

Riflessioni su Innovazione e Appropriatezza
nella terapia del Diabete Mellito tipo 2

Le ipoglicemie iatrogene: impatto sanitario ed economico

20 settembre 2014
Nh Villa Carpegna
Roma

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ipoglicemie: agenda

- CVD
- cause
- frequenza
- ricoveri
- dati Italiani
- costi indiretti e sociali
- conseguenze terapeutiche
- considerazioni finali

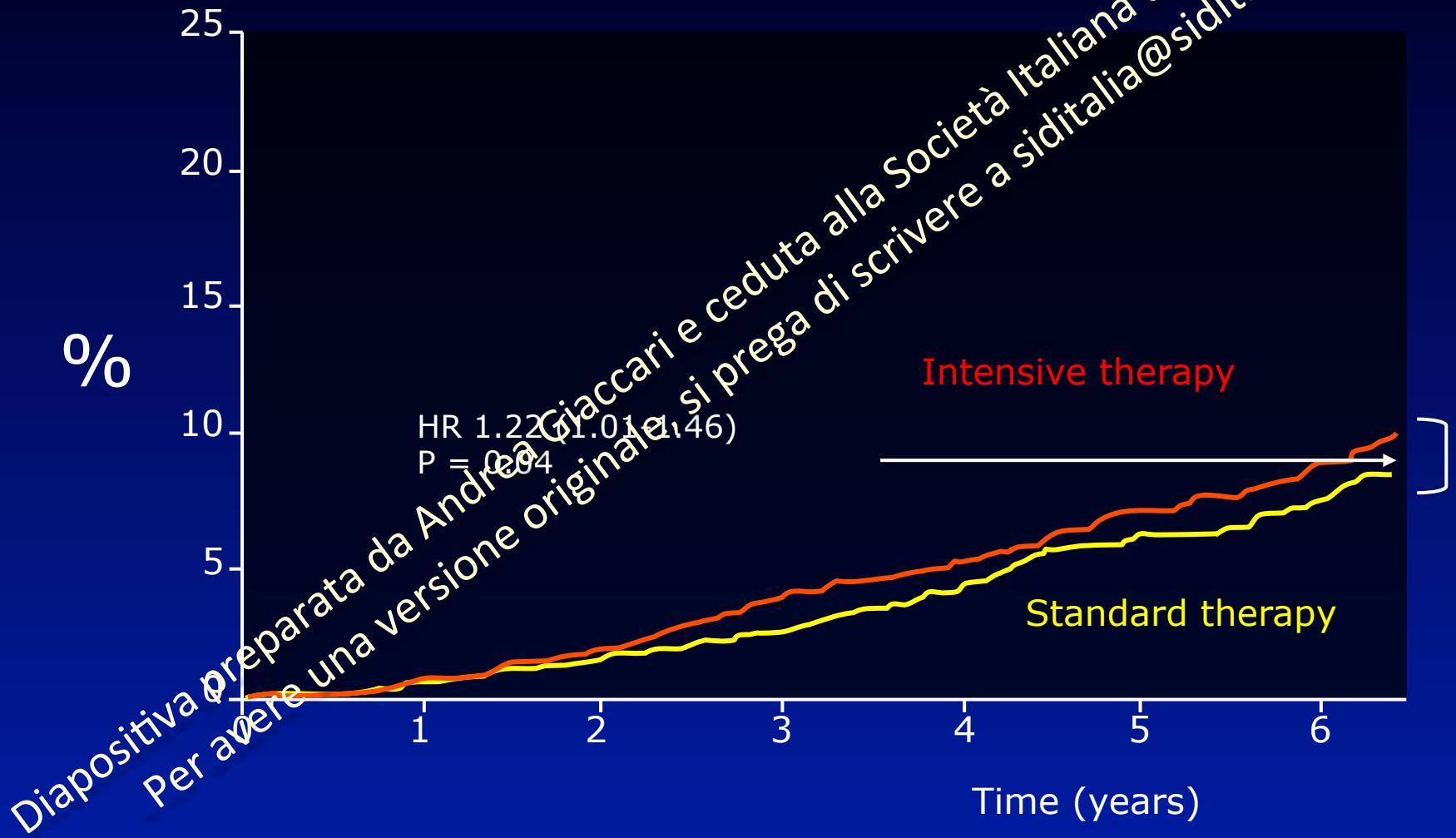
Diapositiva preparata da Andrea Giaccari e ceduta alla Società Italiana di Diabetologia.
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ipoglicemie: agenda

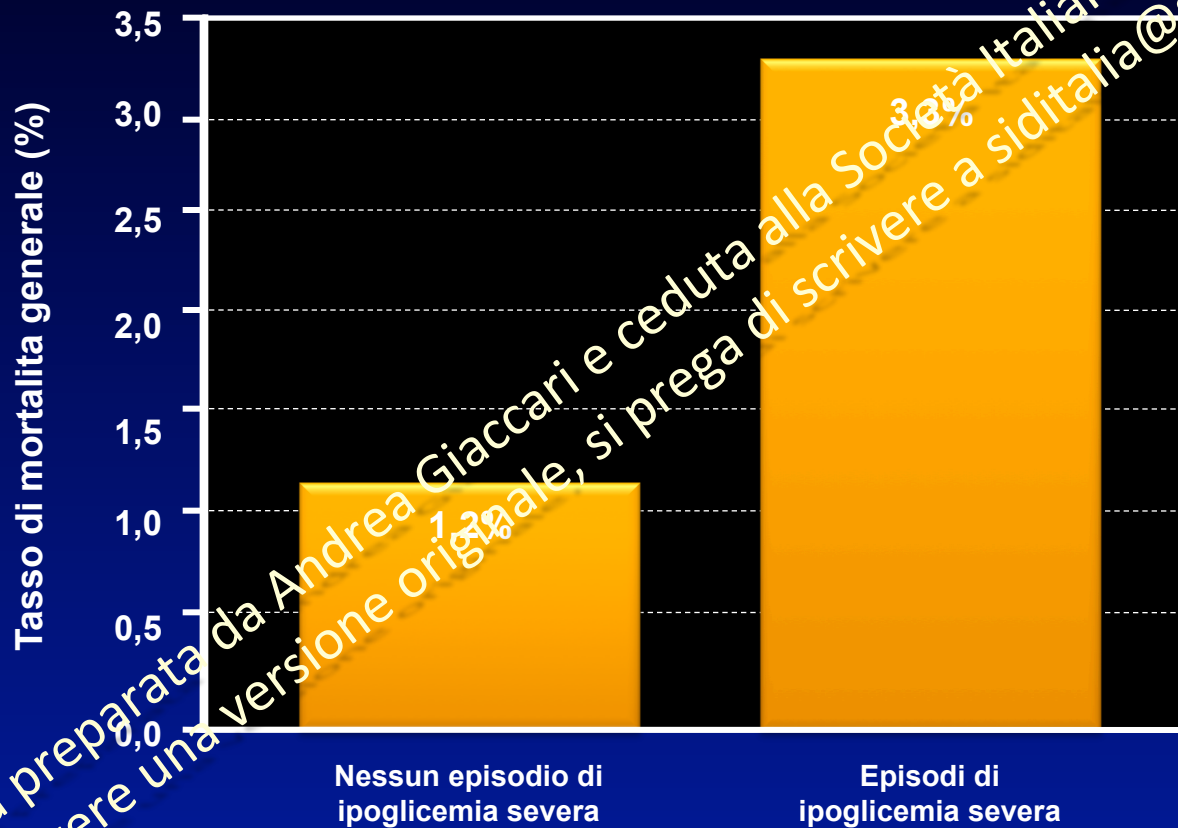
- CVD

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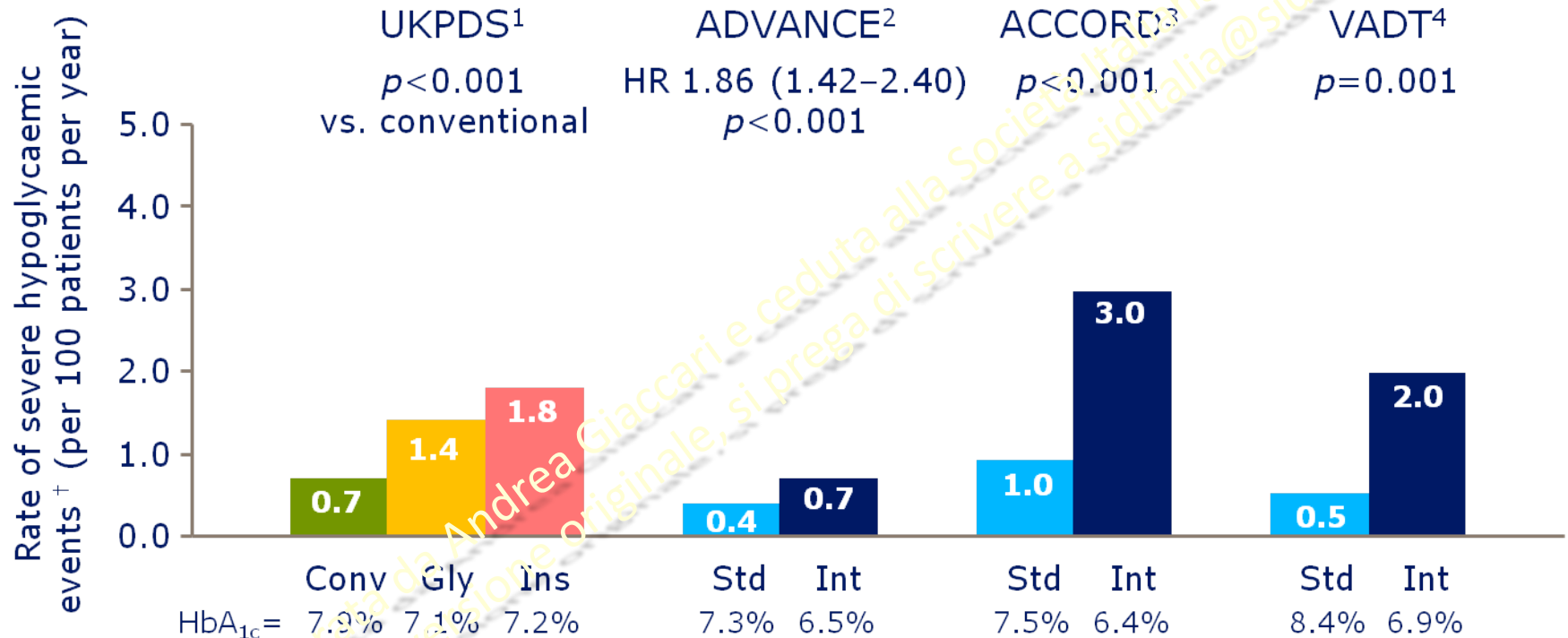
ACCORD: mortalità (tutte le cause)



