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Critical Review of the Diagnostic and Statistical Support for COVID Epidemic in USA

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ABSTRACT

Background: Two major flaws have been identified in collecting and interpreting the COVID epidemic data. 1) The United States ignored the International Guidelines for Certification and Classification (Coding) of COVID-19 as Cause of Death (20 April 2020–WHO). The Guidelines suggested the use of U07.1 code for virus identified (certain) and U07.2 code for virus not identified (suspected but not objectively confirmed) cases of deaths. The American statistic used exclusively the U07.1 code causing confusion and endless disputes about the accuracy of COVID mortality estimates in this country; 2) Large number of natural, age related, expected deaths have been reported as COVID related deaths even if the virus reasonably couldn't play any causative role as the Underlying Cause of Death (UCOD).

Objective: A statistical method is suggested. 1) To estimate the realistic proportion of test-confirmed COVID mortality relative to the less well confirmed causes of COVID deaths there viral-test is missing; 2) to estimate the number of seniors who could have passed away 'with' COVID but not 'because' of COVID infection.

Methods: 1) The estimated maximal possible number of test-confirmed (true) cases of COVID deaths was based on the frequency of viral-test positivity in the population. It was possible because epidemiological studies indicated even distribution of infection in all categories of the persons in the entire population; 2) The age-normalized annual mortality (from actuarial tables) gives an idea how many persons could have died "normally" even without the COVID epidemic.

Results: 1) COVID as the Underlying Cause of Death (UCOD) haven't been verified by specific laboratory viral test in ca. 40.3% of reported causes. These, exclusively HEARSAY information based cases violated the WHO guidelines for reporting COVID related deaths. (Use of U07.1 code); 2) Large number of natural, age related, expected deaths have been reported as COVID related deaths even if the virus reasonably couldn't play any causative role as UCOD. These PSEUDO COVID deaths were ca 46% of all reported COVID deaths. The oldest persons in this group were 85+ years old and comprised as much as 28% to all allegedly COVID fatalities (the GERONTO COVID deaths). These errors significantly inflated the number of COVID deaths and the related mortality statistic.

Conclusion: The number of correctly identified COVID related deaths in our study is about 32% of the officially published number [171K instead of 533K, respectively]. The average FATALITY of COVID stays at ~0.54% and the MORTALITY 53/100K (On May 2021).

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Introduction

There is a disagreement in the COVID literature regarding the lethality of the virus from the beginning of the pandemic [1,2]. The possible reason of the often heated-disagreements is the uncertain quality of the underlying statistical data.

Major flaws in COVID epidemic data

Two major flaws can be identified in collecting and interpreting the COVID epidemic data:

"HEARSAY"-based diagnostic: Defined as diagnosing COVID disease and/or COVID as the Underlying

Cause of Death (UCOD) in the absence of sufficient laboratory evidence. Determination that COVID infection as the UCOD is not possible without access to relevant (timely and accurate) COVID specific viral test that detects the actual presence of the virus (antigen) in the examined person. A physician's epidemiological diagnosis without laboratory test is notoriously uncertain [3].

"PSEUDO"-COVID diagnostic: Defined as diagnosing COVID disease and/or COVID as the Underlying Cause of Death (UCOD) in the non-pathogenic presence of the virus. The virus can be present in any person

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(young or old) without causing any disease on its own right or without significantly contributing to the death of a person who is dying as the consequence of some other disease or simply because of age limitations of the life.

The realistic determination of the status and course of COVID epidemic requires awareness of these possible diagnostic errors and the magnitude of their influence.

The evidence of the existence of these flaws in the COVID statistic and the estimation of their magnitude is based on two undisputable facts:

- The number of COVID related deaths is limited by the number of dying persons infected by the COVID virus. If the maximal number of infected persons is 'x' and the number of COVID related deaths is 'y', $x-y \geq 0$ and never < 0 . If $x-y < 0$ the $|x-y|$ is the number of erroneous determination of UCOD.

[For example: "If somebody tells you that he is working 25 hours a day he is mistaken, because there is only 24 hours in a day. The magnitude of his mistake is 1 hr."]

- Life is a time-limited activity that always ends mostly naturally after a number of years alive. This is certainly one of the most studied and most documented fact in the history of mankind. Large number of actuary tables are continuously constructed and shows the probability of a person at a certain age dying before their next birthday (Supplementary Table 1) [4].

