

DIABETE TIPO 1: COME È CAMBIATO IL TRATTAMENTO INSULINICO?

L'aderenza terapeutica quale cardine per l'ottimizzazione del controllo glicometabolico



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Potenziati conflitti di interesse

Compensi o finanziamenti negli ultimi due anni da:

- Astra Zeneca
- Boehringer Ingelheim
- Eli Lilly
- Mundipharma
- MSD
- Novo Nordisk
- Sanofi
- Servier

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Diabetes is associated with serious complications

Microvascular

Retinopathy,
glaucoma or
cataracts

Nephropathy

Neuropathy

Macrovascular

Cerebrovascular disease

Coronary heart
disease

Peripheral vascular
disease

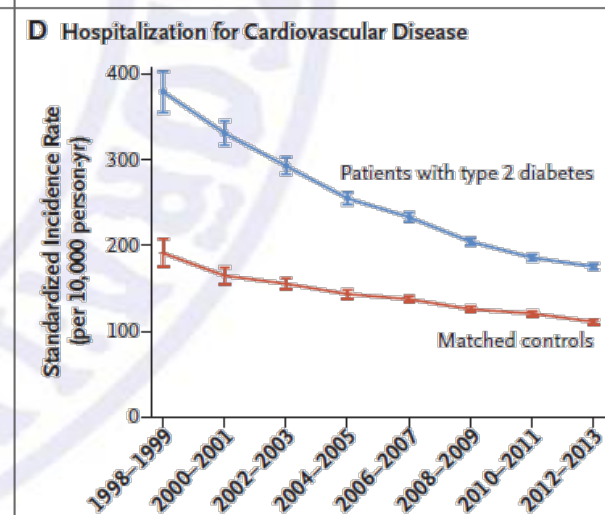
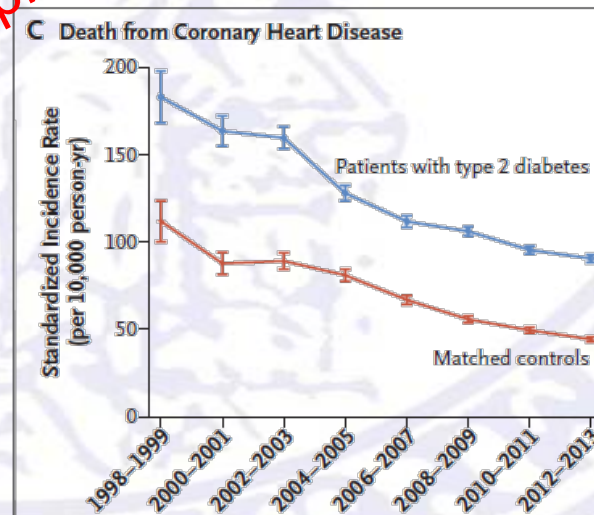
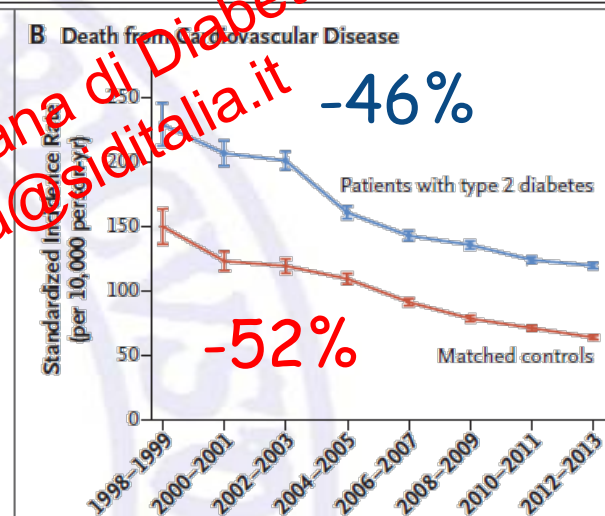
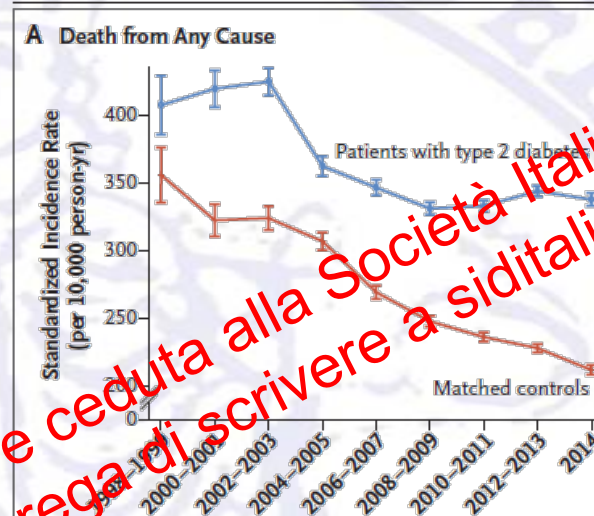
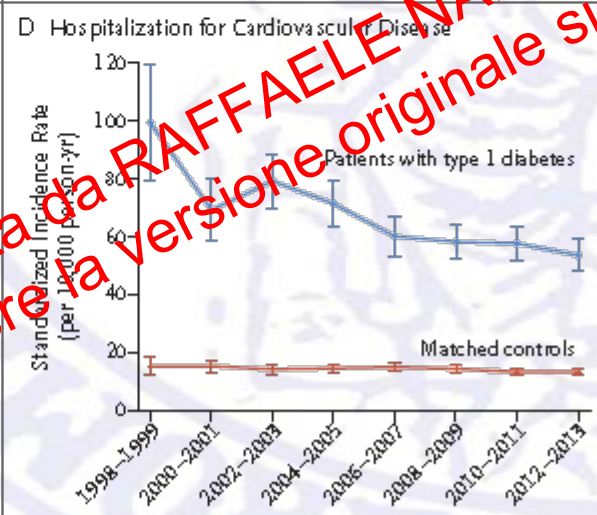
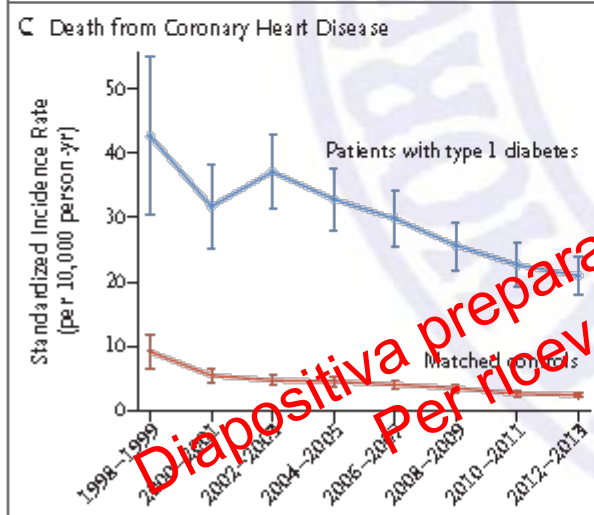
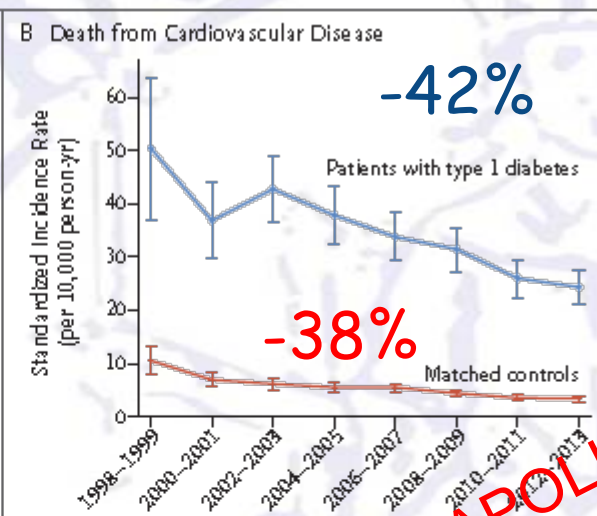
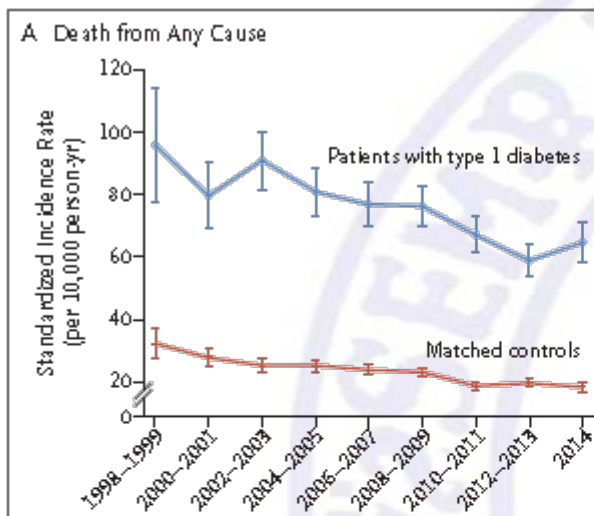


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Diabetes-related deaths in the Swedish NDR, 1998-2014

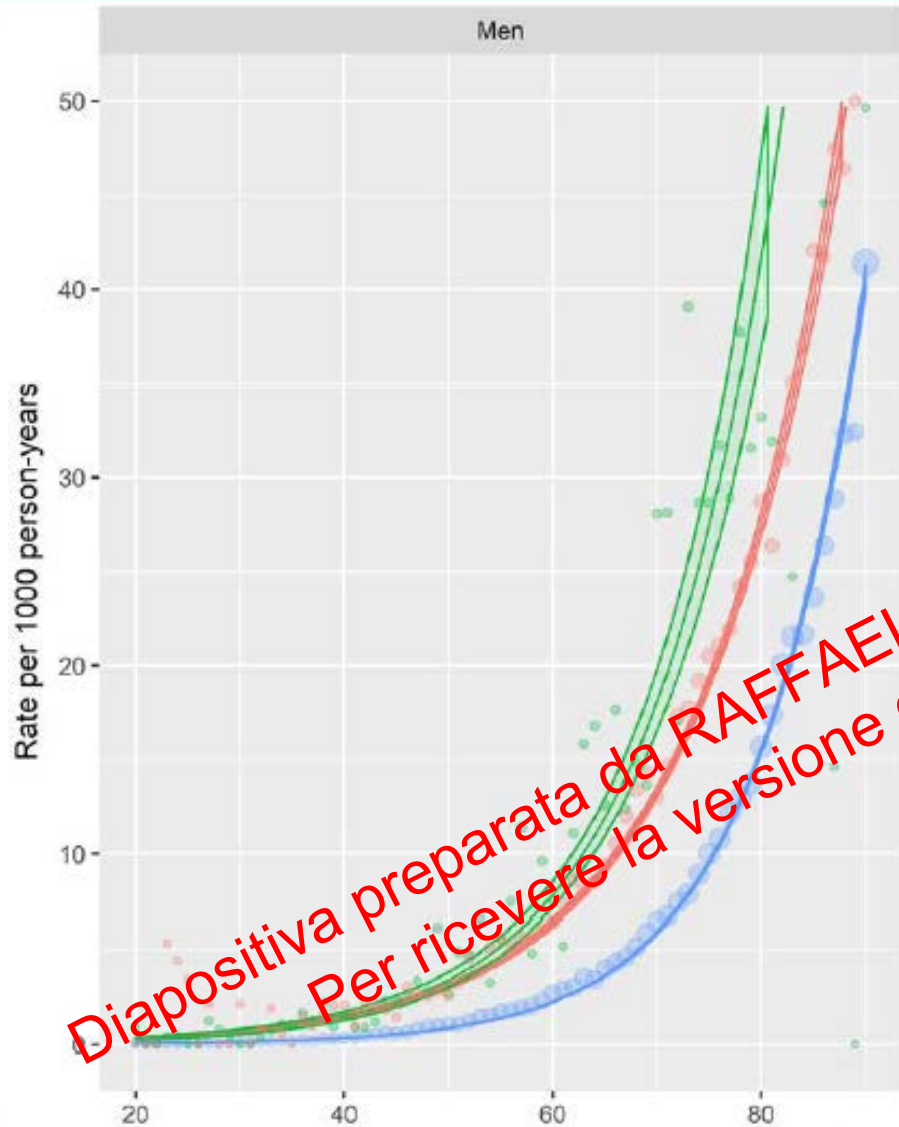
T1D

T2D

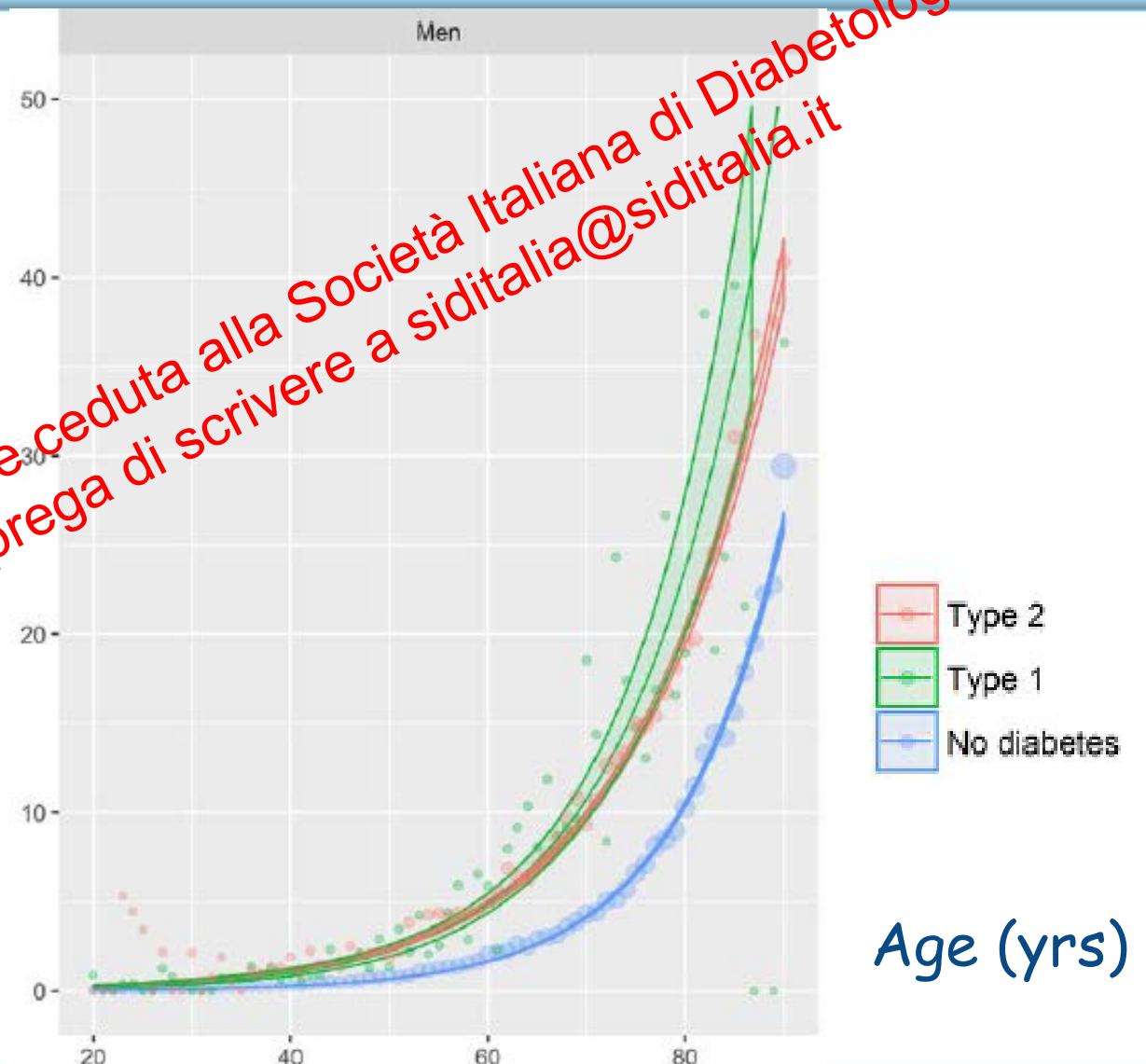


Age-, sex-, and deprivation-adjusted incidence of heart failure hospitalization by diabetes mellitus type and age in men with (A) or without (B) previous ischemic heart disease