Studio ACCORD: alta mortalità nei pazienti che manifestavano episodi di ipoglicemia severa



Higher rate of severe hypoglycaemia with intensive glycaemic control*



*Intensive glycaemic control was defined differently in these trials

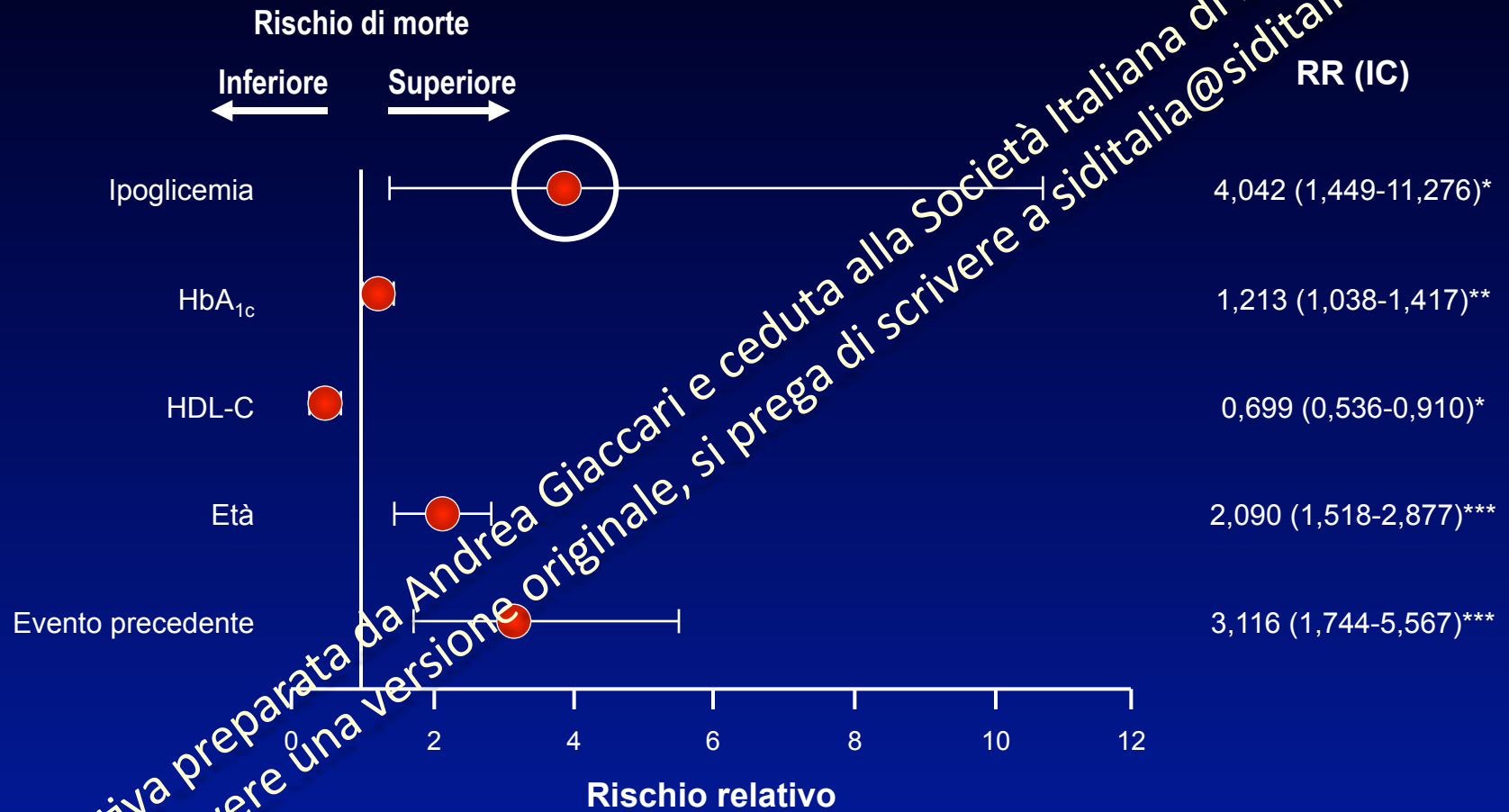
[†]Hypoglycaemia requiring any assistance in glucose-lowering trials

Conv, conventional therapy; gly, glibenclamide; HR, hazard ratio; ins, insulin; int, intensive therapy; std, standard therapy

1. UKPDS Group. *Lancet* 1998;352:837–53; 2. Patel *et al*; ADVANCE Collaborative Group. *N Engl J Med* 2008;358:2560–72;

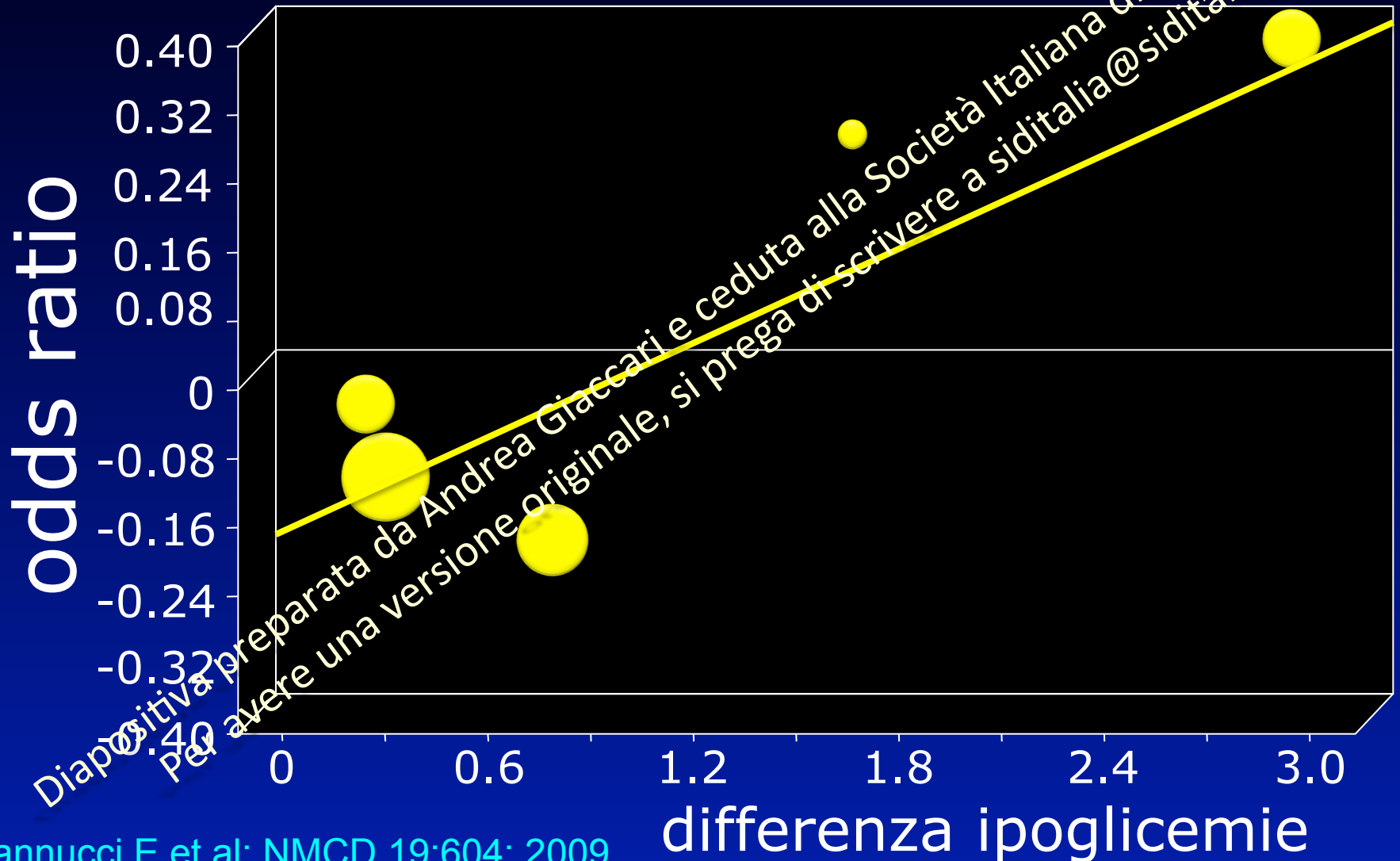
3. Gerstein *et al*; ACCORD Group. *N Engl J Med* 2008;358:2545–59; 4. Duckworth *et al*. *N Engl J Med* 2009;360:129–39