Persons dying as COVID positives will certainly receive corresponding UCOD determination. It might be correct at the bed-side, but certainly erroneous if it remains un-corrected and propagates into the CDC reports and incorrectly, misleadingly inflates vital parameters of the epidemic.

For example: (Say, that an 85 years old COVID test positive woman dies. The physician will not be able to decide if the UCOD was really COVID in that single individual case or a "PSEUDO-COVID DEATH" where the virus positivity had no clinical significance. However, an epidemiologist who have 1000 similar cases should understand that 516 women of 1000 in the same age are already dead without COVID infection and he should correct the COVID death statistic by removing 516 cases as "pseudo-COVID deaths").

CDC instruction for determination COVID related deaths and reporting using the U07.1 code

The Centres for Disease Control and prevention (CDC)/ US Dep. of Health and Human Services-ultimate health authority in USA.

- a) Adopted the WHO's code U07.1 for reporting

COVID-19 deaths in cases when the virus had been identified (laboratory test, viral test, confirmed) [5-7].

[ICD-10-CM Official Guidelines for Coding and Reporting FY 2021-p 28: g.1) (a) "Code only a conformed diagnosis of the 2019 novel coronavirus disease (COVID-19) as documented by the provider or documentation of a positive COVID-19 test result. For confirmed diagnoses, assign code U07.1, COVID-19."]

- b) Did not adopt the WHO created code U07.2 for reporting COVID-19 when the virus was not identified (clinically diagnosed) however clearly instructed the providers not to use U07.1 for reporting uncertain cases [8].

[IDEM, p.29: "If the provider documents "suspected," "possible," "probable," or "inconclusive" COVID-19, do not assign code U07.1. Instead, code the signs and symptoms reported."].

- c) Explained the importance of accurate and timely death reporting as fundamental to assess accurately the effects of pandemic and appropriately direct public health response [9].

["Monitoring the emergence of COVID-19 in the United States and guiding public health response will also require accurate and timely death reporting. The purpose of this report is to provide guidance to death certifiers on proper cause-of-death certification for cases where confirmed or suspected COVID-19 infection resulted in death. As clinical guidance on evolves, this guidance may be updated, if necessary. When COVID-19 is determined to be a cause of death, it is important that it be reported on the death certificate to assess accurately the effects of this pandemic and appropriately direct public health response"]

Numerous warnings have been published on the internet - mainly from practicing physicians - disclosing that the COVID epidemic is far less dangerous than the national media told the public. The COVID cases looked like a regular flue and not like a fatal disaster. a) The necessity of extreme restrictions has been criticized; b) It was suggested, that politicians and healthcare authorities are "using a canon to kill a mosquito"; c) It became more and more obvious, that the original information for political decisions - the COVID statistic - is erroneous, the number of COVID deaths are over-estimated.

However, it was not possible to estimate the magnitude of this incorrect estimation and the source of errors remained obscure.

Materials and Methods

The sources of statistical data

Publicly available, official databases served as the sources to our analyses, like WORLDOMETER and CDC [10,11].

Calculation life expectancies was based on Actuarial Life Tables, using the mean values of the sexes [4]. Calculation of the states 'political ratio', D/R was performed by dividing the number of left/democrat oriented (D) persons with the number of right/republican oriented (R) persons in the 50 states, based on the 2018 Gallup tracking and 2018 Gallup Poll Social Series surveys. Cited in State Party Identification and Leaning, 2018 [12].

Clarifications [abbreviations]

- COVID-19 Deaths [CD] includes viral test confirmed [CD+] and viral test missing [CD?] lethality's (U07.1 AND U07.2, respectively), $CD=[CD+]+[CD?]$
- Total Tests [T] means COVID viral tests which detect active, ongoing virus infection-opposed to antibody tests which detect previous, already passed infection and the presence of immune response.
- Total Cases [C] means virus positive tests at the time of the sampling.
- Testing and positive tests are representative for the entire population and, consequently, the calculated frequency of test positivity - C/T - is approximately the same for all groups of the society, including those who die of any reason. (https://www.cdc.gov/covid/?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/COVID-data/investigations-%2520-discovery/hospitalization-death-by-age.html) (Supplementary Table 2).
- COVID viral test positivity doesn't mean COVID disease (majority of test positive persons are and remains symptom-free).
- By the same token, dying COVID test positive doesn't mean that the person's death was caused by the virus. The causal connection between test positivity and COVID death is not automatic.

