Uso antibiotici in Italia:

usati troppo e spesso in modo inappropriato

Nicola Magrini, DG AIFA

Presentazione Rapporto OsMED Antibiotici 2020

Roma, 10 Marzo 2022

Uso degli Antibiotici: occorre cambiare

1. 5500 tonnellate di antibiotici in EU – Diciamo basta? Quando?
    a) Ne siamo consapevoli? Il ruolo dei media
    b) One Health non è ancora passato come concetto di awareness/consapevolezza sociale - Imparare dai Paesi del Nord Europa
2. La storia degli antibiotici: davvero molto istruttiva fin dall'inizio
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    c) Nuovi contratti sui prezzi per incentivare il NON USO dei nuovi antibiotici

STORY - Tuesday, 15 February 2022 - 05:40 GMT

Health professionals call for European action to preserve colistin for human use

Keywords : #amr #pharmacy #public health

EUROPEAN UNION

BRUSSELS, 15 Feb (APM) - Some 150 European health professionals wrote on Tuesday to the European Commission urging action to prevent the use of colistin in animals and to preserve it for human use.

They point out that colistin is now a last-resort antibiotic to treat infections caused by gram-negative bacteria that are resistant to carbapenems - notably used to treat pulmonary bacterial infections in cystic fibrosis patients.

Colistin is one of the last-resort antimicrobials used in farming, they add.

Citing the EU's One Health Action Plan and the commitment to reducing the emergence and spread of antimicrobial resistance, they argue that a reduction in the unnecessary use of antimicrobials will be crucial to achieving this objective - particularly targeting antimicrobials used in food-producing animals.

Of the 5,500 tonnes of antimicrobials sold in Europe for food production in 2020 alone, some 800 tonnes were antimicrobials identified as 'highest priority critically important' by the WHO - that is, last-resort antimicrobials vital for human health.

Of these, more than 150 tonnes were colistin.

Instead the EU should be focusing on increasing the development and availability of new effective antimicrobials, they add.

The letter is supported by more than a dozen health organisations, including the Standing Committee of European Doctors, Compassion in World Farming EU, Doctors against Factory Farming, the European Association of Hospital Pharmacists, the European Forum for Primary Care, and Health Care Without Harm.

pod/nh

peter.odonnell@apmnews.com

[75878]

APMHE LIVE

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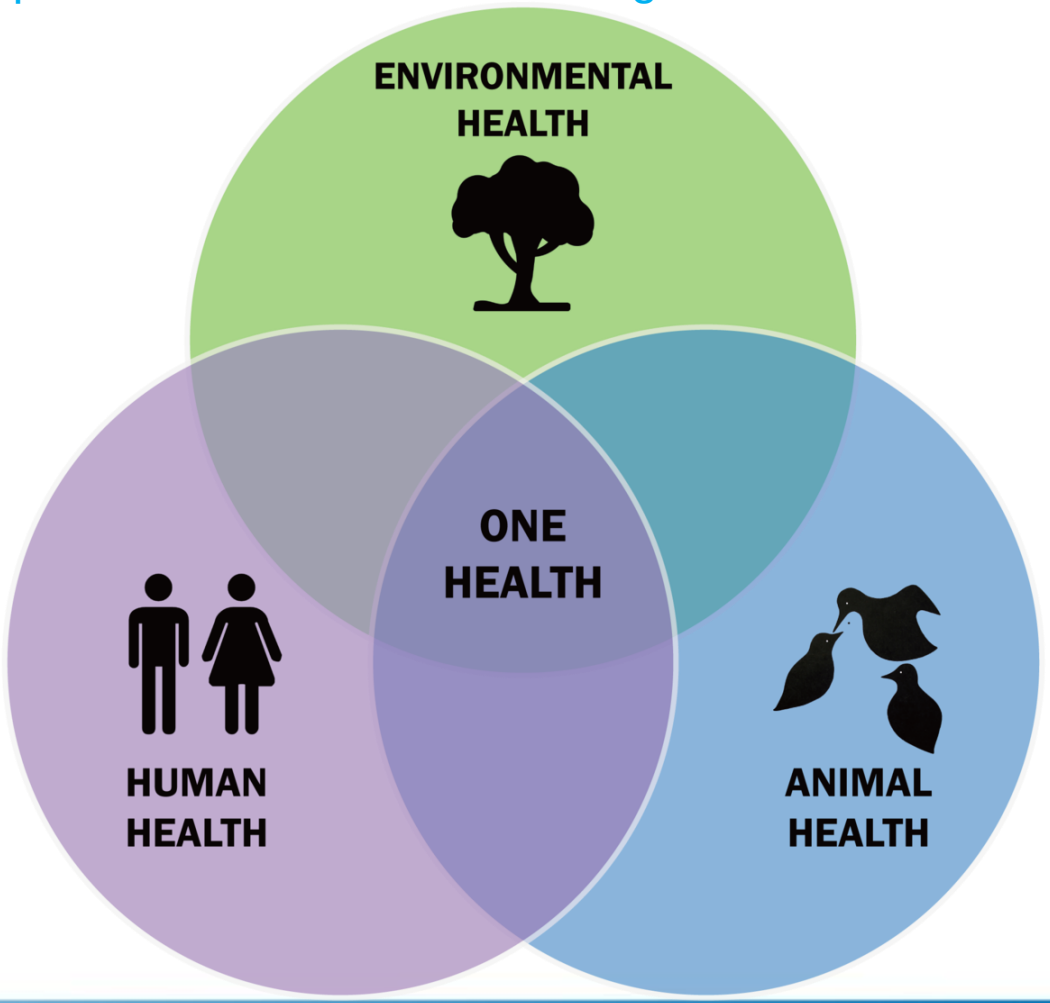
Uso degli Antibiotici: One Health