A



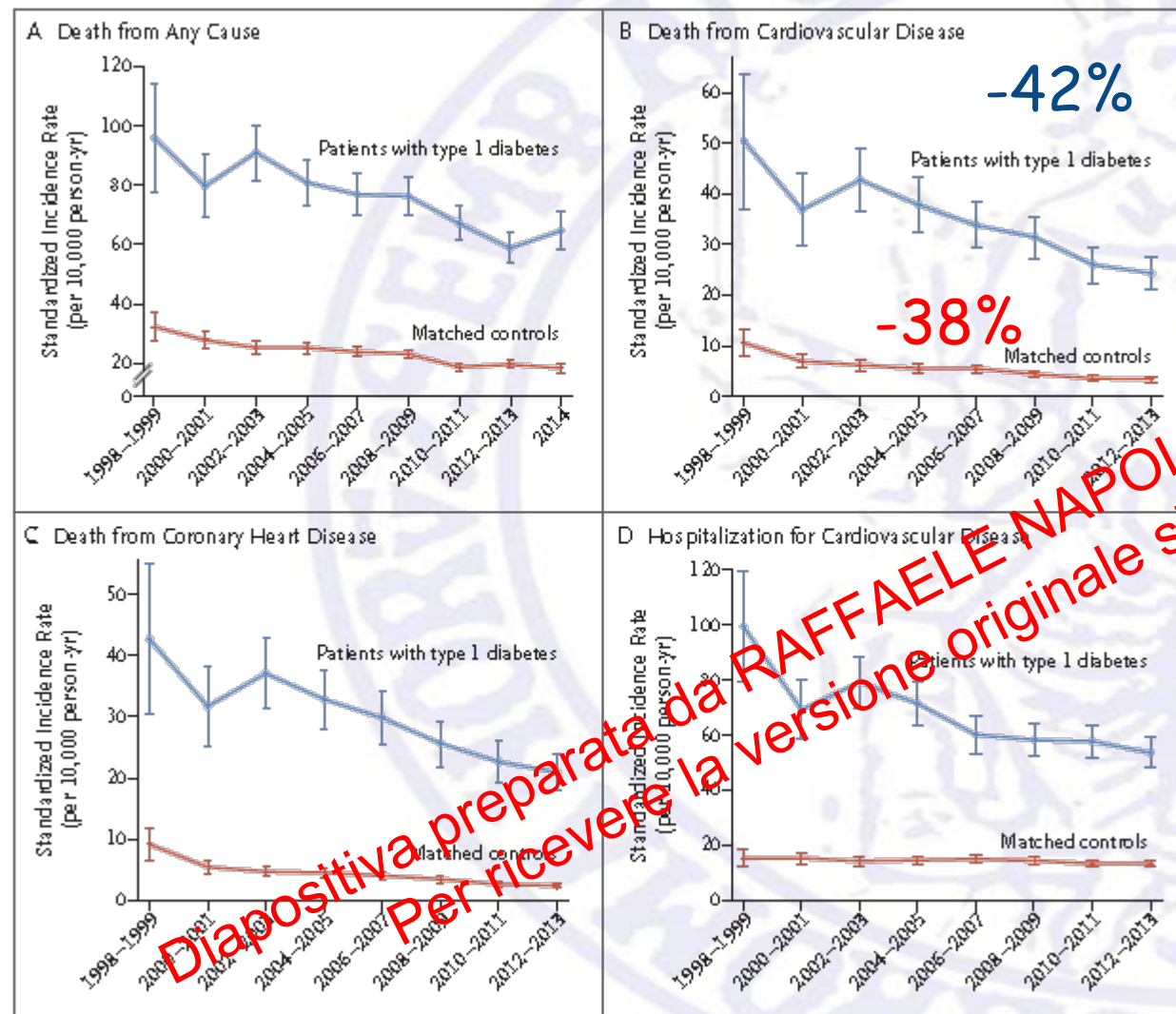
B



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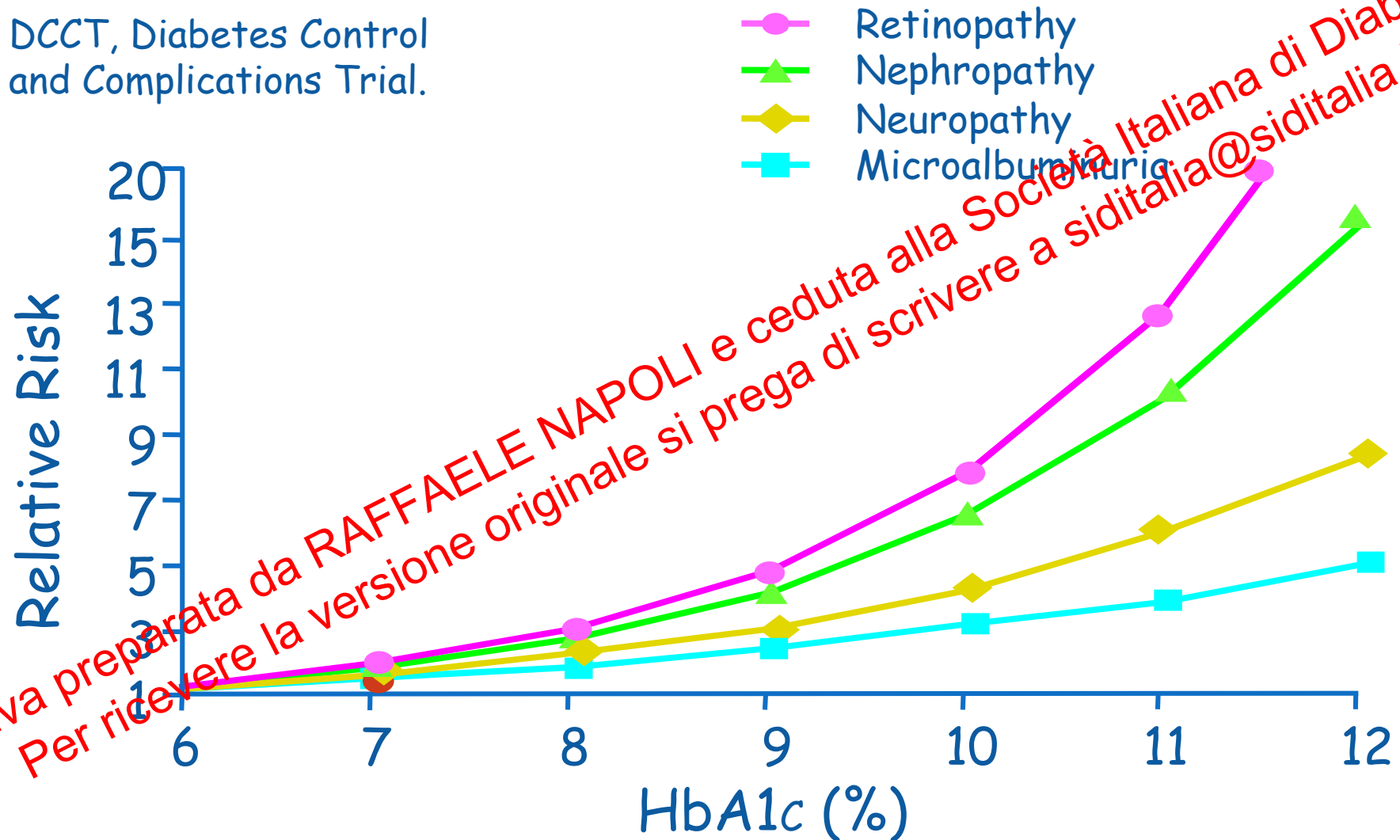
T1D



HbA1c
66.2 (8.2) → 68.4 mmol (8.41%)
-42%
-38%
+0.21%

HbA1c and Relative Risk of Microvascular Complications

DCCT, Diabetes Control and Complications Trial.



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Impact of Intensive Therapy for Diabetes

Study	Microvasc		CVD		Mortality	
UKPDS	↓	↓	↔	↓	↔	↓
DCCT / EDIC*	↓	↓	↔	↓	↔	↔
ACCORD	↓	↓	↔	↔	↑	↑
ADVANCE	↓	↓	↔	↔	↔	↔
VADT	↓	↓	↔	↔	↔	↔

* in T1DM

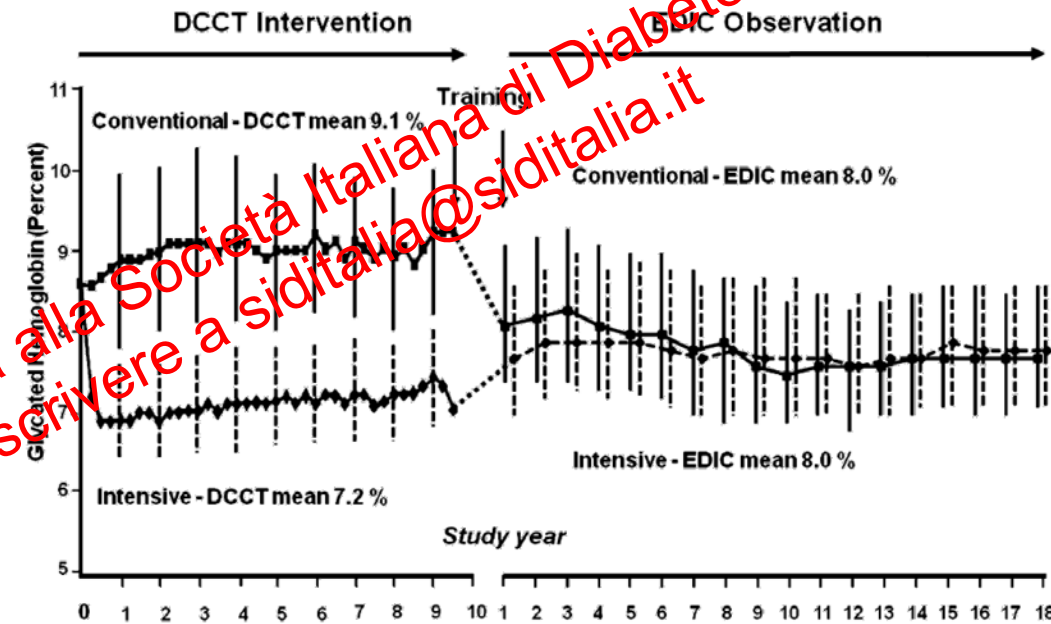
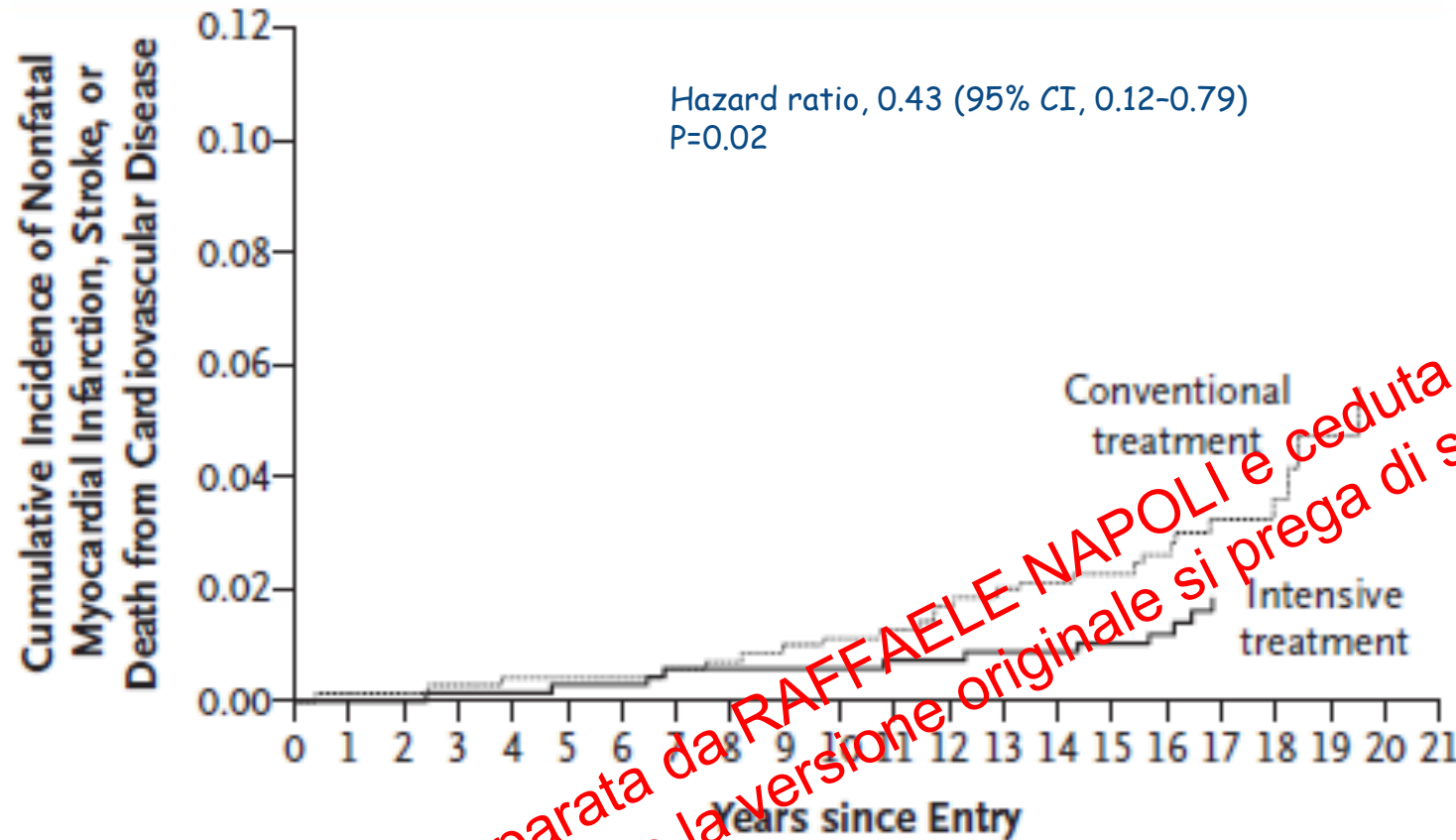