Results

Statistical analyses

Statistical analyses were carried out to evaluate the correlation between COVID-19 death reporting and political orientation across the 50 states. The percentage of total COVID cases [C] and total viral tests [T] were used to determine test positivity rates. Additionally, the reported COVID deaths [CD] were compared with the theoretically calculated number of deaths, which were

based on test-confirmed cases [CD+]. The analysis aimed to estimate the proportion of deaths labeled as "HEARSAY," where laboratory confirmation of the virus was missing. Statistical correlations were drawn between the prevalence of unconfirmed COVID deaths and the political ratio (D/R) of the states.

A. Calculation of the "Hearsay-Based" determination of 'UCOD': [Assuming COVID related counts of death in the absence of laboratory confirmation by specific viral test].

The ratio of Total COVID cases (viral test positives), [C] and the number of total viral tests performed [T] provided an estimate of the frequency of COVID cases in the population. As much as 413 M viral test have been completed in the USA by the end of the 15 months of the initial period of the epidemic. [That is more than the entire population of the USA]. The number of positive tests were 31 M corresponding to 7.7% of the tests, $[C]/[T]$.

However, the frequency of test positives (C/T) showed very large State-by-State variation, from 1.5% in VT to 26.5% in SD.

The theoretical maximal number of persons who died when they were infected by the virus (viral test positives, but not necessarily sick or dying due to COVID) is 7.7% of the total number of deaths, that is $[CD+]=318,369$. However, the reported number of COVID deaths was $[CD]=533,291$.

The difference between theoretical maximum and reported number of COVID deaths gives us an estimate of the cases when the UCOD were determined to be COVID infection but it hadn't been confirmed by the necessary laboratory evidence, the specific viral test. These cases represent the "hearsay COVID deaths". The number of "hearsay COVID deaths" is estimated to be $[CD?]=214K$ deaths which is 40.3% of all reported "allegedly" COVID deaths (Table 1).

The "hearsay COVID death" reporting by individual States had been estimated by the same way (Figure 1).

The proportion of COVID death reporting without laboratory test confirmation, - $[CD?]$ or "hearsay based", allegedly COVID deaths - showed significant correlation with the Political Score (D/R ratio) of the respective States: Left dominated (democrat) States filed more "hearsay COVID deaths than right (republican) states. In some States as much as 90% of reported COVID deaths WERE NOT verified by viral test, i.e. they were "hearsay" cases (Figure 2).

The most extreme contributors to "hearsay based" COVID death reporting are listed in Table 2.

The seven selected states reported 225K COVID related

deaths that is close to half of all COVID deaths in 50 States. However only 33% could have been confirmed by viral test and as much as 67% remained unconfirmed because of the absence of laboratory evidence. These are “hearsay” based COVID deaths. All these states had higher than average D/R score.

B. Determination of “pseudo-COVID” and “geronto-COVID” deaths: Lethality’s their causative role of

COVID infection is reasonably negligible.

The concept of determination of the “pseudo-COVID deaths is not meant for bed- side use on individual cases. It works only on larger statistical samples as a correct method to avoid overestimation of the fatality/ mortality of a disease that might increase the anxiety of the public and might trigger overreaction of media and politicians.

Table 1. COVID statistic (status on 2021.04.08)*.

Statistics	Abbreviations	No's	%
USA population	(POP)	327,533,774	-
Total deaths*	(D)	4,161,167	-
Total mortality-all deaths	(T-MO)	1,270/100K	-
Total COVID tests	(T)	413,582,156	-
Total COVID cases (test pos.)*	(C)	31,642,996	-
Case/test (%)	(C)/(T)	7.65	-
Total COVID deaths (reported)*	(CD)-0	533,291	100%
“Pseudo”-COVID deaths	(P-CD)	245,206	46%
“Geronto”-COVID deaths: 85+ year old (cd) after correction for (p-cd)	(G-CD) (CD)-1	151,618 288,085	(28%) 54%
COVID deaths (test confirmed): 7.7% of (d)	(CD+)	318,329	59.70%
“Hearsay”-COVID deaths (no test)	(CD?)	214,962	40.30%
Sum		533,291	100.00%
cd-1 minus 40.3%=116,098	(CD+)-2	171,987	32.25%
Mortality (corrected)	(MO)	52.5/100K	-
Fatality (corrected)	(FA)	0.54%	-
Note: *Sum of 15 months data.			