One Health' is **an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes**. The 'One Health' approach is critical to addressing health threats in the animal, human and environment interface.



Antimicrobial Resistance in the EU/EEA

A One Health Response

Key messages

Antimicrobial resistance remains a serious challenge for everyone, a silent pandemic that calls for a One Health response in the EU/EEA.

Misuse of antibiotics is among the main drivers underpinning the development of antimicrobial resistance (AMR). Resistance to last-line antibiotics also compromises the effectiveness of life saving medical interventions such as intensive care, cancer treatment and organ transplantation.

Overall consumption of antibiotics in humans in the European Union/European Economic Area (EU/EEA) decreased by 23% between 2011 and 2020, especially during the Coronavirus Disease 2019 (COVID-19) pandemic (between 2019 and 2020, the mean total consumption of antibiotics dropped by almost 18%). However, relative use of broad-spectrum antibiotics has increased and significant variability across countries suggests that reductions are still possible.

Efforts to reduce unnecessary use of antibiotics in food-producing animals have resulted in a 43% decrease in use between 2011 and 2020 in 25 countries with consistent reporting.

Despite reductions in antibiotic consumption in both humans and food-producing animals, AMR in bacteria from humans in the EU/EEA has increased for many antibiotic-bacterium combinations since 2011. Particularly worrisome is the rise in resistance to critically important antibiotics used to treat common healthcare-associated infections.

While recent trends have been encouraging, resistance to commonly used antibiotics in bacteria from food-producing animals remains high (>20% to 50%) or very high (>50% to 70%), and there is significant regional variation across the EU/EEA region.

Evidence that AMR can spread between animals, humans and the environment is mounting. Reducing the use of antibiotics in food-producing animals, replacing them where possible and rethinking the livestock production system in a One Health approach is essential for the future of animal and public health.

EU/EEA countries have mad
strides in recent years in de
implementing national actic
but gaps remain. Analyses t
suggest that top priorities f
include:

- Evaluation and monitorin
implementation of nation
- Integrated and expanded
AMR in bacteria from hun
the environment.
- Investing in effective cost
interventions, such as ant
stewardship programmes
prevention and control (IF

Plans for a new EU policy ir
boost the implementation
Health Action Plan against A
opportunity to:

- Continue incentivising ne
treatments (including nev
tests while maximising ac
resources such as antibiot
availability.
- Target antibiotic consump
in long-term care facilities
OECD survey shows that
have policies that specific
in LTCFs, with a majority
countries reporting they p
references to LTCFs in the
action plan.
- Establish a system to shar
implementation of best p
AMR.
- Renew focus on internati
on surveillance and regula
with non-EU/EEA partner

While available data sugges
been a reduction in antibiot
humans during the pandem
serious challenge in the EU/
be contained within border
underlining the need for co
throughout the EU/EEA.

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OECD BETTER POLICIES FOR BETTER LIVES

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

efsa European Food Safety Authority

EMA EUROPEAN MEDICINES AGENCY

A Briefing Note
For EU/EEA countries to inform the French presidency of the EU council

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ALEXANDER FLEMING

Penicillin

Nobel Lecture, December 11, 1945

I am going to tell you about
of the penicillin story which
quently asked why I invente
fectly orthodox lines and coi
penicillin was derived from a
ago the word "Digitalin" w
plant *Digitalis*. To my gene
microbe by another was co
inhibitions and indeed it is s
can pass a week without seei
inite instances of bacterial an

In 1929, I published the results which I have briefly given to you and suggested that it would be useful for the treatment of infections with sensitive microbes. I referred again to penicillin in one or two publications up to 1936 but few people paid any attention. It was only when some 10 years later after the introduction of *sulphonamide* had completely changed the medical mind in regard to chemotherapy of bacterial infections, and after Dubos had shown that a powerful antibacterial agent, *gramicidin*, was produced by certain bacteria that my co-participators in this Nobel Award, Dr. Chain and Sir Howard Florey, took up the investigation. They obtained my strain of *Penicillium notatum* and succeeded in concentrating penicillin with the result that now we have concentrated penicillin which is active beyond the wildest dreams I could possibly have had in those early days.