Initial Trial



Long Term Follow-up

Cumulative Incidence of the First Occurrence of MACE

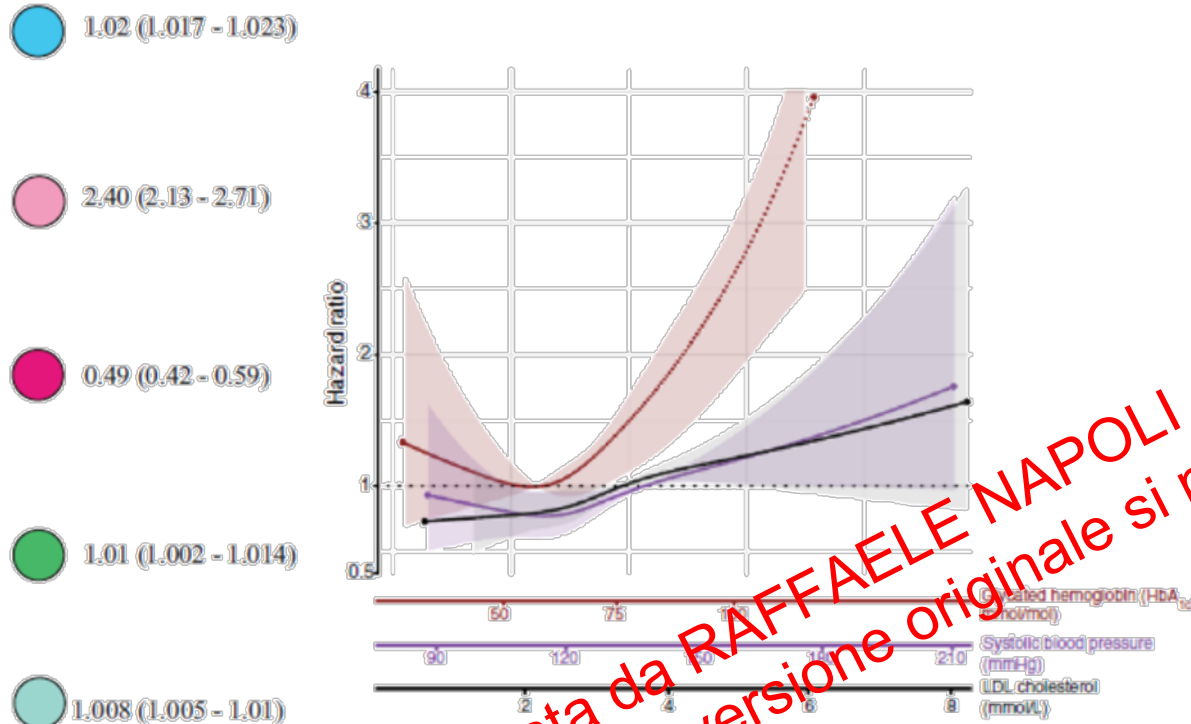


No. at Risk

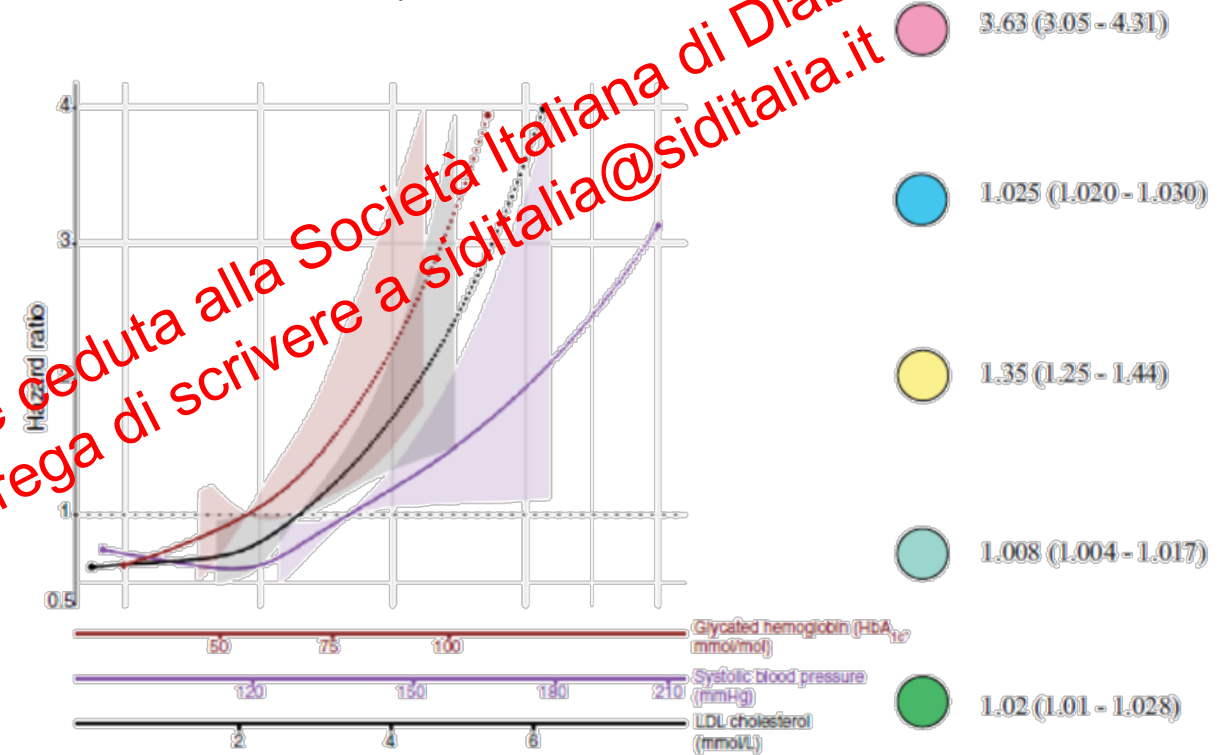
Intensive treatment	705	686	640	118
Conventional treatment	721	694	637	96

Strength of association for the most important risk factors and Hazard Ratio for all-cause mortality and hospitalization for heart failure

All-cause mortality



Heart failure

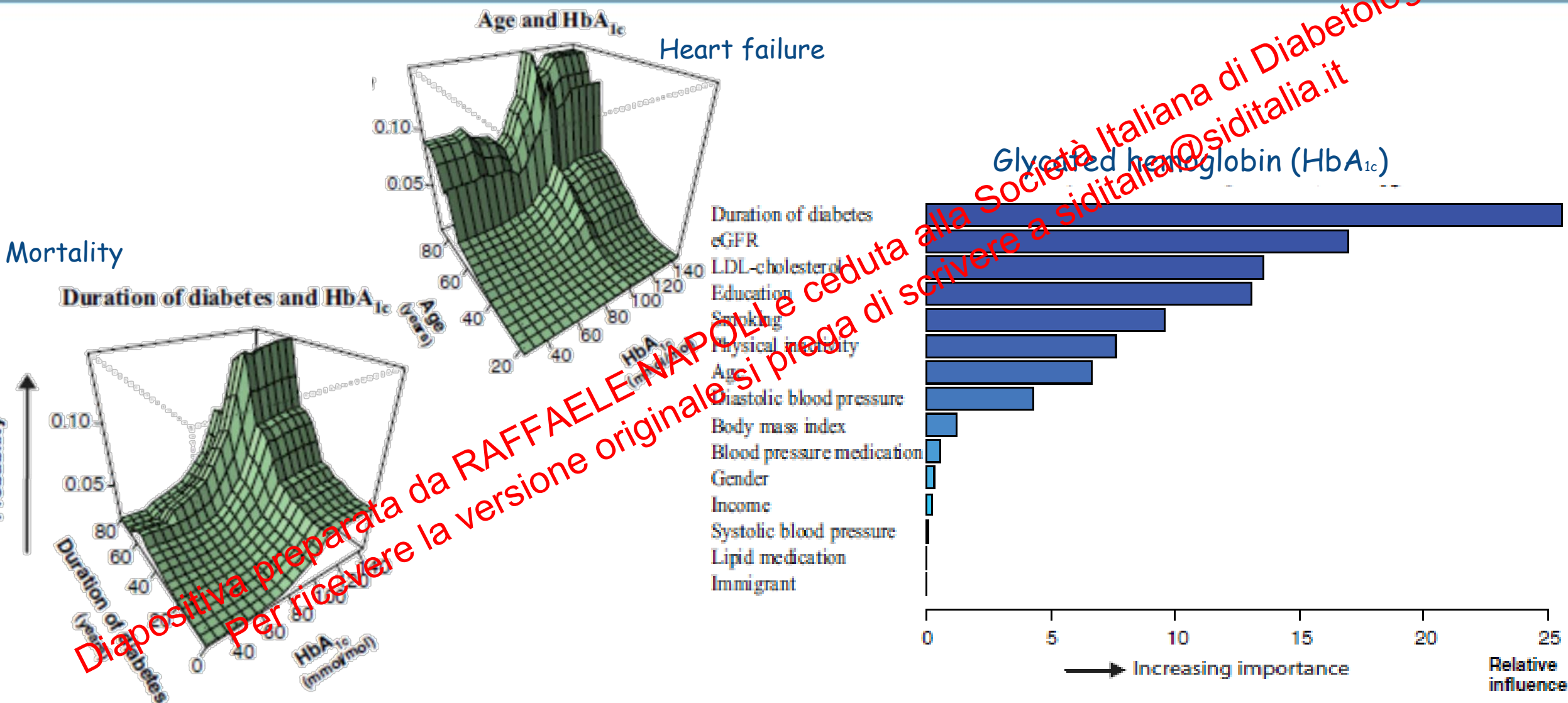


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Legend for risk factors:

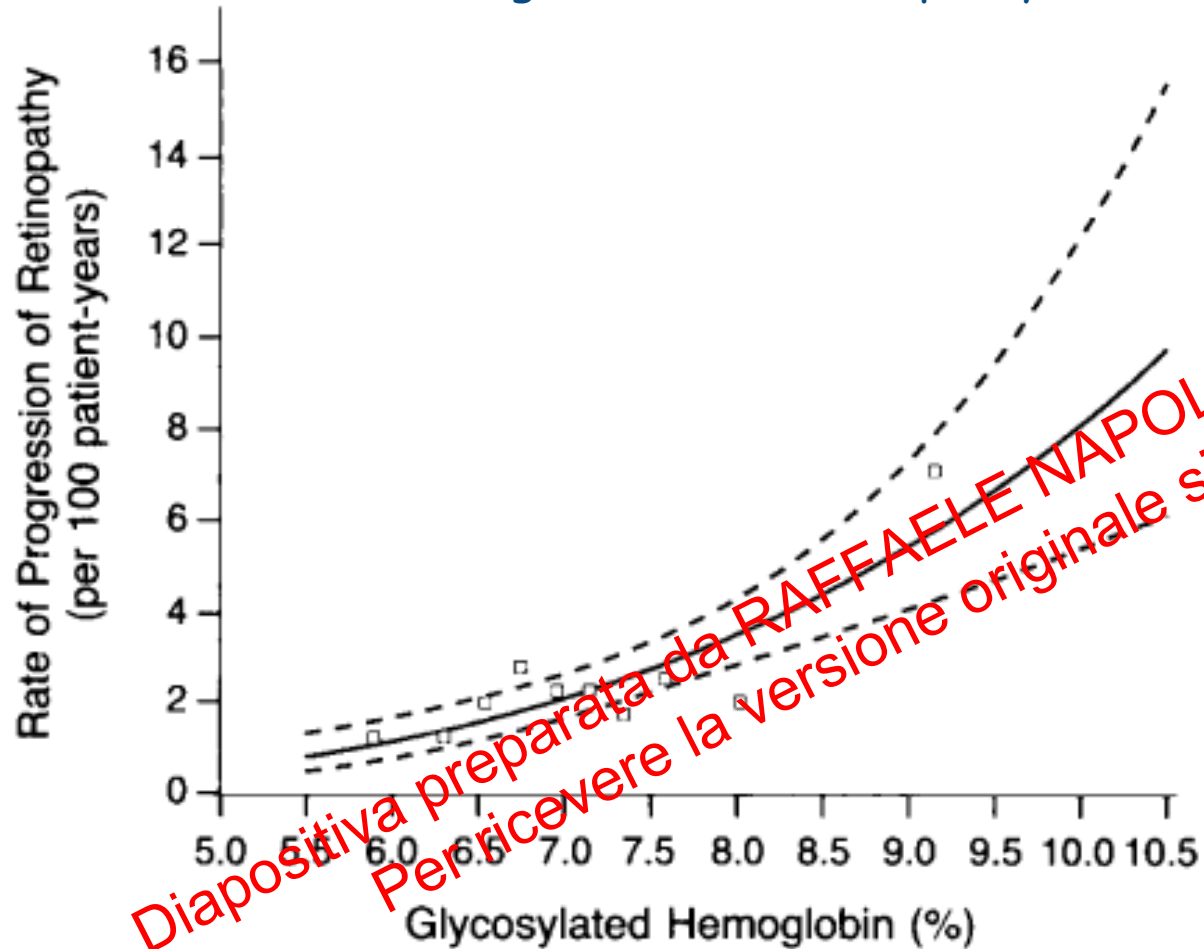
- HbA_{1c} (mmol/mol)
- Income (4 levels)
- Albuminuria/eGFR (micro- or macroalbuminuria /ml/min/1.73 m²)
- Duration of diabetes (years)
- LDL-cholesterol (mmol/L)
- Systolic BP (mmHg)

Costing for Mortality and Heart Failure and Strength of association of predictors for HbA1c in T1D

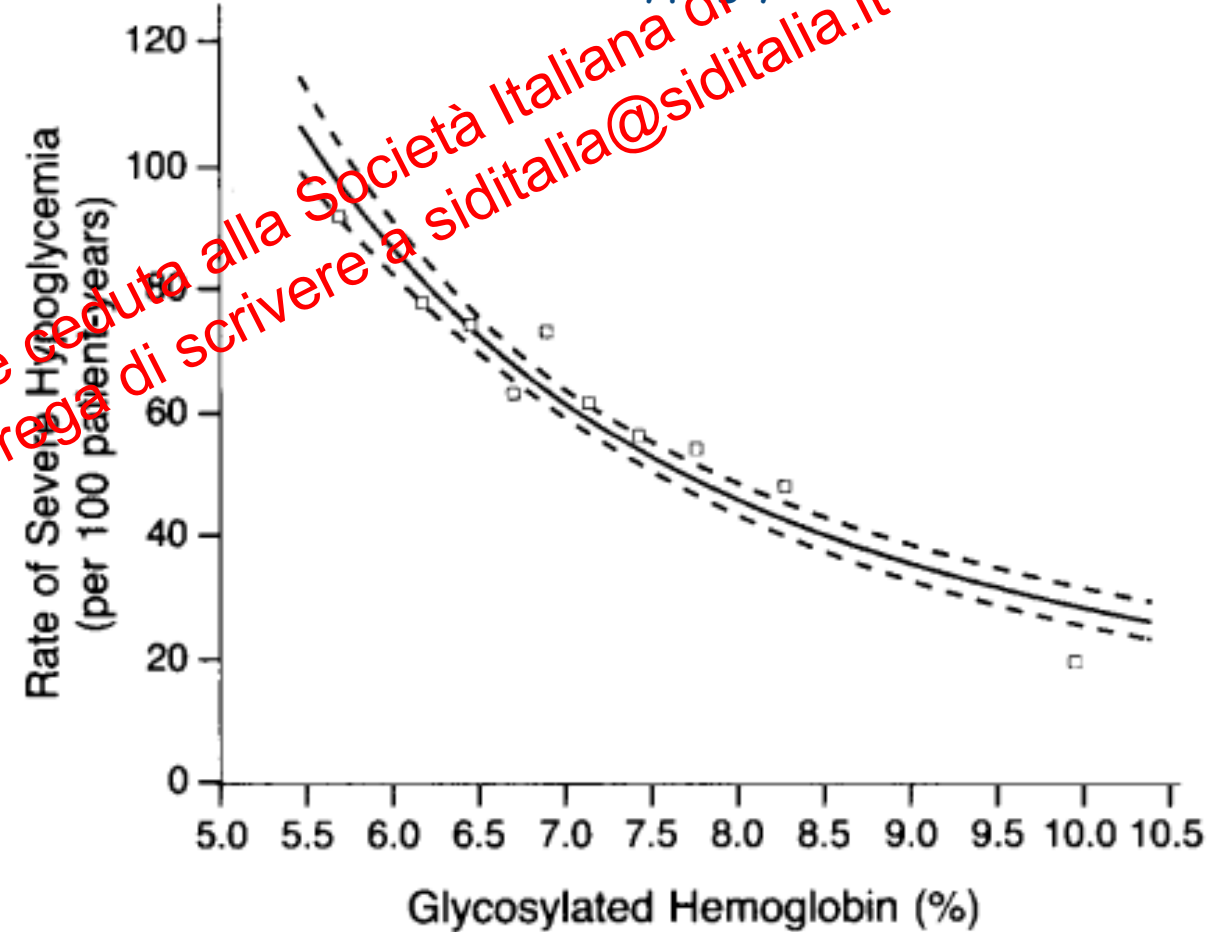


HbA1c, Progression of Retinopathy, and Severe Hypoglycemia

Progression of Retinopathy

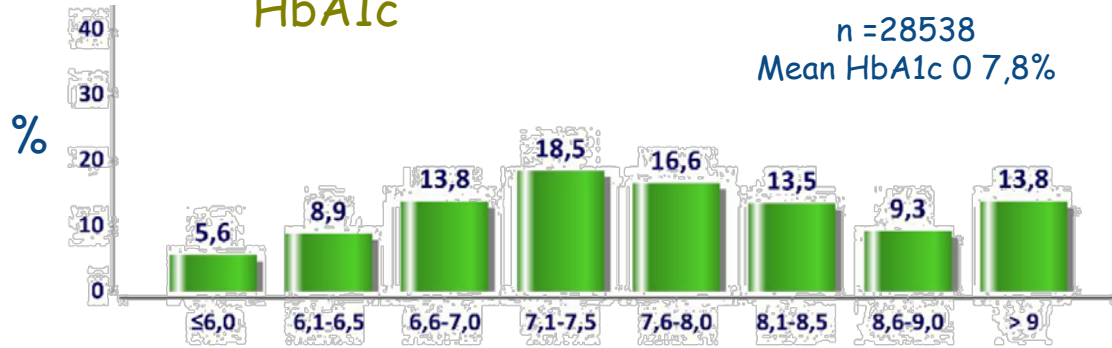


Severe Hypoglycemia

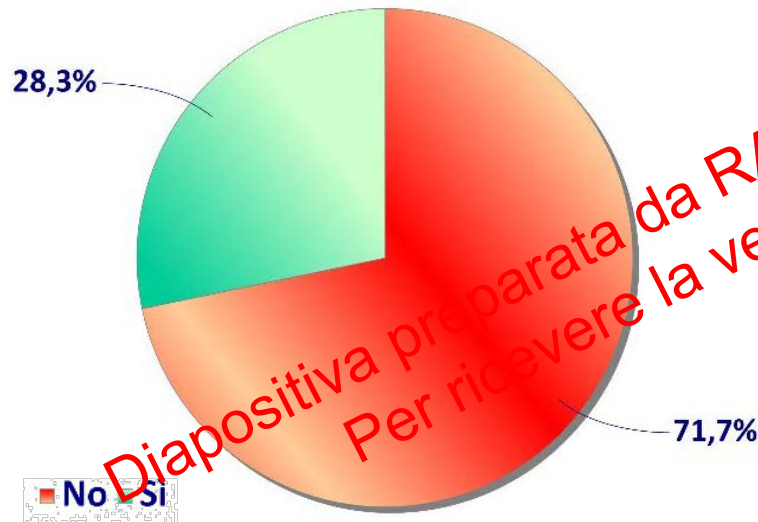


Livelli di HbA1c e Fattori di Rischio Maggiori nei pazienti con T1D

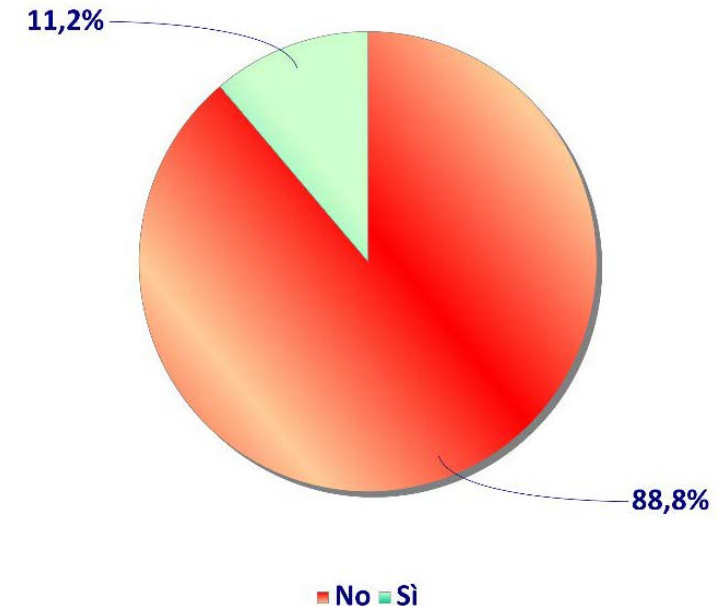
HbA1c



Soggetti con HbA1c ≤ 7,0%



Soggetti con HbA1c ≤ 7,0% (53 mmol/mol), colesterolo LDL < 100 mg/dl e pressione arteriosa < 140/90 mmHg



