



Presentazione del Rapporto sui farmaci in Toscana 2019

11 DICEMBRE 2019

VILLA LA QUIETE - FIRENZE



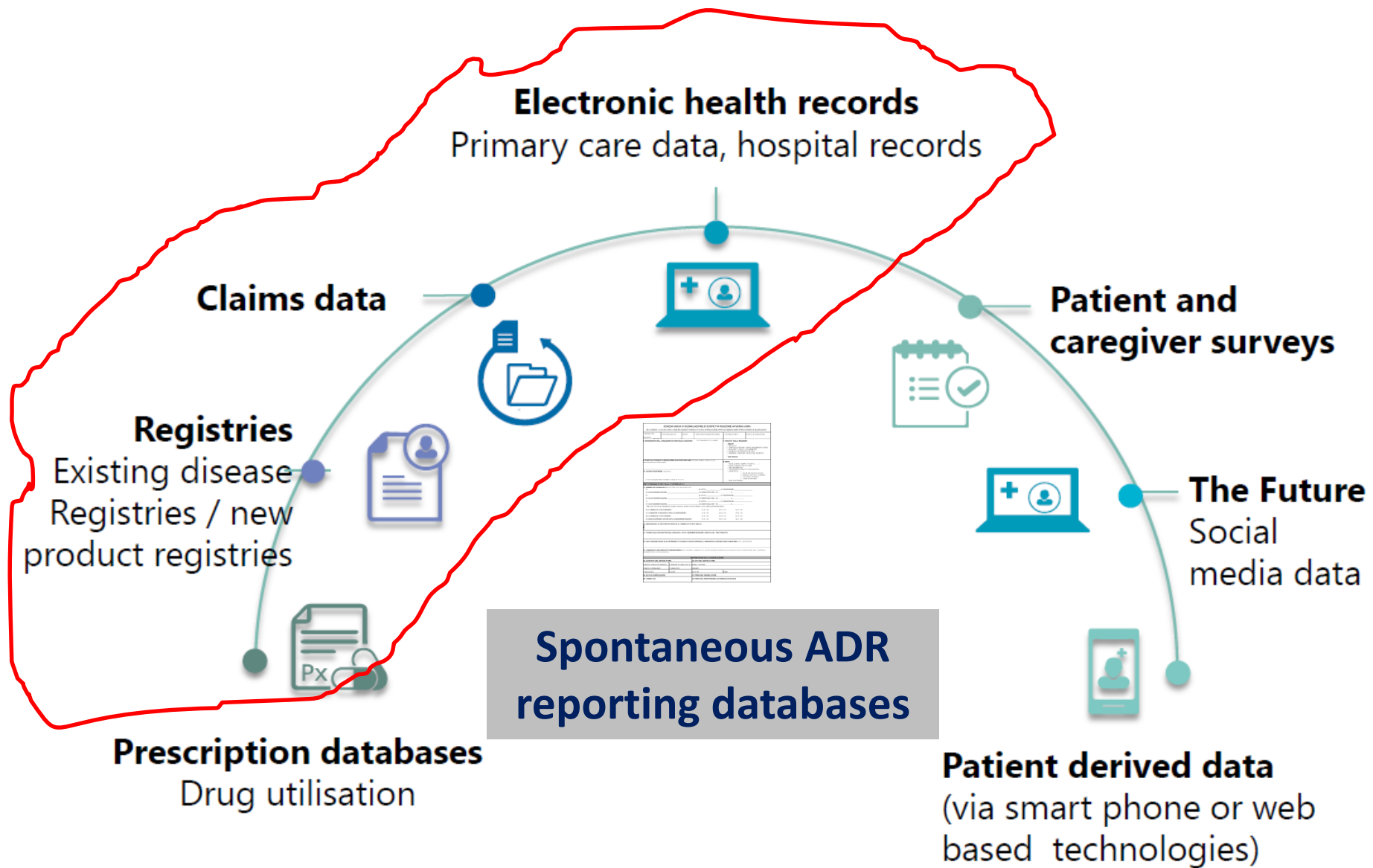
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Agenda

- ❖ The Italian healthcare database landscape
- ❖ For doing what?
- ❖ Future perspectives

The Italian healthcare database landscape



Electronic health records

Primary care data, hospital records

Claims data



Registries

Existing disease Registries / new product registries



Prescription databases

Drug utilisation



Spontaneous ADR reporting databases



Patient and caregiver surveys



The Future

Social media data



Patient derived data

(via smart phone or web based technologies)



