

Dr. Luigi Cantarutti

Coordinatore nazionale progetto Pedianet

NETWORK PEDIANET

Dai primi sistemi informativi
pediatrici alle innovazioni più recenti.
L'esperienza di **PEDIANET**

Milano Mario Negri,
novembre 2012



Sommario



- Che cosa e'
- Che tipo di studi e ricerche può fare
- Che cosa ha fatto
- Che cosa sta facendo
- Che cosa fara' in futuro

Che cosa è Pedianet...



- Un **network** dove collaborano competenze diverse e i migliori esperti internazionali in vari campi.
- Il **lavoro in team** di tutte le componenti rende possibile una ricerca del tutto originale.
- Il network è basato sulla **figura del PLS**, che acquisisce in tal senso un ruolo unico e insostituibile in ambito europeo.

Che tipi di studi...

Rete dei PLS

- **Studi prospettici**
- Raccolta dati ad hoc
- Tempi lunghi

Data-base centrale interrogabile

- **Studi retrospettivi**
- Analisi su dati già raccolti
- Tempi molto brevi



PEDIANET, che cosa ha prodotto...

Ricerca scientifica originale

The Incidence of Varicella: Correction of a Common Misconception

Alfredo Nicolosi,^{1,2} Miriam Sturkenboom,^{2,3} Sabina Luigi Camarero,⁴ and Carlo

Background. Increases in the incidence of varicella (chickenpox) have been reported since the discovery of an effective vaccine, but estimates to date have inconsistently ignored the question of susceptibility.

Methods. We studied the occurrence of varicella in Italy on the basis of 30,145 children (age 0–14 years) cited for 31 pediatricians between 1 October 1997 and 30 September 1998. The two-stage estimator was used to calculate the number of susceptible children. On this basis, we estimated the corrected age-specific and cumulative incidences.

Results. We identified 1749 cases among the estimated 17,780 susceptible children, for a crude incidence of 8.2% (95% confidence interval [CI] = 7.7–8.4). The age-specific incidence in the Italian population 0–14 years of age was 0.5 (CI = 0.5–0.5).

320. The 3–4 years age group, and to 6784. Considerable intercenter and interyear variation in vaccine coverage was observed (88.6%–98.8%).

Key

Clinical Consequences of Gastroenteritis in Europe, The REVEAL Study

Carlo Giaquinto,¹ Pierre Van Damme,² Frédéric Haert,³ Li

and Linaam
Department of
Pediatrics
University of

Background
Method
Results
Conclusions
Key words

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Active monitoring of adverse drug reactions in children

Distribution of Rotavirus Genotypes in Europe, 2004–2005: The REVEAL Study

Pierre Van Damme,¹ Carlo Giaquinto,² Melanie Maxwell,³ Peter Todd,⁴ and Marie Van der Wielen,¹ on behalf of the REVEAL Study Group*

¹Faculty of Medicine, Centre for the Evaluation of Vaccination, World Health Organization Collaborating Centre for the Control and Prevention of Viral Hepatitis, University of Antwerp, Belgium; ²Department of Pediatrics, University of Padova, Italy; ³Clinical Practice Research Unit, Hospital National Health Service Trust, Wirral, Merseyside, United Kingdom

Rotavirus gastroenteritis (RVGE) causes rotavirus genotypes in Europe 2004–2005 RVGE season, a 3 years of age seeking health care of Belgium, France, Germany, e-linked immunosorbent assay chain reaction (RT-PCR) analyses were available for 2712 of the 12 children, 1102 (40.6%) were active samples. G1–G4 and G5 gen, and the United Kingdom types were identified in all studied among the genotypes.

genotypes G1–G4 and G9 a apic and seasonal variation in protection against all major

(RVGE) constitutes a significant contributor to childhood morbidity in industrialized countries [1], but its morbidity in industrialized areas suggested that RVGE accounts for 27.8%–52.0% of AGE cases in emergency department consultations, as a

of the *Reoviridae* family. It is a genome, and 2 surface proteins

Van Damme, Faculty of Medicine, Centre for the Evaluation of Vaccination, WHO Collaborating Centre for the Control and Prevention of Viral Hepatitis, University of Antwerp, Campus 3 Eiken, University of Antwerp (Belgium); ²Carlo Giaquinto, Clinical Practice Research Unit, Wirral, Merseyside, United Kingdom

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Costs of Community-Acquired Pediatric Rotavirus Gastroenteritis in 7 European Countries: the REVEAL Study

Carlo Giaquinto,¹ Pierre Van Damme,² Frédéric Haert,³ Liif Cochebers,⁴ and Marie Van der Wielen,² on behalf of the REVEAL Study Group*

¹Department of Pediatrics, University of Padova, Padova, Italy; ²Faculty of Medicine, Centre for the Evaluation of Vaccination, World Health Organization Collaborating Centre for the Control and Prevention of Viral Hepatitis, University of Antwerp, Antwerp, Belgium; ³Service de pédiatrie 1, Hôpital de la Croix-Rouge, Centre Hospitalier Universitaire Dijon, Dijon, France; ⁴Department of Clinical Sciences, Pediatric, Umeå University, Umeå, Sweden

Background. Morbidity and resource use of acute gastroenteritis (AGE) in young children is high. A cost study was conducted to estimate the economic burden of acute gastroenteritis in Europe.

Multicenter Prospective Study of Rotavirus Acute Gastroenteritis in Europe, 2004–2005

Pierre Van Damme,¹ Carlo Giaquinto,² Frédéric Haert,³ Liif Cochebers,⁴ and Marie Van der Wielen,¹ on behalf of the REVEAL Study Group*

¹Faculty of Medicine, Centre for the Evaluation of Vaccination, World Health Organization Collaborating Centre for the Control and Prevention of Viral Hepatitis, University of Antwerp, Antwerp, Belgium; ²Department of Pediatrics, University of Padova, Italy; ³Clinical Practice Research Unit, Hospital National Health Service Trust, Wirral, Merseyside, United Kingdom

Rotavirus gastroenteritis (RVGE) is the most common cause of acute gastroenteritis (AGE) in young children worldwide. In Europe, many of whom require frequent hospital settings. The results of a multicenter study of acute gastroenteritis in Europe, 2004–2005, are presented.

Background. Rotavirus is recognized as the most common cause of acute gastroenteritis (AGE) in young children worldwide. In Europe, many of whom require frequent hospital settings. The results of a multicenter study of acute gastroenteritis in Europe, 2004–2005, are presented.

