Evidence required: for covid-19 too

Aside from the covid-19 epidemic's many major public-health and economic consequences around the world, it has also raised questions for many people about drug evaluation and the need for evidence before using a drug to treat patients.

In a tweet on 14 March 2020, the French Minister for Health recommended that patients infected with coronavirus avoid nonsteroidal anti-inflammatory drugs (NSAIDs), including *ibuprofen*, due to the risk of exacerbating the infection (1).

This warning came as no surprise in France, since the French drug regulatory agency (ANSM) had already advised against the use of NSAIDs in infections, a recommendation supported by French pharmacovigilance data (2,3). But the European and US drug regulatory agencies (EMA and FDA), and others, were quick to contest the French minister's message (1). According to these agencies and various drug specialists, there is evidence that NSAIDs mask infections, but no evidence that they exacerbate infections.

Could this be because the data collected by French Regional Pharmacovigilance Centres have not been published in international journals, or because these disturbing findings are being ignored?

In late March 2020, a French group attracted media attention over the results of a study portrayed as showing that *hydroxychloroquine* has efficacy in treating covid-19 (4). The news was rapidly disseminated worldwide, causing hopes to soar despite the highly tenuous nature of the published data (5).

More generally, back on 18 March 2020, 615 articles on covid-19 had already been made available in preprint form, reflecting researchers' eagerness to broadcast their results before they had been critically reviewed by their peers and accepted for publication (6).

On 19 March 2020, the EMA urged the scientific community to conduct randomised comparative trials designed to generate robust evidence on covid-19 treatments (7). Sound advice indeed.

In the post-covid-19 world, the EMA may need to be reminded that this rule applies to all drug evaluations and all clinical situations, and that includes cancer and multiple sclerosis, not just covid-19.

Prescrire

▶ Translated from *Rev Prescrire* **July 2020**
Volume 40 N° 441 • Page 532

References **1-** Pesce NL "Does ibuprofen make the coronavirus worse? Is it still safe to take aspirin?" 20 March 2020. marketwatch.com accessed 24 March 2020: 3 pages. **2-** ANSM "Anti-inflammatoires non stéroïdiens (AINS) et complications infectieuses graves - Point d'information" 18 April 2019: 2 pages. **3-** Prescrire Editorial Staff "NSAIDs: serious infections" *Prescrire Int* 2020; 29 (212): 44. **4-** Gautret P et al. "Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial" *Int J Antimicrob Agents*: https://doi.org/10.1016/j.ijantimicag.2020.105949: 24 pages. **5-** Prescrire Editorial Staff "Covid-19 and drug trials: what to make of the initial results?" 23 March 2020. www.english.prescrire.org: 1 page. **6-** Maisonneuve H "Covid-19: la bagarre pour publier vite n'est pas acceptable car de mauvais articles sont diffusés aux journalistes et patients" 19 March 2020. www.redactionmedicale.fr accessed 24 March 2020: 1 page. **7-** EMA "Call to pool research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on COVID-19 treatments" 19 March 2020: 2 pages.

EDITORIAL