Adherence to recommendations for diabetes treatment

- self-monitoring of blood glucose,
- administration of insulin or oral hypoglycemic agents,
- diet,
- physical activity
- foot care,
- other self-care practices

Cardiovascular health in adults with type 1 diabetes

T1D Exchange Clinic registry (67 US endocrinology practice)

Ideal cardiovascular health factor	All n = 7153
Hemoglobin A1c < 7%	1820 (27%)
Exercise ≥ 150 min/week	2377 (33%)
Blood pressure < 120/80 mm Hg*	2319 (46%)
Body mass index < 25 kg/m ²	2295 (42%)

Brasil

Author	Number	HbA1c (%) (mean ± SD)	Percentage of patients on glycemic target*
Rodrigues et al. 2010 [10] ^a	573	9.0 ± 2.9	22.0 %
Mendes et al. 2010 [49] ^b	979	-	7.0 %
Gomes et al. 2012 [50] ^c	5591	9.1 ± 2.3 to 9.4 ± 2.6	12.2 to 21.4 %
Gomes et al. 2012 [51] ^d	1774	9.1 ± 2.2	11.6 %
Viana et al. 2013 [52] ^e	1026	9.3 ± 2.3	13.0 %

Logistic regression analysis of factors associated with HbA1c < 7%

Factor	Adjusted Odds Ratio	95% CI
Education		
<High school diploma	Reference	
Bachelor degree	0.53	0.34-0.81
Master degree	0.43	0.27-0.66
Professional or doctoral degree	0.40	0.25-0.66
Employment		
Retired	Reference	
Full- or part-time	1.7	1.3-2.1
Student	1.7	1.2-2.4
Marital status		
Married	Reference	
Single	1.6	1.3-1.9
General health		
Good-excellent	Reference	
Fair-poor	1.6	1.2-2.1
Missed insulin dose		
Almost never	Reference	
<once/month	1.5	1.2-1.8
<once/week	2.2	1.8-2.8
1-2x/week	3.9	2.9-5.1
3-4x/week	4.2	2.7-6.4
≥5x/week	4.6	2.0-10.9
At least 1x/day	5.02	2.1-11.8
Blood glucose checks/day (each 1-check f)	0.91	0.88-0.93
Use of continuous glucose monitor		
No	Reference	
Yes	0.74	0.6-0.9
T1D duration (each 1-year f)	1.02	1.01-1.02

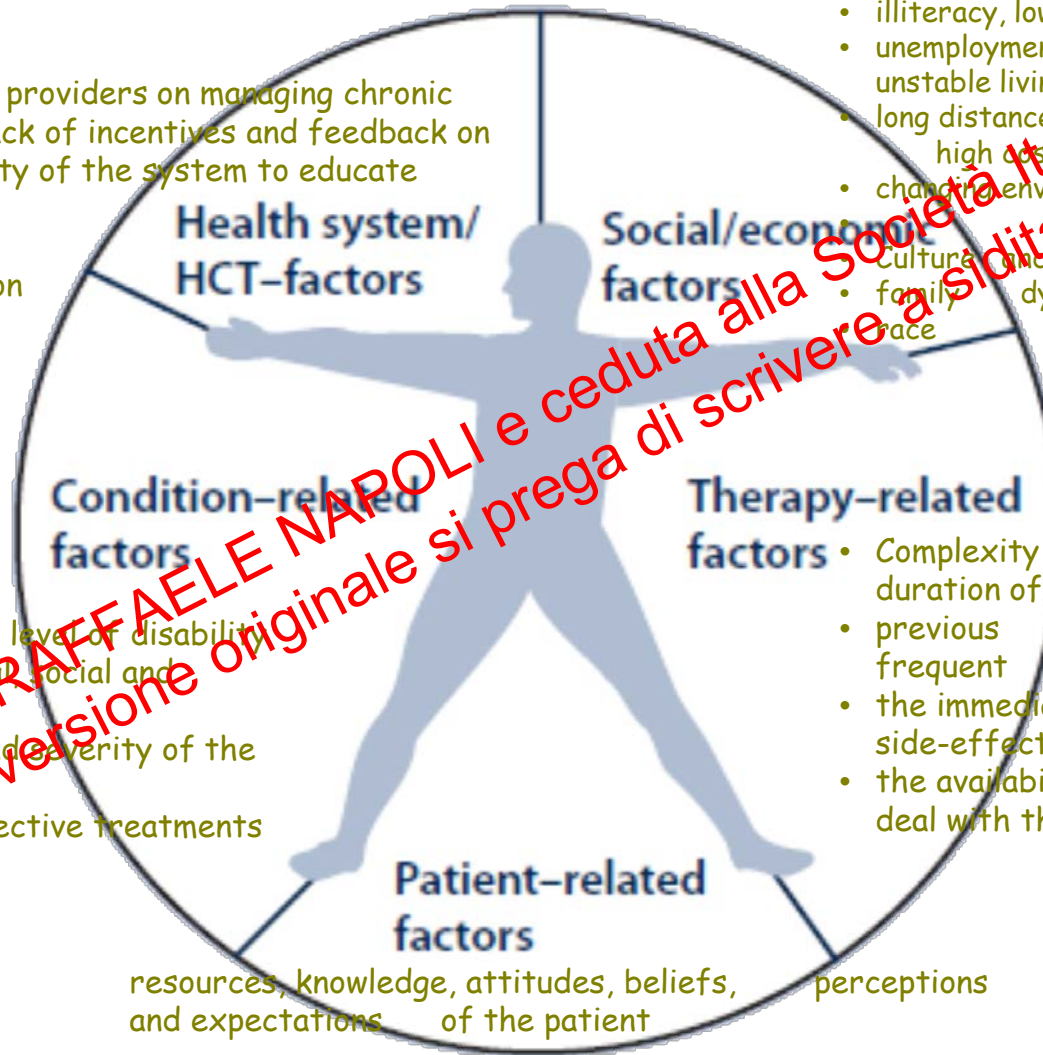
Adherence to long term therapy

'the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes - corresponds with agreed recommendations from a health care provider'.

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The five dimensions of adherence

- poorly developed health services with inadequate or non-existent reimbursement by health insurance plans,
- poor medication distribution systems,
- lack of knowledge and training for health care providers on managing chronic diseases, overworked health care providers, lack of incentives and feedback on performance, short consultations, weak capacity of the system to educate patients and provide follow-up,
- inability to establish community support and self-management capacity, lack of knowledge on adherence and of effective interventions for improving it.



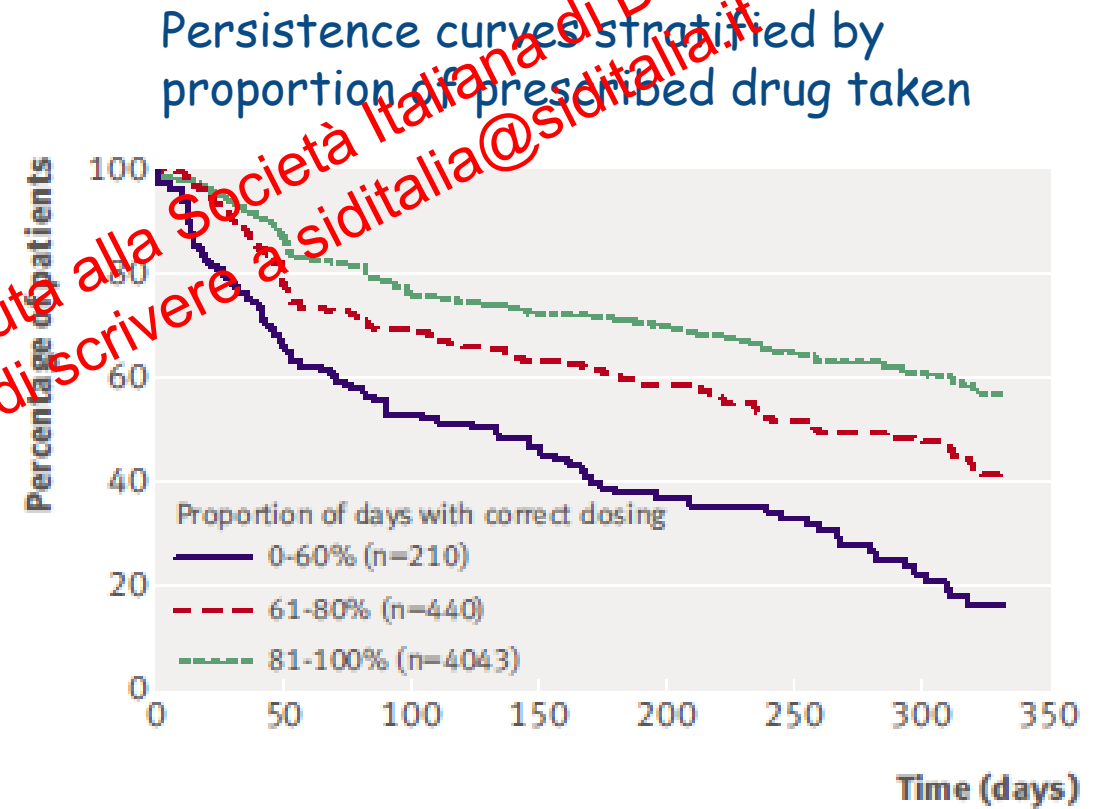
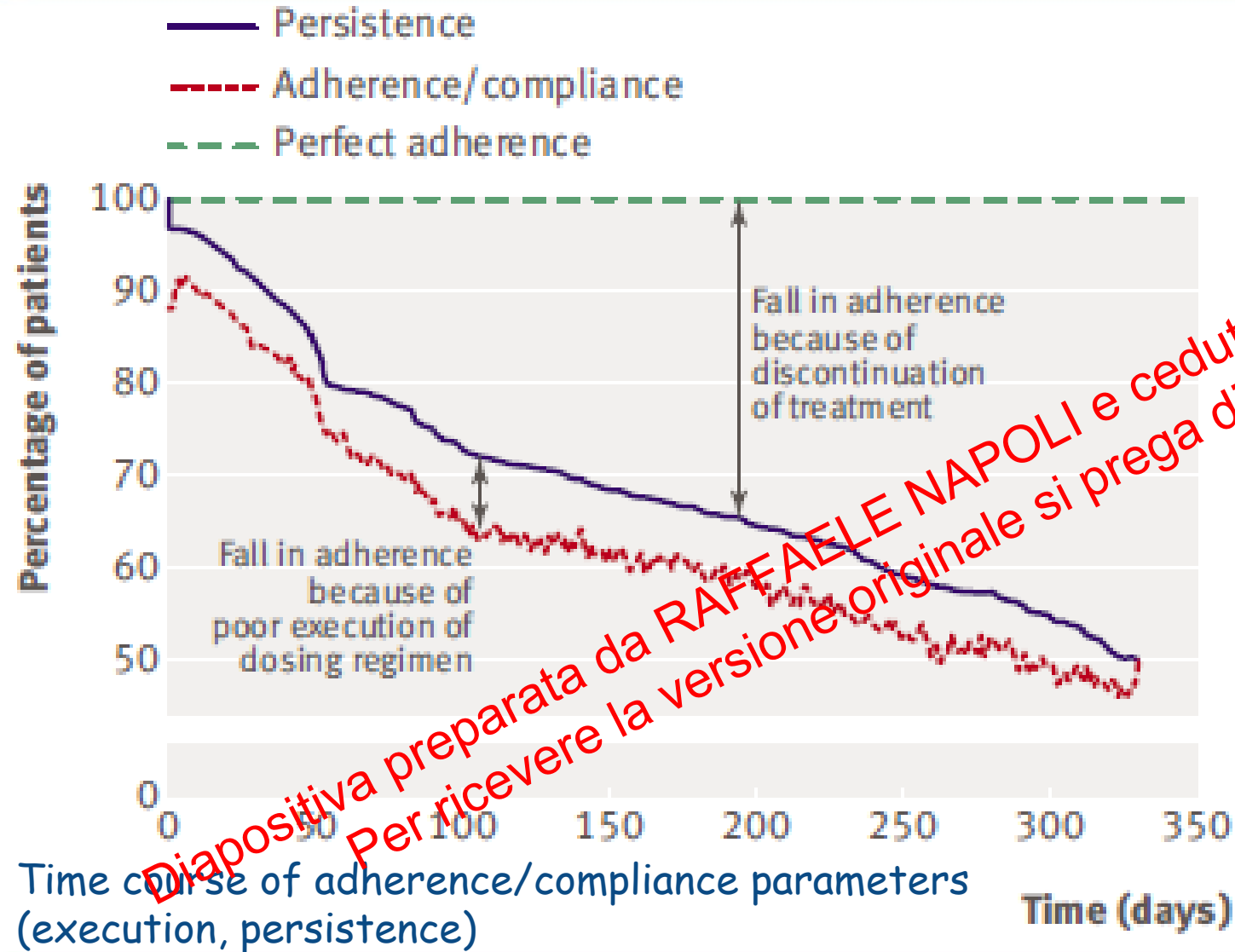
- poor socioeconomic status,
- illiteracy, low level of education,
- unemployment, lack of effective social support networks, unstable living conditions,
- long distance from treatment centre, high cost of transport, high cost of medication,
- changing environmental situations,
- cultural and lay beliefs about illness and treatment,
- family dysfunction, age, race

- severity of symptoms, level of disability (physical, psychological, social and vocational),
- rate of progression and severity of the disease,
- the availability of effective treatments
- co-morbidities,

- Complexity of the medical regimen, duration of treatment,
- previous treatment failures, frequent changes in treatment,
- the immediacy of beneficial effects, side-effects, and
- the availability of medical support to deal with them.

resources, knowledge, attitudes, beliefs, and expectations of the patient

Persistence, Adherence and compliance



Methods for assessing adherence to a medication regimen.