L'ipoglicemia è predittore di mortalità CV: VADT



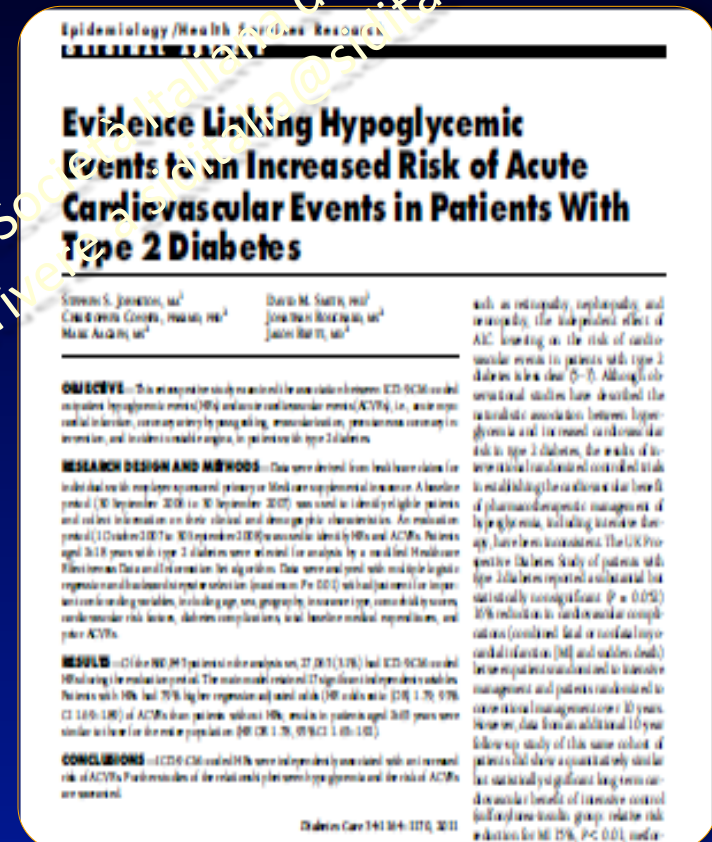
* $P=0,01$; ** $P=0,02$; *** $P<0,01$

metaregressione ipoglicemie

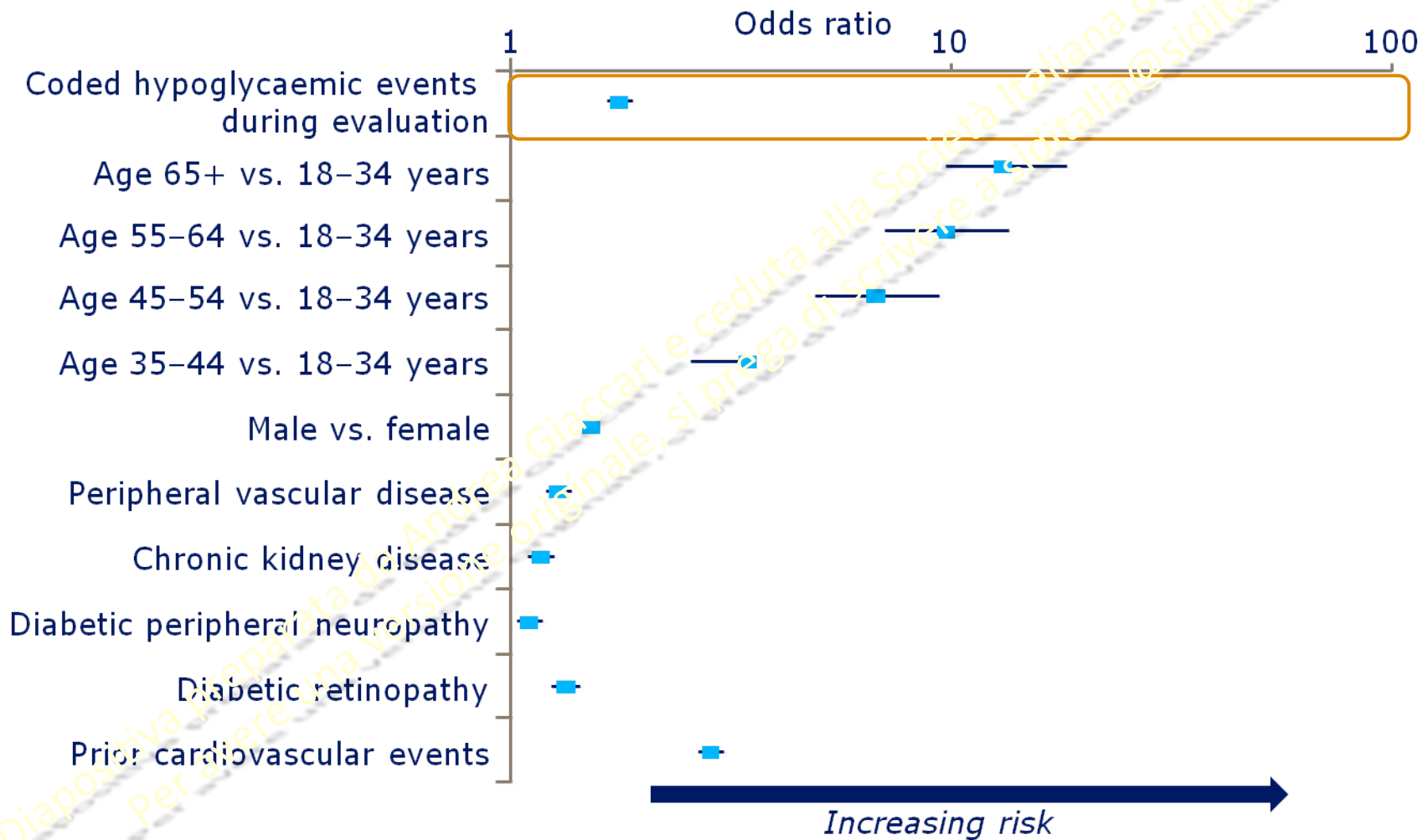


Link between hypoglycaemia and acute cardiovascular events in type 2 diabetes

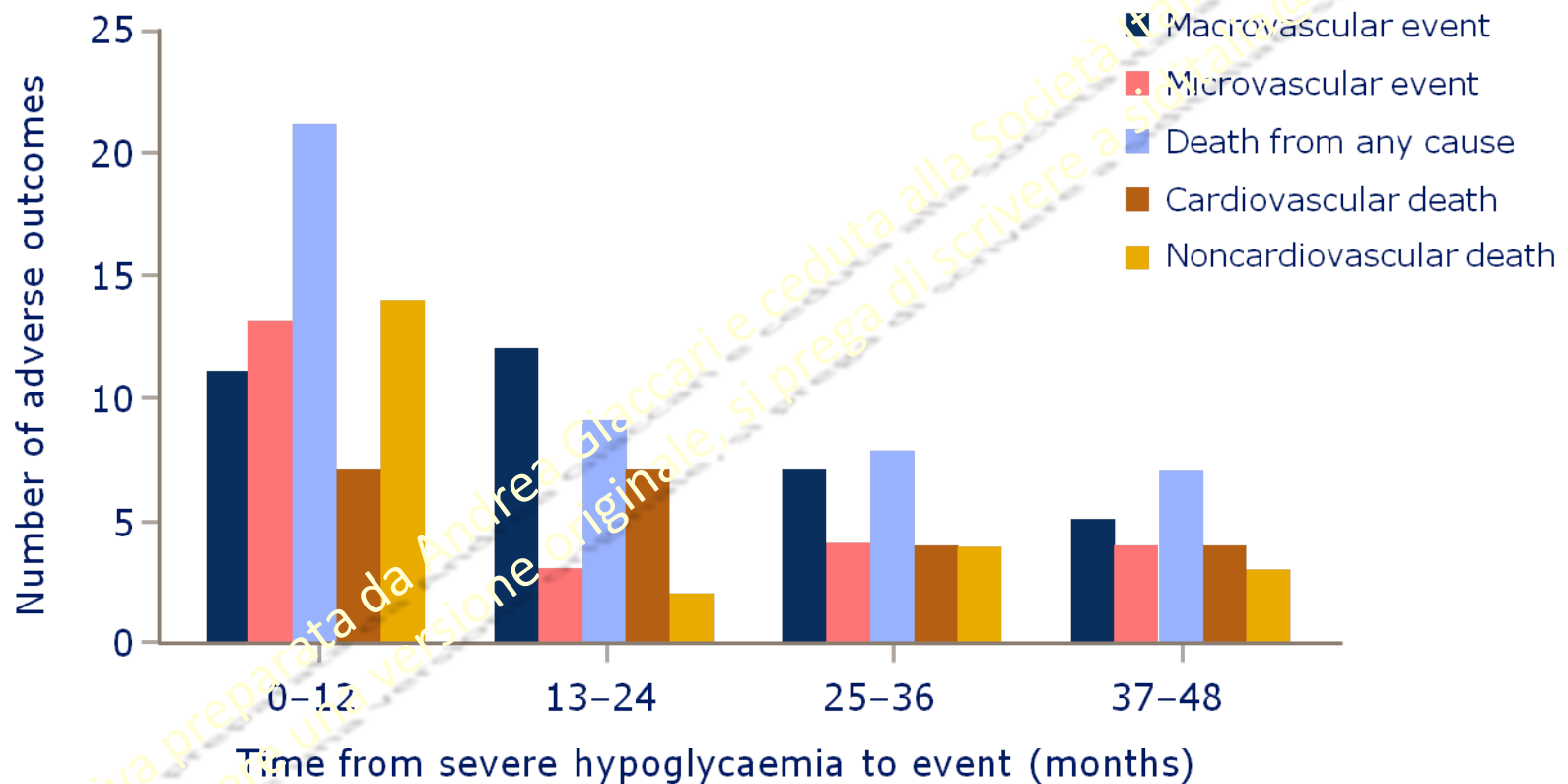
- Retrospective, observational study (n=860,845) assessing association between hypoglycaemic events and acute cardiovascular events
- 3.1% patients had a hypoglycaemic event during the evaluation period (1 year)
- Patients with hypoglycaemic events had 79% higher odds of acute cardiovascular events than patients without hypoglycaemic events



Multiple logistic regression of acute CV events as a function of hypoglycaemic events



Adverse outcomes among patients with type 2 diabetes experiencing severe hypoglycaemia



ipoglicemie: agenda

- CVD
- cause

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What is hypoglycaemia?