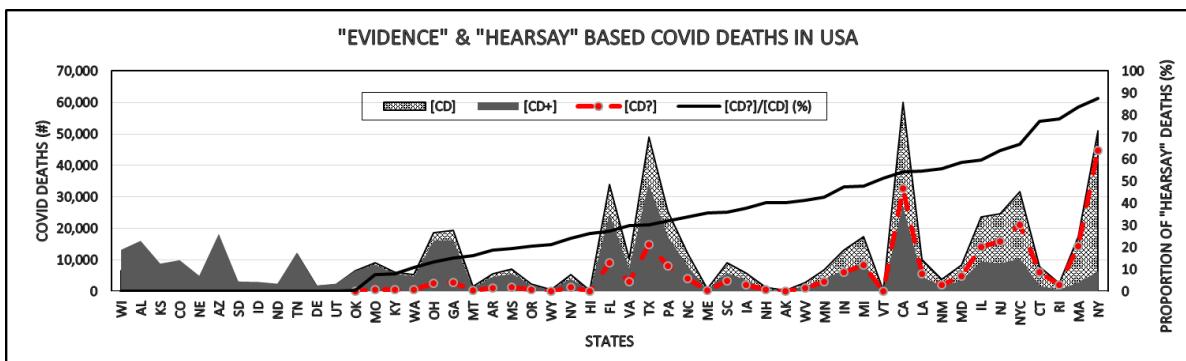


Figure 1. The total number of reported COVID deaths [CD] are the sum of determinations: A) when the virus infection as the Underlying Cause of Death was “EVIDENCE based” (confirmed by laboratory viral test) [CD+] or b) “HEARSAY based” (laboratory viral test confirmation was missing) [CD?]. States were sorted in ascending order of the [CD?]/[CD+] ratio (%) that is the proportion of “HEARSAY deaths”.

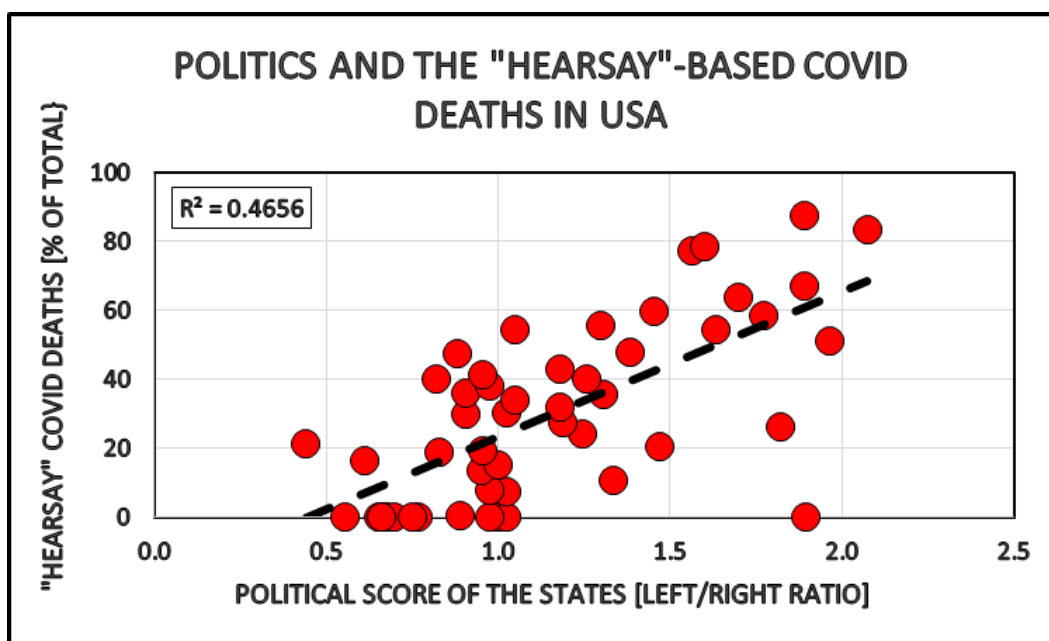


Figure 2. The proportion of COVID deaths determinations without laboratory viral test evidence (“HEARSAY” cases) were plotted against the Political Score of the respective States.

Table 2. The most extreme contributors to the “hearsay” COVID death reporting.