Their results were first published in 1940 in the midst of a great war when ordinary economics are in abeyance and when production can go on regardless of cost. I had the opportunity this summer of seeing in America some of the large penicillin factories which have been erected at enormous cost

overdose and poisoning the patient. There may be a danger, though, in underdosage. It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body.

HOWARD W. FLOREY

Penicillin

Nobel Lecture, December 11, 1945

I have recently had the honour
the properties of penicillin cam
and the development in the cl
acquired. It occurred to me tha
repeat much of what I then saic
great activity in the investigati
development of appropriate m
indicate the many directions in
ceeding.

In 1939 Dubos, after long study and preparation of soil bacteria, described the isolation of a powerful antibacterial substance from a spore-forming soil bacterium known as *Bacillus brevis*. In collaboration with others he pursued the investigation of this substance, now known as tyrothricin, both from a chemical and biological point of view and in the clinic. Tyrothricin was found to consist of two polypeptides, gramicidin and tyrocidine, which were crystallized. These have now been thoroughly examined and, though of great interest from many points of view, they have proved too toxic to act as chemotherapeutic agents, though they have had some use as local applications. They have proved to be of great interest to the crystallographers, who find them useful for the study of protein structure by X-ray methods, as they and other substances from similar organisms are some of the simplest crystalline polypeptides known.

The art of medicine

Antibiotic antagonist: the curious career of René Dubos

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http://dx.doi.org/10.1016/
S0140-6736(15)00470-5

"I would rather be remembered for my paradoxes than for my prejudices."

René Dubos

The history of antibiotics is usually told as triump
followed by tragedy. First comes the bold promise of th
sulpha drugs, then the dawning of the antibiotic era prop
with the discovery of streptomycin and the rediscove
of penicillin; then the sobering realisation that thes
wonder drugs could have an expiry date. In this story
antibiotic hope and "antibiotic abandon"—to borro
James Whorton's prescient phrase—certain scientis
and drugs figure prominently: Selman Waksman ar
streptomycin, but also Gerhard Domagk and prontos
Howard Florey and penicillin.

Only rarely do historians mention another miracle dru
gramicidin, and the Rockefeller researcher who discovered
René Dubos. To some extent this is understandable: despi
being hailed in 1939 as a "hundred thousand times" mo
powerful than the sulpha drugs, gramicidin proved high
toxic when administered intravenously and although it w

To appreciate the impact of Dubos's discovery it is sufficient to recall that in the 1930s nearly all the available chemotherapeutic agents were based on poisonous

However, gramicidin was the first antibacterial agent to emerge from systematic scientific research and, together with tyrothricin, its less pure form, the first to be produced commercially and used clinically. As such, it arguably has a greater claim than streptomycin to have launched the antibiotic revolution. Yet no sooner had Dubos unveiled gramicidin than he withdrew from research in this field, convinced that such antimicrobial agents would only encourage the growth of bacterial resistance. The result was that by 1943 Dubos was advising premedical students not to follow the example of their elder colleagues who practise "the wasteful and inconsiderate use of antibiotics", and by the late 1950s he was explicitly warning that "at some unpredictable time and in some unforeseeable manner nature will strike back". Dubos thus presents a paradox for historians of antibiotics, disrupting the triumphant phase of the narrative and foreshadowing the tragedy that follows.

Think globally, act locally

Rene Dubos

Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis

*Antimicrobial Resistance Collaborators**

Summary

Background Antimicrobial resistance (AMR) poses a major threat to human health around the world. Previous publications have estimated the effect of AMR on incidence, deaths, hospital length of stay, and health-care costs for specific pathogen–drug combinations in select locations. To our knowledge, this study presents the most comprehensive estimates of AMR burden to date.