- **A state of neuroglycopenic and/or neurogenic symptoms due to low plasma glucose levels**
- Low plasma glucose levels defined as:
 - ≤ 70 mg/dL (3.9 mmol/L) (ADA)¹
 - < 54.1 mg/dL (3.0 mmol/L) (EMA)²
 - < 72 mg/dL (4.0 mmol/L) (CDA)³
- Symptoms respond to the administration of carbohydrate³

ADA, American Diabetes Association; CDA, Canadian Diabetes Association; EMA, European Medicines Agency

Hypoglycaemia is inconsistently reported and defined

- Reports of symptoms by patients with diabetes vary¹
- Inter-individual variations in symptom thresholds
- The most common symptoms of hypoglycaemia are not always the first to be reported¹
- Asymptomatic or unrecognised episodes can be missed,^{3,4} especially those occurring at night and/or during sleep³⁻⁵

Fattori di rischio per ipoglicemia

- Età avanzata
- Numero medicine
- Digiuno
- Ipoalimentazione
- Malattie intercorrenti
- Malattie epatiche
- Attività fisica
- Alcool
- Malattie endocrine
- Perdita controregolazione
- Unawareness

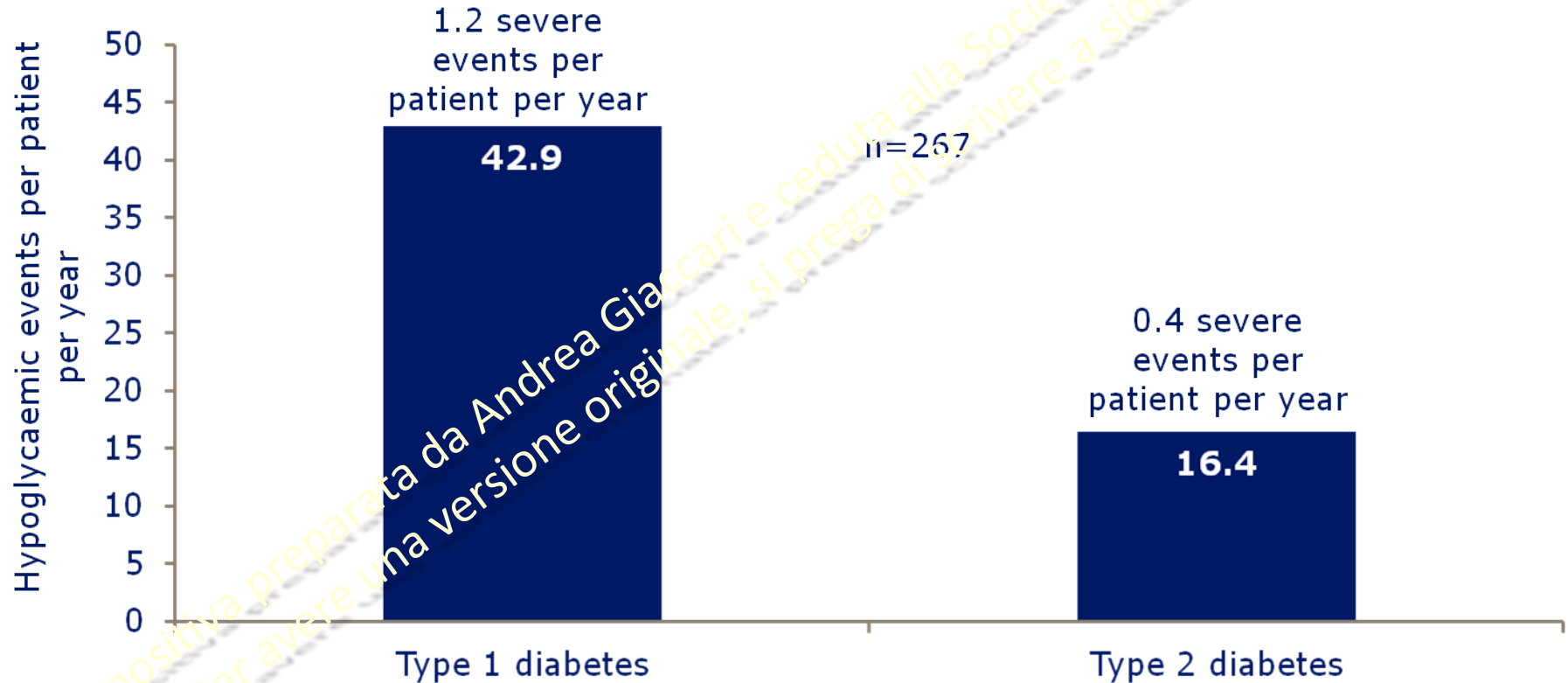
ipoglicemie: agenda

- CVD
- cause
- frequenza

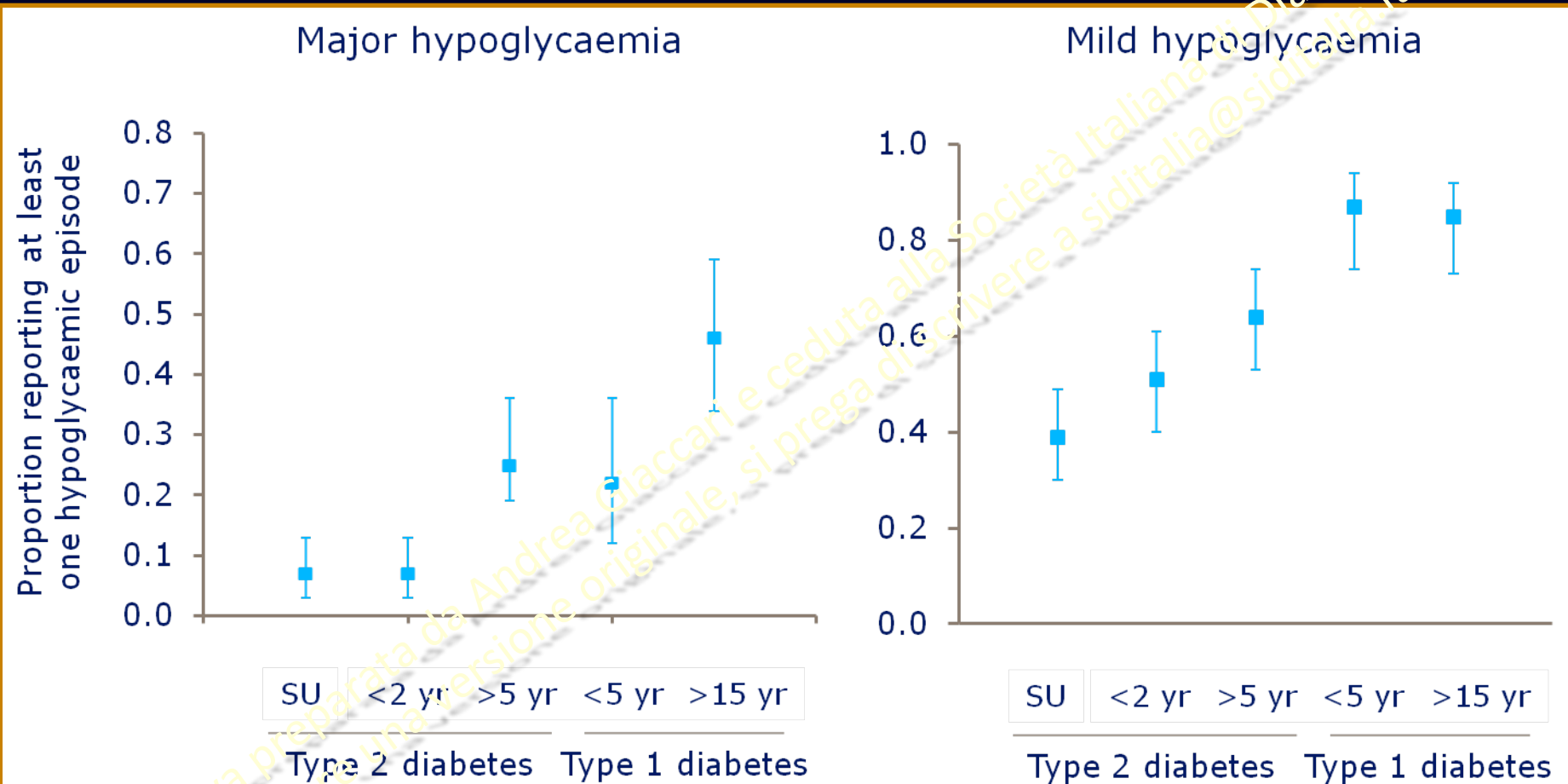
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Hypoglycaemic events occur frequently

- Patients with type 1 and 2 diabetes

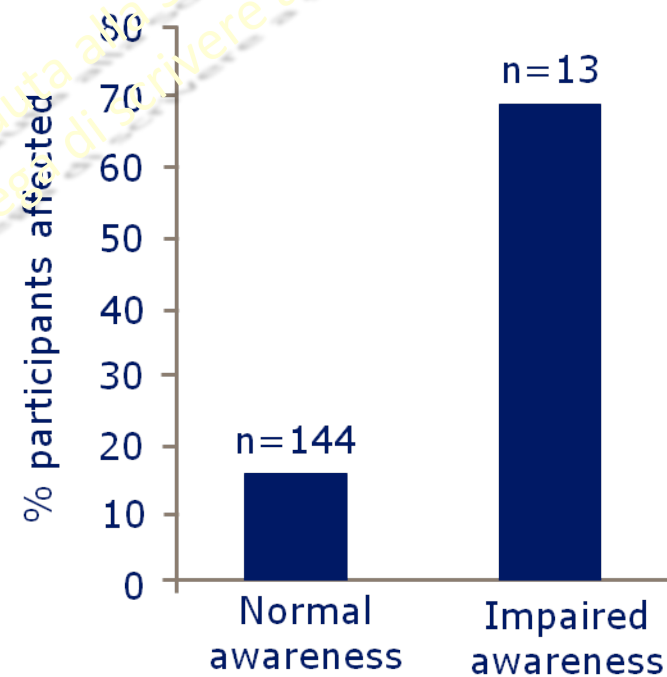
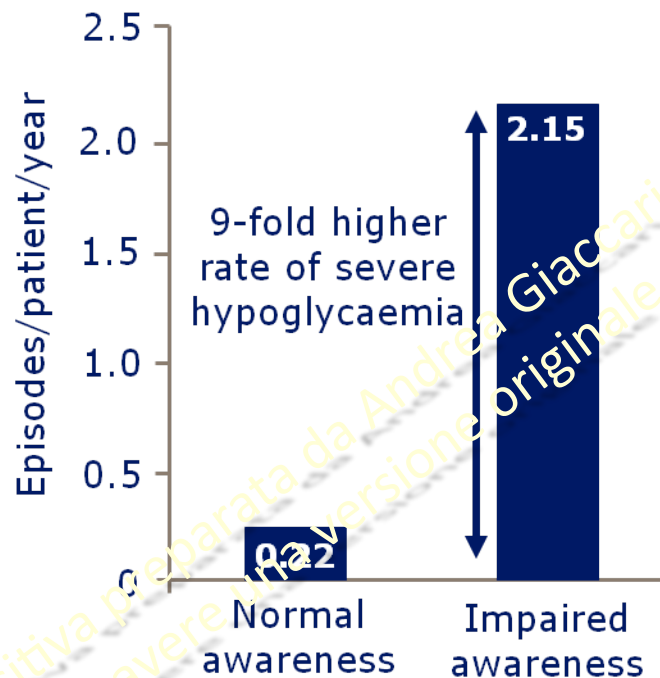


Epidemiology of hypos in UK



SU, sulphonylurea

Impaired awareness of hypoglycaemia is associated with higher rate of severe hypoglycaemia (type 1 or type 2)



ipoglicemie: agenda

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- ricoveri

eventi avversi iatrogeni (farmaci)

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Emergency Hospitalizations for Adverse Drug Events in Older Americans

Daniel S. Budnitz, M.D., M.P.H., Maribeth C. Lovegrove, M.P.H.,
Nadine Shehab, Pharm.D., M.P.H., and Chesley L. Richards, M.D., M.P.H.

