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ISDB 2021 Newsletter

Remarks from Dick Bijl, Chairman of ISDB


Dick Bijl, Chairman of ISDB

Dear friends,
It's been almost a year since the ISDB published a newsletter but our member organizations have been busy promoting rational pharmacotherapy as well as contributing to knowledge about treatments and vaccines to deal with the pandemic. A major concern of ISDB is the issue of transparency of data, and the importance of openness around pandemic-related drugs and vaccines. Around the world, vaccine hesitancy is very much a real thing and we believe that governments could better instill confidence in Covid vaccines if they were more open with the data used to approve them. We are calling for such openness and have signed a Joint letter prepared by TranspariMed to the Heads of Medicines Agencies on clinical trial reporting.

The fact is that many clinical trials are still missing on EudraCT (the European Union Drug Regulating Authorities Clinical Trials Database) and this continues to create gaps in the medical evidence base.

Below you will see some news from ISDB members, including Prescrire, NoGracias, DTB Navarre, the Therapeutics Initiative and others, and also be introduced to a new member of ISDB, Maryanne Demasi, from Australia. Feel free to share this newsletter.

Contents

Article

Dick Bijls' article entitled "Rational Pharmacotherapy in Times of Pandemic" maintains that the urgency caused by the COVID-19 pandemic has accelerated the demand for rapid development of drugs and vaccines. Yet, even in a pandemic, the vital principles of in dubio abstine (if case of doubt, don't do) and primum non nocere (first do no harm) must be rigorously observed. This means that drugs and vaccines should be evaluated, wherever possible, by proper randomized double-blind, placebo-controlled trials.

Dick Bijl's Book Review:

MENTAL HEALTH SURVIVAL KIT and withdrawal from psychiatric drugs. By Peter C. Gøtzsche, Institute for Scientific Freedom, Copenhagen, 2020. British Journal of General Practice. Link here

MEMBER NEWS

Prescrire

Prescrire's editors are publishing an ongoing series of news updates featuring independent analysis of developments related to the COVID-19 pandemic. Analyses of the 4 vaccines authorised in the European Union are available in English and French via the website. Useful and practical information to help healthcare professionals gain a clear and balanced view.

More info in English

More info in French

In November 2020, the European Commission published a Proposal for a Regulation on a reinforced role of EMA in crisis preparedness and management for medicinal products and medical devices. (Link here) It is now under discussion in the European Parliament and the Health Council for adoption. Prescrire prepared amendments to improve the transparency and access to documents. For more info, contact Prescrire (rkessler@prescrire.org). They will be shortly submitted to members of the European Parliament.

NoGracias

Interesting article from NoGracias Covid19 vaccines suspected serious adverse events AstraZeneca follow-up, by NoGracias.

DTB Navarre

Full examination of four Covid-19 Vaccines currently in use.

Links in English to AZ, Moderna, Pfizer, Janssen.

Links in Spanish here: AZ, Moderna, Pfizer, Janssen.

Salud y Farmacos

Salud y Fármacos, in addition to the quarterly publication of its bulletins, has been advancing its work on clinical trials and ethics:

In November 2020 we published the first country report on how to strengthen the capacity of research ethics committees to better protect human research participants. To date, three (Costa Rica, Panama, Peru) of the seven country reports are available in our website.

In August 2020 we published an article on how Gilead managed to turn remdesivir into a sought-after treatment during the COVID pandemic (COVID-19 y remdesivir: la construcción de un éxito de ventas durante una pandemia). The Spanish version is available in this link. We are in the process of updating it and it will soon be available in English.

We are studying the implementation of ENSEMBLE (Janssen's clinical trial with its COVID vaccine) in Argentina, Brazil, Colombia, Mexico and Peru. In addition to reviewing the literature and the clinical trial documents, we have petitioned information to the regulatory agencies, and interviewed members of the research ethics committees that approved the trials and clinical trial participants. We expect to have a final draft of the report by the end of May. Salud y Farmacos has co-signed a number of petitions aimed at controlling high medicines prices and Covid-19 monopolies.

InfoFarma

Maria Font's article: THE HOME TREATMENT OF THE COVID-19 PATIENTS

Rxisk.Org

David Healy on "How to publish your book on pharmaceuticals that no other publisher will touch." Dr. David Healy writes that "our health services are now effectively surrounded by a thicket of gatekeepers who prevent the publication of anything that might engage with our need for healthcare rather than their ability to provide health services."

Dr. David Healy

Rxisk.Org (continued)

His answer: Samizdat, a new publishing house that will publish anything – fiction or academic – in the health domain where it has become increasingly difficult, if the work touches on commercial interests linked to health services, pharmaceuticals, medical devices or vaccines. Samizdat is open to taking serious but also hard-hitting work which will likely feature drugs/medicines quite heavily whether in the form in fiction, non-fiction, graphic or other forms, that engage with the difficulties and issues thrown up by "health" – a domain that now occupies the place in our lives religion once occupied. Our objective is to ensure that ideas that are now difficult to publish, primarily because even university presses are now nervous about anything that might seem to them to compromise a drug, get the widest possible distribution and earn a return for their authors.