Available claims databases in Italy

Demographics

Exemptions from healthcare services payment

Outpatient drug dispensing

In-hospital drug dispensing to outpatients

Electronic therapeutic plans

Hospitalizations

ED visits

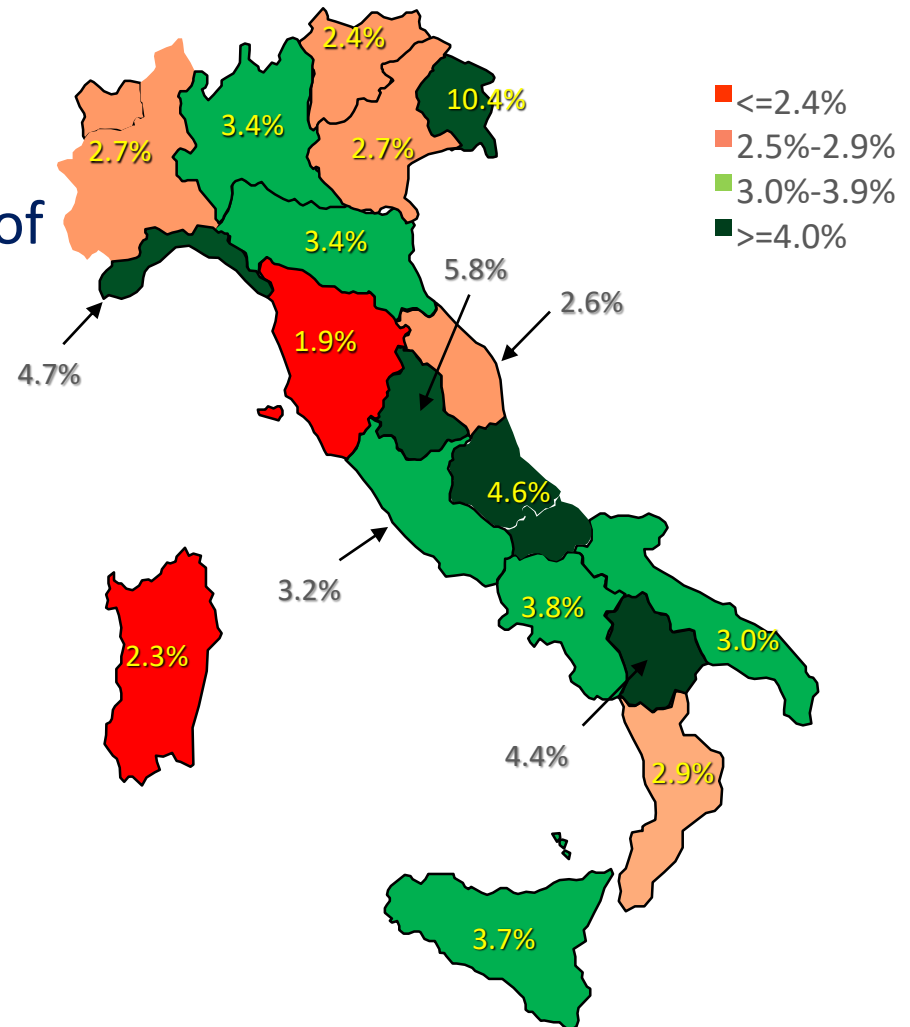
Specialist visits and diagnostic tests

In some Regions/LHUs there are additional claims data and registries that can be linked to each other (es. lab values, histology, indication of use etc..)

Health Search - CSD LPD: the network of Italian GPs

Around 900 GPs, referring to 3.4% of the adult population

- 2 million patients (22M PY)
- 26 million diagnosis
- 260 million diagnostic results
- 180 million prescriptions
- >>10 years of FU



Clinical registries



PSOCARE
AIFA

The logo for PSOCARE AIFA. The word "PSOCARE" is in black, with a green brushstroke underline under the "SO" and "CA" parts. "AIFA" is in blue below it.



Database and research network-based PV

The image is a blue-themed graphic with a world map background and a network of white circles and lines. On the left, contact information for the ENCePP Secretariat is listed. On the right, the ENCePP logo and full name are displayed.