Budnitz DS et al.: N Engl J Med 365:2002; 2011

eventi avversi: categorie farmaci

Table 2. National Estimates of Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, According to Therapeutic Category, 2007–2009.*

Therapeutic Category	Annual National Estimate of Hospitalizations (N = 99,628)		Proportion of Emergency Department Visits Resulting in Hospitalization
	no.	% (95% CI)	%
Hematologic agents	42,104	42.3 (35.5–49.0)	44.6
Endocrine agents	22,726	22.8 (16.7–28.9)	42.1
Cardiovascular agents	9,800	9.8 (7.1–12.5)	42.3
Central nervous system agents	9,621	9.7 (7.6–11.8)	32.2
Antiinfective agents	3,759	3.8 (2.6–4.9)	17.4
Antineoplastic agents	2,882†	2.9 (0.9–4.9)†	51.0
Other agents	3,211	3.2 (2.6–3.8)	15.0
Medications not stated or not known	957	1.0 (0.5–1.5)	20.6
Medications in more than one therapeutic category	4,568†	4.6 (2.7–6.5)	41.2

* Estimates were based on data from the NEISS–CADES project. The proportion of emergency department visits resulting in hospitalization is the ratio of hospitalizations to total emergency department visits for adverse drug events involving the specified therapeutic category.

† The coefficient of variation was greater than 30%.

ipoglicemie: categorie

Table 3. National Estimates of Emergency Hospitalizations for Common Manifestations of Adverse Drug Events in Older U.S. Adults, 2007–2009.*

Therapeutic Category and Adverse-Event Manifestation†	Annual National Estimate of Hospitalizations	Proportion of Emergency Department Visits Resulting in Hospitalization
	% (95% CI)	%
Endocrine agents		
Hypoglycemia with loss of consciousness or seizure	26.0 (13.5–38.4)	57.5
Hypoglycemia with altered mental status or other neurologic sequelae	40.7 (31.8–49.5)	42.4
Hypoglycemia with cardiovascular sequelae	8.3 (6.1–10.4)	49.6
Hypoglycemia with weakness, dyspnea, or respiratory distress	5.7 (3.0–8.5)	47.5
Hypoglycemia with other or unspecified sequelae	14.0 (6.2–21.8)	37.3

eventi avversi: tipi di farmaci

Table 4. National Estimates of Medications Commonly Implicated in Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.*

Medication	Annual National Estimate of Hospitalizations (N=99,628)		Proportion of Emergency Department Visits Resulting in Hospitalization
	no.	% (95% CI)	%
Most commonly implicated medications†			
Warfarin	33,171	33.3 (28.0–38.5)	46.2
Insulins	13,854	13.9 (9.8–18.0)	40.6
Oral antiplatelet agents	13,263‡	13.3 (7.5–19.1)	41.5
Oral hypoglycemic agents	10,656	10.7 (8.1–13.3)	51.8
Opioid analgesics	4,778	4.8 (3.5–6.1)	32.4
Antibiotics	4,205	4.2 (2.9–5.5)	18.3
Digoxin	3,465	3.5 (1.9–5.0)	80.5
Antineoplastic agents	3,329‡	3.3 (0.9–5.8)‡	51.5
Antiadrenergic agents	2,899	2.9 (2.1–3.7)	35.7
Renin–angiotensin inhibitors	2,870	2.9 (1.7–4.1)	32.6
Sedative or hypnotic agents	2,469	2.5 (1.6–3.3)	35.2
Anticonvulsants	1,653	1.7 (0.9–2.4)	40.0
Diuretics	1,071‡	1.1 (0.4–1.8)‡	42.4

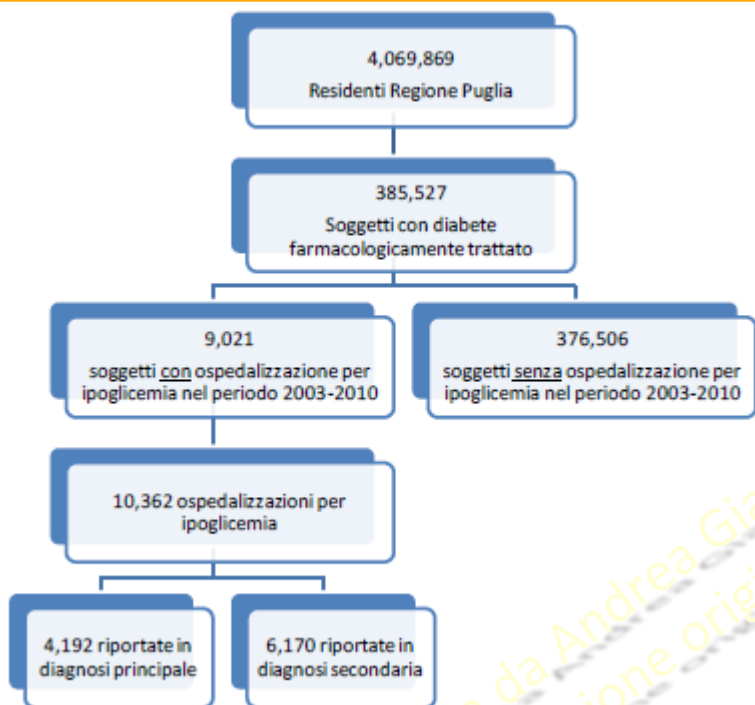
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10362 ospedalizzazioni



40% diagnosi principale
60% diagnosi secondaria

Tabella 1 – Frequenza delle diagnosi principali segnalate in associazione alla diagnosi di ipoglicemia quando questa viene riportata come diagnosi secondaria.

Diagnosi principale	N (%)
Malattie del sistema circolatorio	1646 (26.68%)
Malattie dell'apparato respiratorio	532 (8.62%)
Malattie dell'apparato digerente	524 (8.49%)
Tumori	464 (7.52%)
Malattie del sistema genitourinario	461 (7.52%)
Traumatismi e avvelenamenti	440 (7.18%)
Malattie endocrine, nutrizionali, metaboliche e disturbi immunitari	420 (6.81%)
Malattie del sistema osteomuscolare e del tessuto connettivo	348 (5.68%)
Sintomi, Segni e stati morbosi mal definiti	341 (5.56%)
Malattie del sistema nervoso e degli organi di senso	353 (5.72%)
Malattie della cute e del tessuto sottocutaneo	293 (4.78%)
Disturbi psichici	118 (1.91%)
Malattie del sangue e degli organi ematopoietici	103 (1.67%)
Malattie infettive e parassitarie	31 (0.51%)
Complicanze della gravidanza del parto e del puerperio	17 (0.28%)
Malformazioni congenite	5 (0.08%)
Classificazione supplementare dei fattori che influenzano lo stato di salute e il ricorso ai servizi sanitari (Chemioterapia, Problemi relativi agli arti e altri problemi,...)	74 (1.21)

Tassi di incidenza per anno e per fasce d'età

Figura 2 – Andamento dei tassi di incidenza delle ospedalizzazioni per ipoglicemia nel periodo 2003-2010.

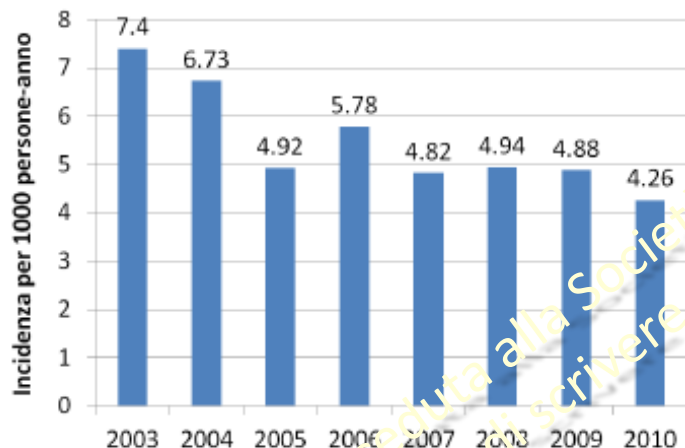
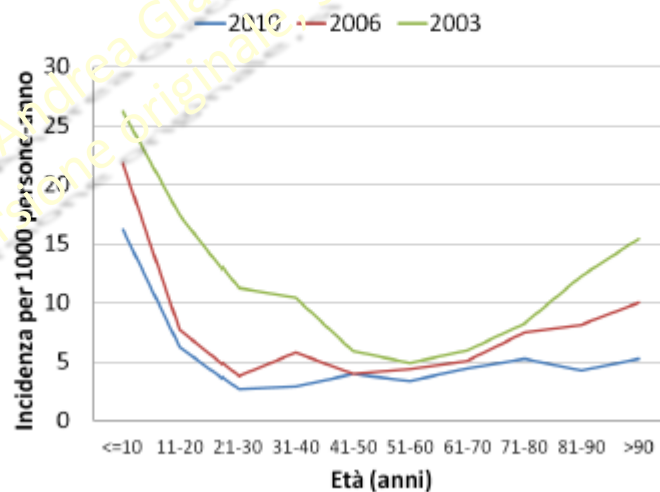


Figura 3 – Andamento dei tassi di incidenza delle ospedalizzazioni per ipoglicemia nel periodo 2003, 2006, 2010 in base all'età.



Diapositiva preparata da Andrea Giaccari e colleghi
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Distribuzione per tipo di diabete ed età

Figura 4 – Percentuale degli eventi sul numero complessivo di eventi nelle diverse fasce di età e confronto 2003-2010.