Method	Type of Data	Advantages	Disadvantages	Method	Type of Data	Advantages	Disadvantages
Drug level in biologic fluids	Qualitative	Recent use verified	Data limited to recent use Patient-specific kinetic variations	Adherence questionnaire	Qualitative	Easy to administer (on site, mail, phone) Validated May explain patient behavior	Lack of continuous data Accuracy is instrument dependent
Biologic markers	Qualitative	Recent use verified	Data limited to recent use Patient-specific kinetic variations	Pill count	Quantitative	Easy to use Inexpensive	No data on regimen adherence Patient may forget or alter unused portion
Direct patient observation	Quantitative	Verified use	Impractical in outpatient setting	Prescription record review, manual	Quantitative	Noninvasive	Limited to specific location
Patient interview	Qualitative	Easy to use Inexpensive	Influenced by question construction and interviewer's skill	Prescription record review, electronic	Quantitative	Noninvasive Long-term data Large populations	Knowledge of database required Validity of variables
Patient-kept diary	Quantitative	Only self-report method with regimen data	Potential for overestimation Patient must return diary	Electronic monitoring	Quantitative	Precise data on regimen adherence	Expensive Inconvenient

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A Systematic Review of Insulin Adherence Measures in Patients with Diabetes

Adherence Measures	Calculation Method	Number of References Using This Measure	Areas of Divergence	Adherence Measure Advantages and Disadvantages
Medication possession ratio	Using prescription data from pharmacy claims $\text{MPR} = \frac{\text{Total days supply of all prescriptions in defined period}}{\text{Number of days in the defined period}}$ Value between 0 and 1, 1 being 100% adherent Patients are usually considered adherent at an $\text{MPR} \geq 0.8$ (80%).¹⁸	n = 22 ¹⁶⁻³⁷	Denominator as number of days from first fill until last fill or 1 year or otherwise modified (e.g., excluding days hospitalized or overlap in fills)	Advantages: • Uses pharmacy claims data • Relatively easy to calculate Disadvantages: • Presence of pharmacy claim does not indicate medication taken • Can overestimate adherence if patients refill prescriptions early • Pharmacy claims data affected by wastage and stockpiling • Relies on days supply in calculation
Adjusted medication possession ratio method	Using prescription data from pharmacy claims $\text{Adjusted MPR} = \frac{\text{Average days between prescription refills}}{\text{Average days supply}}$ Used to account for the differences in pack sizes between insulin devices	n = 11 ^{30,31,35-43}	Correct the issue that almost all prescriptions are dispensed with a 30-day supply period even though patients may have more insulin than ordered due to variations in their daily dosing (dependent on body weight and glyce-mic control). ³⁵	Advantages: • Uses pharmacy claims data • Ability to adjust for differences in insulin pack sizes and correct for prescriptions dispensed with 30-day supply period Disadvantages: • Pharmacy claims data affected by wastage and stockpiling • Adjustment factor not standardized • Relies on days supply in calculation

A Systematic Review of Insulin Adherence Measures in Patients with Diabetes

Adherence Measures	Calculation Method	Number of References Using This Measure	Areas of Divergence	Adherence Measure Advantages and Disadvantages
Proportion of days covered	Using prescription data from pharmacy claims $PDC = \frac{\text{Days supplied between first and last prescription}}{\text{Days between first fill and end of the measurement period}}$ Patients are usually defined as adherent if they have a $PDC \geq 80\%$.⁶⁵ Endorsed by the PQA as the preferred method for measuring medication adherence⁴⁴	n = 10 ⁴⁴⁻⁵³	Can adjust for overlapping prescriptions, different types of medication and adjust for proportion of days spent in hospital. When calculating the PDC for a single drug, it can be considered the same as the MPR measure. It is calculated using the full analysis period as the denominator, if the MPR is capped at 1.⁴⁹	Advantages: • Uses pharmacy claims data • Method endorsed by the PQA as preferred method of measuring adherence • Accounts for overlap in days supply • More accurate when calculating adherence to medication regimens Disadvantages: • Does not account for differences in insulin pack size • Pharmacy claims data affected by wastage and stockpiling • Relies on days supply in calculation
Persistence	Using prescription data from pharmacy claims: Patients remaining on the study drug for the entire follow-up period without discontinuation or switching after initiation of the index drug	n = 24 ^{11,17,24,30,31,35-37,39-43,54-64}	Time between refills (gaps) and proportion of patients not refilling in time	Advantages: • Uses pharmacy claims data • Assesses treatment discontinuation Disadvantages: • Pharmacy claims data affected by wastage and stockpiling • Measure indicates patient is persistent but does not measure compliance with physician's recommendations • A predefined treatment gap is not suitable for measuring persistence with injectables due to variable-dose titration schedules

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Adherence Measures	Calculation Method	Number of References Using This Measure	Areas of Divergence	Adherence Measure Advantages and Disadvantages
Daily average consumption	Using prescription data from pharmacy claims $DA\text{CON} = \frac{\text{Total number of units dispensed}}{\text{Number of days between index date and date of last fill}}$ where Total units dispensed = total milliliters dispensed for all prescriptions in follow-up period $\times$ 100 No benchmark exists for DAICON representing good adherence.	n = 12 ^{30,31,36-39,41-43,56,60,64}	Can adjust for units dispensed and can account for type of insulin administered when interpreting results	Advantages: • Uses pharmacy claims data • Accounts for differences in insulin pack size • Easily calculated • Avoids use of days supply Disadvantages: • No validated threshold for good adherence • Pharmacy claims data affected by wastage and stockpiling • Inter- and intrapersonal variability could confound results in large datasets
Morisky Medication Adherence Scale	Patient self-report measures with 4 or 8 items that can be scored as either yes (0) or no (1) MMAS-4 scores: 0 = high adherence; 1-2 = medium adherence; 3-4 = low adherence MMAS-8 scores: 0 = high adherence; 1-2 = medium adherence; 3-8 = low adherence⁶⁶	MMAS-4 n = 6 ⁶⁷⁻⁷² and MMAS-8 n = 3 ⁷³⁻⁷⁵	Not applicable	Advantages: • Can be used to gather information on reasons for nonadherence • Self-reported surveys often increase compliance, as the individuals know they are being observed Disadvantages: • Self-reported measure where patients may be dishonest • Complexity and cost of data collection when implementing as a quality measure

Correlates of Insulin Injection Omission in T1d And T2D

- Internet survey of 502 U.S. adults self-identified as taking insulin by injection to treat type 1 or type 2 diabetes
- Intentional insulin omission was reported by more than half of respondents (57%); regular omission was reported by 20%.
- Significant independent risk factors for insulin omission were: younger age, lower income and higher education, type 2 diabetes, not following a healthy diet, taking more daily injections, interference of injections with daily activities, and injection pain and embarrassment.
- Risk factors differed between type 1 and type 2 diabetic patients, with diet nonadherence more prominent in type 1 diabetes and age, education, income, pain and embarrassment more prominent in type 2 diabetes.

Multiple regression analysis of frequency of insulin injection omission

	B	SE	β	Significance
Female sex*	0.045	0.077	-0.028	0.499
White race/ethnicity†	-0.005	0.073	-0.003	0.936
Current age (years)	-0.025	0.003	-0.256	<0.001
Education‡				
Some college	-0.001	0.076	-0.001	0.990
College graduate	-0.023	0.100	-0.010	0.818
Graduate school	0.303	0.121	0.109	0.012
Employment§				
Not employed (student)	0.273	0.125	0.094	0.030
Not employed (disabled)	-0.317	0.120	-0.107	0.009
Part-time employment	-0.136	0.104	-0.051	0.192
Full-time employment	-0.108	0.078	-0.061	0.166
Household income (\$)	-0.068	0.017	-0.176	<0.001
History of depression	0.048	0.072	0.028	0.504
History of cardiovascular disease	-0.028	0.072	-0.016	0.699
History of obesity	-0.062	0.070	-0.038	0.371
Type 2 diabetes	0.428	0.092	0.226	<0.001
Duration of diabetes	0.001	0.004	0.019	0.686
Diabetes care provider¶				
Endocrinologist	-0.085	0.077	-0.048	0.270
Nonphysician	-0.169	0.102	-0.066	0.096
Engage in physical activity	-0.093	0.071	-0.057	0.186
Follow healthy diet	-0.157	0.069	-0.098	0.023
Use insulin pen#	-0.001	0.074	-0.001	0.989
Needle change frequency	-0.049	0.070	-0.031	0.479
Daily injection frequency	0.118	0.023	0.203	<0.001
Plan daily activities around insulin injections	0.247	0.079	0.129	0.002
Interference with activity of daily living	0.112	0.033	0.146	0.001
Dissatisfaction with injection pain	0.130	0.042	0.149	0.002
Dissatisfaction with injection embarrassment	0.146	0.041	0.169	<0.001

*Reference category = male. †Reference category = nonwhite. ‡Reference category = no college. §Reference category = other not employed. ||Reference category = type 1 diabetes. ¶Reference category = primary care physician. #Reference category = use syringe.

Factors associated with injection omission/non-adherence in T1D and T2D

Correlates of insulin omission/non-adherence days per month (N=1530).

- Telephone survey of 1530 insulin-treated adults with self-reported diabetes (110 type 1 and 1420 type 2) in several countries.
- Mean age ~60 years, ~15 years duration of diabetes and ~9 years duration of insulin treatment.
- One third (35%) of respondents reported one or more days (mean:~3 days) of insulin omission/non-adherence. Insulin omission/nonadherence differed widely across countries (range=20-44%);
- Most risk factors had similar relationships with insulin omission/non-adherence across countries
- Insulin omission/non-adherence was associated with: male gender, younger age, type 2 diabetes or more frequent hypoglycaemia; pts less successful with other treatment tasks, regarded insulin adherence as less important, had more practical/logistical barriers and difficulties with insulin adherence, were concerned that insulin treatment required lifestyle changes or were dissatisfied with the flexibility of injection timing

National and demographic factors

Country (reference = USA)

China	-0.21***
France	-0.19***
Germany	-0.08**
Japan	-0.07*
Spain	-0.14***
Turkey	-0.16***
UK	-0.04

Female (reference = male)

	-0.06**
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Age (years)

	-0.14***
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Clinical and disease factors

Type 2 diabetes	+0.06*
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Duration of diabetes (years)	+0.04
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Duration of insulin treatment (years)	-0.07
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Insulin delivery system (reference = pen only)	
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Syringe	-0.04
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Other	+0.04
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SMBG frequency	-0.02
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Hypoglycaemia frequency (days/year)	+0.06*
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Psychosocial and behavioural factors

Non-medication regimen adherence	-0.12***
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Insulin regimen adherence perceived as important	-0.05*
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Injections perceived as painful	+0.01
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Injections perceived to affect lifestyle	+0.06*
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Injection difficulty	+0.07*
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Barriers to insulin adherence	+0.10***
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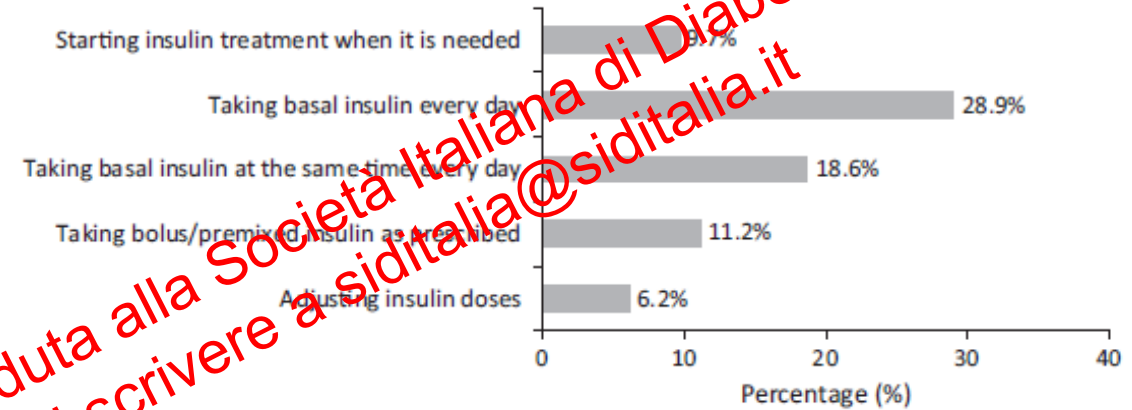
Satisfaction with ability to choose when to take injections	-0.07**
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*p<0.05; **p<0.01; ***p<0.001.

Insulin adherence behaviours and barriers

- Internet survey of 1250 physicians (600 specialists, 650 primary care physicians) who treat patients with diabetes and telephone survey of 1530 insulin-treated patients (180 with Type 1 diabetes, 1350 with Type 2 diabetes)
- 33.2% of patients reported insulin omission/non-adherence at least 1 day in the last month, with an average of 3.3 days. 72.5% of physicians report that their typical patient does not take their insulin as prescribed, with a mean of 4.3 days per month of basal insulin omission/non-adherence and 5.7 days per month of prandial insulin omission/non-adherence.
- Patients and providers indicated the same five most common reasons for insulin omission/non-adherence: too busy; travelling; skipped meals; stress/emotional problems; public embarrassment.
- Most physicians report that many insulin-treated patients do not have adequate glucose control (87.6%) and that they would treat more aggressively if not for concern about hypoglycaemia (75.5%).

Physician report: patient success with insulin treatment tasks (n = 1250)*



Reason	Patients % and rank	Physicians % and rank
Too busy	18.9% 1	41.9% 3
Travelling	16.2% 2	43.6% 2
Skipped meal	15.0% 3	44.8% 1
Stress or emotional problems	11.7% 4	32.2% 5
Embarrassing to inject in public	9.7% 5	36.8% 4
Challenging to take it at the same time everyday	9.4% 6	29.1% 6
Forgot	7.4% 7	2.0% 11
Too many injections	6.0% 8	26.4% 7
Avoid weight gain	4.0% 9	13.4% 9
Regimen is too complicated	3.8% 10	16.8% 8
Injections are painful	2.6% 11	7.8% 10

Patient (n = 530) and physician (n = 964) reported reasons* for insulin omission/non-adherence

Determinants of Adherence to Diabetes Medications: Findings From a Large Pharmacy Claims Database

Data on a cohort of >200,000 patients treated for diabetes with noninsulin medications in the second half of 2010 and had continuous prescription benefits eligibility through 2011. Adherence was defined as a medication possession ratio >0.8.

Odds ratios, 95% CI, and P values for multivariate model of factors associated with diabetes medication adherence

Patient factors	Odds ratio	95% CI	P
Patient exposure to diabetes therapy			
New to therapy vs. continuing therapy	0.39	0.38, 0.40	<0.0001
Patient age-group (years)			
25–44 vs. 45–64	0.61	0.49, 0.53	<0.0001
65–74 vs. 45–64	1.27	1.23, 1.30	<0.0001
>75 vs. 45–64	1.41	1.37, 1.44	<0.0001
Patient sex			
Male vs. female	1.14	1.12, 1.16	<0.0001
Patient education			
Vocational vs. high school equivalent	1.06	0.92, 1.22	0.4105
College grad vs. high school equivalent	1.20	1.17, 1.23	<0.0001
Graduate school vs. high school equivalent	1.41	1.36, 1.46	<0.0001
Patient income			
\$30k to \$60k vs. <\$30k	0.93	0.91, 0.95	<0.0001
>\$60k vs. <\$30k	1.27	1.23, 1.30	<0.0001
Prescription factors			
Prescription drug channel: mail vs. retail	2.09	2.04, 2.13	<0.0001
Total pill burden	1.22	1.21, 1.22	<0.0001
Out-of-pocket costs (30 days)	0.89	0.89, 0.89	<0.0001
Prescriber factors			
Specialty: other specialist vs. primary care	0.91	0.89, 0.94	<0.0001
Prescriber age	1.002	1.002, 1.003	0.004

Patient-reported adherence to insulin regimen is associated with glycemic control among Japanese patients with T2D

Patient characteristics based on insulin injection adherence (based on questionnaire)

Variables	Insulin injection adherence				P-value for trends across insulin injection adherence categories
	All n = 1441	Higher n = 1018	Middle n = 384	Lower n = 39	
Age (y)	65.4 (11.3)	66.6 (12.7)	63.2 (11.6)	57.6 (15.4)	< 0.001
BMI (kg/m ²) ^b	24.7 (24.7)	24.5 (3.8)	25.1 (4.2)	25.6 (4.8)	0.037
Male (%)	58.0	56.0	62.4	69.2	0.011
Insulin injections per day	2.3 (0.8)	2.3 (0.8)	2.4 (0.8)	2.4 (1.1)	0.009
HbA1c (%)	7.8 (1.3)	7.6 (1.2)	8.0 (1.3)	9.4 (2.2)	< 0.001
HbA1c (mmol/mol)	62 (10.0)	60 (10.0)	64 (10.4)	79 (18.5)	< 0.001
Daily insulin dose (IU/kg/day)	0.34 (0.24)	0.33 (0.24)	0.37 (0.25)	0.42 (0.25)	< 0.001

^a Figures in parentheses indicate standard deviations.

^b BMI indicates body mass index.

Patient-reported adherence to insulin regimen is associated with glycemic control among Japanese patients with T2D

Relative risks (RRs) of good glycemic control in patients with type 2 diabetes treated with insulin

	RRs of good glycemic control (95% CI)			P-value for trend
	Insulin injection adherence			
	Higher	Middle	Lower	
Crude model	1.00	0.76 (0.62–0.94)	0.53 (0.25–1.12)	0.003
Multivariable-adjusted relative risk (model 1) ^a	1.00	0.79 (0.64–0.97)	0.56 (0.27–1.17)	0.008
Multivariable-adjusted relative risk (model 2) ^b	1.00	0.82 (0.67–1.00)	0.64 (0.31–1.31)	0.029

^a Model 1 was adjusted for age and sex.

^b Model 2 was adjusted for all the variables in model 1 plus the number of insulin injections per day, daily insulin doses, and body-mass index.

