PEDIANET
Il network italiano della pediatria

Roma

Luigi Cantarutti

What is Pedianet ?

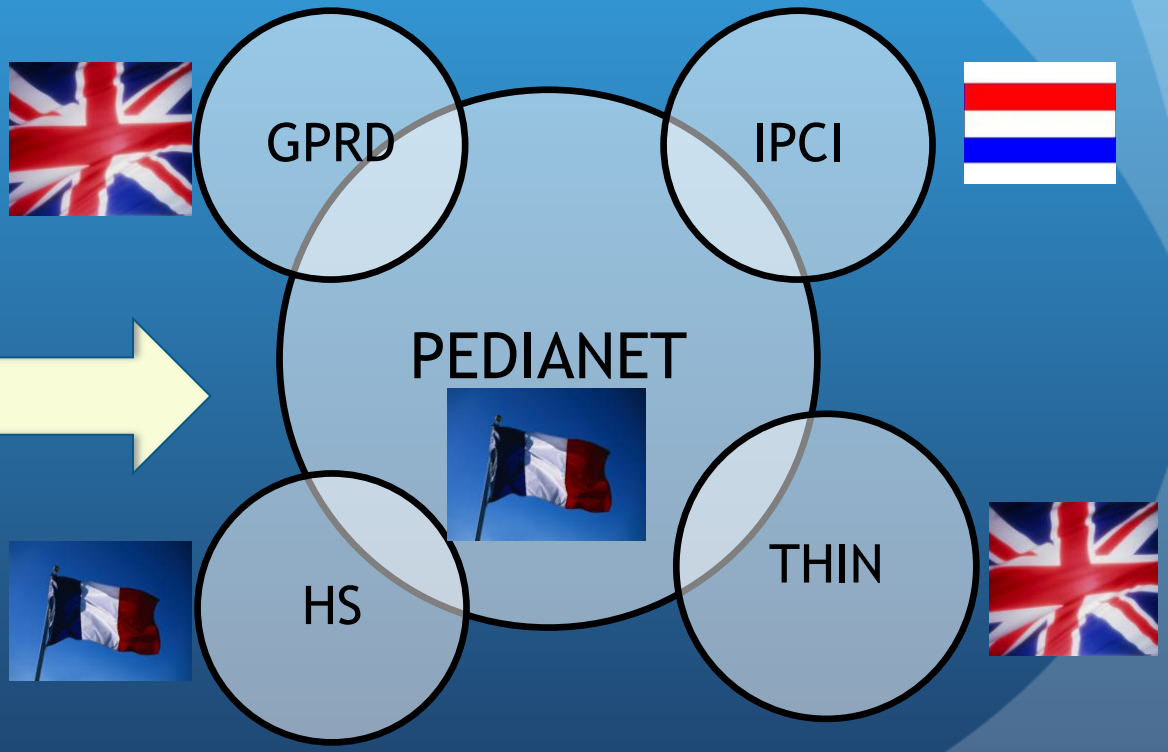
An organised network of more than 400 family pediatricians (FP) to collect information to be used for clinical and epidemiological research.
The network also include pediatricians, researchers, epidemiologist, statisticians, methdologist, computer experts.