Lancet 2022; 399: 629–55

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January 20, 2022
https://doi.org/10.1016/
S0140-6736(21)02724-0

Findings On the basis of our predictive statistical models, there were an estimated 4·95 million (3·62–6·57) deaths associated with bacterial AMR in 2019, including 1·27 million (95% UI 0·911–1·71) deaths attributable to bacterial AMR. At the regional level, we estimated the all-age death rate attributable to resistance to be highest in western sub-Saharan Africa, at 27·3 deaths per 100 000 (20·9–35·3), and lowest in Australasia, at 6·5 deaths (4·3–9·4) per 100 000. Lower respiratory infections accounted for more than 1·5 million deaths associated with resistance in 2019, making it the most burdensome infectious syndrome. The six leading pathogens for deaths associated with resistance (*Escherichia coli*, followed by *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Streptococcus pneumoniae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*) were responsible for 929 000 (660 000–1 270 000) deaths attributable to AMR and 3·57 million (2·62–4·78) deaths associated with AMR in 2019. One pathogen–drug combination, meticillin-resistant *S aureus*, caused more than 100 000 deaths attributable to AMR in 2019, while six more each caused 50 000–100 000 deaths: multidrug-resistant excluding extensively drug-resistant tuberculosis, third-generation cephalosporin-resistant *E coli*, carbapenem-resistant *A baumannii*, fluoroquinolone-resistant *E coli*, carbapenem-resistant *K pneumoniae*, and third-generation cephalosporin-resistant *K pneumoniae*.

Infezioni vie aeree superiori:
> 50% degli antibiotici inappropriato

BMJ Open Quality

Reducing inappropriate outpatient antibiotic prescribing: normative comparison using unblinded provider reports

Richard V Milani, Jonathan K Wilt, Jonathan Entwisle, Jonathan Hand, Pedro Cazabon, Jefferson G Bohan

To cite: Milani RV, Wilt JK, Entwisle J, *et al*. Reducing inappropriate outpatient antibiotic prescribing: normative comparison using unblinded provider reports. *BMJ Open Quality* 2019;**8**:e000351. doi:10.1136/bmjoq-2018-000351

Received 6 February 2018
Revised 3 January 2019
Accepted 4 January 2019

ABSTRACT

Importance Antibiotic resistance is a global health issue. Up to 50% of antibiotics are inappropriately prescribed, the majority of which are for acute respiratory tract infections (ARTI).

Objective To evaluate the impact of unblinded normative comparison on rates of inappropriate antibiotic prescribing for ARTI.

Design Non-randomised, controlled interventional trial over 1 year followed by an open intervention in the second year.

Setting Primary care providers in a large regional healthcare system.

Participants The test group consisted of 30 primary care providers in one geographical region; controls consisted of 162 primary care providers located in four other

deaths in the USA are caused by antibiotic resistant bacteria.[4] If this trend persists, it is estimated by 2050, there will be 10 million antimicrobial resistance deaths worldwide, costing the world up to $100 trillion.[5]

Antibiotics for acute respiratory tract infections (ARTI) in the outpatient setting account for almost half (44%) of the more than 266 million antibiotic prescriptions written each year in the USA, and is a major contributor to antimicrobial resistance.[6 7] It is estimated that approximately half of these prescriptions are inappropriate, given for conditions for which antibiotics provide no benefit.[8] In addition to increasing the preva-

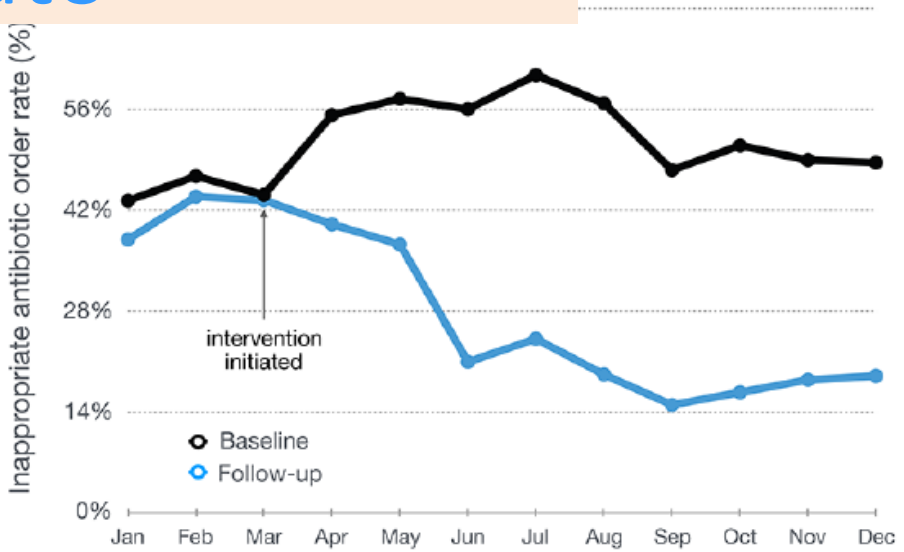

Table 2 Change in antibiotic prescribing over time

Group	Antibiotic prescribing	Baseline, %	Year 1*, %	Year 2†, %
Test	Inappropriate rate for ARTI	51.9	31.0	16.3
Test	Total antibiotic rate all conditions	17.5	15.2	12.3
Control	Inappropriate rate for ARTI	61.3	57.0	34.5
Control	Total antibiotic rate all conditions	14.8	14.4	11.9