ENCePP Secretariat

European Medicines Agency
Patient Health Protection
Pharmacovigilance and Risk Management

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Canary Wharf
London E14 4HB
United Kingdom

Telephone +44 (0)20 7523 7655
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ENCePP

The European
Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Over 160 academic and hospital based research centres, providers of healthcare data and specialised networks across Europe

ENCePP Italian node



	Area Valutazione del farmaco, Agenzia Sanitaria e Sociale Regionale, Regione Emilia-Romagna
	Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto Superiore di Sanità
	Centro Regionale di Farmacovigilanza e Farmacoepidemiologia-Campania
	Centro Regionale di Farmacovigilanza – Lombardia
	Centro Regionale di Farmacovigilanza – Sicilia
	Centro Regionale di Farmacovigilanza – Veneto
	Centro studi GISED
	Consorzio Mario Negri Sud
	Health Search – SIMG
	Dipartimento di Epidemiologia del Servizio Sanitario Regionale, Regione Lazio
	Istituto di Igiene e Epidemiologia DSMB Università di Udine
	Istituto di Ricerche Farmacologiche Mario Negri
	Università di Bologna
	Università di Verona
	Medineos
	Osservatorio di Epidemiologia, Agenzia Regionale di Sanità della Toscana
	Neurofarba Department, Università di Firenze
	Centro Regionale di Farmacovigilanza-Regione Sardegna (CRFV Sardegna)
	Laboratory of Pharmacoepidemiology & Healthcare Research - Unit of Biostatistics Epidemiology & PublicHealth - Dept of Statistics & Quantitative Methods, Università Milano-Bicocca
	-CESP -Università di Milano-Hospital " L. Sacco", Department of Biomedical and Clinical Sciences, Unit of Clinical Pharmacology.
	University Hospital of Pisa- Unità di monitoraggio delle reazioni avverse
	Unit of Medical Statistics and Cancer Epidemiology

23 Italian centres out of 165

The role of European healthcare databases for post-marketing drug effectiveness, safety and value evaluation: where does Italy stand?

Gianluca Trifirò^{1*}, Rosa Gini², Francesco Barone-Adesi³, Ettore Beghi⁴, Anna Cantarutti⁵, Annalisa Capuano⁶, Carla Carnovale⁷, Antonio Clavenna⁸, Mirosa Dellagiovanna⁹, Carmen Ferrajolo⁶, Matteo Franchi⁵, Ylenia Ingrasciotta¹, Ursula Kirchmayer¹⁰, Francesco Lapi¹¹, Roberto Leone¹², Olivia Leoni⁹, Ersilia Lucenteforte¹³, Ugo Moretti¹², Alessandro Mugelli¹³, Luigi Naldi¹⁴, Elisabetta Poluzzi¹⁵, Concita Rafaniello⁶, Federico Rea⁵, Janet Sultana¹, Mauro Tettamanti¹⁶, Giuseppe Traversa¹⁷, Alfredo Vannacci¹³, Lorenzo Mantovani¹⁸, Giovanni Corrao⁵

For doing what?

What can we explore with Italian healthcare databases?