New Associate Member: Dr Maryanne Demasi, PhD (Australia)

Dr. Maryanne Demasi, PhD.

One of the newest associate members of ISDB is Dr Maryanne Demasi, an award-winning investigative journalist and TV producer/presenter with over 12 years of experience in TV production. Previously, she worked for the Australian Broadcasting Corporation (ABC TV) and Channel 7 in Australia and is a former medical scientist, with a PhD in Rheumatology from the University of Adelaide, South Australia.

While working for the ABC, Dr Demasi produced several hard-hitting documentaries investigating the over-prescription of drugs and medical procedures and exposed the financial corruption plaguing nutrition science. Vested interests pressured ABC executives to censor her work and eventually, the ABC capitulated. Dr Demasi gives a snapshot of what really happened behind the scenes (Link).

Currently, Dr Demasi is the deputy director of the Institute for Scientific Freedom, working alongside Danish physician, Prof Peter Gøtzsche, immersing herself in critical analyses of drugs and pharmacotherapy, and writing about nutrition and related health subjects. Recently, she published an impressive comment on COVID-19 vaccine passports in the BMJ (Link) and published an editorial about the ways to mitigate complications in people who contract COVID-19 (Link) in the BMJ-Evidence Based Medicine.

Therapeutics Initiative (Canada)

The Therapeutics Initiative is in the process of setting up a searchable website for international drug safety advisories in the context of the Drug Safety Advisories Letter; (see link here).

The Therapeutics Initiative has started providing prescribing feedback to all the physicians in BC. Portrait project in the context of the Audit & Feedback Letter, including a description of how we are using Letter and Portrait as a combo intervention on select topics with the early/delayed design to evaluate impact. (see link here)

Come and see the TI's Methods Speaker Series. One researcher associated with the Therapeutics Initiative, Carole Lunny is developing a new risk of bias tool for Network Meta-Analyses. See her presentation here.

Jim Wright, who was the Co-director of the Therapeutics Initiative and Editor-in-Chief of Therapeutics Letter for 25 years just retired. He is well known among ISDB members and many of you would have met him when the Therapeutics Initiative hosted the ISDB meeting in Vancouver in 2012. Even in retirement, Jim continues to work hard, and remains the Editor-in-Chief of Cochrane Hypertension.

Dr. Jim Wright

Anouncing ISIUM:

The International Society to Improve Use of Medicines (ISIUM) is a new membership-based organisation, established in 2019 to reinvigorate the global movement for Rational Use of Medicines (RUM), also known as Responsible or Rational Drug Use. By providing a platform to share knowledge and experience, ISIUM seeks to raise awareness and promote the best use of medicines throughout the world to improve health and the management of disease, including all situations that involve or affect health and the use of medicines in the wider environment. ISIUM believes there needs to be better decision-making regarding the use of medicines. Good choices depend on context, underlying determinants of ill health, independent information and

Announcing ISIUM (continued):

reliable advice and a 'medicines-smart' community. It is essential that we put people's needs at the centre of our efforts to define the place of medicines in society, to provide equitable access to medicines and to ensure they are used properly. Just prior to COVID in 2020, ISIUM held its first conference in Thailand with 175 participants who brought enormous energy, vision and new knowledge to the questions of poor use of medicines in society, health and wellbeing for individuals and their families, communities, and countries. Subsequent Webinars have continued to build momentum and provide opportunities for members to discuss, think, connect and innovate for better use of medicines.

International Society to Improve the Use of Medicines

ISIUM is an inclusive organisation that invites all people and organisations committed to better health and use of medicines to join. You can find out more at **isium.org**

RESTORING INVISIBLE & ABANDONED TRIALS SUPPORT CENTER

Do you have a "Concern" about a clinical trial?
RIAT is launching an "Expression of Concern" campaign.

A "RIAT Expression of Concern" is a letter to the editor that aims to publicly register a serious concern about a clinical trial. Serious concerns include evidence of under- or misreporting (e.g. incorrectly reporting trial results), evidence of serious trial design flaws (e.g. use of a comparator that prohibits a fair assessment of adverse events), and inadequate transparency (e.g. a lack of data sharing for a public health intervention). RIAT Expressions of Concern bring attention to these issues and call for the record to be corrected (for example, through an erratum). Such letters are a small but critical early step towards correcting errors in the published literature.

To learn more, check out this link.

One Further Announcement...

The ISDB has had several attempts to hack our website. If you receive an email that appears to come from Dick Bijl or any other member of the ISDB committee asking for money, please delete the email or report it as spam to your email provider.