Methods. A prospective, multicenter study was conducted in 7 European countries (Belgium, France, Germany, Italy, the Netherlands, Sweden, and the United Kingdom) from October 2004 to September 2005. A total of 2846 children with acute gastroenteritis (AGE) were enrolled in the study.

Results. A total of 2846 children with acute gastroenteritis (AGE) were enrolled in the study. The most common genotype was G1 (40.6%), followed by G2 (27.8%), G3 (20.0%), G4 (11.6%), and G5 (1.0%).

Conclusions. Rotavirus is the most common cause of acute gastroenteritis (AGE) in young children worldwide. In Europe, many of whom require frequent hospital settings. The results of a multicenter study of acute gastroenteritis in Europe, 2004–2005, are presented.

Key words: Rotavirus, acute gastroenteritis, Europe, 2004–2005.

Rotavirus is the most common cause of acute gastroenteritis (AGE) in young children worldwide. In Europe, many of whom require frequent hospital settings. The results of a multicenter study of acute gastroenteritis in Europe, 2004–2005, are presented.

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ASTHMA PREVALENCE AND DRUG PRESCRIPTION IN ASTHMATIC CHILDREN

A. Barbato (1), C. Panizzolo (1), L. Biserna (2), L. Canterutti (3), C. Giaquinto (1), F. Frati (4), F. Marzulli (4), C. Mancioffi (1), R. Testi (5), R. di Blasi (5), MCJM Sturkenboom (6) and the Pedianet Family Pediatricians Asthma Study Group (F-PASG).

Summary

A cross-sectional study was conducted on 28,656 children aged from birth to 14 years to determine the prevalence of asthma and assess its treatment in a sample of asthmatic children. Children diagnosed with asthma were identified by a sensitive algorithm applied to the information stored in the computerized medical records between 1997 and 1998. Pediatricians then reviewed and validated the diagnosis. Specific information was obtained, after age stratification under 5 years and over 5 years from the medical records and by interview regarding their personal details and treatment of asthmatic patients. In all, 1,263 cases of asthma were identified (4.4% aged with a prevalence of 4.2% among males and 4.6% among females in under 5 year-olds, and 3.9% for males and 2.1% for females in over 5 year-olds). The prevalence of asthma diagnosed directly by the pediatrician was consequently higher among under 5 year-olds, in both genders, than among the older children. Consistent with the international guidelines, pediatricians prescribed more oral corticosteroids and inhaled short-acting β_2 -agonists for children under 5 years old than for over 5 year-olds (13.9% Vs 4.8%, and 25% Vs 10.9%, respectively, $p < 0.001$). For the 5–14 year-olds, the most commonly prescribed treatments were oral corticosteroids (13.9% Vs 13.8%), inhaled corticosteroids via metered-dose inhaler (30.8% Vs 28.7%) and sodium chromoglycate (12.1% Vs 4.8%, $p < 0.001$).

Key-words: Childhood asthma, Prevalence, Therapy.

INTRODUCTION

Asthma is the most common chronic disease of childhood [1] and its prevalence has been rising in recent decades [2–5], with a considerable variability in industrialized countries [6].

It is the main reason for hospitalization among children in the USA [7], where it is the cause of approximately 1% of all health expenditure [1,8].

In 1997–98, several reports were published containing essentially similar guidelines for the treatment of asthma in adults and children [9–11]. These recommendations have undergone further revision by the Global Initiative for Asthma (GINA) [12], demonstrating that the guidelines are continuously evolving. Though they appear to be clear and straightforward, few studies

1) Dept of Pediatrics, University of Padova, Italy; 2) Pediatric Unit of Bergamo, Italy; 3) Family Pediatrician, coordinate Pediatric group; 4) Dept of Clinical, Gastroenterology and Pediatric Sciences, University of Bergamo, Italy; 5) GlasnostKline SpA, Verona, Italy; 6) Child Health Services, Dept of Epidemiology & Biostatistics and Medical Informatics, Statens MC, Stockholm, Netherlands.

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trial for Merck, Sanofi Pasteur MSD, and GlaxoSmithKline Biologicals, Kr which the University of Antwerp receives research grants. C.G. has an educational grant from and a consultation agreement with Sanofi Pasteur MSD, GlaxoSmithKline, Abbott, Roche, Boehringer Ingelheim, LG, has been principal investigator of vaccine trials for GlaxoSmithKline, Merck, Sanofi Pasteur MSD, Wyeth, and MedImmune. All other authors report no potential conflicts.

Presented in part: XXV Annual Meeting of the European Society of Pediatric Infectious Diseases, Basel, Switzerland, 2–6 May 2006 (abstract 36); 7th Annual International Rotavirus Symposium, Lisbon, Portugal, 12–15 June 2006; European Academy of Paediatrics Congress, Barcelona, Spain, 7–10 October 2006.

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* Further details of the REVEAL Study Group are provided after the text.

PEDIATRICS

Incidence of Maculopapular Reactions in Children Treated With Niflumic Acid, Other Nonsteroidal Antiinflammatory Drugs, or Nonopioid Analgesics

Miriam Sturkenboom, Alfredo Nicolosi, Luigi Camarero, Salvatore Mammino, Gino Piccoli, Antonio Scanzarone, Carlo Giaquinto and for the NS.AID: Paediatric Research Group

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This information is current as of July 21, 2005

The online version of this article, along with updated information and services, is located on the World Wide Web at: <http://www.pediatrics.org/cgi/content/full/116/1/e26>

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In sintesi...

- 20 studi pubblicati sulle piu' importanti riviste internazionali (Lancet, BMJ, Epidemiology, European Annals of Allergy and Clinical Immunology, Pediatric Disease Journal, The Journal of Infectious Disease, Lancet Oncol, Pharmacological Research, Pediatr Drugs...)
- 70 comunicazioni o abstract ai congressi

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STUDI PROSPETTICI

Il primo studio...

Active monitoring of adverse drug reactions in children

In March, 1996, the project was presented to 32 family paediatricians practising in the Veneto Region, who volunteered to participate. They represented 8% of all family paediatricians in the region's health service. 29 agreed to participate in the study and were trained accordingly.

Each week (from April, 1996 to March, 1997) the participating paediatricians sent, by modem, a detailed electronic report of each observed ADR to the Mattonai Institute of Public Health (Istituto Superiore di Sanità) in Rome, where data were analysed and reported back to the doctors.