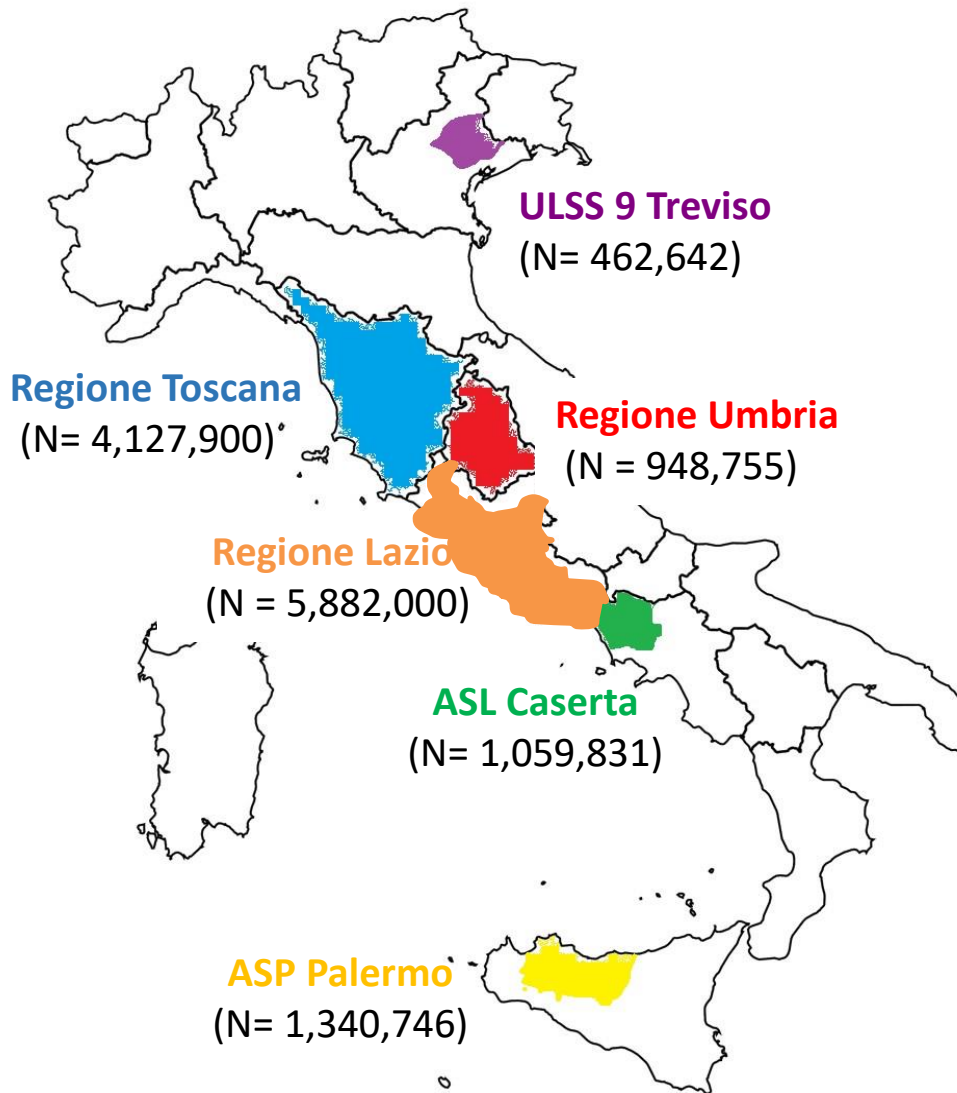
- ❑ Burden of disease and unmet clinical needs
- ❑ Pattern of use in special populations
- ❑ Quality of care and prescribing appropriateness
- ❑ Drug safety signal strengthening and validation
- ❑ Implementation and effects of risk minimization measures
- ❑ Comparative effectiveness research
- ❑ Cost-effectiveness of drugs
- ❑ ...



Assessment of short and long term risk-benefit profile of biologics/biosimilars through healthcare database network in Italy