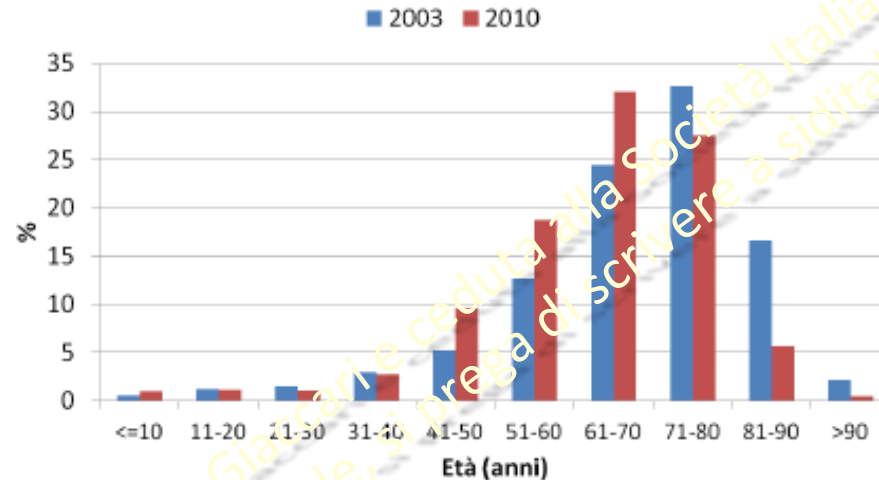


Tabella 5 – Distribuzione delle ipoglicemie in relazione al tipo di diabete e all'anno di osservazione.

Anno di osservazione	DM1	DM2
2003	72/968 (7.44%)	896/968 (92.56%)
2004	65/1026 (6.34%)	961/1026 (93.66%)
2005	78/817 (9.55%)	739/817 (90.45%)
2006	98/1056 (9.28%)	958/1056 (90.72%)
2007	90/939 (9.58%)	849/939 (90.42%)
2008	90/1033 (8.71%)	943/1033 (91.29%)
2009	94/1101 (8.54%)	1007/1101 (91.46%)
2010	70/965 (7.25%)	895/965 (92.75%)
Totale	657/7905 (8.31%)	7248/7905 (91.69%)

Diapositiva preparata da A. Nicolucci
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Distribuzione per tipologia di trattamento

= ↑ ↑ ↓ =

Tabella 7 – Distribuzione degli eventi ipoglicemici in base ai regimi terapeutici e al tipo di diabete nei diversi anni di osservazione.

Anno di osservazione	DM1	DM2 BOT	DM2 BB	DM2 OT	DM2 Other
2003	72/968 (7.44%)	6/968 (0.62%)	44/968 (4.55%)	544/968 (56.20%)	302/968 (31.20%)
2004	65/1026 (6.34%)	31/1026 (3.02%)	51/1026 (4.97%)	531/1026 (51.75%)	348/1026 (33.92%)
2005	78/817 (9.55%)	28/817 (3.43%)	43/817 (5.26%)	390/817 (47.74%)	278/817 (34.03%)
2006	98/1056 (9.28%)	43/1056 (4.07%)	66/1056 (6.25%)	508/1056 (48.11%)	341/1056 (32.29%)
2007	90/939 (9.58%)	39/939 (4.15%)	77/939 (8.20%)	469/939 (49.95%)	264/939 (28.12%)
2008	90/1033 (8.71%)	47/1033 (4.55%)	93/1033 (9.00%)	515/1033 (49.85%)	288/1033 (27.88%)
2009	94/1101 (8.54%)	60/1101 (5.45%)	122/1101 (11.08%)	497/1101 (45.14%)	328/1101 (29.79%)
2010	70/965 (7.25%)	49/965 (5.08%)	140/965 (14.51%)	423/965 (43.83%)	283/965 (29.33%)
Totale	657/7905 (8.31%)	303/7905 (3.83%)	636/7905 (8.05%)	3877/7905 (49.04%)	2432/7905 (30.77%)

DM1, Diabete di tipo 1; DM2, Diabete di tipo 2; BOT, Basal Oral Therapy; BB, Basal Bolus; OT, Oral Therapy; Other, Altri schemi terapeutici

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costi indiretti delle ipoglicemie

Table 2 – Diabetes management after last NSHE.

	Total	USA	UK	Germany	France	P value
Used to recover from last NSHE, N (%)						
Glucose tablets or gel	295 (21.0%)	95 (23.2%)	94 (24.4%)	41 (18.6%)	62 (16.6%)	0.028*
Sugar packs, candy or cake	373 (26.6%)	84 (20.5%)	66 (17.1%)	65 (27.5%)	158 (42.2%)	<0.001*
Soda, juice, sweet tea or milk	421 (30.0%)	145 (35.5%)	113 (29.4%)	65 (28.0%)	97 (25.9%)	0.026*
Light meal (e.g. sandwich)	324 (23.1%)	118 (28.9%)	98 (25.5%)	45 (19.1%)	63 (16.8%)	<0.001*
Full meal (e.g. lunch or dinner)	150 (10.7%)	57 (13.9%)	31 (8.1%)	14 (5.9%)	48 (12.8%)	0.002*
Other	66 (4.7%)	28 (6.8%)	23 (6.0%)	4 (1.7%)	11 (2.9%)	0.005*
Number of extra blood sugar tests after last NSHE, mean (SD)						
First day (day of NSHE)	1.9 (2.9)	1.7 (3.2)	1.8 (1.9)	1.8 (1.6)	2.1 (3.9)	0.173
Second day	1.1 (2.5)	0.8 (3.7)	1.1 (1.7)	0.9 (1.4)	1.4 (2.1)	0.017
Third day	0.8 (2.8)	0.7 (4.4)	0.8 (1.5)	0.7 (1.2)	1.1 (2.2)	0.251
Fourth to seventh day	2.2 (5.2)	1.4 (3.7)	2.5 (6.3)	1.8 (4.2)	3.1 (5.7)	<0.001
Total (7 days after NSHE)	5.6 (3.5)	3.9 (6.8)	6.2 (9.7)	5.1 (7.5)	7.3 (9.1)	<0.001
Contacted a health-care professional [†] after last NSHE						
Yes, N (%)	349 (24.9%)	56 (13.7%)	99 (25.7%)	56 (23.7%)	138 (36.9%)	<0.001*
Did your LAST NSHE cause you to decrease your normal insulin dose?						
Yes, N (%)	351 (25.0%)	109 (26.7%)	101 (26.2%)	33 (14.0%)	108 (28.9%)	<0.001*
Total units decreased, mean (SD)	6.5 (13.1)	6.3 (8.0)	6.2 (9.9)	6.5 (9.3)	6.8 (19.4)	0.988 [‡]
Days decreased, mean (SD)	3.6 (5.1)	4.7 (6.5)	3.1 (4.2)	3.1 (4.8)	3.2 (4.0)	0.062 [‡]

NSHE, non-severe hypoglycemic event; SD, standard deviation.

* Chi square.

[†] Primary care doctor, hospital, diabetes clinic, other.

[‡] Analysis of variance (ANOVA).

costi sociali delle ipoglicemie.

Table 3 – Productivity impact of an NSHE.

	Total	USA	UK	Germany	France	P value
NSHE during working hours, N (with 5% trim)*	N = 963	N = 278	N = 232	N = 170	N = 283	
Missing work time, N (%)	176 (18.3%)	30 (10.8%)	54 (23.3%)	15 (8.8%)	77 (27.2%)	<0.001 ^s
If missing work time, what was the amount of work time lost, mean (SD)	9.9 (8.4)	10.2 (9.5)	11.4 (9.2)	8.3 (7.1)	8.9 (7.6)	0.467
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, (N) %	231 (23.8%)	48 (17.2%)	65 (28.8%)	29 (17.0%)	86 (30.1%)	<0.001 ^s
NSHE outside working hours, N (with 5% trim) [†]	N = 1046	N = 307	N = 287	N = 173	N = 279	
Missing work time, N (%)	150 (14.3%)	26 (8.5%)	41 (14.3%)	14 (8.1%)	69 (24.7%)	<0.001 ^s
If missing work time, what was the amount of work time lost, mean (SD)	12.6 (11.0)	11.1 (10.5)	15.1 (13.6)	9.2 (7.4)	12.4 (9.9)	0.268
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, N (%)	173 (16.4%)	39 (12.7%)	49 (17.0%)	17 (9.7%)	68 (24.2%)	<0.001 ^s
Nocturnal NSHE, N (with 5% trim) [‡]	N = 612	N = 205	N = 153	N = 88	N = 166	
Missing work time, N (%)	139 (22.7%)	29 (14.1%)	43 (28.1%)	14 (15.9%)	53 (31.9%)	<0.001 ^s
If missing work time, what was the amount of work time lost, mean (SD)	14.7 (11.6)	14.3 (11.8)	14.2 (10.2)	12.5 (12.7)	15.9 (12.5)	0.787
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, N (%)	197 (31.8%)	48 (23.3%)	62 (40.3%)	20 (22.2%)	67 (39.4%)	<0.001 ^s

NSHE, non-severe hypoglycemic events.

* The top 5% was trimmed for these results. This dropped 9 patients (1 from the USA, 4 from the UK, 1 from Germany, and 3 from France).

† The top 5% was trimmed for these results. This dropped 7 patients (2 from the UK, 3 from Germany, and 2 from France).

‡ The top 5% was trimmed for these results. This dropped 8 patients (1 from the USA, 1 from the UK, 2 from Germany, and 4 from France).

^s Chi square.

^{||} Analysis of variance (ANOVA).

costi aggiuntivi delle ipoglicemie

Table 5 – Monthly out-of-pocket costs.

	Total	USA	UK	Germany	France	P value
Total out of pocket costs, \$,* (SD), N	\$ 25.29 (30.74) N = 1044	\$ 35.56 (37.04) N = 298	\$ 16.94 (23.26) N = 299	\$ 22.71 (25.50) N = 178	\$ 24.91 (30.37) N = 269	<0.001
Extra/special groceries	\$ 21.48 (21.84) N = 375	\$ 32.94 (28.25) N = 104	\$ 12.28 (12.45) N = 121	\$ 19.59 (16.41) N = 51	\$ 21.55 (20.30) N = 99	<0.001
Food or drink from vending machines or café/restaurants	\$ 7.29 (7.75) N = 609	\$ 7.82 (8.44) N = 183	\$ 5.33 (6.47) N = 195	\$ 7.70 (7.52) N = 93	\$ 9.09 (8.12) N = 138	<0.001
Glucose products such as tablets, gum, gel tubes, etc.	\$ 8.24 (8.44) N = 513	\$ 8.86 (7.71) N = 159	\$ 5.79 (8.33) N = 165	\$ 8.46 (7.53) N = 85	\$ 11.01 (9.38) N = 104	<0.001
Extra test strips, lancets	\$ 17.23 (19.51) N = 385	\$ 23.58 (22.40) N = 159	\$ 8.01 (12.50) N = 85	\$ 17.81 (17.79) N = 59	\$ 14.07 (16.09) N = 82	<0.001
Using a taxi, bus or other transportation	\$ 19.43 (19.10) N = 143	\$ 35.83 (23.32) N = 12	\$ 11.97 (13.13) N = 67	\$ 20.95 (18.26) N = 26	\$ 26.39 (21.59) N = 38	<0.001
Other (specify)	\$ 8.33 (11.95) N = 32	\$ 12.50 (15.16) N = 12	\$ 7.53 (11.38) N = 12	\$ 2.69 (2.72) N = 5	\$ 4.23 (3.02) N = 3	0.410

* Costs provided in US dollars (USD).

