Dear Editor,

Please do find enclosed our manuscript “Reply. Data miscalculation yielding wrongful evaluation of treatment effect in hospital. The 16000 deaths evaluation is totally fabricated and hence misleading” in reply to the article by Pradelle et al “Deaths induced by compassionate use of hydroxychloroquine during the first COVID-19 wave: an estimate”, published in Biomedicine & Pharmacotherapy”.

We have discussed at length in our group the significant negative impact of data miscalculation and results fabrication of this publication. We also debated the format of a letter of concern or demand for retraction.

One of the co-authors is director of publication of a media and he reminded us the charter of journalism, namely the duty number 6: correct any information immediately as soon as you are made aware that it is wrong.

This publication entails significant science misconduct and therefore it is your duty to consider the elements presented and draw the consequences. Retraction should be considered

Yours sincerely

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#General comment

We are very surprised by the tone of this letter, which questions our scientific integrity and medical ethics. The accusation comes from individuals with unclear or possibly fabricated affiliations, such as Xavier Azalbert, who is a graduate of Toulouse Business School but not a faculty member (1).

It is important to remember that this is an estimate based on parameters from the existing literature to approximate the number of deaths related to the compassionate use of HCQ.

Reply. Data miscalculation yielding wrongful evaluation of treatment effect in hospital. The 16000 deaths evaluation is totally fabricated and hence misleading

We read with interest the article by Pradelle et al, “Deaths induced by compassionate use of hydroxychloroquine during the first COVID-19 wave: an

estimate », published in Biomedicine & Pharmacotherapy [1].

Even though the authors stated that the level of evidence was low, this paper presents findings that are unreliable as there are some clear issues of data miscalculation (Belgium data) and results fabrication: Belgium hospitalisation and hydroxychloroquine (HCQ) intervention data,

Spanish HCQ intervention data. Several aspects raise significant concerns over data veracity and scientific integrity.

Within three days of publication, it has received significant press coverage in France and many countries, hence yielding a significant trust issue on science.

Data integrity – data miscalculation and results fabrication:

This study includes data miscalculation and results fabrication. They fall into two categories (1) issues on hospitalisation data at a country level and (2) issues on HCQ usage in the target countries for both prescription timing and differences in drug dosages.

1. The Belgian data were miscalculated, yielding a results fabrication for Belgium

- Pradelle et al wrongly calculated that 10 018 hospitalised patients would have been treated with HCQ during the first Covid-19 wave. A 51% HCQ prescription rate was artificially generalised and applied to a hospitalised patient base of 19 644.
- In fact, the national Belgium study conducted until 24 May 2020 provided the basis for the 51% HCQ prescription rate, with 4542 patients of 8910 patients receiving HCQ (Dauby et al International Journal of Antimicrobial Agents Oct 2020 [2].

#Our reply

This publication pertains to a cohort based on the registration of patients by clinicians, as reported in the methods section: "Sciensano's data collection of patients hospitalized with confirmed COVID-19 was initiated on 14 March 2020, 2 weeks after the first symptomatic case was reported in Belgium, and systematic registering was strongly encouraged by health authorities. Two independent online secured questionnaires in LimeSurvey (LimeSurvey GmbH, Hamburg, Germany) were made available: one with information after admission and the second after discharge." It is by no means an exhaustive registry of all COVID patients in Belgium.

- Therefore, there is a huge discrepancy between the 4542 patients who received HCQ according to the national data and the Pradelle et al. calculation of 10 018. It does not correspond to real life data. Two external data sources validate this (1) Sciensano (Belgium Health Institute) confirmed in August 2020 that 4500 patients have received HCQ [3]; (2) On 16 June 2020, the Belgium health minister stated, in a public session of the Chamber of Representatives, that 5000 patients had received HCQ in Belgium [4].

#Our reply

The Sciensano website states that the collection of COVID cases is not exhaustive: "Since the beginning of the COVID-19 pandemic, Sciensano has been collecting data on COVID-19 patients hospitalized in the <u>majority</u> of Belgian hospitals to study the progression of these patients and identify risk factors for severe illness or death." (2). Consequently, the estimates are inherently underestimated.

- Pradelle et al did not validate the Belgium hospitalised patients data on the cut-off date. On 17 July 2020, Pradelle et al stated that 19 644 patients had been hospitalised whereas, Sciensano shows that the number of 19 652 hospitalised patients was only reached on 31 August 2020 [3].