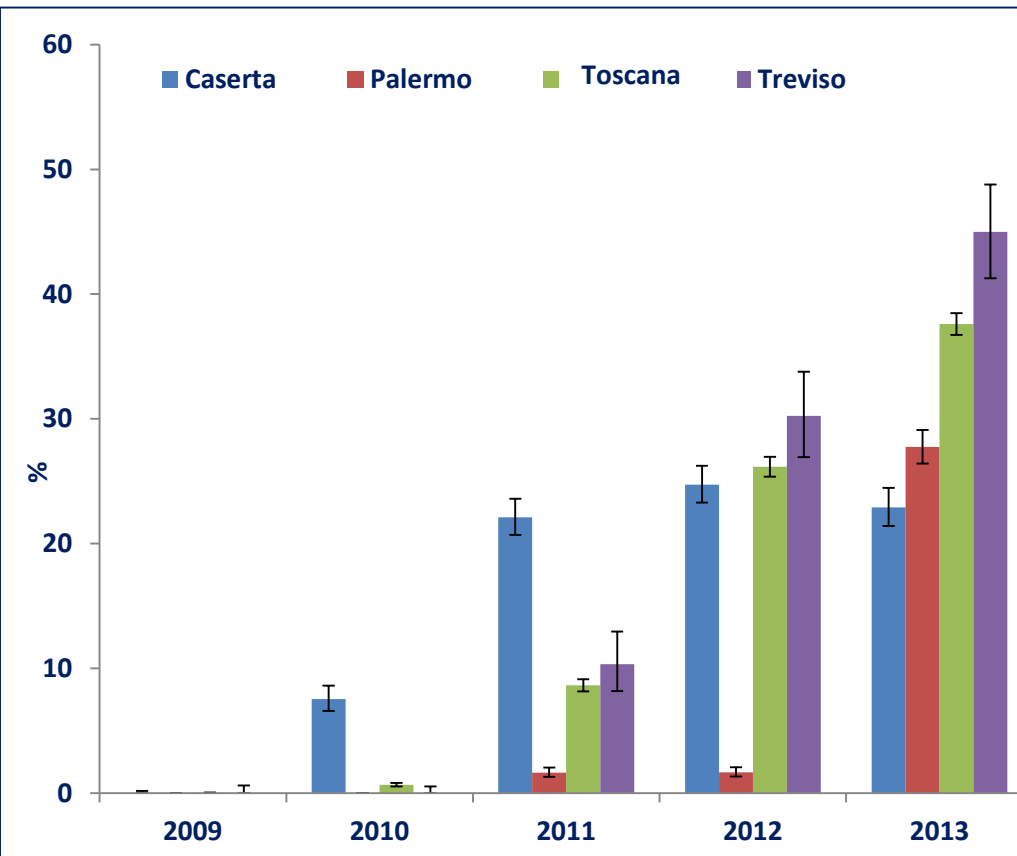


Ministero della Salute



To investigate drug prescribing pattern

Uptake dei biosimilari di epoetine nei centri in studio nel 2009-2013



% biosimilari epoetine sul totale di utilizzatori epoetine: ~40%

Primo intervento che ha promosso l'uso di biosimilari:

Campania: Novembre 2009

Toscana: Giugno 2010

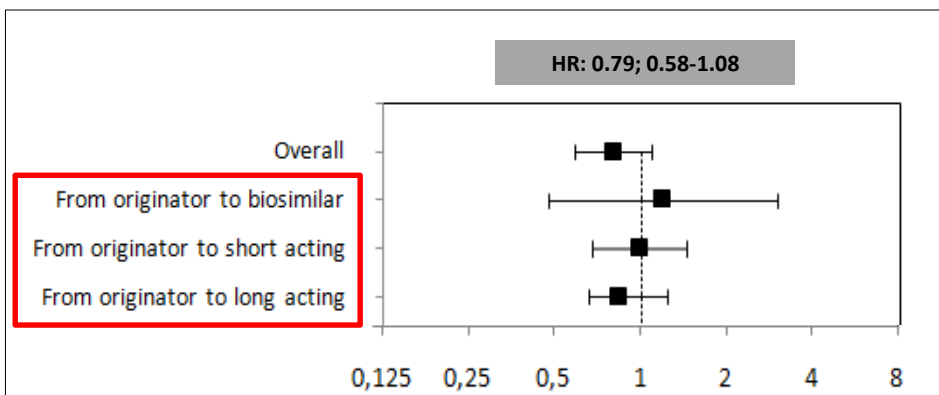
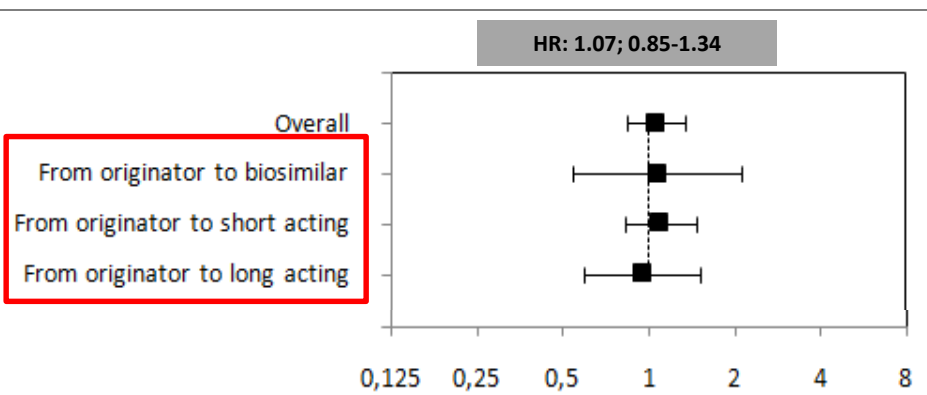
Treviso: Novembre 2010

Palermo: Marzo 2013

To integrate pre-marketing evidence on effectiveness and safety

Effectiveness of the switching in CKD

Safety of the switching in CKD



Effectiveness outcomes: blood transfusions/anaemia hospitalizations;

Safety outcomes: hypersensitivity reactions/major cardiovascular events/dyscrasias.