Diapositiva preparata da Andrea Sacchari
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- costi indiretti e sociali
- conseguenze terapeutiche

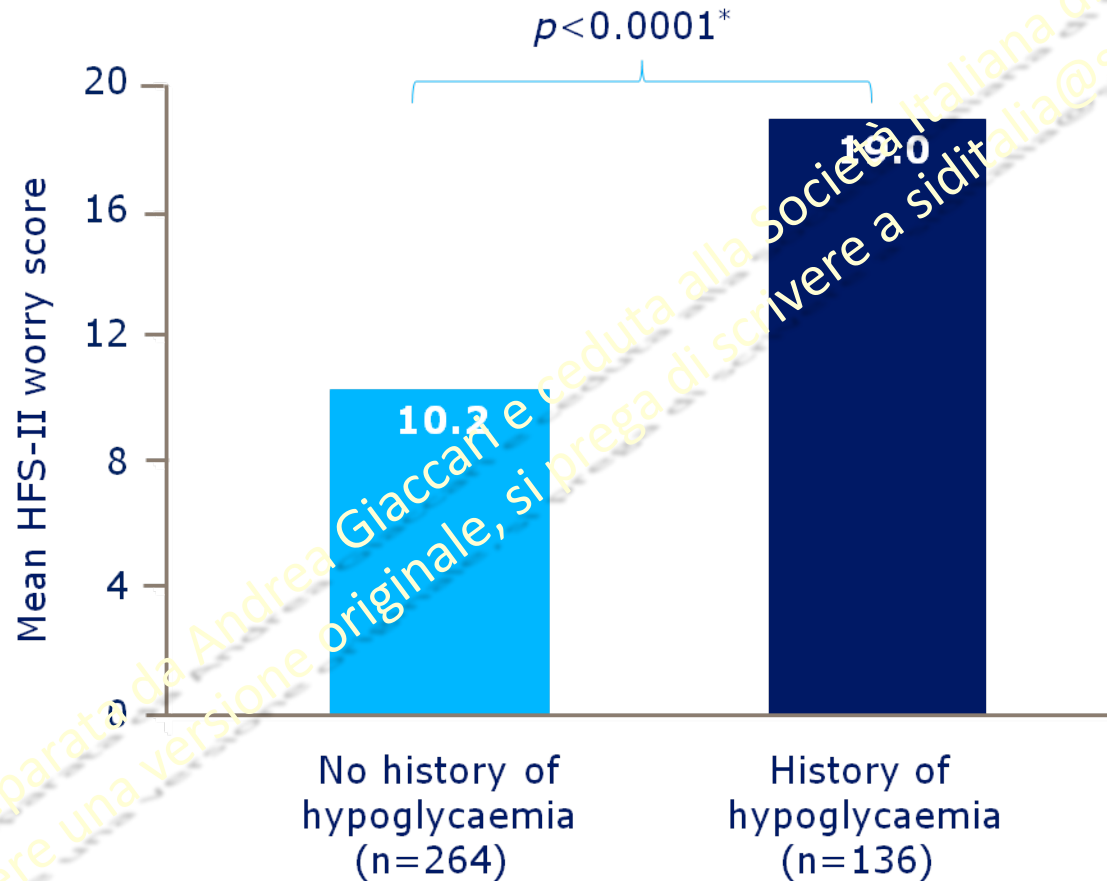
Diapositiva preparata da Andrea Giaccari e ceduta alla Società Italiana di Diabetologia.
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reazioni del Paziente alle ipo

Table 4. Percentage of patients who “sometimes” or “always” made lifestyle changes following a hypoglycemic episode†

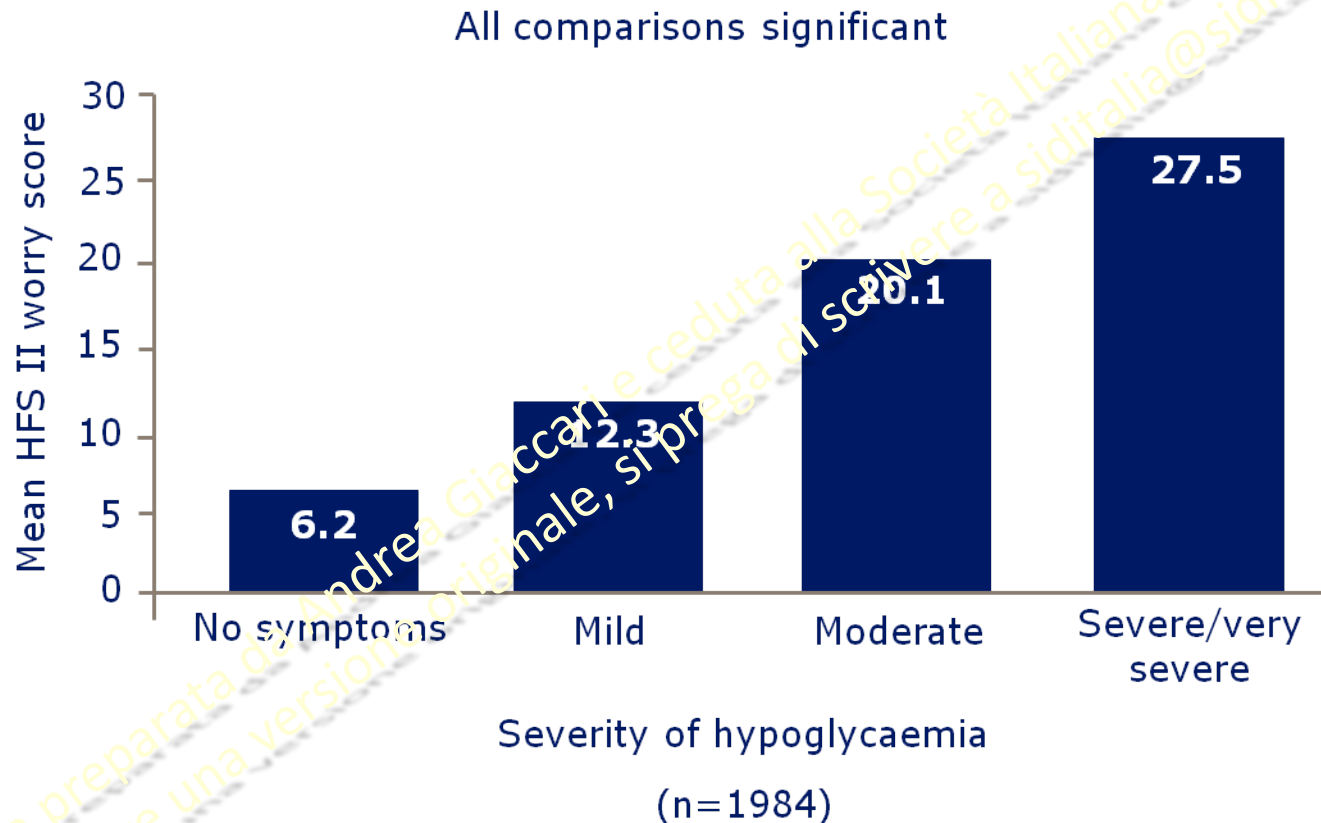
Lifestyle changes	Mild or moderate hypoglycemic episodes		Severe hypoglycemic episodes	
	Type 1 diabetes n=193	Type 2 diabetes n=97	Type 1 diabetes n=55	Type 2 diabetes n=19
Modified insulin dose to avoid future hypoglycemia	74.1%	43.3%*	78.2%	57.9%
Ate extra food	66.8%	62.9%	70.9%	63.2%
Had greater fear of future hypoglycemia	37.8%	29.9%	63.6%	84.2%
Had additional concerns about driving	29.2%	9.4%*	36.4%	15.8%
Asked someone to check on them	9.3%	14.4%	45.5%	57.9%
Went home from school, work, activities	6.7%	10.3%	25.5%	32.0%
Stayed home the next day	1.6%	9.3%**	20.0%	26.3%

Patient fear of hypoglycaemia increases with history of hypoglycaemia



HFS-II, Hypoglycaemia Fear Survey-II

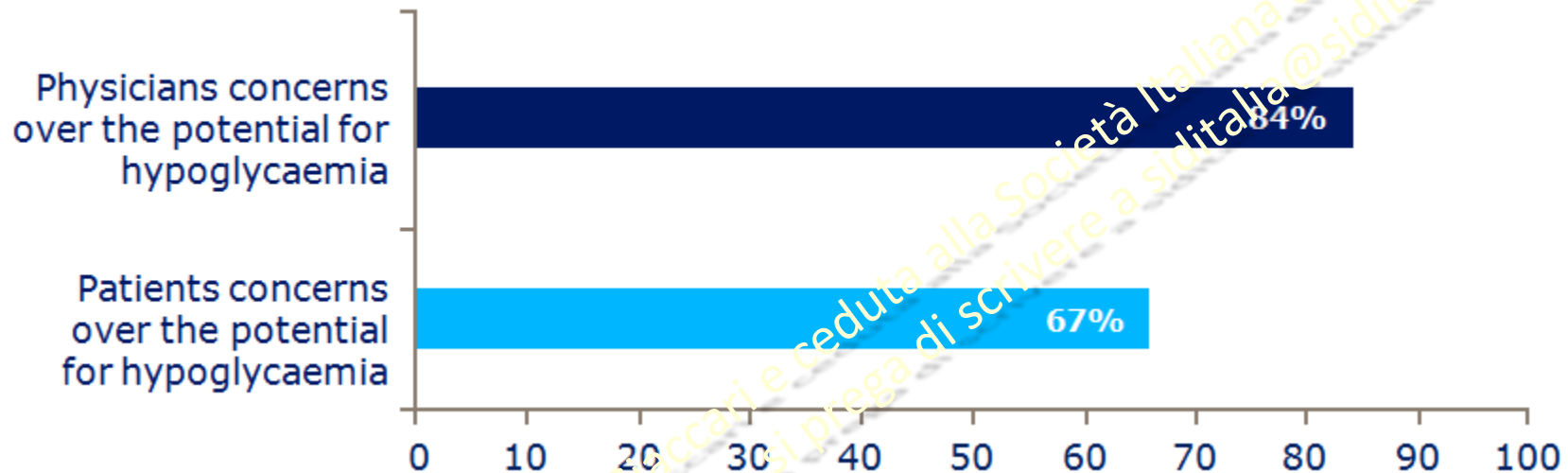
Patient fear of hypoglycaemia increases with increased severity of hypoglycaemia