- Prospective Studies
- Research database
- Monitoring of disease management

www.pedianet.it

Data-base europei con dati pediatrici

Dati clinici
esclusivamente
pediatrici



Country	Italy					NL		UK		Sweden		DK
Name of datasource	**Health Search**	**Regional database Tuscany**	**Regional database Lombardy**	**Regional database Emilia Romagna**	**Pedianet**	**IPCI**	**PHARMO**	**GPRD**	**THIN**	**National**	**GePaRD**	**Aarhus**
Type of datasource	Electronic medical record	Administrative database	Administrative database	Administrative database	Electronic medical record	Electronic medical record	Record linkage system	Electronic medical record	Electronic medical record	Record linkage	Administrative database	Record linkage
Period covered now	2000-now	2002-2007	2002-2008	??	2000-now	2002-now	1998-now	1990-now	1990-now	2005-2010	2004-2008	1995-now
No. source population	1.5 million	3 million	9 million	3 million	200,000 children	1.1 million	4 million	8 million	4 million	9 million	15 million	2 million
Setting	primary care	Outpatient care	Outpatient care	Outpatient care	Primary care	primary care	Out and in patient care	Primary care	Primary care	Primary care	In- and outpatient care	In- and outpatient care
Diagnosis terminology	ICD-9 and free text	ICD-9	ICD-9	ICD-9	ICD-9 and text	ICPC and free text	ICD-9	READ codes	READ codes	ICPC and free text	ICD-10-GM codes	ICD-10
Type of diagnoses	In-outpatient	In-outpatient	Outpatient	Outpatient	In-outpatient	In-outpatient	Outpatient	In-outpatient	In-outpatient	In-outpatient	In-outpatient	In-outpatient
Causes of death	Incomplete	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Incomplete	Not directly	Yes
Vaccinations	Yes	Yes	Yes	No	Yes	Yes (to be linked)	Yes (to be linked)	Yes	Yes	Yes	Yes	Yes (to be linked)
Childhood	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Influenza	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Travel	no	no	no	No	No	no	no	no	no	no	no	No
Drugs	Prescriptions	Dispensings	Dispensings	Dispensings	Prescriptions	Prescriptions	Dispensings	Prescriptions	Prescriptions	Prescriptions	Dispensings	Dispensing
Laboratory values	Yes	No	No	No	Yes	Yes	Yes (subset)	Yes	Yes	Yes	No	Yes

Necessità di dati pediatrici

- Alla luce delle stime ufficiali del Comitato Pediatrico presso l'Agenzia Europea del Farmaco (EMA), si assisterà ad un significativo aumento degli studi farmacologici in età pediatrica in osservazione al nuovo Regolamento Pediatrico.
- I bambini risultano ancora una popolazione scarsamente indagata per quanto concerne l'uso razionale dei farmaci. Questa situazione non è peculiare solo della realtà italiana, ma comune a livello internazionale.

The system (1)

- The network links (FPs) who use the same software (Junior Bit) in their professional practice.
- About 3700 FP (50% of the total) use JB in Italy and they are all potential candidates to be part of the system
- Anonymous information required for research is sent trough an internet link to a central server located in Padova where the data is validated and processed.

Pedianet database structure

Patients (code)

Demographics (race/gender/dob)

date of registration/moving out

Prescription

Type

Dosing regimen

Medical files

Visits (date/motive)

Diagnosis

Exams (date/type)

Vaccination

Certificates

Measures(date/weight/height)

Hospitalization: (date/reason/outcome)

Specialist visits (date/referrals/diagnosis)

Free texts are also routinely collected

Possibility to contact the patients through the FP

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

Ethics and confidentiality

Informed written consent is requested to child's parents/tutors for data collection and centralised analysis

All information and data are collected **anonimously** and the name of the patients is known just to the FP (L.657/96-676/96) . Only pooled analysis can be done.
Data are transmitted with a code that allows retracing of all patients information only through the FP.

Pedianet research database (1)

All the information recorded by the FP in their routine practice are anonimously sent to a central server. The following data about each encounter are collected:

- Demopgraphic including auxology
- Reason for access the paediatric clinic
- Patient's personal data (strictly anonymous)
- Diagnosis
- Prescriptions (drug, lab, exams etc)
- Outcomes

Pedianet research database (2)

Facts and figures 2003 -2012 :

- 350,000 children in follow up
- 5,200,000 encounters
- 4.300,000 diagnosis
- 3,000,000 drug prescriptions
  (60% with dosing info)
- 340,000 specialist referrals
- 40,000 hospital admission

