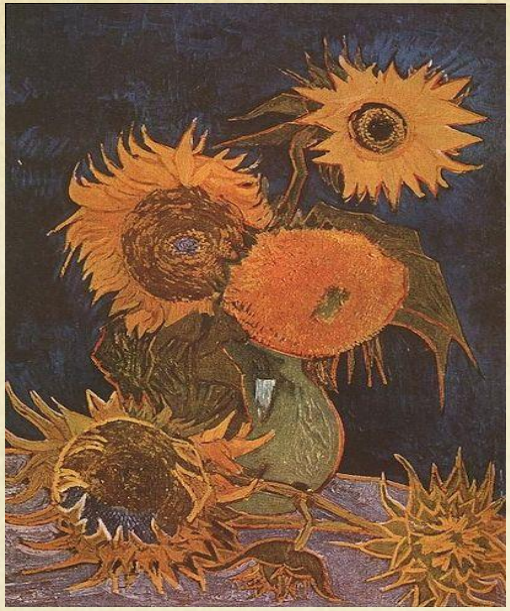
- Ridurre gli sprechi è di gran lunga la più grande, più umana, più intelligente opportunità per assicurare un sistema sanitario sostenibile.
- I margini peraltro sono così ampi che anche una piccola frazione può consentire di tutelare il SSN senza inficiare l'assistenza/trattamenti ai pazienti

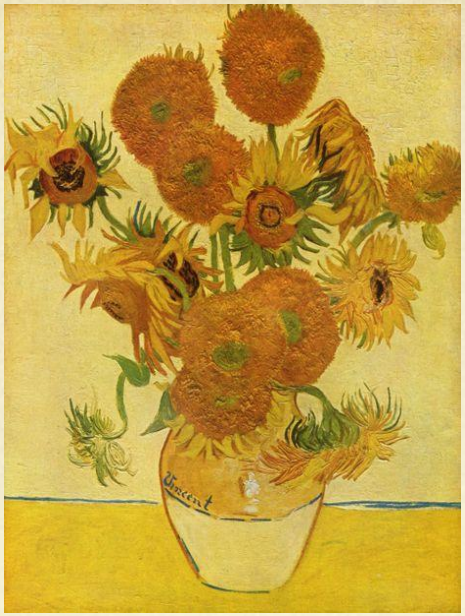
Spesa evitabile in 1 anno con **multidose** al 100% (€)	Spesa evitabile in 1 anno con **monodose** al 20% (€)
1.442.000	**980.000**

“Agisci sempre
come se le tue azioni
facessero la
differenza.

La fanno.”

William James





Grazie per l'attenzione

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