About 24 000 children were enrolled on the lists of the 29 paediatricians. We analysed 244 reports that included 388 events, with a suspected correlation with 266 prescriptions of 73 different substances.

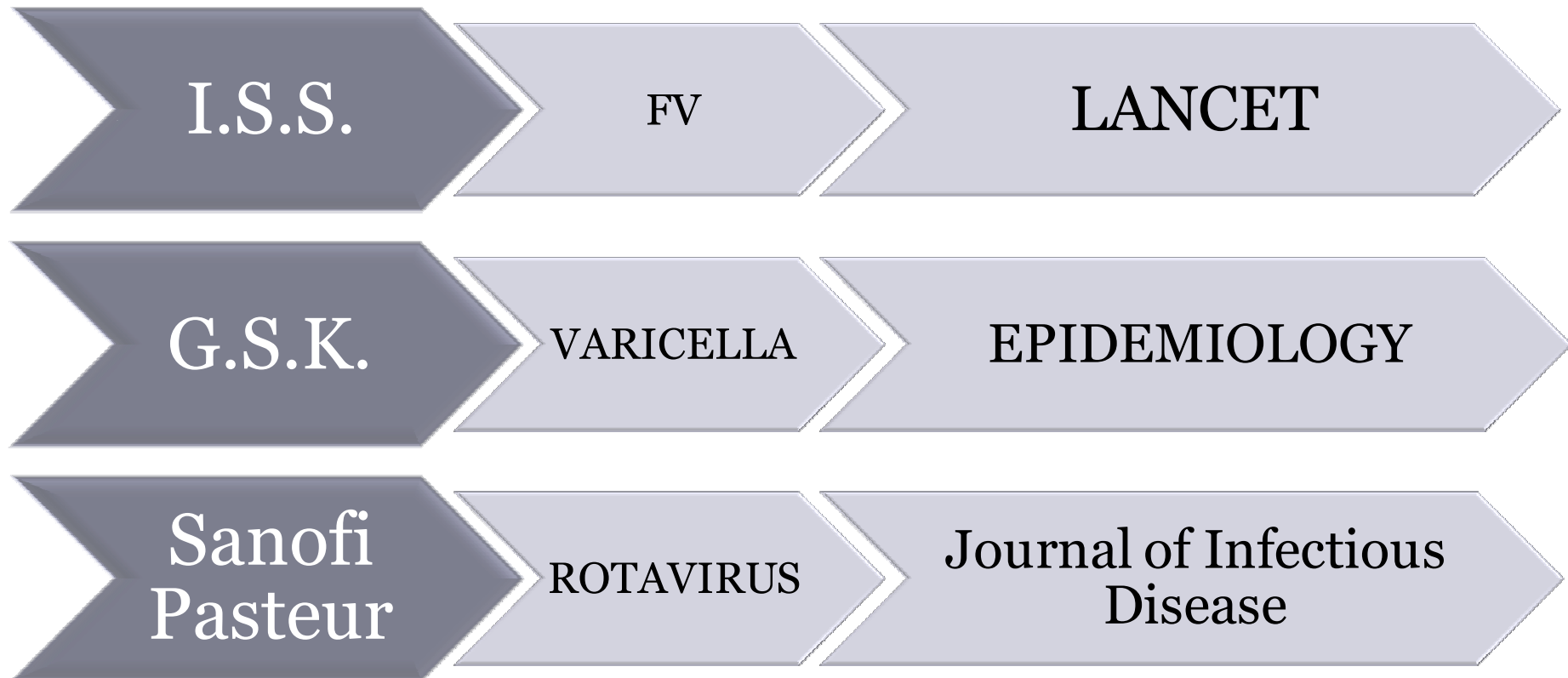
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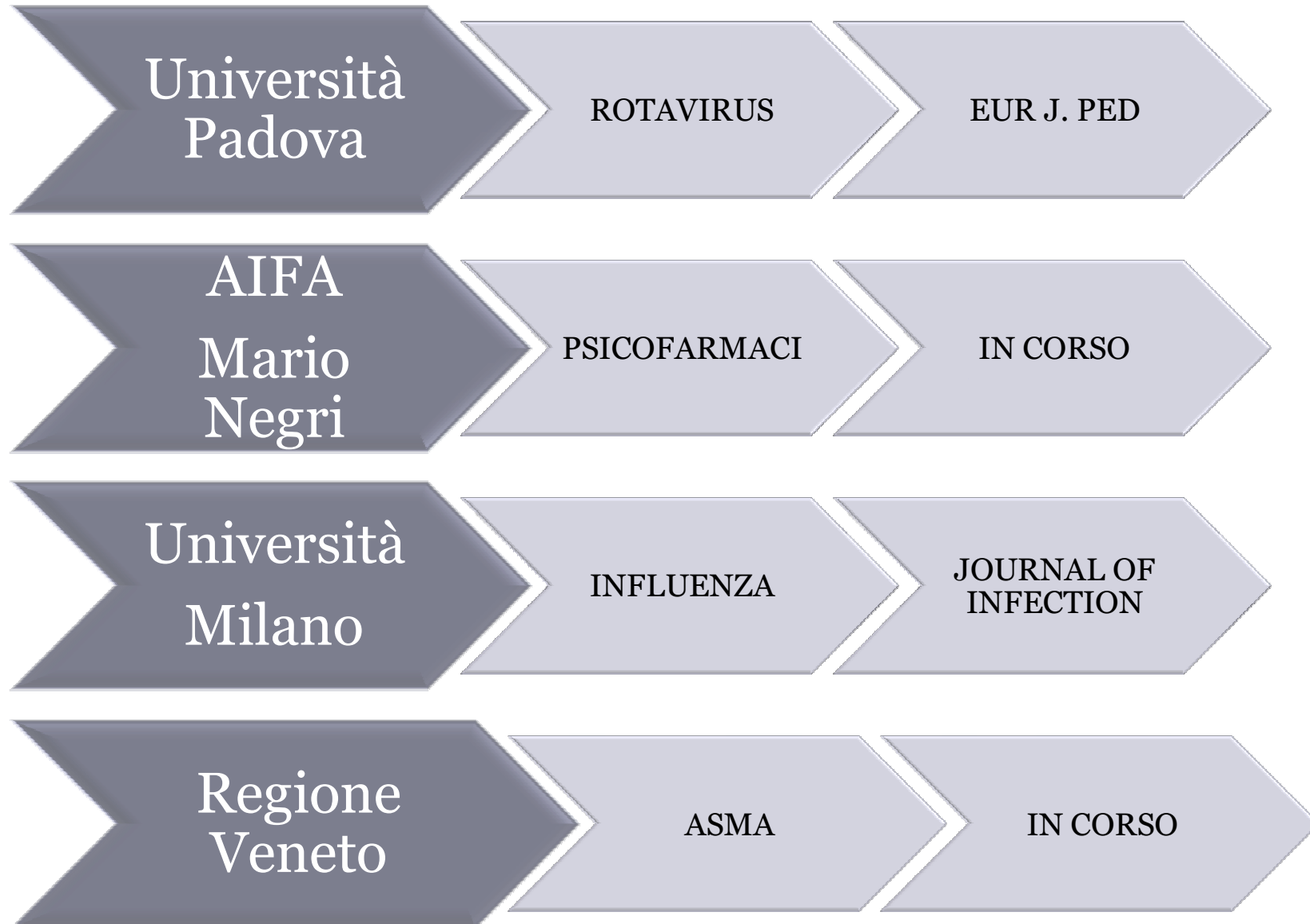
Procedure di attivazione di una ricerca prospettica