#Our reply

The Sciensano website states that the collection of COVID cases is not exhaustive: "Since the beginning of the COVID-19 pandemic, Sciensano has been collecting data on COVID-19 patients hospitalized in the majority of Belgian hospitals to study the progression of these patients and identify risk factors for severe illness or death." (2). Consequently, the estimates are inherently underestimated. It should be noted that references [2] and [3] used by the authors of the present letter are identical: reference [3] is a press release of publication [2]. The figure 19,652 is not found in reference [3] cited by the authors.

- Pradelle et al calculated that 10 018 patients would have received HCQ. This is impossible.

(1) Sciensano shows that 17 357 patients had been hospitalised in Belgium and only 4542 had received HCQ on 24 May 2020.

(2) The difference shows that 2287 (19 644 – 17 357) additional patients would have been hospitalised between 24 May 2020 and 17 July 2020.

(3) The difference of patients receiving HCQ, 10 018 (from Pradelle et al on 17 July) minus 4542 (from Dauby et al on 24 May 2020) is 5476 patients [1, 2].

(4) it is impossible that 5476 hospitalised patients would have received HCQ in the period with only 2287 additional hospitalised patients in the same period.

#Our reply

Our results are an extrapolation based on the methods described in the methods section. The number of 10,018 patients treated with HCQ is based on data from the University of Oxford regarding the total number of hospitalizations in Belgium, and the prescription rate is calculated based on the study of Catteau et al. [2] cited by the authors of the letter. We reported in the discussion section the fragility of our estimation, which is based on a single estimate of the prescription rate.

- The over-mortality attributed to HCQ in Belgium, resulting in 240 deaths as stated by Pradelle et al is in complete contradiction with the national Belgium study that concluded that there is a reduced mortality rate for patients receiving HCQ [2].

#Our reply

Observational studies are subject to numerous biases (confounding bias, indication bias, differential follow-up bias, amount of missing data, information bias) and therefore cannot challenge the results of clinical trials.

The methods of the study of Catteau et al. (cohort study using adjustment with propensity score) and ours (estimates from microsimulation) are different.

- Finally, the relative HCQ effect on death (OR=1.11) used in the model to estimate the over-mortality was issued from Axfors et al, that used HCQ over-dosages (2400 mg the first day) [5, 6, 7]. This dosage, 4 times higher than the maximum authorized dosage, is potentially lethal. It is well known that an overdose of HCQ may be used for suicide.

#Our reply

The doses used in the trials are based on PK/PD modeling, allowing for the achievement of therapeutic concentrations (3,4).Therefore, this is not an "overdosed drug". The authors of this letter do not provide any data to support the hypothesis of an "overdose", in the pharmacological sense of the term.

Three of the authors (A Lacout, V Lounnas and C Perronne) have received a response from the investigators of the RECOVERY trial in the New England Journal of Medicine on the same topic: "*The dosing schedule of hydroxychloroquine in the RECOVERY trial was therefore designed to provide the highest tissue concentrations that were safe in order to provide the maximum antiviral activity and thus the best chance of therapeutic benefit.*" (5).

- Considering the errors quantum identified for Belgium, it is very likely that the data estimated for the other countries will also be erroneous, hence leading to results fabrication.

#Our reply

This is an unsupported assertion. We cannot respond to this unsubstantiated accusation.

2. A flawed model yielding results fabrication

The model used is Ndeath = Nhospitalised patients × mortality rate × HCQ exposuremedian, min, max × ORHCQ-mortality is by design constructed to model an overestimation of death as it uses a constant (ORHCQ-mortality =1.11) as the relative HCQ effect on death.

#Our reply

To date, no study has shown a predictive (or theranostic) factor associated with variability in the toxicity of hydroxychloroquine. Therefore, it is logical to have considered this effect as constant.

It is therefore unsurprising that the authors find an over-mortality as this is their ingoing hypothesis.

The ORHCQ-mortality =1.11 is issued from Axfors et al, [5] that uses HCQ dosages that are highly superior to the ones used and recommended in various countries (Belgium above, IHU Mediterranée 600mg but also Spain and Turkey).

o It is not representative of the dosage used in hospitals in the various countries.