Originator: epoetin alpha (Eprex®); **Biosimilars:** epoetin alpha (Binocrit®, Abseamed®) epoetin zeta (Retacrit®); **Short acting ESAs:** epoetin beta (Neorecormon®), epoetin theta (Eporatio®); **Long acting ESAs:** darbepoetin alpha (Aranesp®), Nespo®, hoxypolyethyleneglycol-epoetin beta: (Mircera®).

Management of Cancer-Associated Anemia With Erythropoiesis-Stimulating Agents: ASCO/ASH Clinical Practice Guideline Update

Julia Bohlius, MD, MScPH¹; Kari Bohlke, ScD²; Roberto Castelli, MD, PhD³; Benjamin Djulbegovic, MD, PhD⁴; Maryam B. Lustberg, MD, MPH⁵; Massimo Martino, MD⁶; Giannis Mountzios, MD, PhD⁷; Namrata Peswani, MD⁸; Laura Porter, MD⁹; Tiffany N. Tanaka, MD¹⁰; Gianluca Trifirò, MD, PhD¹¹; Hushan Yang, PhD¹²; and Alejandro Lazo-Langner, MD, MSc¹³

Clinical Question 5

Among adult patients who receive an ESA for chemotherapy-associated anemia, do darbepoetin, epoetin beta and alfa originator, and currently available biosimilars of epoetin alfa differ with respect to safety or efficacy?

Recommendation 5. The Expert Panel considers epoetin beta and alfa, darbepoetin, and biosimilar epoetin alfa to be equivalent with respect to effectiveness and safety. (Type: informal consensus; evidence quality: intermediate; strength of recommendation: moderate)

These results were confirmed in **Italian retrospective cohort studies** which **did not find a difference** in hemoglobin response among new users of either **biosimilars or reference product** of epoetin alfa or other ESAs in either **CKD or cancer patients** during the first three months of treatment

To educate healthcare professionals through clinical audit based on Real World Data