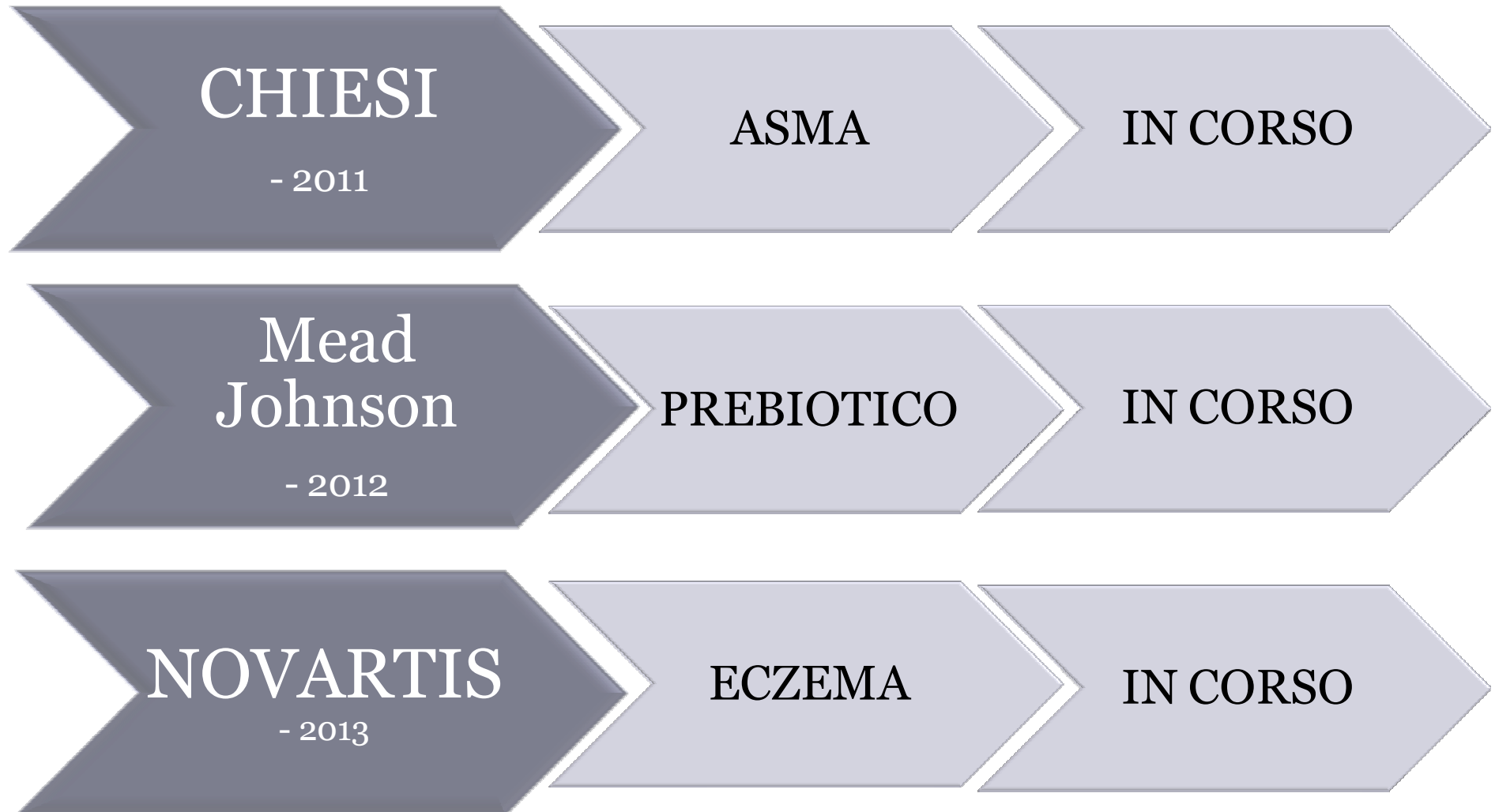
Esempi di studi prospettici...



Altri studi prospettici...



Altri studi prospettici...





STUDI RETROSPETTIVI

Si effettuano sul data-base centrale:

- Caratteristiche del sistema
- Contenuti

Il database centrale, caratteristiche

Studi retrospettivi



- Rete telematica attiva dal 1998
- 184 PLS
 - Formazione
 - Cartella cl. Informatizzata
- Struttura indipendente ([CS](#))
- Dati anonimi / aggregati
- Pazienti con consenso scritto al progetto
- Server centrale
- Data-set mensile composto da:
 - Motivi accesso
 - Diagnosi
 - Prescrizioni
 - Posologie
 - Ricoveri
 - Dati auxologici
 - Vaccinazioni
 - Diari clinici

Structure Pedianet



Patients (code)
Demographics (race/gender/dob)
date of registration/moving out

Medical files
Visits (date/motive)
Exams (date/type)
Vaccination (date/type)
Certificates
Measures(date/weight/height)
Hospitalization:
(date/reason/outcome)
Specialist visits
(date/referrals/diagnosis)

Prescription
Type
date
Product code
Dosing regimen
number
indication

Anamnestic: pregnancy, delivery, complications, drug use neonatal screening

Che cosa contiene...