HFS: Hypoglycaemia Fear Survey

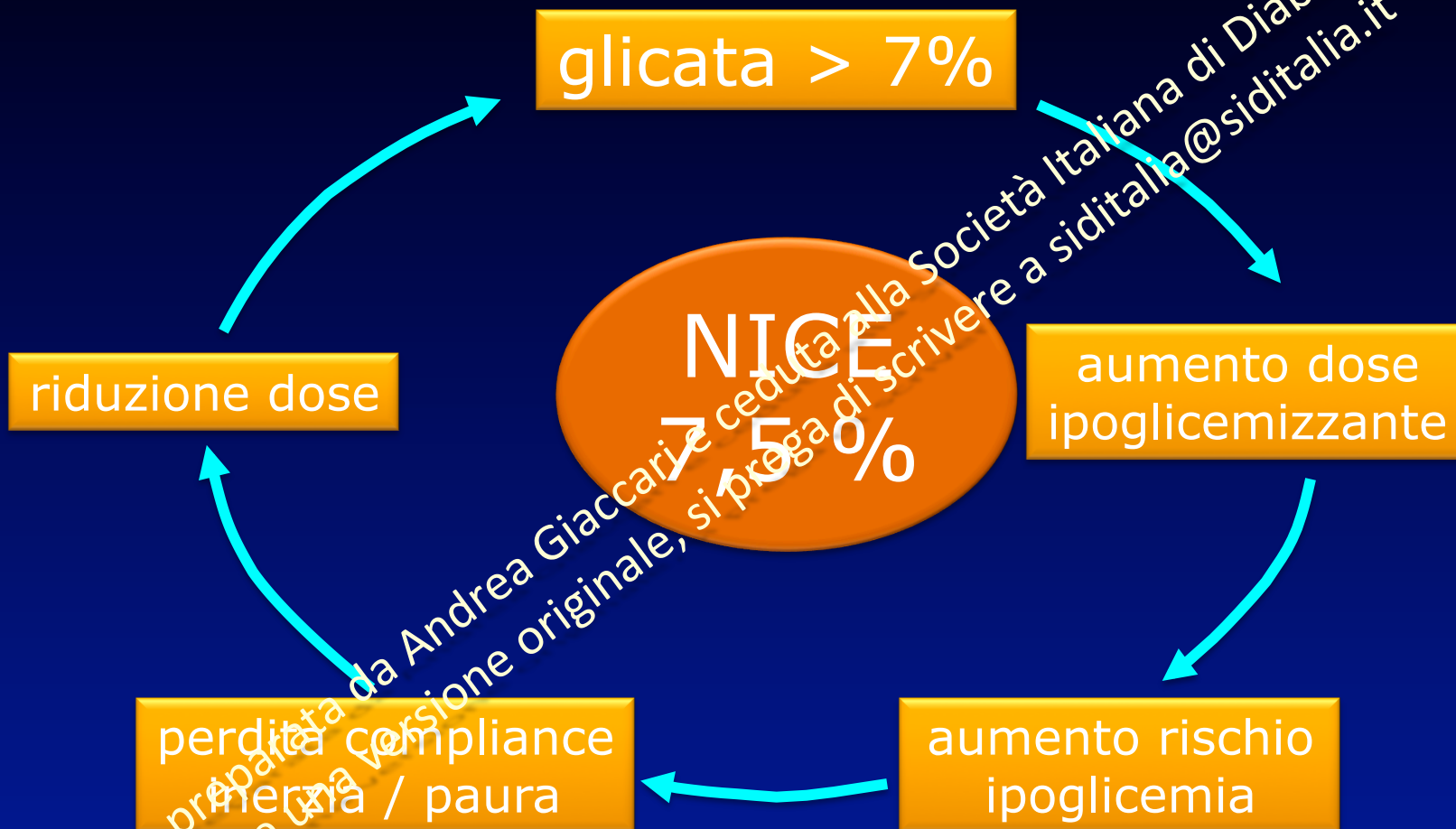
Hypoglycaemia is a barrier to effective glycaemic management

Results:



- High levels of concern over hypoglycaemia
- 60% of patients experienced a hypoglycaemic event in the past 12 months
- 76% of patients said that hypoglycaemia is one of the most fearful parts of having diabetes
- 74% of physicians would treat patients' diabetes more ambitiously if there was no concern over hypoglycaemic events

L'INERZIA



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Frequency of hospitalization for hypoglycemia and of all emergency calls in T2DM patients exposed to vildagliptin vs insulin secretagogues: an analysis of the national French health-insurance database

Results:

1440 patients were exposed to vildagliptin and 10019 to insulin secretagogues. After adjustments, rates of HH and of all emergency calls were significantly lower with vildagliptin vs insulin secretagogues

Adjusted comparison of the frequency of events in the 2 cohorts

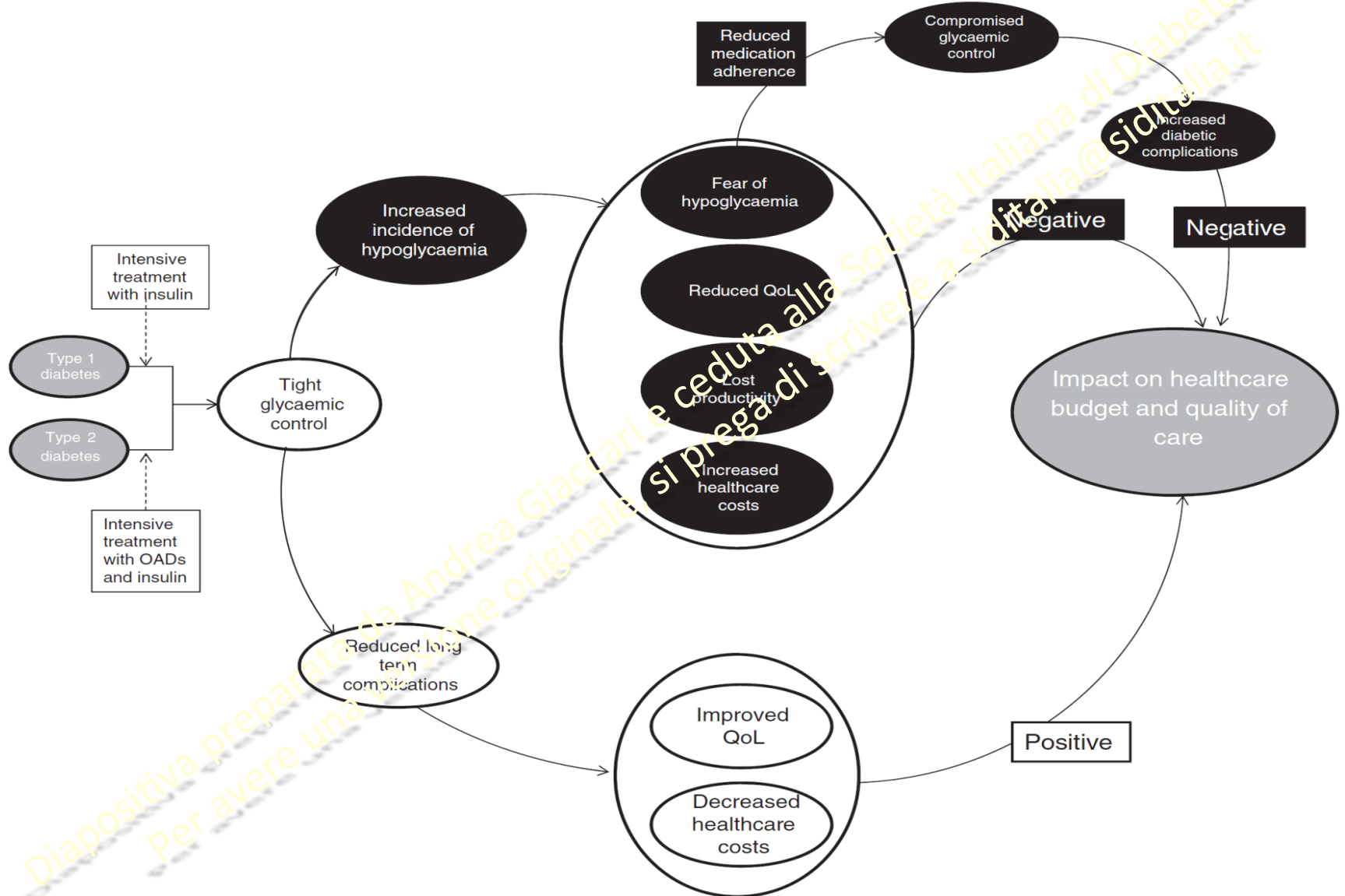
	Vildagliptin N=1440	Sulfonylurea /glinide N=10019	p-value
Patient-year (PY) exposure	581	4403	
No. of patients with hospitalization for hypoglycemia	0 (0.0%)	59 (0.59%)	p=0.0034
No. of hospitalizations for hypoglycemia	0	60	
Adjusted rates of hospitalizations for hypoglycemia/1000 PY	0.0 [0.0 ; 0.0]	13.6 [10.4 ;17.5]	p=0.0003
No. of patients with emergency calls (any cause)	60 (4.20%)	823 (8.21%)	p<0.0001
No. of emergency calls	77	1035	
Adjusted rates of emergency calls/1000 PY	132.6 [104.6; 165.6]	235.0 [220.9; 249.8]	p<0.0001

ipoglicemie: agenda

- CVD
- cause
- frequenza
- ricoveri
- dati Italiani
- costi indiretti e sociali
- conseguenze terapeutiche
- considerazioni finali

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Fidler C. et al.: J Med Economics 14:646; 2011



Le conseguenze dell'ipoglicemia