JAMA Pediatrics | Original Investigation

Short- vs Standard-Course Outpatient Antibiotic Therapy for Community-Acquired Pneumonia in Children
The SCOUT-CAP Randomized Clinical Trial

Derek J. Williams, MD, MPH; C. Buddy Creech, MD, MPH; Emmanuel B. Walter, MD, MPH; Judith M. Martin, MD; Jeffrey S. Gerber, MD, PhD; Jason G. Newland, MD, MSCE; Lee Howard, MD; Thomas M. Conrad, MS, PhD; Marina S. Lee, PhD; Henry F. Chambers, MD; Theoklis E. Zaoutis, MD

IMPORTANCE Childhood community-a
days of antibiotics. Shorter courses ma
decreased potential for antibiotic resis

OBJECTIVE To compare a short (5-day)
CAP in young children.

RESULTS A total of 380 children (189 randomized to short course and 191 randomized to standard course) made up the study population. The mean (SD) age was 35.7 (17.2) months, and 194 participants (51%) were male. Of the included children, 8 were Asian, 99 were Black or African American, 234 were White, 32 were multiracial, and 7 were of unknown or unreported race; 33 were Hispanic or Latino, 344 were not Hispanic or Latino, and 3 were of unknown or unreported ethnicity. There were no differences between strategies in the DOOR or its individual components. Fewer than 10% of children in either strategy had an inadequate clinical response. The short-course strategy had a 69% (95% CI, 63-75) probability of a more desirable RADAR outcome compared with the standard-course strategy. A total of 171 children were included in the resistome analysis. The median (range) number of antibiotic resistance genes per prokaryotic cell (RGPC) was significantly lower in the short-course strategy compared with the standard-course strategy for total RGPC (1.17 [0.35-2.43] vs 1.33 [0.46-11.08]; $P = .01$) and β-lactamase RGPC (0.55 [0.18-1.24] vs 0.60 [0.21-2.45]; $P = .03$).

CONCLUSIONS AND RELEVANCE In this study, among children responding to initial treatment for outpatient CAP, a 5-day antibiotic strategy was superior to a 10-day strategy. The shortened approach resulted in similar clinical response and antibiotic-associated adverse effects, while reducing antibiotic exposure and resistance.

To give or not to give antibiotics is not the only question

Catarina Magalhães, Margarida Lima, Patrick Trieu-Cuot, Paula Ferreira

In a 1945 Nobel Lecture, Sir Alexander Fleming warned against the overuse of antibiotics, particularly in response to public pressure. In the subsequent decades, evidence has shown that bacteria can become resistant to almost any available molecule. One key question is how the emergence and dissemination of resistant bacteria or resistance genes can be delayed. Although some clinicians remain sceptical, in this Personal View, we argue that the prescription of fewer antibiotics and shorter treatment duration is just as effective as longer regimens that remain the current guideline. Additionally, we discuss the fact that shorter antibiotic treatments exert less selective pressure on microorganisms, preventing the development of resistance. By contrast, longer treatments associated with a strong selective pressure favour the emergence of resistant clones within commensal organisms. We also emphasise that more studies are needed to identify the optimal duration of antibiotic therapy for common infections, which is important for making changes to the current guidelines, and to identify clinical biomarkers to guide antibiotic treatment in both hospital and ambulatory settings.

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Introduction

the number of articles in this field has continued to

World Health Organization

ADULTS

Bronchitis

Definition

A self-limiting inflammation of the trachea and bronchi characterized by persistent cough +/- fever usually caused by a viral infection

Diagnosis

Clinical Presentation

- Acute onset (<2 weeks) of cough lasting > 5 days +/- sputum production and shortness of breath (colour of the sputum does not indicate bacterial infection) +/- fever
- Generally a mild condition; cough usually lasts 10-20 days (can last longer)

Important: Symptoms can overlap with pneumonia and this can lead to inappropriate treatment with antibiotics. This should be avoided with a careful patient assessment
- **Bronchitis:** Less severe presentation, usually self-limiting (but cough may take weeks to resolve)
- **Pneumonia (see "Community-acquired pneumonia" infographic):** More severe presentation with shortness of breath and systemic signs of infection (e.g. increased heart and respiratory rate)

Microbiology Tests

Usually not needed; consider testing for Influenza virus or SARS-CoV-2 (e.g. during influenza season or outbreaks based on local epidemiological risk/situation/ protocols)