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Real-world factors affecting adherence to insulin therapy in patients with T1D or T2D

Adherence in patients initiating therapy with a vial/syringe or a pen device or switching from a vial/syringe to a pen device

Reference and country	Adherence measure (n)	Adherence with vial/syringe	Adherence with pen device	P-value
Initiating insulin therapy				
Buyzman <i>et al.</i> , 2011 [31] USA	Medication possession ratio (1876)	38%	53%	< 0.001
Lee <i>et al.</i> , 2011 [32] USA	Proportion of days covered (4088)	45.2%	54.6%	< 0.001
Pawaskar <i>et al.</i> , 2007 [34] USA	Medication possession ratio (1330)	50%	53%	
Switching from a vial/syringe to a pen device				
Baser <i>et al.</i> , 2010 [30] USA	Medication possession ratio (1064)	13% *	22%	< 0.001
Lee <i>et al.</i> , 2006 [33] USA	Medication possession ratio (1156)	62% †	69%	< 0.01
Pawaskar <i>et al.</i> , 2007 [34] USA	Medication possession ratio (1120)	56% *	45%	< 0.05
	Insulin therapy	90% *	92%	< 0.05
	All medication			

*Patients remaining using vial/syringe.

†Adherence before switching to a pen device.

Real-world factors affecting adherence to insulin therapy in patients with T1D or T2D

Summary of predictive factors for adherence to insulin and strategies for improving adherence to insulin

Positive predictors of adherence to insulin	Negative predictors of adherence to insulin	Strategies for improving adherence
Changing insulin therapy • Switching from a vial/syringe to a pen device [30,33] • Initiating insulin therapy with a pen device instead of a vial/syringe [31,32,34] Changing type of insurance plan • Switching from a traditional formulary scheme to a value-based insurance design [36,37] Predictive factors for adherence to insulin • Older age [23,25] • Support from a diabetic nurse specialist [22] • Physical disability [23] • Higher household income [23] • Following a healthy diet [23] • Perceived self-efficacy [25] • Hypoglycaemia awareness [24] • Previous experience of liaison psychiatry [24] • Previous experience of cognitive behavioural therapy [24] Patient-perceived barriers to insulin adherence • Lower perceived consequences of diabetes [27] • Higher perception of personal control [27]	• Switching from a vial/syringe to a pen device [34] • Older age [21] • Female gender [21,22] • Single status [21] • Lower HbA_{1c} levels [21] • Being a student [23] • Having the highest level of education [23] • Needing a large number of injections [23] • Type 2 diabetes (vs. patients with Type 1 diabetes) [23]	• Increased use/availability of pen devices • Reduce the financial burden of insulin therapy to the patient • Provide additional medical support to patients (e.g. nurses, psychiatrists) • Educational programmes to increase awareness of diabetes • Develop therapies that allow for fewer injections and increased flexibility in treatment regimen • Provide additional medical support to patients (e.g. nurses, psychiatrists)

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REWIND

- Median follow-up of 5.4 years comprising 51 820 person-years.
- 2171 (43.8%) of 4952 participants assigned to placebo had at least one discontinuation of study drug during follow-up
- 3520 (71.1%) assigned to placebo were taking study drug at the last visit.
- Participants assigned to placebo took study drug for 83.1% of the follow-up time from randomisation until either a primary outcome event or final follow-up.

The Impact of Treatment Noncompliance on Mortality in T2D

UK general practice, Health Improvement Network (THIN, N = 15,984)

Number of death events, length of follow-up periods, crude event rates, and crude relative risks

Compliance group	n	Deaths	Follow-up (patient-years)	Mortality rate (per 1,000 patient-years)	Relative risk (95% CI) (reference is compliant)	P
Compliant	9,475	1,546	38,109	40.7		
Diagnosis of medication noncompliance*	705	99	2,870	52.9	1.302 (1.057–1.588)	0.014
Clinic nonattendance**	6,227	621	18,532	44.3	1.089 (1.000–1.169)	0.049
1–2 missed appointments**	4,346	500	13,657	43.6	1.073 (0.976–1.179)	0.1446
>2 missed appointments**	1,881	225	4,875	46.2	1.135 (0.985–1.303)	0.080

*Includes patients in clinic nonattendance rows. **Includes patients in medication noncompliance row.

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The Impact of Treatment Noncompliance on Mortality in T2D

Multivariate Cox regression
model of all-cause mortality
(N = 13,401)*

	HR (95% CI)	P
Age (years)	1.085 (1.070–1.099)	<0.001
Smoking status (reference is nonsmoker)		<0.001
Ex-smoker	1.139 (1.028–1.262)	0.013
Current smoker	1.210 (1.270–1.701)	<0.001
Female (reference is male)	0.805 (0.731–0.886)	<0.001
Systolic blood pressure (mmHg)	0.995 (0.992–0.997)	<0.001
HbA _{1c}	1.047 (1.015–1.080)	0.004
Primary care contacts in prior 12 months	1.011 (1.008–1.014)	<0.001
Renal disease	1.703 (1.416–2.048)	<0.001
Medication noncompliance	1.579 (1.167–2.135)	0.003
Clinic nonattendance		<0.001
1–2 missed appointments	1.163 (1.042–1.299)	0.007
>2 missed appointments	1.605 (1.356–1.900)	<0.001
Interaction terms		0.017
Medication noncompliance and 1–2 missed appointments	0.685 (0.419–1.120)	0.132
Medication noncompliance and >2 missed appointments	0.397 (0.205–0.766)	0.006

*All estimates adjusted for known risk factors for mortality in patients with type 2 diabetes reaching threshold significance ($P < 0.05$) in the multivariate model.

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OAD Medication Adherence and Hospitalization, Mortality, and Healthcare Costs in Adult Ambulatory Care Patients With T2D

Retrospective cohort study of 40,082 patients enrolled in Korea's national health insurance program

	Patients N (%)	Hospitalization			Death		
		All Cause	Diabetes/CVD*/Renal Disease		All Causes		
		N (%)	OR	95% CI	N (%)	OR	95% CI
Model 1: Level of adherence for the 2-years period							
Adherence	11,800 (29.4)	1456 (12.3)	1.00		319 (2.7)	1.00	
Nonadherence	28,282 (70.6)	3714 (13.1)	1.21	1.13-1.31	760 (2.7)	1.26	1.08-1.47
Adherence							
80% ≤MPR	11,800 (29.4)	1456 (12.3)	1.00		319 (2.7)	1.00	
Nonadherence							
60% ≤MPR <80%	6098 (15.2)	760 (12.5)	1.13	1.03-1.24	174 (2.9)	1.22	1.01-1.47
40% ≤MPR <60%	5184 (12.9)	672 (13.0)	1.20	1.03-1.33	149 (2.9)	1.27	1.04-1.56
MPR <40%	17,000 (42.4)	2282 (13.4)	1.36	1.23-1.50	437 (2.6)	1.30	1.07-1.59
Model 2: Level of adherence for the first year/the second year							
Adherence/adherence	9085 (22.7)	1091 (12.0)	1.00		232 (2.6)	1.00	
Adherence/nonadherence	2987 (7.5)	571 (12.4)	1.12	0.99-1.27	89 (3.0)	1.30	1.01-1.66
Nonadherence/adherence	4368 (10.9)	587 (13.4)	1.24	1.11-1.38	134 (3.1)	1.36	1.09-1.69
Nonadherence/nonadherence	23,642 (58.9)	3021 (13.2)	1.30	1.19-1.42	624 (2.6)	1.37	1.15-1.64

Adjusted for gender (male, female), age (continuous variable), insurance type (health insurance, Medical Aid), number of ambulatory care visits, main attending medical institution (specialized general hospital, general hospital, hospital, clinic, public health center), comorbidity (hypertension, ischemic heart disease, stroke, renal disease), oral antihyperglycemic medications (single/multiple).

Model 1: Level of medication adherence for the 2-years period (adherence: ≥ 584 d covered for filled prescription out of 730 d; MPR, ≥ 80%).

Model 2: Level of medication adherence for the first year and the second year (adherence: ≥ 292 d covered for filled prescription out of 365 d; MPR, ≥ 80%, respectively).

*CVD represents both ischemic heart disease and stroke.

CI indicates confidence interval; MPR, medication possession ratio; OR, odd ratio.

Factors associated with HbA1c levels in 979 Brazilian patients with type 1 diabetes

Independent variable	Participants, n	HbA1c means in % (SD)	β Coefficient (95% CI)	P value
Education				
At least some college	154	9.13 (1.82)	Ref	0.002
Secondary/high school	424	9.21 (2.15)	0.084 (−0.325 to 0.492)	
Primary school or less	398	9.70 (2.40)	0.565 (0.154 to 0.977)	
Self-perception of adherence to diet				
Excellent	129	8.79 (2.22)	Ref	<0.001
Good	327	9.13 (2.09)	0.344 (−0.103 to 0.792)	
Fair/poor	523	9.72 (2.25)	0.931 (0.508 to 1.354)	
Self-perception of adherence to insulin				
Excellent	750	9.28 (2.12)	Ref	<0.001
Good	144	9.59 (2.30)	0.315 (−0.074 to 0.703)	
Fair/poor	62	10.82 (2.49)	1.543 (0.978 to 2.107)	
Regular medical visit in the last year				
Yes	878	9.34 (2.19)	Ref	0.020
No	101	9.89 (2.42)	0.541 (0.084 to 0.998)	

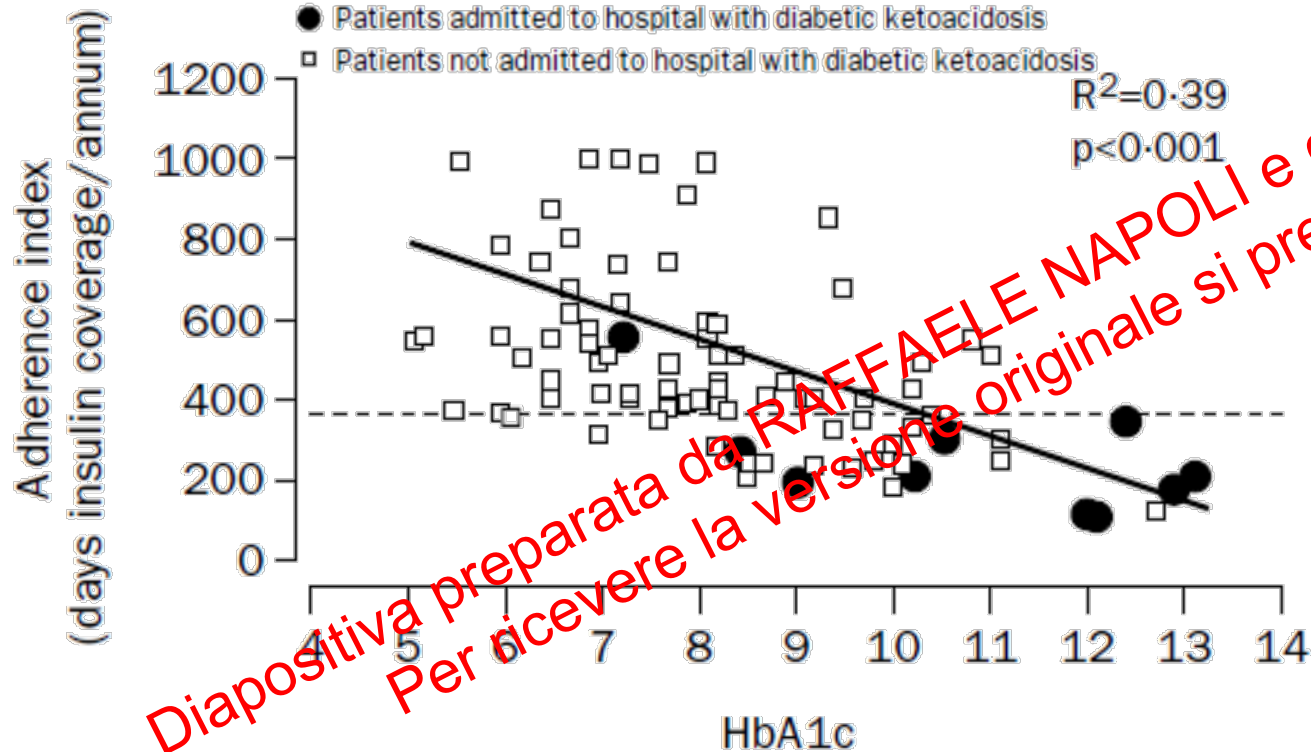
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Adherence to insulin treatment, glycaemic control, and ketoacidosis in insulin-dependent diabetes mellitus

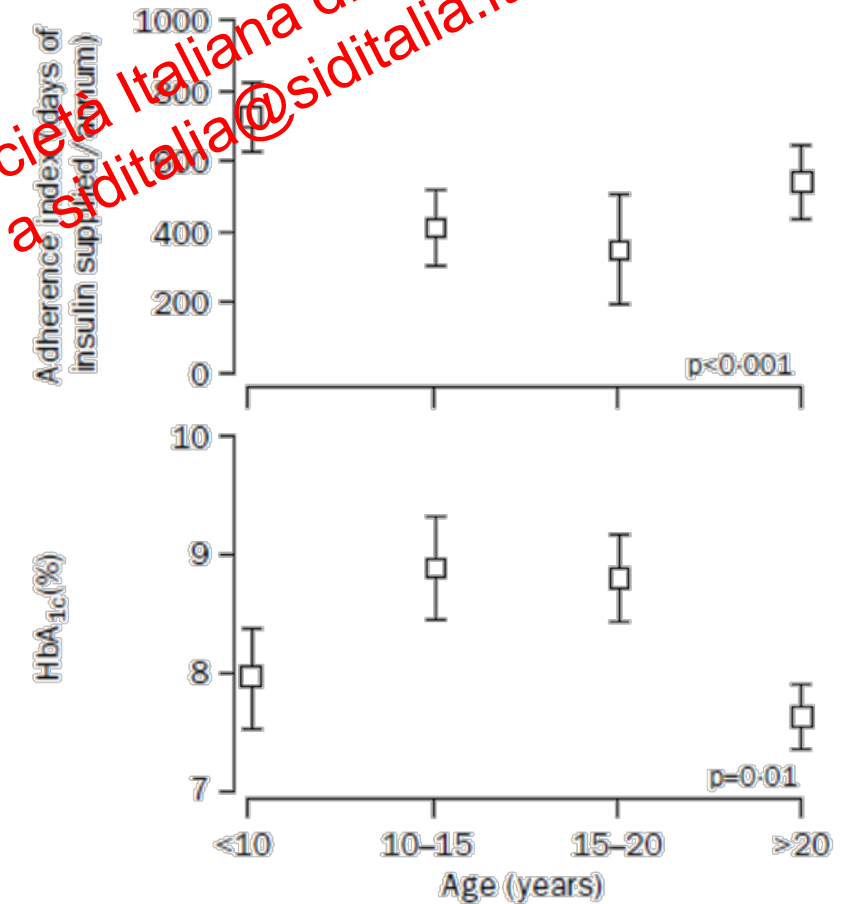
89 patients, mean age 16 (SD 7) years, diabetes duration 8 (4) years, and glycosylated haemoglobin (HbA_{1c}) 8.4 (1.9)%,

The medically recommended insulin dose and cumulative volume of insulin prescriptions supplied were used to calculate the days of maximum possible insulin coverage per annum, expressed as the adherence index

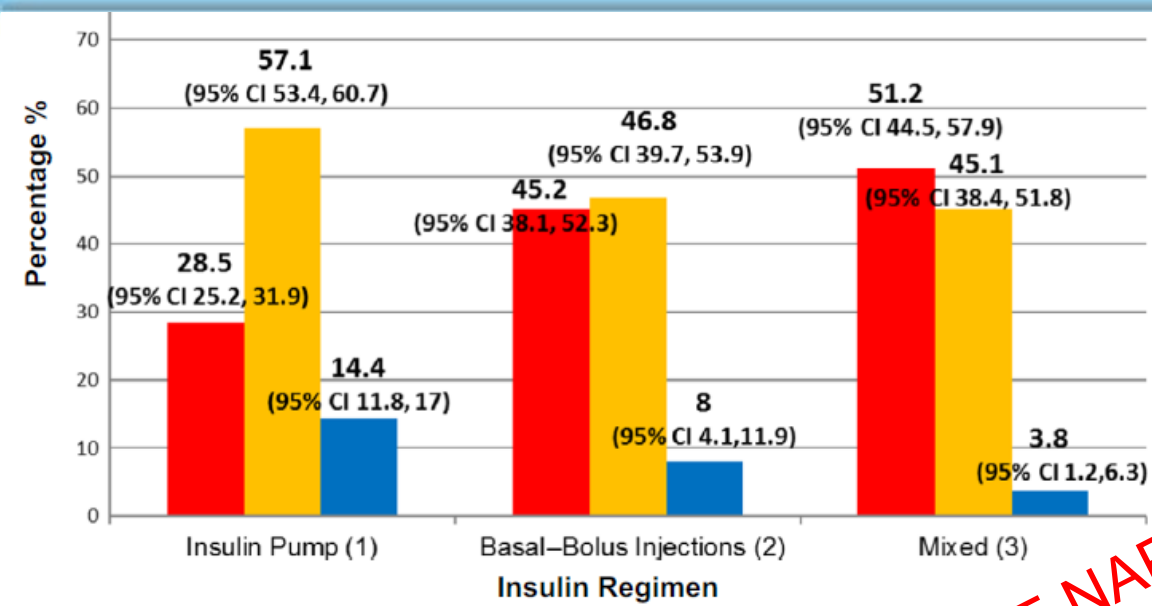
Association of age to glycaemic control (bottom panel) and age to adherence index (upper panel)