- Pazienti arruolati: 173.198
- Numero visite registrate: 4.637.201
 - Diagnosi codificate: 3.616.860 (77%)
 - Con diagnosi e/o mot. contatto 4.266.040 (92%)
- Prescrizioni farmacologiche: 2.602.697
 - Di fascia A: 1.988.000
 - Con posologie associate: 54.94%
- Misure auxologiche: 1.362.169
- Ricoveri: 37.565
- Visite specialistiche: 574.984
- Esami strumentali: 297.180
- Esami ematologici: 611.349

Monitoraggio e verifica della qualità

- 1). **Percentuale dei pazienti arruolati sul totale dei pazienti seguiti**
E' necessario arruolare almeno il 70% dei pazienti nei primi due anni di adesione a Pedianet
- 2). **Numero totale di contatti registrati e numero medio di visite / paziente / anno**
- 3). **Percentuale dei contatti con testata compilata**
La testata deve essere compilata in una percentuale di contatti superiore all'80%.
- 4). **Percentuale dei contatti con "Motivo del contatto" compilato**
- 5). **Totale prescrizioni farmacologiche (divise in fascia A e in fascia C)**
La registrazione deve riguardare tutti i farmaci in fascia A e i farmaci in fascia C che richiedono ricetta medica
- 6). **Percentuale di prescrizioni farmacologiche legate alla diagnosi relativa.**
Attesa una percentuale di legame superiore al 70%.
- 7). **Percentuale di posologie presenti**
Per i farmaci di fascia A la percentuale di compilazione della posologia dovrebbe essere superiore al 70%
- 8). **Numero ricoveri registrati**
- 9). **Pazienti deceduti**
vanno registrati tutti i decessi con l'indicazione della data del decesso e, se conosciuto, anche del motivo del decesso.

Formazione e monitoraggio

Sistema automatico di valutazione basato su indicatori

Dott XY, Veneto, id :::::

1. Totale pazienti seguiti al 31/12/2009: 1363 Pazienti arruolati in Pedianet: 1067 (78.28%)
2. numero di visite registrate nel periodo considerato: 4420
3. numero medio di visite registrate per paziente pedianet: 4.14
4. numero di visite con testata compilata: 4326 (97.87%)
5. numero di visite con Motivi del Contatto compilato: 4036 (91.31%)
6. numero di prescrizioni registrate: 2010
7. rapporto prescrizioni/pazienti pedianet: 1.88
8. numero di prescrizioni in fascia A: 1200 (59.70%)
9. numero di prescrizioni in fascia C: 810 (40.30%)
10. numero di prescrizioni con legame-diagnosi: 1919 (95.47%)
11. numero di prescrizioni con posologia: 1881 (93.58)
12. numero di ricoveri registrato: 93
13. pazienti deceduti: 2 (manca data e causa del decesso)

Considerazioni:

I suoi dati sono di buona qualità.

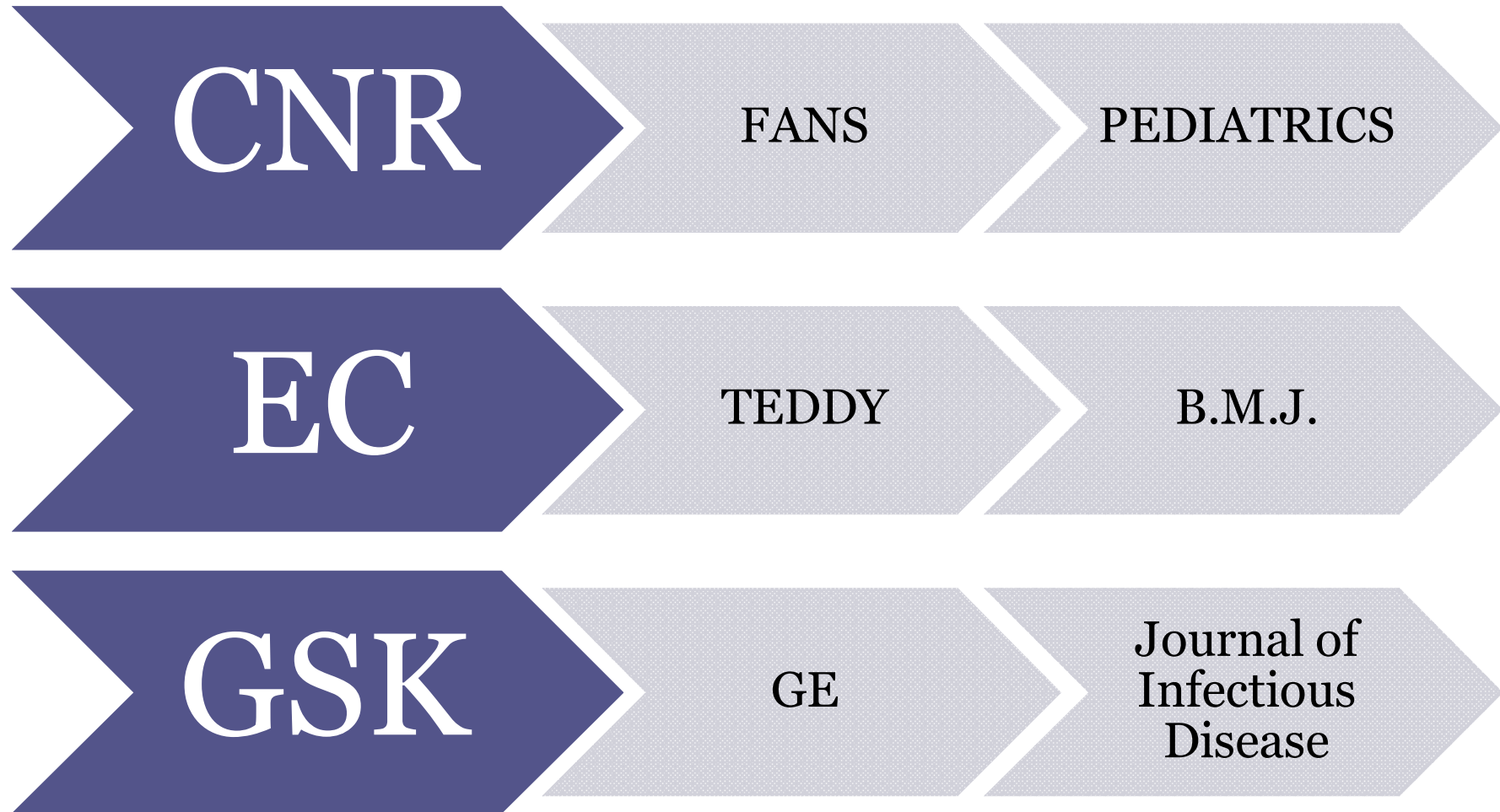
Miglioramento possibile: registrare sempre la data e la causa di eventuali decessi