Other Laboratory Tests

Usually not needed

Imaging

Usually not needed

Most Likely Pathogens

Respiratory viruses:
- Rhinovirus
- Influenza virus (A and B)
- Parainfluenza virus
- Coronavirus (including SARS-CoV-2)
- Respiratory syncytial virus
- Metapneumovirus
- Adenovirus

Treatment

No Antibiotic Care

- Symptomatic treatment
- Bronchodilators (in case of wheezing), mucolytic or antitussive agents, can be considered based on local practices and patient preferences

Patients should be informed that:
- Great majority of cases are self-limiting and of viral origin
- Cough can persist for several weeks

Symptomatic Treatment

Ibuprofen 200-400 mg q6-8h (Max 2.4 g/day)

OR

Paracetamol (acetaminophen) 500 mg-1 g q4-6h (max 4 g/day)
- **Hepatic impairment/cirrhosis:** Max 2 g/day

Antibiotic Treatment

Antibiotic treatment is **not recommended and should be avoided** as there is no evidence of a significant clinical benefit and there is a risk of side effects of antibiotics

AIFA AGENZIA ITALIANA DEL FARMACO

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Parsimonia

nell’uso ottimale degli antibiotici

Nel linguaggio della moderna teoria dell'informazione, si può dire che l'informazione è *una differenza che produce una differenza* …

e che le differenze sono rapporti

Gregory Bateson,

Ultima conferenza, 1979

Antibiotici in Italia

Messaggi chiave e conclusioni

A mo’ di conclusioni

Antibiotici in Italia: verso cambiamenti radicali

Necessità di una visione OneHealth:

1. Ridurre drasticamente l'uso di antibiotici in veterinaria, in agricoltura e anche in salute umana
2. Numerosi studi hanno evidenziato la fattibilità di riduzioni massive (oltre il 50% e fino al 70%) nelle infezioni respiratorie, assieme a riduzioni di durata delle terapie antibiotiche
3. Da molti anni si cerca di ridurre drasticamente l'uso degli antibiotici nelle sinusiti e otiti con risultati migliori nei Paesi del Nord Europa
4. Il rapporto OSMED è uno strumento fondamentale assieme a nuove campagne informative
5. AIFA OPERA sta sviluppando raccomandazioni e politiche per l'uso ottimale degli antibiotici per modificare le attuale pratiche prescrittive

La conoscenza della safety è a 4 livelli

1. **RCT: Sicurezza come emerge da B/R**
    a. I dati dei grandi studi registrativi – 94-95% di efficacia
    b. La efficacia reale (RWE) dei programmi di vaccinazione: simile alla efficacia dei trials ed graduale riduzione effetto (waning) a partire dal 3-4 mese per rischio reinfezione
    c. **Effetto placebo/nocebo**

JAMA Network Open

Original Investigation | Public Health

Frequency of Adverse Events in the Placebo Arms of COVID-19 Vaccine Trials
A Systematic Review and Meta-analysis

Julia W. Haas, PhD; Friederike L. Bender, MS; Sarah Ballou, PhD; John M. Kelley, PhD; Marcel Wilhelm, PhD; Franklin G. Miller, PhD; Winfried Rief, PhD; Ted J. Kaptchuk

Abstract

IMPORTANCE Adverse events (AEs) after placebo treatment are common in randomized clinical drug trials. Systematic evidence regarding these nocebo responses in vaccine trials is important for COVID-19 vaccination worldwide especially because concern about AEs is reported to be a reason for vaccination hesitancy.

OBJECTIVE To compare the frequencies of AEs reported in the placebo groups of COVID-19 vaccine trials with those reported in the vaccine groups.

DATA SOURCES For this systematic review and meta-analysis, the Medline (PubMed) and Cochrane