#Our reply

This assertion is not supported by any reference. Therefore, it cannot be considered superior to the exposure data collected in the cohorts included in our study. Conversely, we found a protocol using a loading dose of 1200 mg in frail patients during the first wave of COVID-19 (6).

o The Recovery study weights 73.7% in the OR calculation. It has a regimen of 2400 mg of HCQ on day 1 and 9600 mg over 10 days. 10% of the patients had a negative SARS CoV-2 test, 27% had a cardiac underlying condition and patients received HCQ at a very late stage of the disease (median 9 days after symptoms, and 3 days after hospitalisation), at a time where antiviral drugs are not effective anymore.

#Our reply

The calculation of the effect of HCQ comes from a collaborative meta-analysis led by the Stanford team (7). We leave it to the authors of this letter to contact the corresponding author of this publication if they deem it necessary. For the record, the study by Axfors et al. has not been the subject of any letter on the Nature Communications website or in the Pubmed database.

o It is neither scientific, nor medical good practices, nor ethical to use the death rate of an overdosed drug to prove the harmfulness of a drug used in normal doses and known for decades to be safe in the treatment of numerous pathologies.

#Our reply

The doses used in international trials are based on PK/PD modeling to achieve therapeutic plasma concentrations from the first few days (3,4). Therefore, this is not an "overdosed drug". The authors of this letter do not provide any data to support the hypothesis of an "overdose", in the pharmacological sense of the term.

Three of the authors (A Lacout, V Lounnas and C Perronne) have received a response from the investigators of the RECOVERY trial in the New England Journal of Medicine on the same topic: "*The dosing schedule of hydroxychloroquine in the RECOVERY trial was therefore designed to provide the highest tissue concentrations that were safe in order to provide the maximum antiviral activity and thus the best chance of therapeutic benefit.*" (5).

As the authorities of many countries dissuaded from prescribing HCQ, HCQ exposure levels used in the model are questionable, either for Belgium (51%) or for Spain (84%).
#Our reply
The argument is not supported by any reference. In addition, We have not received any inquiries from physicians or regulatory agencies in these two countries questioning the use of HCQ in these countries. Therefore, it is merely conjecture on the part of the authors.

Even if Pradelle et al removed the data from Belgium, the other data should be removed due to miscalculation. Indeed, as we demonstrated that the model itself allows the fabrication of the results.
The model relies on a constant OR as the measure of the HCQ risk.
#Our reply
To date, no study has shown a predictive (or theranostic) factor associated with the variability in hydroxychloroquine toxicity. Therefore, it is logical to consider this effect as constant.

In addition, the other variables are non-independent from one another, hence not surprisingly they find an over-mortality. The model is flawed by design as it can only find this result.
#Our reply
This remark is incomprehensible. It is likely that the authors, who do not come from the modeling world, are struggling to express the concepts they are using.

3. There are significant medical errors that are not considered in this study.
Antiviral treatment should have been prescribed to outpatients early in the viral phase of the disease to decrease the viral load and prevent the aggravation of the disease and the probability of requiring oxygen and/or hospitalisation. General practitioners were prevented from prescribing HCQ, leading to a loss of chance for patients and a risk of aggravation and then hospitalization. This resulted in HCQ being prescribed far too late at a stage when its efficacy had greatly diminished or even disappeared. So prescribing HCQ to impaired hospitalised patients is a flawed medical reasoning. By comparison, oseltamivir is effective to

decrease influenza severity, only if prescribed early, especially during the first 48h of the symptomatic phase.

#Our reply

All trials have shown at best a lack of efficacy of hydroxychloroquine including for prevention, and at worst an increased risk of death or need for mechanical ventilation (4,8). The assertions only reflect the personal opinions of the authors, without reference to factual data.

It's also astonishing that the sole effect of HCQ could be identified as lethal in an environment where the patient is monitored, particularly for potassium plasmatic level and ECG (to prevent cardiac rhythm disorders). Several other factors could have been taken into consideration such as the patients characteristics of age, comorbidities as can be identified in some of the underlying studies for example in Bartoletti et al, that concludes the lack of efficacy of corticosteroids [8]. From that same study, Pradelle et al, infer that since 85.5% of patients had received HCQ, it had a lethal consequence without taking into consideration other factors. In Fummagali et al, the authors retain the partial information that among the deceased patients, 35% had received HCQ and were 79-year-old on average, but they did not take into consideration the fact that among survivors 57% had taken HCQ and were 64-year-old on average [9].