Linear regression of the association between (HbA_{1c}) and adherence index



Clinical correlates of poor glycaemic control within insulin regimens among children with T1D



Self- or parent-reported data from 1095 children with Type 1 diabetes aged 10-17 years (694 on insulin pump, 188 on BB, and 213 on mixed regimen)

OR (95% CI) for logistic regression model predicting poor glycaemic control [HbA1c $\geq 9.5\%$] within insulin regimens in children with Type 1 diabetes

Factor	1 Insulin pump N=596 (171 events)		2 Basal-bolus injections N=160 (68 events)		3 Mixed insulin N=171 (90 events)	
	Adjusted OR (95% CI)*	P	Adjusted OR (95% CI)*	P	Adjusted OR (95% CI)*	P
Medicaid/Medicare Insurance (Referent: Private insurance)	2.0 (1.19, 3.38)	0.0090	0.8 (0.29, 1.93)	0.5565	2.2 (0.985, 5.17)	0.0649
Number of times missed insulin		<0.0001		0.1360		0.2130
1-5/week vs <1 week	4.0 (2.40, 6.75)	<0.0001	§	§	§	§
1+/day vs <1 week	2.4 (1.27, 4.73)	0.0075	§	§	§	§
Family conflict survey (parent report)†	1.1 (1.05, 1.15)	<0.0001	1.2 (1.10, 1.35)	0.0002	1.1 (1.03, 1.22)	0.0103
Low blood sugar survey (parent report)†	0.97 (0.95, 0.99)	0.0004	0.93 (0.90, 0.97)	0.0001	1.0 (0.98, 1.03)	0.6998
Eating problem survey†	1.0 (0.99, 1.04)	0.2609	1.1 (0.99, 1.12)	0.0857	1.0 (0.97, 1.06)	0.4114
Problem not receiving care (access barrier; Referent: No problem receiving care)	0.9 (0.32, 2.28)	0.7476	0.4 (0.06, 2.80)	0.3716	0.1 (0.03, 0.51)	0.0038
Problem not spending enough time with provider (process barrier; Referent: No problem spending enough time with provider)	1.3 (0.85, 2.11)	0.2136	1.4 (0.57, 3.48)	0.4649	3.8 (1.47, 9.64)	0.0058

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Missing bolus doses has profound effect on metabolic control in T1D CSII-treated adolescents

90 CSII-treated (>6 months), aged 12-18 yr, from diabetes clinics in Sweden. They recorded their meal intake the previous day, which was compared with downloaded pump data, and the frequency of missed boluses was stated. HbA1c and diabetes-related data were recorded. HRQOL and treatment satisfaction were measured with questionnaires.

Comparisons between the groups who had missed <15 or >15% of the bolus doses the day before the visit

	Missed ≤15% (n = 56)	Missed >15% (n = 34) 38%	p Level
Age (yr)	14.8 ± 2.2	14.9 ± 2.0	0.849
Diabetes duration (yr)	7.6 ± 2.8	8.3 ± 3.7	0.372
Pump therapy duration (yr)	3.1 ± 1.8	3.9 ± 1.9	0.070
BMI (kg/m ²)	22.1 ± 3.6	21.8 ± 3.8	0.719
BMI SDS (kg/m ²)	1.2 ± 1.1	1.0 ± 1.3	0.449
HbA1c (%)	7.0 ± 1.0	7.8 ± 1.2	0.001
Mean doses per day for 4 wt (n)	5.3 ± 1.7	3.8 ± 1.7	<0.001
SMBG per day (n)	3.6 ± 1.8	2.4 ± 1.8	0.003
Insulin dose (U/kg)	0.83 ± 0.18	0.82 ± 0.17	0.862
Basal dose/total dose (%)	55 ± 12	65 ± 14	0.001

BMI SDS, BMI standard deviation scores; HbA1c, haemoglobin A1c; SMBG, self-monitoring of blood glucose. Data are mean ± SD.

Insulin restriction is associated with increased rates of diabetes complications and increased mortality risk in women with T1D

- 11-year follow-up study of 234 women with type 1 diabetes. Mean age was 45 years, diabetes duration was 28 years, BMI was 25 kg/m², A1C was 7.9%.
- Restriction likely due to general psychological distress (such as depression and anxiety), diabetes-specific distress, fear of hypoglycemia, concern about weight gain, and related eating disorder behaviors

Characteristics of women who died during follow-up

	Appropriate insulin users 163	Insulin restrictors 71
n	16	10
Age at death	57.7 ± 11	44.7 ± 11*
Diabetes duration at death	33.2 ± 12	26.5 ± 11
Baseline characteristics		
A1C (%)	9.4 ± 1.5	11.1 ± 2.1†
BMI (kg/m ²)	29 ± 8	28 ± 7
Problem Areas in Diabetes Survey	48.4 ± 38.6	83.8 ± 27.6†
Hypoglycemia Fear Survey	41.4 ± 24.3	41.9 ± 24.2
Self-Care Inventory	65.3 ± 17.7	46 ± 20.1†
Brief Symptom Inventory (depression)	58.5 ± 10.6	58.6 ± 14.5
Brief Symptom Inventory (anxiety)	55.8 ± 11.5	60.5 ± 11.8
Brief Symptom Inventory–Global Severity Index	56.7 ± 13.4	62.1 ± 10.1
Bulimia Test-Revised	55 ± 24	85 ± 30*
Eating Disorders Inventory (drive for thinness)	3.6 ± 3	5.9 ± 3
Eating Disorders Inventory (bulimia)	1.5 ± 2	4.1 ± 4†
Eating Disorders Inventory (body dissatisfaction)	9.3 ± 6	11.6 ± 5
Eating Disorders Inventory (total score)	29.6 ± 19.5	47.6 ± 24†

Data are means ± SD. *P < 0.01; †P < 0.05; ‡trend P = 0.07 (P values associated with Wilcoxon exact tests).

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Treatment non-compliance is associated with increased all-cause mortality in patients with T1D

Baseline characteristics according to diagnosis of medication non-compliance and clinic non-attendance.

	Adherent		Non-compliant/ DNA		P
N	2079		867		
Gender					
Male	1216	58.5%	515	59.4%	0.647
Female	863	41.5%	352	40.6%	
Smoking status					
Non-Smoker	1494	71.9%	523	60.3%	<0.001
Current Smoker	228	11.0%	116	13.4%	
Ex-Smoker	357	17.2%	228	26.3%	
Age (years)	27.9	19.2	29.1	17.4	0.090
BMI	23.7	4.9	24.6	5.0	0.002
HbA1c (%)	8.5	1.7	8.9	2.0	0.001
HbA1c (mmol/mol)	69	14	73	17	
Cholesterol (mmol/L)	4.7	1.0	4.7	1.1	0.731
Systolic blood pressure (mmHg)	124.1	18.1	121.3	16.7	0.799
Diastolic blood pressure (mmHg)	78.4	11.0	73.9	10.7	0.005
Charlson Index	1.5	0.9	1.6	0.9	0.123
PCP contacts in prior 12 months	3.9	4.6	7.0	8.9	<0.001
Prior large vessel disease	63	3.0%	31	3.6%	0.443
Prior renal disease	14	0.7%	9	1.0%	0.305
Prior visual complication	147	7.1%	62	7.2%	0.938

Continuous data are presented as mean (SD) and categorical data as n (%).

- Observational cohort study of data extracted from The Health Improvement Network (THIN) database, comprising data on patients served by over 350 primary care practices in the UK
- Of 2946 patients with type 1 diabetes, 867 (29.4%) had a record of either appointment nonattendance or medication non-compliance in the 30 month compliance assessment period

Multivariate Cox regression model of medication non-compliance and clinic nonattendance on mortality risk

	Hazard ratio	95.0% CI		p
		Lower	Upper	
Age (years)	1.066	1.054	1.078	<0.001
PCP contacts in prior 12 months	1.020	1.004	1.036	0.014
Charlson index	1.344	1.184	1.527	<0.001
Non-compliance/attendance (compliant group)	1.642	1.055	2.554	0.028

Medication Nonadherence is prevalent in T2D and is associated With Hospitalization and Mortality

A retrospective cohort study of 11 532 patients (Kaiser Permanente of Colorado)

Association Between Medication Nonadherence and Outcomes

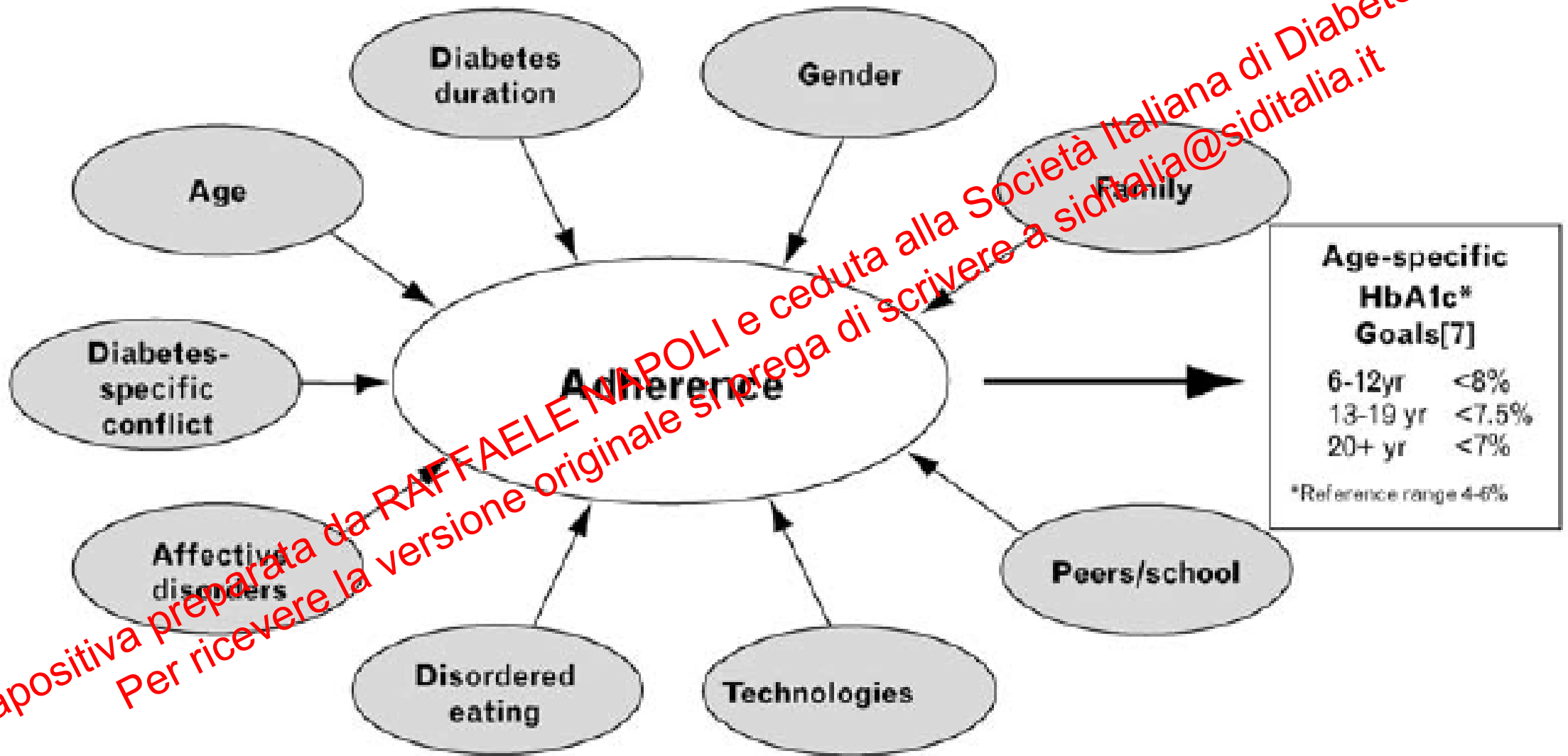
PDC = proportion of days covered

Nonadherence Measure	Nonadherent Patients, %	No. of Patients	Odds Ratio (95% Confidence Interval)			
			All-Cause Mortality		All-Cause Hospitalization	
			Unadjusted	Adjusted*	Unadjusted	Adjusted*
Summary measure	21.3	11 532	1.49 (1.22-1.81)	1.81 (1.46-2.23)	1.27 (1.15-1.42)	1.58 (1.38-1.81)
Antihypertensives	19.1	6217	1.54 (1.20-1.97)	1.58 (1.22-2.05)	1.39 (1.21-1.60)	1.44 (1.24-1.67)
Statins	24.8	6486	1.60 (1.21-2.13)	2.07 (1.54-2.80)	1.17 (1.01-1.36)	1.39 (1.18-1.63)
Oral hypoglycemics	20.3	7883	1.25 (0.97-1.62)	1.39 (1.07-1.82)	1.31 (1.16-1.49)	1.38 (1.21-1.58)

Association Between Medication Nonadherence and Outcomes Using Different PDC Cutoffs

PDC Cutoff, %	Summary Measure		Oral Hypoglycemics		Antihypertensives		Statins	
	Mortality	Hospitalization	Mortality	Hospitalization	Mortality	Hospitalization	Mortality	Hospitalization
<50	2.01 (1.38-2.94)	1.66 (1.24-2.04)	1.74 (1.17-2.59)	1.50 (1.22-1.86)	2.16 (1.46-2.80)	2.02 (1.46-2.80)	2.30 (1.49-3.56)	1.39 (1.09-1.78)
<60	2.02 (1.51-2.73)	1.66 (1.34-2.04)	1.56 (1.12-2.18)	1.60 (1.35-1.89)	2.07 (1.42-3.02)	1.56 (1.23-1.99)	2.45 (1.70-3.51)	1.28 (1.04-1.58)
<70	1.56 (1.53-2.00)	1.49 (1.26-1.77)	1.54 (1.16-2.06)	1.49 (1.29-1.73)	2.09 (1.56-2.81)	1.62 (1.35-1.94)	2.22 (1.60-3.10)	1.39 (1.16-1.67)
<80	1.81 (1.46-2.23)	1.58 (1.38-1.81)	1.39 (1.07-1.82)	1.38 (1.21-1.58)	1.58 (1.22-2.05)	1.44 (1.24-1.67)	2.07 (1.54-2.80)	1.39 (1.18-1.63)
<90	1.71 (1.42-2.07)	1.48 (1.32-1.66)	1.48 (1.16-1.89)	1.36 (1.20-1.54)	1.57 (1.25-1.98)	1.45 (1.27-1.65)	1.76 (1.34-2.32)	1.28 (1.11-1.47)
<100	1.47 (1.22-1.77)	1.35 (1.24-1.50)	1.49 (1.17-1.89)	1.44 (1.27-1.62)	1.34 (1.07-1.68)	1.38 (1.23-1.56)	1.40 (1.07-1.82)	1.27 (1.11-1.44)