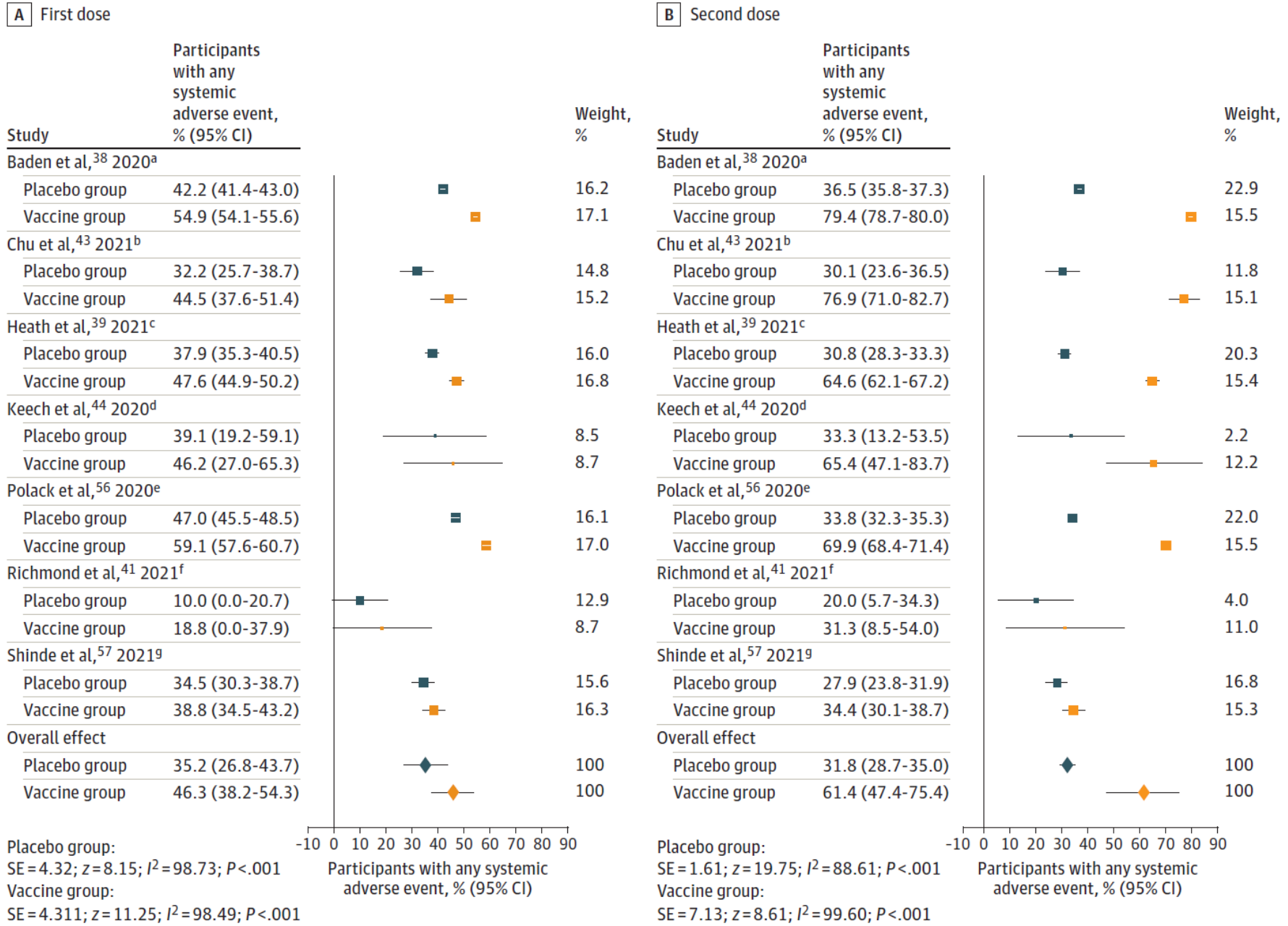
Findings In this systematic review and meta-analysis of 12 articles including AE reports for 45 380 trial participants, systemic AEs were experienced by 35% of placebo recipients after the first dose and 32% after the second. Significantly more AEs were reported in the vaccine groups, but AEs in placebo arms ("nocebo responses") accounted for 76% of systemic AEs after the first COVID-19 vaccine dose and 52% after the second dose.

Meaning This study found that the rate of nocebo responses in placebo arms of COVID-19 vaccine trials was substantial; this finding should be considered in public vaccination programs.

Placebo nocebo effect

Adverse events seemingly elicited by placebos are often called *nocebo responses*[14] and are thought to be caused by misattribution of routine background symptoms,[15] anxiety,[16] and expectations of AEs.[17,18] Emerging research has shown that informing patients about nocebo responses[19,20] and providing a positive framing of potential AEs[21-24] may be associated with reduced AE-related anxiety and nocebo responses. Although nocebo phenomena have been investigated in many contexts involving medication,[18,25-28] evidence of their influence in vaccination remains scarce. However, a recent meta-analysis suggested that a significant proportion of placebo recipients in influenza vaccine trials experienced systemic AEs, such as headache or fatigue, owing to nocebo responses.[29]

Figure 2. Forest Plots of Any Systemic Adverse Events After the First and Second Doses of the COVID-19 Vaccine or Placebo



Placebo nocebo effect

full disclosure and education about nocebo responses may be helpful.[19,20] For example, adding simple but accurate information about nocebo responses to the usual informed consent procedure (eg, "participants in the placebo arm of the randomized clinical trials testing this intervention reported similar AEs, probably because of worry and anxiety") helped reduce medication-related AEs in a clinical population.[20] Highlighting the probability of not experiencing AEs might also be beneficial.[21] Although more research on these communication strategies is needed, such honest information adds to full disclosure and is unlikely to cause harm. In addition, informing the public about the potential for nocebo responses may help reduce worries about COVID-19 vaccination, which might decrease vaccination hesitancy.[9,31]

> second dose, with headache and fatigue being the most common. This nocebo response accounted for 76.0% of systemic AEs after the first dose of COVID-19 vaccine, and for 51.8% after the second dose. Public vaccination programs should consider these high nocebo responses.