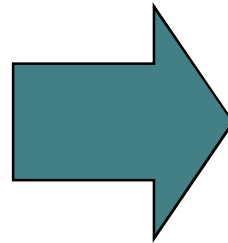
Punti di forza del sistema PEDIANET

- Presenza delle DIAGNOSI di malattia
- Presenza della POSOLOGIA dei farmaci
- Legame delle prescrizioni con le diagnosi
- Possibilità di ritornare al paziente per info supplementari
- Attività di raccolta dati routinaria che non incide con carichi ulteriori di lavoro

Ricerche retrospective effettuate

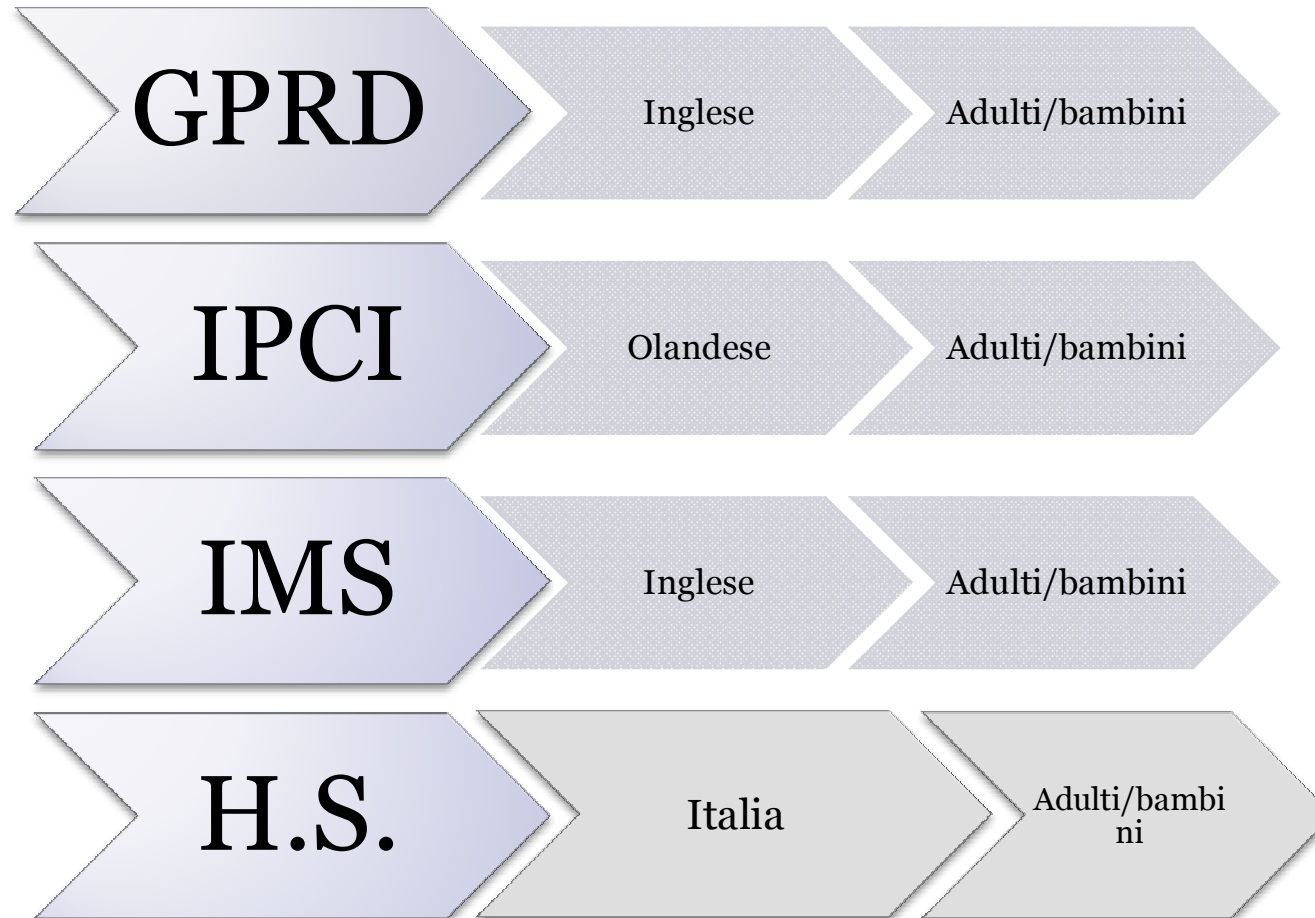


Che cosa sta facendo...