#Our reply

The subgroup data from the RECOVERY trial do not show interaction based on patient characteristics. Therefore, we did not vary the effect of hydroxychloroquine in our simulation.

Neither the dosage of HCQ nor the duration of treatment is taken as a parameter nor mentioned. Some studies, such as Recovery, have overdosed hydroxychloroquine, and it can induce a paradoxical deleterious effect by shunt effect (which explains the happy hypoxia and can, moreover, mimic a severe Covid) [10].

#Our reply

This point has already been discussed previously.

4. Pradelle et al refer to various studies carried out in the countries concerned.

Among these studies, only a few assessed the mortality rate associated with HCQ, either alone or in combination with azithromycin and most conclude that there is a reduction in mortality. When a model reaches the opposite conclusion to those of the referenced studies, the methodology should be questioned as the results are not validated by real life observations.

- For Spain, the only study mentioning the mortality rate linked to HCQ concludes « Half of the COVID-19 patients were treated with the combination hydroxychloroquine + azithromycin, which is associated with a significant decrease in mortality. » [11].
- An Italian study concluded: « HCQ use was associated with a 30% lower risk of death in COVID-19 hospitalized patients. » [12].
- For the USA, one study concluded « According to a protocol-based treatment algorithm, among hospitalized patients, use of hydroxychloroquine alone and in combination with azithromycin was associated with a significant reduction in-hospital mortality compared to not receiving hydroxychloroquine. » [13].
- An Italian study concluded: « HCQ use was associated with a 30% lower risk of death in COVID-19 hospitalized patients. » [12]. For the USA, one study concluded « According to a protocol-based treatment algorithm, among hospitalized patients, use of hydroxychloroquine alone and in combination with azithromycin was associated with a significant reduction in-hospital mortality compared to not receiving hydroxychloroquine. » [13].

#Our reply

The effect of HCQ on mortality comes from randomized trials and pharmacovigilance (9,10). Therefore, the observational study cited by the authors cannot challenge this association (11).

5. A serious interrogation – why did Pradelle et al not use UK data in their model?

Hospitalised data is available for the UK, which was an inclusion criteria. As UK data contributed to 74% of the OR calculation (1.11), why did the authors not use the UK data to support their case and address the issue that they were using an OR calculated mainly from UK data, without applying it to the UK country data to prove their case? The ONS (UK office of national statistics) reports that between 20 March 2020 and 10 July 2020, 235 863 persons have died in the UK of which 50 946 would have been from Covid-19. In the same period 95 574 patients have died in hospital of which 32393 (34%) with Covid-19 [14]. In Recovery study, only 14% of patients (1561 in the HCQ arms out of the 11 197 patients enrolled) received HCQ. That is probably the reason why Pradelle et al would not want to include this study as if they generalise a prescription rate of 14% to all hospitalised patients in the UK that would lead to questioning their argument for other countries. Choosing not to take UK data into account makes it possible to artificially obtain (false) results in favour of HCQ toxicity.

This is cherry-picking, a method used a priori to reach the conclusion you want at the outset.

#Our reply

We conducted a systematic review. This review did not identify any cohorts in the UK. We understand that compassionate prescribing was not allowed during the first wave, within the context of inclusions in the RECOVERY trial. The absence of cohorts in the UK reporting compassionate prescriptions has been confirmed by a second systematic review, which led to a presentation by our team at the EACPT Congress in 2024.

To confirm our results, we contacted Prof. Munir Pirmohamed (Chair of Medicine and NHS Chair of Pharmacogenetics, Director of the Centre for Drug Safety Science and the Wolfson Centre for Personalised Medicine, and Director of Health Data Research UK North) who confirmed that hydroxychloroquine was not available in the hospital during the first wave.

Prof Munir Pirmohamed 's response: "*HCQ was never authorised in the UK, and the MHRA advice was that if HCQ was to be used, it should only be used in a clinical trial setting. Of course, a lot of people may have accessed HCQ at the peak of the pandemic using internet sources of supply, but there are no good estimates of how many people did use this outside the normal UK prescribing pathways*."

