ACADÉMIE NATIONALE DE MÉDECINE

**Clinical Research and Covid-19: Science is not an option**
**Press release of the French National Academy of Medicine**
**May 8, 2020**

Scientific truth cannot be decreed by the applause meter. It does not emerge from political discourse, petitions or social networks. In science, it is neither the majority weight nor the argument of authority that rules.

It is, however, in this kind of drift that the search for active drug treatments against Covid-19 went astray: too much haste in communication, too many premature announcements, too much discord between the teams, too much pressure of all kinds, but not enough science.

The scientific approach requires time, method and critical thinking. In the field of medicine, it is necessary not only to verify that a substance is effective, but also to ensure that its benefits far outweigh its undesirable effects, given the seriousness of the target disease. This is the benefit/risk balance. The randomized controlled clinical trial is the only method to answer these questions with a high level of evidence.

With regard to Covid-19, in the absence of a reference treatment that can serve as a comparator, each candidate drug should be compared to a placebo. This choice is legitimate in situations of uncertainty, that is to say when it is not known *a priori* whether the patient to be included in the therapeutic trial will benefit from being in one group rather than the other. But the passionate, even compassionate, positions taken in favour of hydroxychloroquine before any comparative trial were so numerous, and the pressures so strong in an anxiety-provoking context, that the patients only agreed to enter the trial with the certainty of not being included in the placebo arm, which is incompatible with the very principle of the controlled trial. As a result, few agreed to contribute to the advancement of science.

Furthermore, the spontaneous favourable course of infection with SARS-CoV-2 in 85% of cases requires the recruitment of a large number of participants to demonstrate the efficacy of any treatment in the initial phase of the disease. However, the unfortunate dispersion of trials limits the size of the samples and reduces the statistical power of the results.

Finally, as the hype in favour of hydroxychloroquine moved towards remdesivir and tocilizumab on the basis of modest preliminary results, it is important to remain cautious while waiting for confirmation.

While the anxiety surrounding the pandemic is stimulating the competition between research teams worldwide, this imperative cannot justify the use of inappropriate methods, botched studies, or communication eager for exclusivity. Rushing the evaluation of a drug candidate means exposing patients to potential adverse effects without being sure to bring them any benefit. Fortunately, there are responsible teams who are imaginative and proactive in shortening as much as possible the time to obtain results.

The time for research and science is not that of media and social network immediacy. The doubt, inherent in any scientific process, is as intolerable for the public seeking to allay its anxiety as it is for the politicians seeking to back up their decisions. In times of crisis, if doubt exasperates, beliefs are harmful and often dangerous.

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**Faced with the challenge of Covid-19, the National Academy of Medicine recalls that therapeutic research must**:

- rely on scientifically rigorous and ethically irreproachable clinical trials, despite the constraint of optimized deadlines;
- be based on solid pharmacodynamic and pharmacokinetic bases;
- coordinate national and international teams in large multicentre studies;
- be committed to a careful and responsible communication by researchers, to disclose only controlled and validated results, and to refrain from raising false hopes and provoking unwarranted general public enthusiasm.

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