npj | Primary Care Respiratory Medicine

www.nature.com/npjpcrm

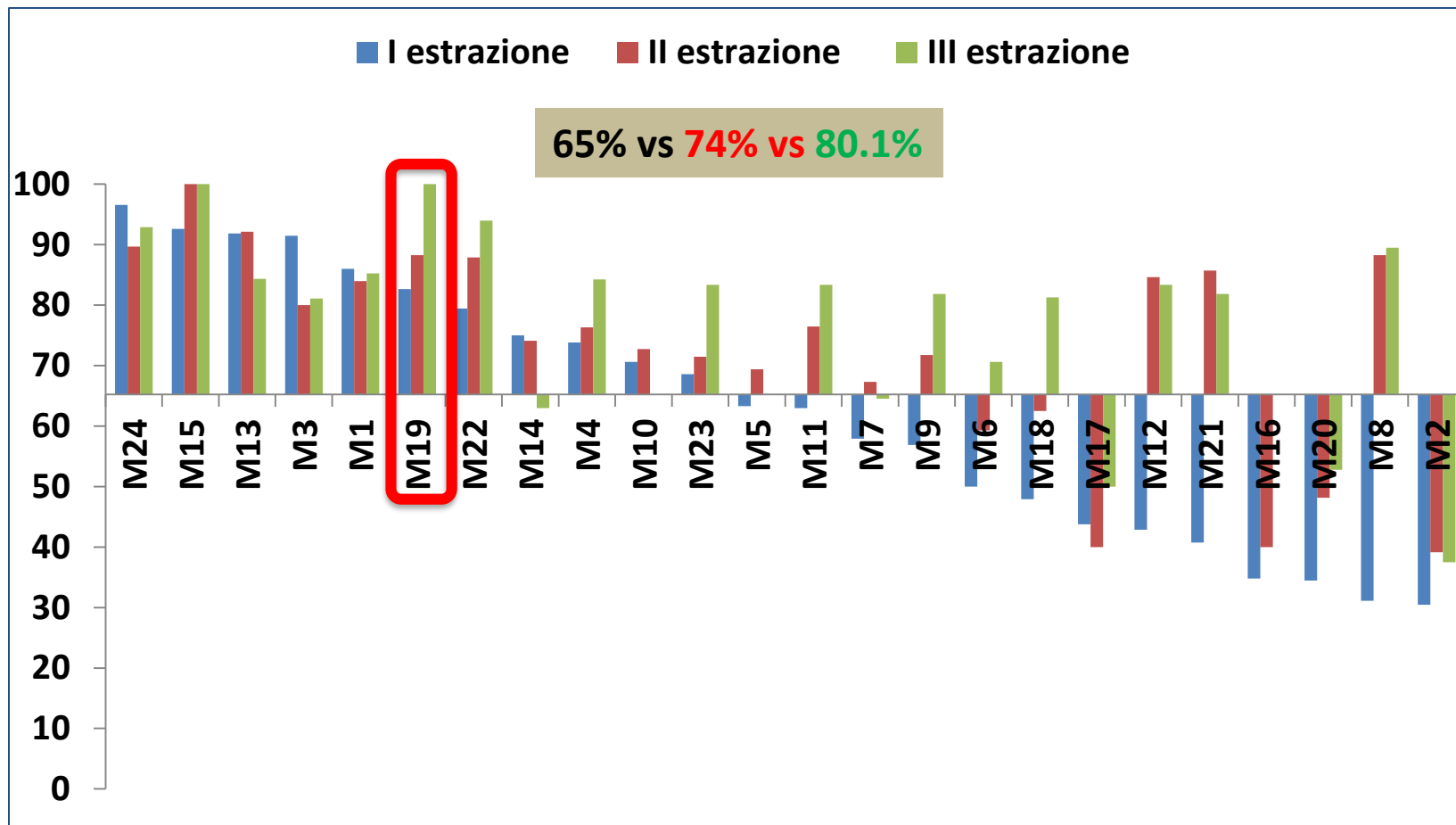
ARTICLE OPEN

Improvement in the management of chronic obstructive pulmonary disease following a clinical educational program: results from a prospective cohort study in the Sicilian general practice setting

Rosarita Ferrara¹, Valentina Ientile¹, Carlo Piccinni², Alessandro Pasqua³, Serena Pecchioli³, Andrea Fontana⁴, Umberto Alecci⁵, Riccardo Scoglio⁵, Francesco Magliozzo⁵, Sebastiano Emanuele Torrisi⁶, Carlo Vancheri⁶, Patrizio Vitulo⁷, Giovanna Fantaci⁸, Carmen Ferrajolo⁹, Mario Cazzola¹⁰, Claudio Cricelli⁵, Achille Patrizio Caputi¹ and Gianluca Trifirò^{1,11}

Studio inizialmente sponsorizzato da Novartis e poi da Regione Sicilia con fondi FV

% pazienti BPCO con ≥ 1 esame spirometrico per MMG



La % dei tuoi pazienti con BPCO che hanno avuto almeno una spirometria è notevolmente aumentata ed è più alta rispetto alla media.

Ti ricordiamo che tutti i pazienti con BPCO dovrebbero avere una conferma diagnostica spirometrica sulla base delle linee guida GOLD 2014.

Indicator	Baseline N=1,465	Post-intervention at 2 years N=1,388	Achievement of goal
Diagnostic process indicators (%)			
Spirometry lifetime	59.7	80.1	😊
Spirometry lifetime among smokers	70.5	81.0	😊
Spirometry in the last year	25.3	32.1	😊
Mean n. spirometry in the last two years	1.9	3.2	😊
Preventive measures indicators (%)			
BMI registration lifetime	75.8	81.7	😊
Smoking registration lifetime	76.5	81.0	😊
Influenza vaccination in the last year	57.2	55.7	😞
Pneumococcal vaccination in the last 4 years	32.6	35.1	😊
Therapeutic process indicators (%)			
Drugs targeting obstructive airway diseases in the last year	61.0	63.3	😊
ICS in monotherapy in the last year	9.6	9.9	😐
Occasional use of LABA and/or LAMA (\pm ICS) in the last year	8.5	6.3	😐
Leukotriene receptor antagonists use in the last year	2.3	1.9	😊
Low adherence to LABA and/or LAMA (\pm ICS)	61.6	54.7	😊
Prolonged use of ICS	5.8	5.1	😊

Ferrara R, et al. Improvement in management of COPD following clinical educational program: results from prospective cohort study in Sicilian general practice setting. **npj Primary Care Respiratory Medicine**.