Monitoraggio e verifica 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**

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

Ricerca prospettica e retrospettiva

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

Risultati di Pedianet

- Ricerca originale pediatrica sulla popolazione generale.
- Importante produzione articoli scientifici pubblicati sulle più importanti riviste pediatriche del mondo.
- Partecipazione stabile di Pedianet, tramite il network di eccellenza europeo, ai più importanti progetti di salute pubblica e ricerca gestiti dalla CE

Major Studies performed in the Pedianet research database

- NSAIDS safety
- Effect of exclusion from reimbursement of antihystamines
- Acute gastroenteritis and intestinal occlusion
- Characteristics of use of leukotriene in asthmatic children
- Incidence and management of zoonosis in children
- Characteristics of use of Breva and Lunibron in paediatrics
- Clinical Management of Acute Gastroenteritis
- Clinical management and costs of Acute Otitis Media
- Mathematical modelling to evaluate Rotavirus incidence
- Epidemiological registers

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

Miriam Sturkenboom, Alfredo Nicolosi, Luigi Cantarutti, Salvatore Mannino, Gino Picelli, Antonio Scamarcia, Carlo Giaquinto and for the NSAIDs Paediatric Research Group

Pediatrics 2005;116;26-33; originally published online Jun 1, 2005;

Objective: To estimate the incidence of mild and severe mucocutanuoes reactions in children receiving NSAIDS with particular attention to Niflumic acid

Study design: Retrospective cohort study

Study population: a total of 194,000 children, 45,351 of whom recieved at least one NSAID prescription for a total of 85,000 prescriptions

Prospective observational studies

- Pharmacosurveillance
- IV antibiotics
- Varicella
- Asthma
- Acute Respiratory Tract Infections
- Passive smoking
- Rotavirus REVEAL
- Evaluation of early response to asthma controller
- Rotavirus SPRIK
- Psychotropic drugs
- Otitis media (EPI-STREPT)
- Asthma utilisation Study
- Rotavirus incidence and management (2010 – 2011)
- Management of most common ped disease (UTI, AOM, pn etc)
- Management of asthma in chidren

RICERCHE PUBBLICATE

pedianet

Active monitoring of adverse drug reactions in children

THE LANCET

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

ASTHMA PREVALENCE AND DRUG PRESCRIPTION IN ASTHMATIC CHILDREN

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

Clinical Consequences of Gastroenteritis in Europe, The REVEAL Study

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 beha of the REVEAL Study Group*

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

Francesca Menniti-I Raschetti Robert Giaquinto Luigi C It Pharmacosurveilla

PEDIATRICS

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

Miriam Stuckenboom, Alfredo Nicolosi, Luigi Cantarutti, Salvatore Mannino, Gino Picelli, Antonio Scamarcia, Carlo Giaquinto and for the NSAIDs Pediatric Research Group

Pediatrics 2005;116;26-33; originally published online Jun 1, 2005; DOI: 10.1542/peds.2004-0040

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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American Academy of Pediatrics
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Multicenter Prospec of Rotavirus Acute in Europe, 2004–20

Pierre Van Damme,[1] Carlo Giaquinto,[2] Fréd and Marie Van der Wielen,[1] on behalf of t

[1]Faculty of Medicine, Centre for the Evaluation of Vac of Viral Hepatitis, University of Antwerp, Antwerp, Be Hôpital d'Enfants, Centre Hospitalier Universitaire Dijo Sweden; [2]Clinical Practice Research Unit, Wirral Hosp

Background. Rotavirus is recognized hensive data on the burden of rotavirus c
Methods. A prospective, multicenter, selected areas of Belgium, France, Germany of acute gastroenteritis (AGE) and rotavi care in primary care, emergency departm
Results. A total of 2846 children with ELISA results were available, 1102 (40.6% of RVGE was 2.07–4.96 cases/100 childre age, with 56.7%–74.2% of all RVGE case to account for 27.8%–52.0% of AGE cas emergency department consultations, as w
Conclusions. Rotavirus infections acc age in Europe, many of whom require fre or hospital settings. The results of the p months of age could significantly reduce

