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PATIENT AND HEALTH

The interests of sponsors above those of the public

Fabbri A, Parker L, Colombo C, et al.

Patient groups play an important part in healthcare: educating consumers, funding medical research, and contributing to decisions on approval and public coverage of drugs and treatments patient groups often rely on multiple sources of financial support, including the pharmaceutical and medical device industries. Concerns have been raised about the financial relationships between industry and patient groups because of conflicts of interest and potential threats to the integrity and independence of groups. Industry funding of patient groups is common in many high income countries and in different clinical areas, but the extent of industry funding of patient groups in low and middle income countries is unknown. Few patient groups have policies that govern corporate funding and transparency is inadequate. Studies that examined associations between funding status and policy positions were limited but reported that industry funded groups generally supported sponsors' interests. Conclusions that could be drawn are limited by the low quality of available data on key study outcomes.

BMJ 2020; 368: l6925.
http://dx.doi.org/10.1136/bmj.l6925

MENTAL HEALTH

Psychosocial interventions for mental health

Barbui C, Purgato M, Abdulmalik, J, et al.

A relatively large amount of evidence suggests the benefit of psychosocial interventions on various mental health outcomes in low-income and middle-income countries (LMICs). However, strength of associations and credibility of evidence were quite variable, depending on the target mental health condition, type of population and setting, and outcome of interest. This varied evidence should be considered in the development of clinical, policy, and implementation programmes in LMICs and should prompt further studies to improve the strength and credibility of the evidence base.

Lancet Psychiatry 2020; 7: 162-72.

PRACTICAL GUIDE

Severe hypertension in children?

Baracco R.

Severely elevated blood pressure in children should be evaluated and treated emergently, particularly if the child is exhibiting life-threatening symptoms. Evaluation of severe hypertension may require extensive investigations, which should not delay the treatment.Treatment of a child with severe hypertension should be instituted immediately with short-acting medications.

Pediatric Drugs 2020; 22: 13-20.

GENERAL PRACTICE

Adverse events following cannabis for medical use

Crescioli G, Lombardi N, Bettiol A, et al.

Despite a significant increase in using cannabis for medical purposes, current evidence on its safety in real-world clinical practice is still poorly characterised. By a case-by-case analysis of spontaneous reports of suspected adverse events (AEs) collected in Tuscany within the Italian phytovigilance database.

It was found that cannabis was generally well tolerated and the majority of AEs were mild and transient. The analysis highlighted important safety issues for clinical practice, in particular the need for an accurate prescription monitoring during the titration phase, particularly in the presence of concomitant medications.

Br J Clin Pharmacol 2020; 86: 106-20.

VACCINES

Vaccines: an achievement of civilization

Rappuoli R, Santoni A, Mantovani A.

Vaccines represent a land of opportunity for research in fundamental immunology, vaccinology sensu stricto, and social sciences. The latter is imperative to counter the spreading of anti-science attitudes, of which "no-vax" is the vanguard. Addressing the challenges and taking the opportunities are briefly summarized at the level of civil society and research, in a global health perspective, is imperative to fulfill the reality and potential of vaccines to serve as a safety belt and insurance policy for humankind at present and in the future.

J Exp Med 2019; 216: 7-9.

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INNOVATIVENESS

Using GRADE to assess innovation of new drugs

Fortinguerra F, Tafuri G, Trotta F, et al.

In April 2017 the Italian Medicine Agency (AIFA) developed new criteria to grant any new medicinal product with an innovative designation.

The new AIFA innovation criteria resulted in a much more flexible and transparent model to define and assess what constitutes a therapeutic innovation. In particular, the choice of AIFA to use the GRADE methodology to evaluate the quality of clinical evidence within a process of drug innovativeness assessment is essential for the early identification of the discrepancy between the need for patients of a rapid access to innovative therapies and the available clinical data needed to make decisions on drug innovativeness.

Br J Clin Pharmacol 2020; 86: 93-105.

DRUG REGULATION

Times and clinical evidence on novel drugs approval

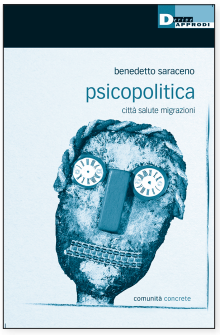
Joppi R, Bertele' V, Vannini T, et al.

The Food and Drug Administration (FDA) and European Medicines Agency (EMA) now have expedited review procedures for new drugs. In 2015-2017 the FDA licensed 113 drugs, 66 of which reached Europe. The median review time was longer at the EMA than FDA and was shorter for drugs undergoing FDA-expedited programmes compared to the same drugs approved by the EMA through the standard procedure. Differences regarding the evidence submitted to the 2 regulators for 7 drugs were found. The greater use of expedited programmes by the FDA and administrative time at the European Commission mainly explain the later access of new drugs to the European market. The additional evidence submitted to the EMA is generally scant and limited to a few drugs.

Br J Clin Pharmacol 2020; 86: 170-4.

Lavorare per la felicità con il coraggio della speranza

Città, salute, migranti e psicopolitica. Si dipanano lungo questo percorso il pensiero critico e il richiamo all'azione di Benedetto Saraceno, psichiatra militante che ha lavorato con Franco Basaglia e che è stato per oltre un decennio direttore del Centro salute mentale dell'Organizzazione Mondiale della Sanità. La sofferenza urbana – che include la sofferenza psicologica e sociale di chi in città vive condizioni di povertà, violenza, insicurezza, emigrazione forzata, esclusione – viene gestita da istituzioni pubbliche e private attraverso una governance che Saraceno schematizza – per facilità di analisi – in sei strategie. Dalla collusione passiva di molte amministrazioni pubbliche che non si occupano del benessere delle persone più marginali, per disinteresse o inefficienza, alla collusione attiva, consapevole, connotata da corruzione e violenza, alla strategia dell'ordine e della sicurezza associati alla costruzione di una percezione identitaria che si contrappone all'altro e al diverso da espellere. La testimonianza dal basso – propria del privato sociale e di quello che l'autore definisce universo filantropico – produce esperienze di valore che però non influiscono sulla governance e non diventano quindi politiche. Sono invece le politiche dall'alto dell'amministrazione pubblica che hanno potere ed effetto gestionali, ma non incontrano le soggettività. L'ultima strategia è quella dell'accompagnamento, che si confronta



BENEDETTO SARACENO
Psicopolitica
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