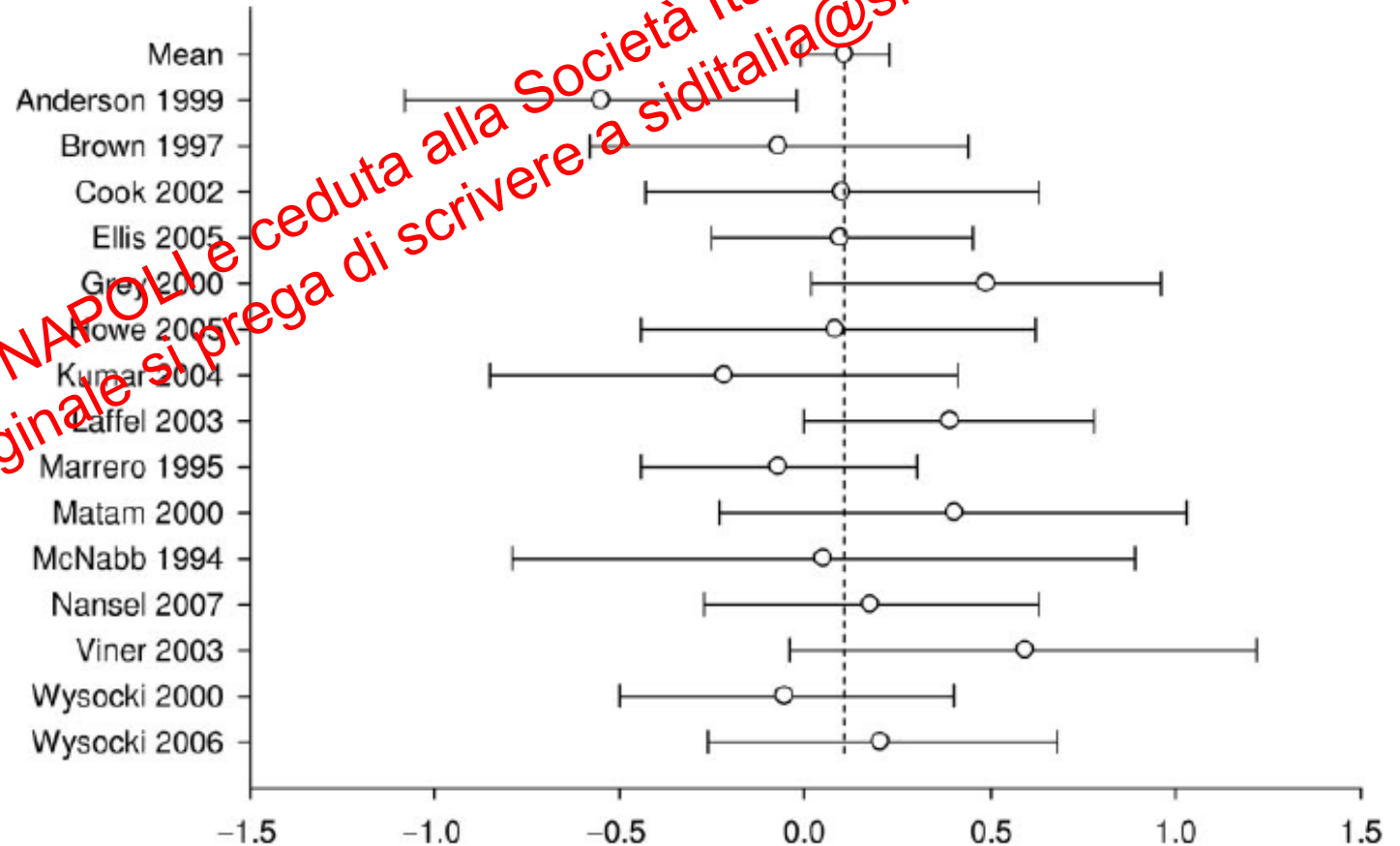
Factors affecting treatment adherence in adolescents with T1D



Interventions With Adherence-Promoting Components in Pediatric T1D

- 15 studies meta-analysis including 997 youth with type 1 diabetes.
- Direct interventions were those that focused entirely on direct, behavioral processes.
- Combined interventions focused on one or several behavioral tasks, but the emphasis of the intervention was on promoting coping or problem-solving skills or a family process involved in diabetes management.

Effect sizes and confidence intervals for the individual studies



Diapositiva preparata da RAFFAELE NAPOLI e ceduta alla Società Italiana di Diabetologia.
Per ricevere la versione originale si prega di scrivere a siditalia@siditalia.it

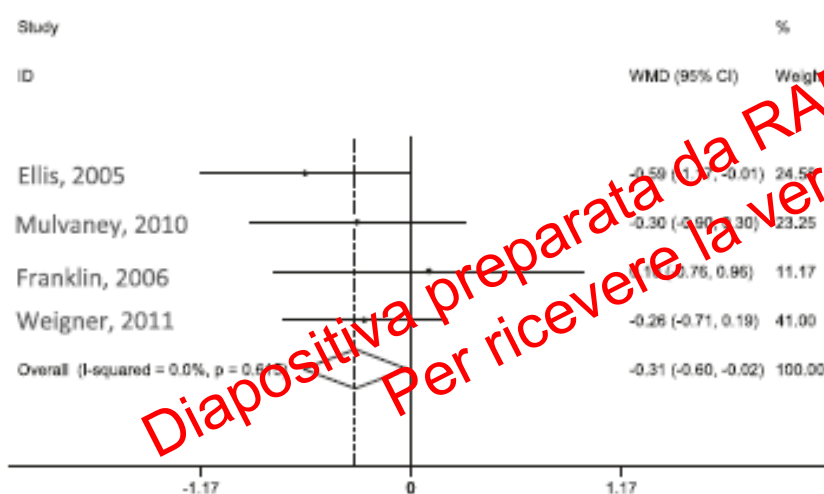
Improving Patients' compliance to lower HbA1c in T1D

Meta-analyses of RCT of psychological, telecare, and educational interventions

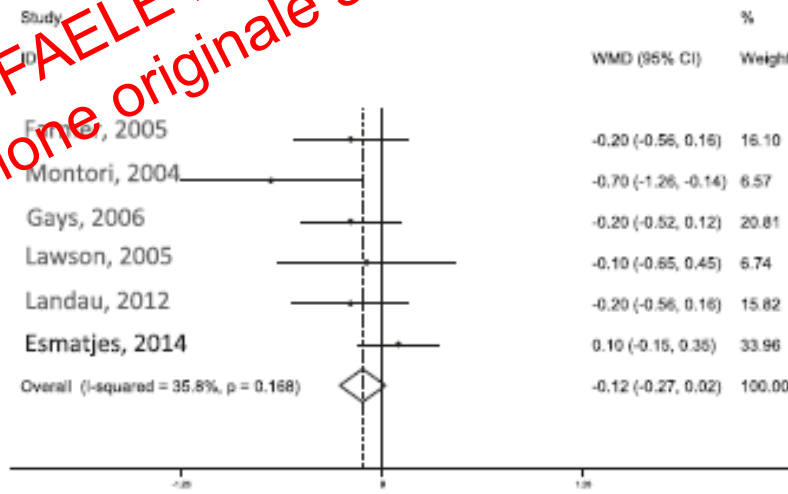
- 19 articles met the inclusion criteria (1782 pts, 49.4% males, age 18 years. The RCTs (2 to 24 months in duration) were divided into 4 groups: psychology (7 studies; 818 patients), telecare (6 studies; 494 patients); education (5 studies; 349 patients), and psychoeducation (1 study; 153 patients). All studies reported some type of adherence measurement of the interventions.
- Decrease in HbA1c was observed after psychology (MD -0.310; 95 % CI, -0.599 to -0.0210; $p = 0.035$) but not after telecare (MD -0.124 %; 95 % CI, -0.268, 0.020; $P = 0.090$) or educational (MD -0.001; 95 % CI, -0.202, 0.200; $P = 0.990$) interventions.

Forest plots of interventions to improve compliance with lower HbA1c in patients with T1D

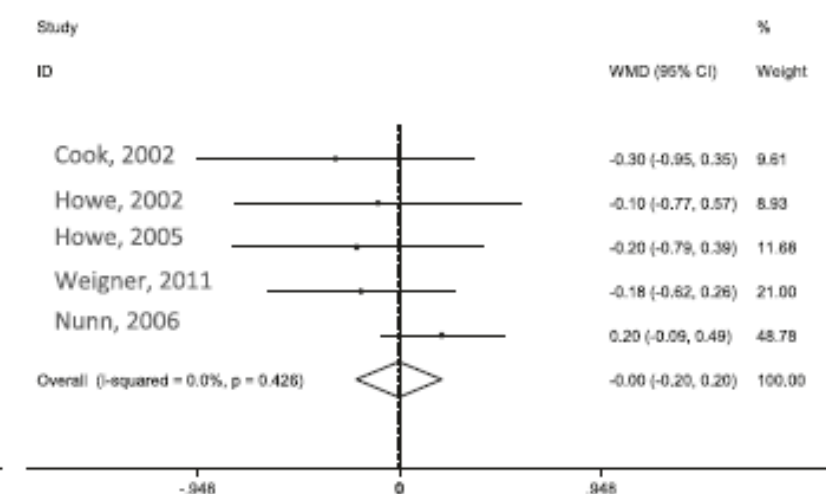
A) Psychology



B) Telecare

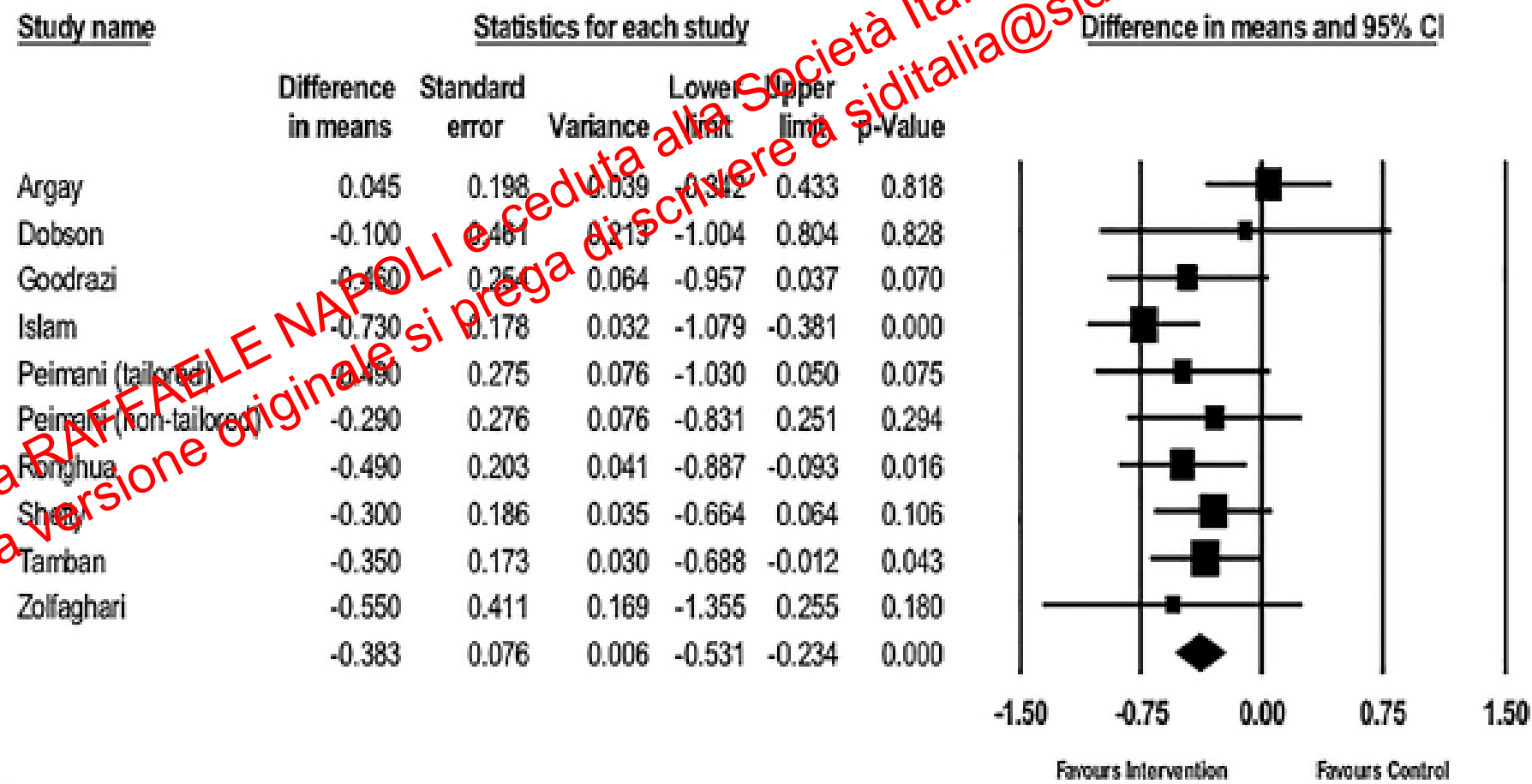


C) Education



Mobile phone text messaging in improving glycaemic control for patients with T2D

- Eleven randomized controlled trials were included in the final review, with a total of 1710 participants. One study focused on medication adherence only, while the remaining had educational and motivational messages.
- Five studies showed a significant improvement in HbA1c with the intervention. The remaining studies demonstrated a trend to improvement in HbA1c. Our meta-analysis on 9 of the 11 studies found an overall reduction in HbA1c of 0.35% (-0.53; -0.23, p-value 0.001)..

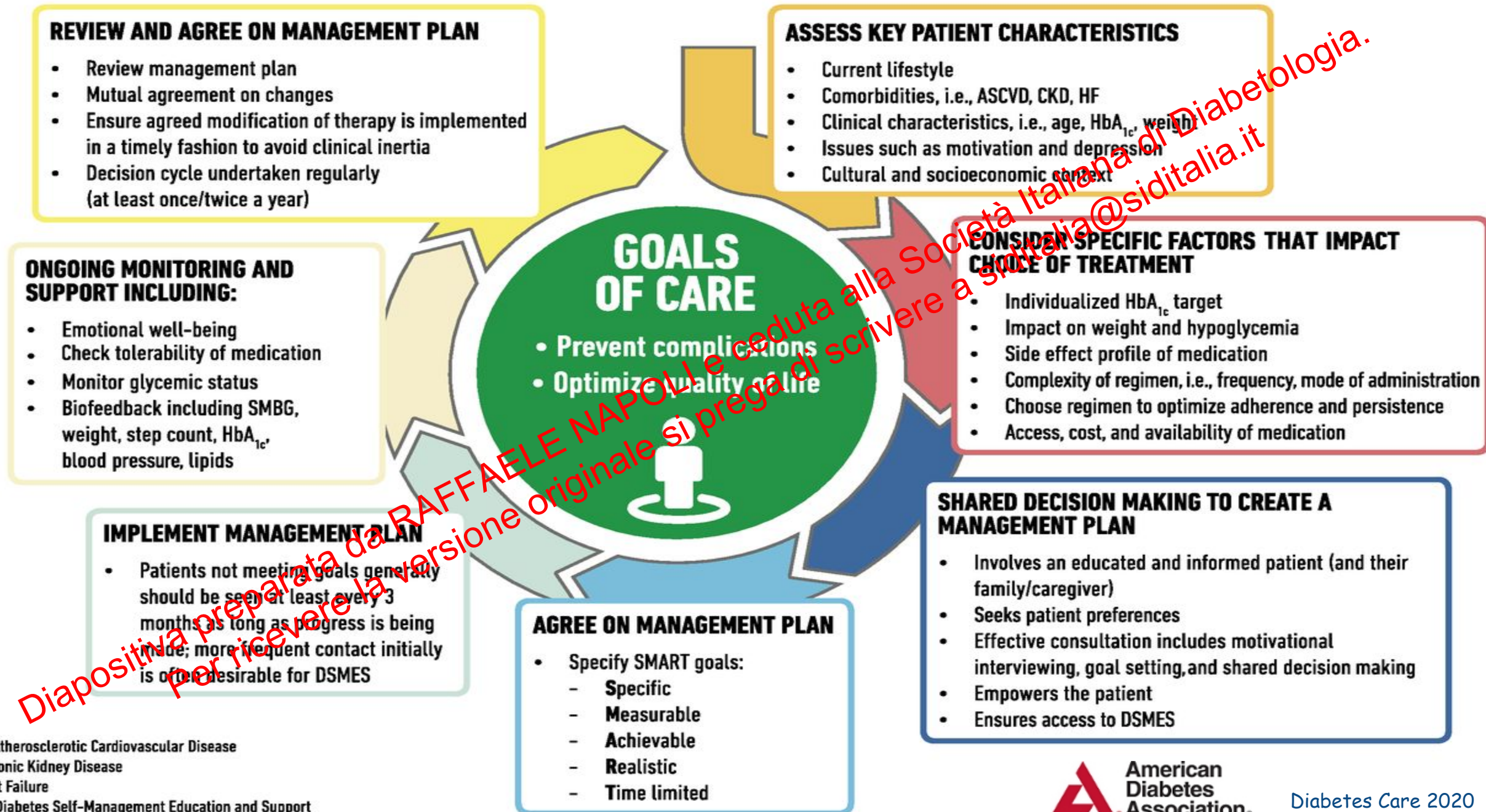


Interventions to improve safe and effective medicines use by consumers: an overview of systematic reviews (Review)

- Medicines self-monitoring and self-management programmes appear generally effective to improve medicines use, adherence, adverse events and clinical outcomes; and to reduce mortality in people self-managing antithrombotic therapy.
- Other promising interventions to improve adherence and other key medicines-use outcomes, which require further investigation to be more certain of their effects, include:
 - simplified dosing regimens: with positive effects on adherence;
 - interventions involving pharmacists in medicines management, such as medicines reviews (with positive effects on adherence and use, medicines problems and clinical outcomes) and pharmaceutical care services (consultation between pharmacist and patient to resolve medicines problems, develop a care plan and provide follow-up; with positive effects on adherence and knowledge).

There are many different potential pathways through which consumers' use of medicines could be targeted to improve outcomes, and simple interventions may be as effective as complex strategies. However, no single intervention assessed was effective to improve all medicines-use outcomes across all diseases, medicines, populations or settings.

DECISION CYCLE FOR PATIENT-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES



Diapositiva preparata da RAFFAELE NAPOLI e ceduta alla Società Italiana di Diabetologia.
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