[…] uno spazio di discussione tra l'ambito regolatorio e quello più ampio ed articolato della comunità scientifica a degli operatori sanitari, delle associazioni dei malati e del mondo delle imprese, al fine di condividere aspetti metodologici, etici e di *governance* delle diverse tematiche che riguardano il mondo del farmaco.

Seminari Scientifici - AIFA

17 Feb 2021	**La resistenza antimicrobica: pensare l'impensabile** **>>> 1,508 iscritti**	**Mike Sharland** ***ST. GEORGE'S UNIVERSITY LONDON*** *WHO EML Antibiotic Working Group Chair*
15 Apr 2021	**Causalità e casualità nei recenti segnali di farmacovigilanza dei vaccini Covid-19: quali evidenze per le decisioni di salute pubblica?** **>>> 2,648 iscritti**	**Bernard Bégaud** **EMERITUS PROFESSOR OF CLINICAL PHARMACOLOGY, UNIVERSITY OF BORDEAUX** *Chair of the Scientific Committee EPI-PHARE*
19 Mag 2021	**Il sistema regolatorio oltre l'autorizzazione dei medicinali** **>>> 1,443 iscritti**	**Bert Leufkens** **UTRECHT UNIVERSITY** **Emeritus Professor of Regulatory Science**
24 Giu 2021	**Il consenso informato nelle sperimentazioni dei vaccini Covid-19:la soluzione è il problema?** **>>> 902 iscritti**	**Ezekiel J. Emanuel** **Levy University Professor** **Perelman School of Medicine and The Wharton Sch** **UNIVERSITY OF PENNSYLVANIA**

Messaggi chiave e conclusioni

A mo’ di

Offline: COVID-19 as culture war

Lancet, 22 Jan 2022

When Dr Anthony Fauci challenged Senator Rand Paul last week during US congressional hearings, he exposed how politicians have exploited the COVID-19 pandemic for their own personal advantage. Fauci showed screenshots of Senator Paul's website, which included the message "Fire Dr Fauci". He pointed out that Paul was inviting people to send donations to firefauci.org. He explained how Paul's exaggerations were creating

- Un eccesso di polarizzazione e strumentalizzazione politica del Covid19
- Una ridotta partecipazione dei medici e degli operatori sanitari alle discussioni sulle politiche sanitarie
- Una visione più chiara e coerente della nostra società nel post pandemia per un *build back fairer*, un ritorno a una normalità migliore

personal gain . As the pandemic enters its third year, the difficult truth is that the political debate about COVID-19 has evolved into a bitter culture war, where arguments have become struggles between different social groups holding different beliefs about how society should be constructed and governed. As one UK

error. On Dec 14, 2021, Dr Angelique Coetzee, a South African doctor with first-hand experience of managing patients infected with omicron, pointed out that the UK's reaction "is out of all proportion to the risks posed by this variant". Her message was clear: "I can reassure you that the symptoms presenting in those with Omicron are very, very mild compared with those we see with the far more dangerous Delta variant." Coetzee

version of the Paul–Fauci culture war. "It's Boris versus the scientists", proclaimed the front page of the *Daily Mail* on Dec 16, 2021. It took a month for the UK Health Security Agency to agree with the testimony of Coetzee that omicron caused a low severity of disease in adults.

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Vaccini Covid19, sicurezza e rapporto B/R

Una molteplicità di approcci ha confermato:

1. L'efficacia molto elevata dei vaccini Covid-19 nel prevenire infezioni Covid-19 e soprattutto le forme gravi – dimostrata in RCT di grandi dimensioni
2. Un rapporto beneficio rischi molto favorevole e una sicurezza complessiva molto elevata studiata in tutti gli ambiti (anche in ambiti salute riproduttiva, fertilità, …) con livelli di precisione delle stime mai visti prima
3. Una prevalenza di effetti indesiderati (fino al 75% degli effetti sistemici) riferibili al placebo (nocebo)
4. Una aperta e stretta collaborazione internazionale della *research community (della comunità dei ricercatori a livello internazionale)*
5. La possibilità di uscire dalla pandemia con l'dea di rafforzare i sistemi sanitari pubblici ed universalistici, la ricerca, la solidarietà sociale e l'equità globale

La filosofia consiste nell’imparare a vedere daccapo il mondo

Maurice Merleau-Ponty