Rotavirus is the most common cause of gastroenteritis (AGE) in young children w 4]. Rotavirus gastroenteritis (RVGE) can l dehydration [2, 5], and, consequently, it that RVGE accounts for ~39% of all d diarrhea in children <5 years of age wo Although mortality rates associated with RVGE in industrialized countries are low, rotavirus is a significant cause of disease and hospitalization [2], with 1 in 54 children <5 years of age being hospitalized with RVGE in the European Union [7]. Rotavirus is also a frequent

us gastroenteritis (RVGE) cons rotavirus genotypes is require 2004–2005 RVGE season, a p 5 years of age seeking health c of Belgium, France, Germany, e-linked immunosorbent assa chain reaction (RT-PCR) analy s were available for 2712 of the 12 children, 1102 (40.6%) were itive samples. G1–G4 and G9 len, and the United Kingdom otypes were identified in all st oted among the genotypes. us genotypes G1–G4 and G9 a aphic and seasonal variation i e protection against all major

(RVGE) constitutes a signifi ildren <5 years of age world ontributor to childhood mor eveloping countries [1], but it morbidity in industrialized iate suggested that RVGE ac 87,000 hospitalizations, and nt visits annually within the

r of the *Reoviridae* family. It icle, with a double capsid, a genome, and 2 surface pro

erre Van Damme, Faculty of Medicine, Centre 40 Collaborating Centre for the Control and ity of Antwerp, Campus 3 Eiken, Universi ijk), Belgium (pierre.vandamme@ua.ac.be).

s 2007;195:S17–25 ociety of America. All rights reserved.

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0022-1899/2007/19503S1-0002$15.00
DOI: 10.1086/516714

Summary

A cross-sectional study was conducted on among 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 semi-fixe 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, other age stratification under 5 yr and over 6 yr, 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 (0.6% males) with a prevalence of 0.3% among males and 4% among females in under 5 year-olds, and 3.9% for males and 2.1% for females in over 6 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. Contrary to the international guidelines, pediatricians prescribed more oral corticosteroids and nebulized short-acting β-2 agonists for children under 5 yr olds than for over 6 year-olds (13.3% Vs 4.8%, and 2.5% Vs 10.9%, respectively, p<0.001). For the 0–6 year-olds, the most commonly prescribed treatments were oral corticosteroids (13.9% Vs 13.4%), 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 on 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 have been carried out to date to assess adherence to these guidelines [13, 14].

The aim of the present study was to verify the prevalence of asthma cases diagnosed directly by the family pediatrician in a sample of children. Another aim was to analyze the prescription of medication for different age groups.

MATERIALS AND METHODS

SETTING

Within the framework of Health Service, every child is registered at birth and receives free medical care up to 14 years of age from one of the approximately 6,000 family pediatricians working for the Health Service. Our study was based on a population-based database, called "Pedianet", by means of which a national network of pediatricians using a software called "JB 95[th]" take part in a common epidemiological and clinical research project on child care. JB95 is a standardised and validated software used by family pedi-

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trials for Merck, Sanofi Pasteur MSD, and GlaxoSmithKline Biologicals, for 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, Tibotec, and Boehringer Ingelheim. L.G. 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: XXIV Annual Meeting of the European Society of Pediatric Infectious Diseases, Basel, Switzerland, 3–5 May 2006 (abstract 36); 7th Annual International Rotavirus Symposium, Lisbon, Portugal, 12–13 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.