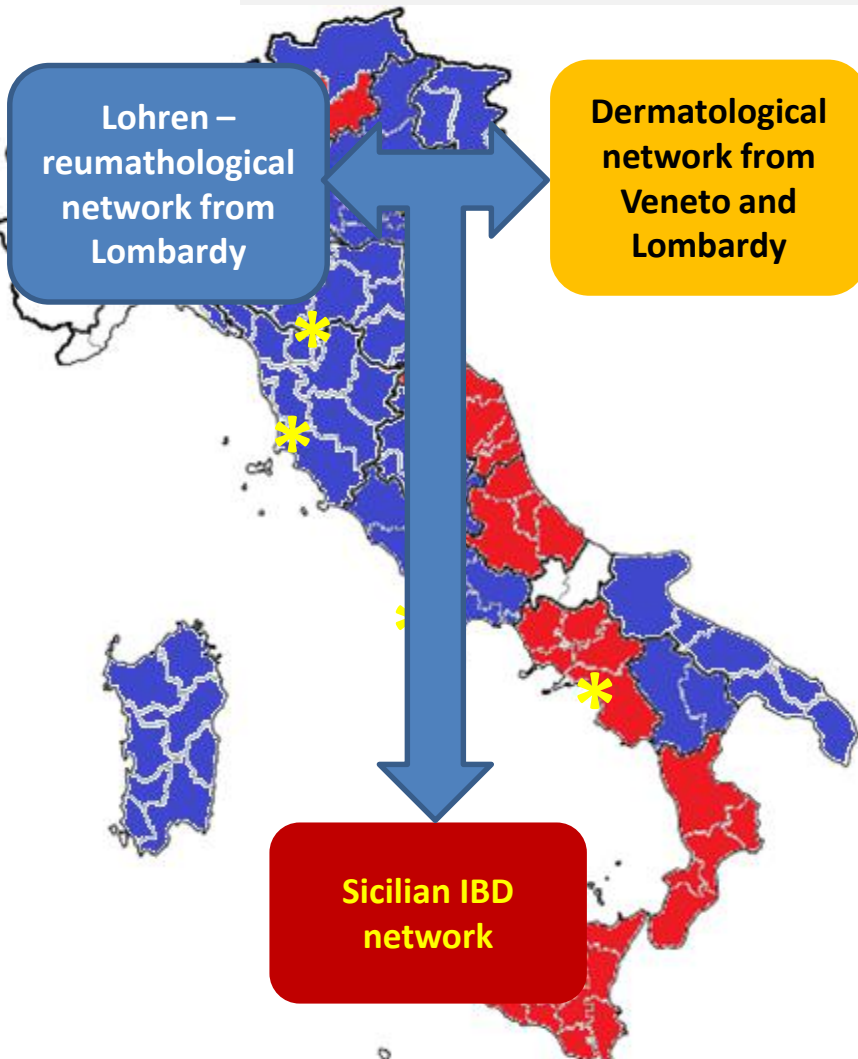
Future perspectives

VALutazione post-marketing del profilo beneficio-rischio dei farmaci biologici Originator e biosimilari in area dermatologica, reumatologica, gastroenterologica ed onco-ematologica tramite la costituzione di un network unico multiregionale per l'analisi integrata di dati provenienti da banche dati sanitarie, sorveglianze attive e REgistri clinici – Progetto VALORE

Costituire un network multiregionale tramite integrazione di dati provenienti da diverse **banche dati amministrative** regionali, **registri clinici** e raccolti tramite **sorveglianze attive** con il fine ultimo di:

- Valutare **appropriatezza d'uso ed effectiveness e safety** a breve e lungo termine dei farmaci **biologici inclusi i biosimilari** in real world setting *in area **dermatologica, reumatologica, gastroenterologica ed onco-ematologica***;
- Costituire un punto di riferimento nazionale per la **generazione di RWE** su biologici inclusi i biosimilari in particolare da utilizzare come **fonte di informazione** per formare il personale sanitario.

Data framework



Sicilia: N= 5,094,937
Calabria: N= 1,980,533
Campania: N= 5,801,692
Marche: N= 1,525,271
Provincia Autonoma di Trento: N= 539,898
Abruzzo: N=1,311,580

* FV Regional projects

Lombardia: N=10,060,574	Emilia Romagna: N=4,459,477
Basilicata: N=562,869	Friuli Venezia Giulia: N=1,215,220
Lazio: N=5,879,082	Trentino-Alto Adige: N=1,072,276
Veneto: N=4,905,854	Umbria: N=882,015
Puglia: N=4,029,053	
Toscana: N=3,729,641	
Sardegna: N=1,639,591	

Total population: 54,116,263

On a total population of 54 million persons, more than **162,000 users** of biological drugs can be yearly identified from the network of claims databases, with at least **10%** being biosimilars.

Thanks for your attention

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