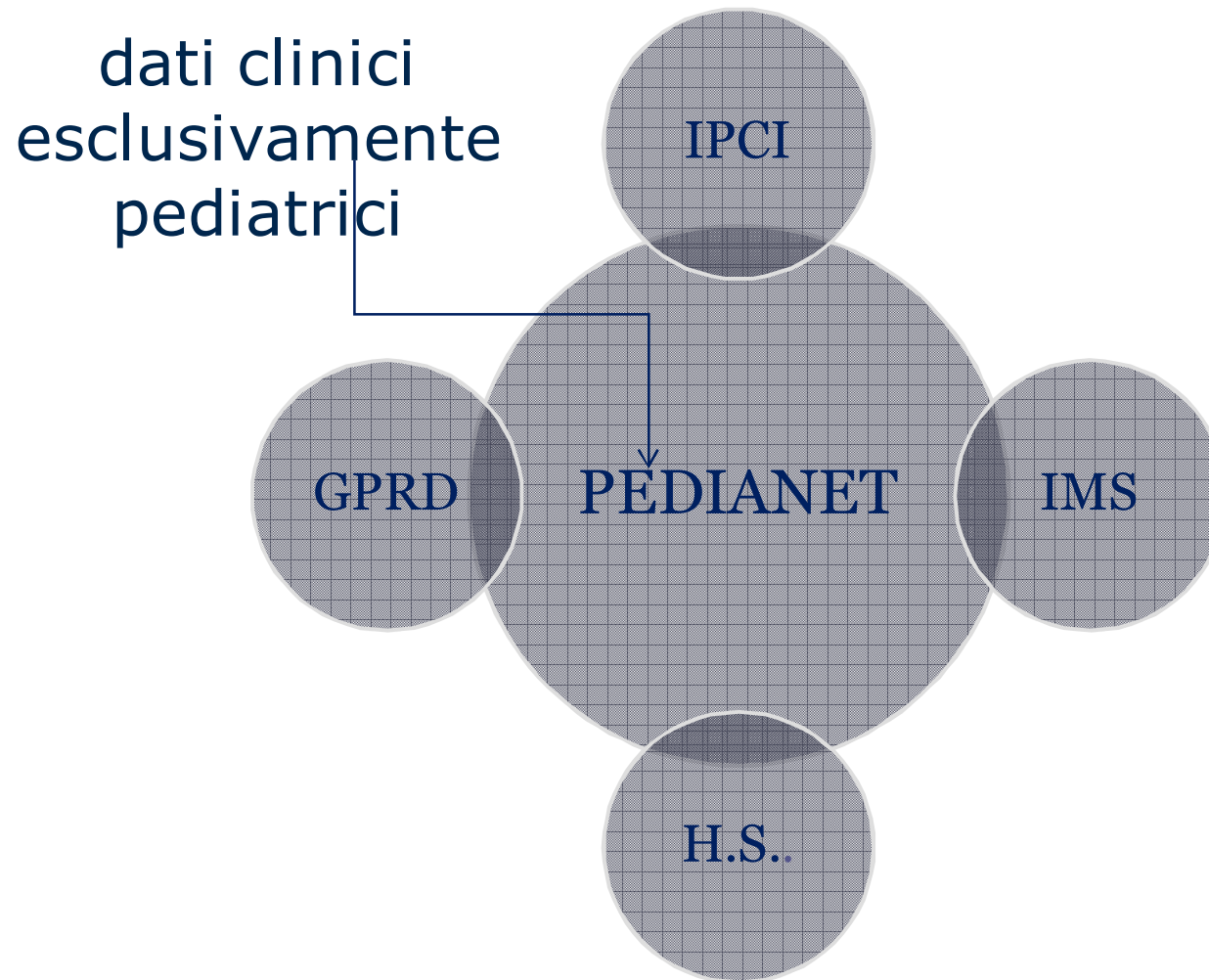


Studio Prebiotici
Studio Asma Veneto
Studio dermatite atopica
Vaccino varicella Reg. Veneto

Database europei



Data-base europei con dati pediatrici



Progetti finanziati dalla Commissione Europea

Progetto TEDDY - 2005

Task force in Europe for Drug
Development for the Young

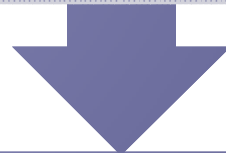
Farmacoepidemiologia e
Farmacovigilanza



Progetto SOS

Safety of non steroidal
antiinflammatory drugs

Sicurezza NSAIDs



Progetto ARPEC

Antibiotic Resistance and
Prescribing in European Children

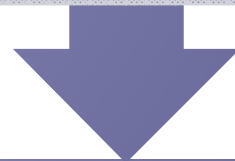
Utilizzo e resistenza ab

Progetti finanziati dalla Commissione Europea

Progetto GRIP

Global Research in Paediatrics

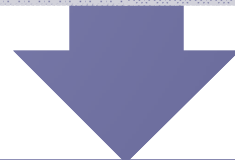
Farmacoepidemiologia



Progetto EMIF

European Medical Information
Framework

Diabete Alzheimer



Progetto EU-ADR

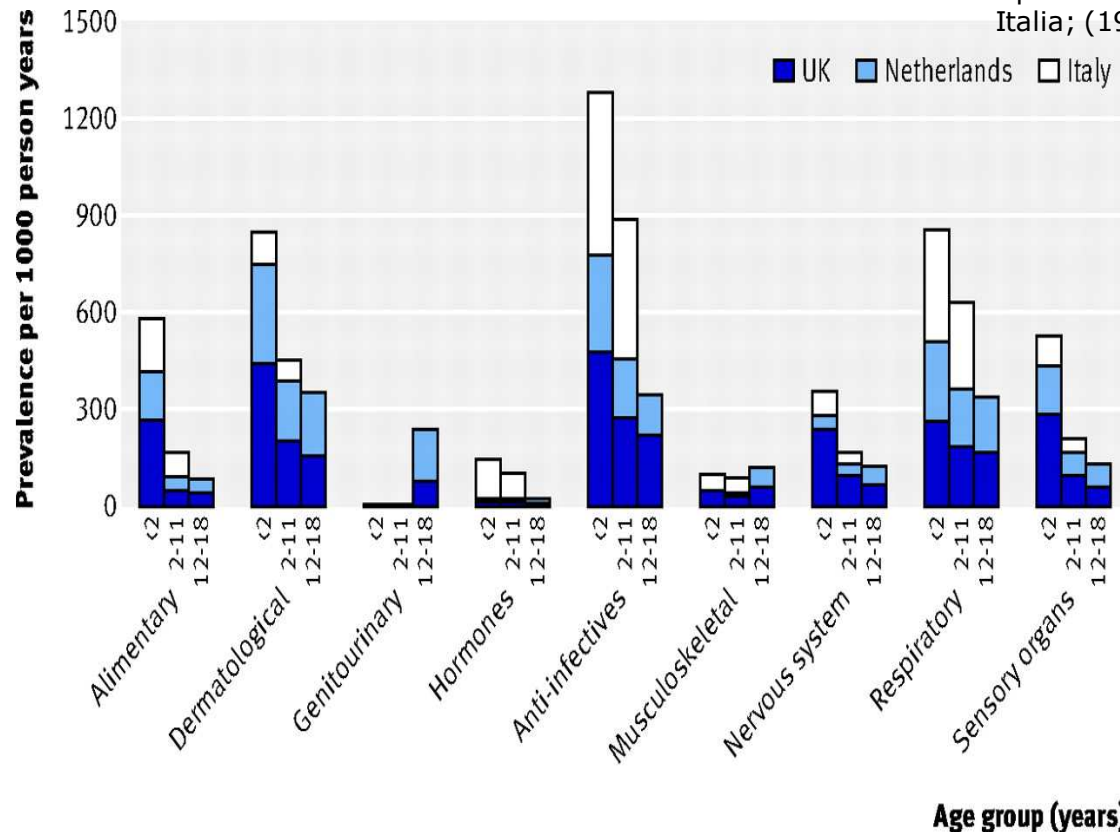
Early detection of adverse drug events
by integrative mining of clinical records
and biomedical knowledge