6. Reality is always more reliable than a model.

Calibration to real world data is necessary

- Pharmacovigilance committees of countries cited by Pradelle et al, transmit their data to the WHO Vigibase. Vigibase collects data from more than 120 countries since 1968, due to the Thalidomide disaster. Over a 50-year period, in these 120 countries, WHO shows only 114 deaths attributable to HCQ for tens of billions of doses of HCQ administered over this period. That, in itself, demonstrates the total inconsistency in the 16 000 deaths calculated by Pradelle et al. In France, over a three-year period, a very strict pharmacovigilance showed 8 deaths possibly due to HCQ, while the cause of death could be the cardiac complications linked to SARS-CoV-2 infection.

#Our reply

We understand that the authors are referring to the publication by Gérard et al. (8). In this publication, 8 deaths are described in the context of COVID-19 during a one-month observation period in France. Given the underreporting of adverse effects by health care professionals (12), with estimates suggesting that only 6–10% of all events are reported (13,14), it is very likely that this number is more in the range of 50-100 deaths

per month. This figure is consistent with the estimate produced in our study, within the limits of uncertainty. It should be noted that extrapolating the tolerance of HCQ from patients with rheumatoid arthritis to those with COVID-19 was an error in the generalization of compassionate prescriptions during the first wave.

- For calibration of their model, Pradelle et al could have cited Emmerich. Emmerich showed in Brazil that the state of Para (296 deaths per million) had 5.5 times less deaths than the state of Amazonas (1645 deaths per million) during the same period [15]. Therefore, it is impossible that HCQ alone could have yielded such a number of deaths.

#Our reply

The limitations of observational studies in drug effect assessment were addressed previously.

- Pradelle et al did not refer to the 30 423 patients treated at the Marseille IHU in France. The data are accessible online, complete and undisputable, as verified by a bailiff. The published study (Outcomes after early treatment with hydroxychloroquine and azithromycin: An analysis of a database of 30,423 COVID-19 patients) concludes to an adjusted OR of 0.55 in favour of HCQ plus azithromycin [16].

#Our reply

This observational study of the Marseille IHU raised concerns from the publisher. "*Concerns have been brought to the attention of the journal regarding potential non-compliance with Elsevier's publishing ethics policies regarding the appropriate conduct of research involving human participants.The journal is investigating the concerns as detailed in the recent Publisher's Note [1], including contacting the authors, in line with Committee on Publication Ethics (COPE) guidelines and Elsevier's policies*." We will not comment on the results regarding its limitation (15). We do not find, as the authors do, convincing evidence of a positive effect from the administration of HCQ-azithromycin. We are surprised that the authors cite as useful a non-randomized study that exposed patients to ineffective drugs, despite the numerous previous trials conducted (7,8).

7. The Pradelle et al study has already received significant media attention in the first 3 days of publication from mainstream media in France and many countries anchoring the wrong fact that some 16 000 patients would have died from HCQ usage. This is creating an issue of

public trust and confidence in science as the journalists do not question the methodology or the presence of biases in the study.

#Our reply

We do not understand the concept of mainstream media, other than that these media do not reflect the concept of journalism held by Mr. Azalbert, the third signatory of this letter and owner of the France Soir website. Currently, this site is seen as disseminating conspiracy theories and false information (16). We regret that following our publication, the last author was associated with the eugenic policies of the Nazi regime on the France Soir website of Mr. Azalbert (17).

The communication regarding this publication has not been commented on by the employers of the authors (Hospices Civils de Lyon and Université Lyon 1, France; Université Laval, Canada) or the Conseil National de l'Ordre des Médecins (i.e. the Medical Council ensuring compliance with medical ethics in France).

We specifically highlighted the challenges faced by physicians during the first wave due to the lack of data and the pressure from patients to receive treatments. Our communication in the media has been praised for being factual and balanced, including acknowledging the limitations of our study (18).

In conclusion, these significant issues of data miscalculation including statistical errors involving the aggregation of disparate data, errors in medical reasoning, disconnected from reality on the ground, do not add up, but multiply, resulting in results fabrication. Therefore, this paper does not meet the required standards of the scientific community leading to an erroneous and dishonest evaluation of the treatment.

#Our reply

The severity of this opinion is inversely correlated with the strength of the arguments presented by the authors of this letter, none of whom are specialists in COVID-19 or pharmacological modeling.

Conflict of interest :

The authors declare no conflict of interest

#Our reply

The financial interests of Mr. Azalbert as owner of France Soir website (16) and President of Bonsens.org (20) constitute major undisclosed conflicts of interest in this letter due to the numerous donations received to support the pro-HCQ stance in the media (21).

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