Le ricerche e le pubblicazioni

- 20 studi
- 41 pubblicazioni sulle piu' importanti riviste internazionali (Lancet, BMJ, Pediatrics, Epidemiology, European Annals of Allergy and Clinical Immunology, Pediatric Disease Journal, The Journal of Infectious Disease, Lancet Oncol, Pharmacological Research, Pediatr Drugs…)

Pedianet partnership in EU Funded research projects/networks

Task force in Europe for Drug Development for the Young – TEDDY (FP6 – NoE) *Funded 2006 – 2010 (subcontract)*

Safety of non steroidal antiinflammatory drugs –SOS (FP7 – STREP) *Funded 2008 – 2011 (subcontract)*

Antibiotic Resistance and Prescribing in European Children-ARPEC (DG SANCO) *Funded 2010 – 2013 (PARTNER)*

Early detection of adverse drug events by integrative mining of clinical records and biomedical knowledge – EUADR (FP7 – IP) *Funded 2008 - 2012 (PARTNER)*

Global Research in Paediatrics – GRIP (FP7 – NoE) *Funded 2011 – 2015 subcontract*

European Medical Informatic Network (EMIF) (FP7 IMI) *Funded 2013-2017 (PARTNER)*

Ricerca, Innovazione, Sviluppo

pedianet

- Reti Europee di farmacovigilanza
- Attività di surveillance post-marketing
- Rete di sorveglianza sulle vaccinazioni
- Monitoraggio PDT / appropriatezza
- Studi di farmacoeconomia
- Pediatric investigation plan



pedianet

Il network italiano della pediatria





L’organizzazione del network

- Rete telematica attiva dal 1998
- 184 PLS
  - Formazione
  - Cartella cl. Informatizzata
- Struttura indipendente (CS)
- Pazienti con consenso scritto al progetto
- Dati anonimi / aggregati

I dati presenti

- Pazienti arruolati: 173.198
- Numero visite registrate: 4.637.201
  - Con diagnosi 4.266.040 (92%)
- Prescrizioni farmacologiche: 2.602.697
  - Di fascia A: 1.988.000
  - Con posologie associate: 62.94%
- Misure auxologiche: 1.362.169
- Ricoveri: 37.565
- Visite specialistiche: 574.984
- Esami strumentali: 297.180
- Esami ematologici: 611.349

Progetti Europei

- TEDDY (subcontraente)
- SOS (subcontraente)
- EU- ADR (partner)
- EMIF (partner)
- GRIP (subcontraente)
- ARPEC (partner)

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ALERT: Early detection of adverse drug events by integrative mining of clinical records (FP7 – IP) *Funded (PARTNER)*

GRIP: Global Research in Paediatrics (FP7 – NoE) *Funded (subcontract)*

EMIF: European Medical InformaticNetwork (FP7IMI) *Funded (partner)*

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European Medical Informatic Network **EMIF** (FP7 IMI) *Funded 2013-2017*

PEDIANET: le sue peculiarità

- Unica banca dati / concentratore epidemiologico esclusivamente pediatrico in Europa
- Dati sanitari della popolazione pediatrica generale
- Completezza dei dati raccolti (diagnosi, posologie, diari clinici …)
- Monitoraggio costante della qualità del dato
- Utilizzo del network per studi prospettici
- Utilizzo della banca dati per studi retrospettivi
- Articoli scientifici e progetti
- Collaborazioni in Italia
- Collaborazioni in Europa

Pedianet partnership in EU Funded research projects/networks

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European Medical Informatic Network (EMIF) (FP7 IMI) *Funded*

Ricerche retrospettive

PEDIATRICS

- CNR Milano FANS

B.M.J.

- TEDDY FARMACOEPIDEMIOLOGIA

JOURNAL of INFECTIOUS DISEASE

- GSK GASTROENTERITI

Studi prospettici

EUROPEAN JOURNAL of PEDIATRICS

- Università Padova ROTAVIRUS

JOURNAL of INFECTION

- Università di Milano INFLUENZA

Studi prospettici

LANCET

- I.S.S. FARMACOVIGILANZA

EPIDEMIOLOGY

- G.S.K VARICELLA

JOURNAL of INFECTIOUS DISEASE

- SANOFI PASTEUR ROTAVIRUS