Farmacosorveglianza

PROGETTO TEDDY

Titolo	Missione	Fondi	Periodo
TEDDY Task-force in Europe for Drug Development for the Young	Il progetto mira a ottimizzare l'uso pediatrico dei farmaci esistenti, e promuovere lo sviluppo di nuovi farmaci utilizzando tutti gli strumenti per sviluppare la ricerca pediatrica, incorporando le novità che derivano dagli sviluppi della farmacogenetica e dando particolare attenzione alla variabilità della risposta ai farmaci nelle diverse età pediatriche dal periodo prenatale all'adolescenza.	Sesto Programma Quadro	2005 - 2010

PARTNERS: (1) Consorzio per le Valutazioni Biologiche e Farmacologiche, Italia; (2) Azienda Ospedaliera di Padova, Italia; (3) University College London, Regno Unito; (4) Rijksuniversiteit Leiden, Olanda; (5) Consiglio Nazionale delle Ricerche - Istituto di Tecnologie Biomediche, Italia; (6) Erasmus University Medical Center, (Olanda); (7) Istituto Superiore di Sanità, Italia; (8) Romanian Angel Appeal, Romania; (9) Linköpings Universitet, Svezia; (10) Institut National de la Sante et Recherche Medicale, Francia; (11) Medical Research Council - Clinical Trials Unit, Regno Unito; (12) Hospital Carlos III, Spagna; (13) Universite de Liege, Belgio; (14) Institute of Physiology, Academy of Sciences, Lab. of Neurophysiology of Memory, Rep. Ceca; (15) Technion - Israel Institute of Technology, Israele; (16) Charité - Universitätsmedizin Berlin, Germania; (17) Tecnofarmaci - Società Consortile per Azioni - per lo Sviluppo della Ricerca Farmaceutica, Italia; (18) IRIDIA Srl, Italia; (19) School of Pharmacy, Regno Unito.



**BMJ. 2008 Nov
24;337:a2245. doi:
10.1136/bmj.a2245.**

Sturkenboom MC, Verhamme KM, Nicolosi A, Murray ML, Neubert A, Caudri D, Picelli G, Sen EF, Giaquinto C, Cantarutti L, Baiardi P, Felisi MG, Ceci A, Wong IC;

TEDDY European Network of Excellence Drug use in children: cohort study in three European countries.

BMJ. 2008 Nov 24;337:a2245. doi: 10.1136/bmj.a2245.

Che cosa potrai fare...

- Reti Europee di farmacovigilanza
- Modello organizzato stabile per attività di surveillance post-marketing
- Rete di sorveglianza sulle vaccinazioni
- Monitoraggio PDT
- Studi di farmacoeconomia
- Pediatric investigation plan



Fine presentazione



Progetto GRIP

- FARMACOLOGHI PEDIATRI
- STATISTICI
- INDUSTRIE
- COMITATI ETICI
- LINEE GUIDA RICERCHE

Progetti finanziati dalla Commissione Europea

pedianet

Progetto TEDDY (FP6 - NoE)

- Task force in Europe for Drug Development for the Young



Progetto SOS (FP7)

- Safety of non steroidal antiinflammatory drugs (NSAIDs)



Progetto ARPEC (FP7)

- Antibiotic Resistance and Prescribing in European Children

Progetto EU-ADR (FP7)

- Early detection of adverse drug events by integrative mining of clinical records and biomedical knowledge



Progetto GRIP (FP7 - NoE)

- Global Rsearch in Paediatrics

Comitato esecutivo

Luigi Cantarutti (Coordinatore del Progetto Pedianet)

Pediatra di Libera Scelta, Padova

Adriana Ceci

Università di Bari, Pediatria e Farmacologia
Membro del gruppo Farmaci in Pediatria dell'AIFA
Coordinatrice Commissione Farmaci della SIP

Carlo Giaquinto (Coordinatore del Progetto Pedianet)

Dipartimento di pediatria, Università di Padova

Giroto Silvia

Pediatra di Libera Scelta, Venezia

Alfredo Nicolosi

Direttore Dipartimento Epidemiologia ed Informatica Medica, CNR, Milano
Addetto Scientifico Ambasciata Italiana a Bruxelles

Paolo Rossi

P.O. di Pediatria, Università di Tor Vergata, Roma
Rappresentante Italiano al Comitato Pediatrico dell'EMA

Miriam Sturkenboom

Dep. Medical Informatics and Epidemiology & Biostatistics, Erasmus University Medical Center, Rotterdam, Olanda
Presidente International Society Pharmacoepidemiology

Comitato scientifico

Baiardi Paola
Direttore Consorzio per le Valutazioni Biologiche e
Farmacologiche

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Pediatria di Libera Scelta, Nuoro

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Pediatria di Libera Scelta, Caltanissetta

Tambaro Paolo
Pediatria di Libera Scelta, Caserta

Valpreda Andrea
Pediatria di Libera Scelta, Torino

Collaborazioni



- Ospedale Bambin Gesù, Roma
- Dipartimento di Pediatria, Padova
- Federazione Italiana Medici Pediatri (FIMP)
- Commissione Europea (FP6, FP7)
- Agenzia Italiana del Farmaco (AIFA)
- International Pharmacoepidemiology and Pharmacoeconomics Research Centre
- CNR/ITBA, Milano
- Centro Valutazioni Biologiche e Farmacologiche (CVBF), Pavia
- Istituto Superiore di Sanità
- Regione Veneto
- Erasmus University, Rotterdam
- Società scientifiche
- Aziende farmaceutiche (GSK, BMS, SP-MSD, Abbott, Merck etc)

Publicazioni TEDDY

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- Ceci A, Giaquinto C, Aboulker JP, Baiardi P, Bonifazi F, Della Pasqua O, Nicolosi A, Taruscio D, Sturkenboom M, Wong I.
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