State	(CD)	(CD+)	(CD?)	D/R	(CD?)/ (CD) (%)
Michigan (MI)	17,373	9,051	8,322	1.38	47.9
California (CA)	59,985	27,391	32,594	1.63	54.3
Illinois (IL)	23,702	9,524	14,178	1.45	59.8
New Jersey (NJ)	24,749	8,937	15,812	1.7	63.9
New York City (NYC)	31,598	10,448	21,150	1.89	66.9
Massachusetts (MA)	17,358	2,854	14,504	2.07	83.6
New York (NY)	51,120	6,412	44,708	1.89	87.5
Sum	225,885	74,617	151,268		
%	100	33	66.9	171	66.2

Note: (CD): Total number of reported COVID deaths; (CD+): Theoretical maximum of test positives; (CD?): Deaths without laboratory evidence (“hearsay” cases); D/R: Political score, democrat/republican ratio.

The number of all allegedly COVID related deaths in different age groups was taken from the relevant database of CDC [11]. The number of reported COVID deaths in each age group were further divided into subgroups, using a Periodic Life Table (Supplementary Table 1). A) Those who could be alive; B) Those who ‘statistically’ were already dead even without COVID infection.

The number of persons who statistically could have

been expected to be dead even without COVID infection was estimated to be [PSE-CD]=245,205 [45.9%] of all reported COVID deaths [CD]=533,291=100%. This group represents not real COVID deaths, but “PSEUDO-COVID” deaths (or “GERONTO-COVID” cases). The remaining-[V-CD]=288,085,=54% are statistically not predicted cases i.e., they can be real viral COVID deaths (Table 3 and Figure 3).

Table 3. Separation of “pseudo-COVID” subgroup of COVID deaths*.

Age group	COVID deaths (CD)	Pseudo-COVID (PSE-CD)	Viral-COVID (V-CD)	Total deaths (TD)	Ratio (%) (CD) (TD)
<1	57	0	57	22,249	0.3
01-04	31	0	31	4,010	0.8
05-14	87	1	86	6,479	1.3
15-24	792	8	784	41,940	1.9
25-34	3,470	72	3,398	86,859	4
35-44	9,104	328	8,776	1,24,861	7.3
45-54	25,394	1,559	23,835	2,30,166	11
55-64	64,756	7,503	57,253	5,33,464	12.1
65-74	1,17,252	25,872	91,380	8,24,289	14.2
75-84	1,48,166	62,187	85,979	1,002,845	14.8
85+	1,64,182	1,47,676	16,506	1,226,820	13.4
All ages (SUM)	5,33,291	2,45,205	2,88,085	4,103,982	13.0
% of (CD)	100	45.9	54.00	769	

Note: *Sum of 15 months data.

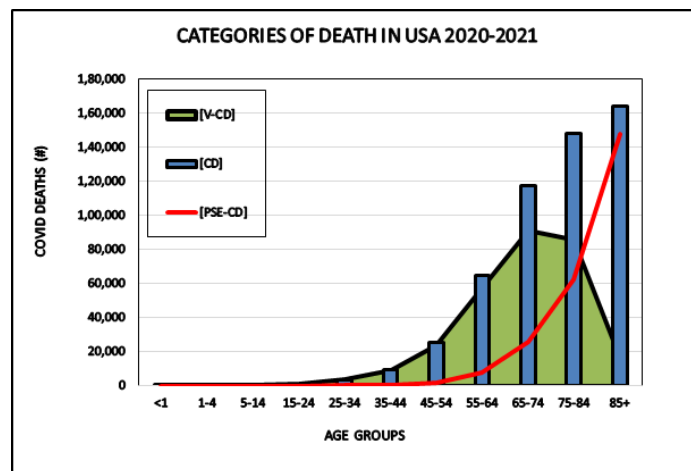


Figure 3. All categories cover period 2020.01.01-2021.03.31. [CD]: Reported number of all allegedly COVID related deaths. [TD]: Total number of all kinds of deaths in USA. [PSE-CD]: Pseudo-COVID deaths, [V-CD]: Real, viral COVID death.

Discussion

COVID epidemic is taken very seriously even if significant differences exist between the States regarding the length and enforcement of the restrictions. There are critical voices-already from the beginning of the epidemic-suggesting that in reality we are only dealing with another winter flu and our protective reactions are like “using a cannon to kill a mosquito”. However, the “flu-theory” have been rejected and the moderating voices have been silenced. The main argument for unusually strong defences came from early mortality data, which suggested that COVID mortality is far higher than the regular flu’s (1-3.4% compared to 0.1%). It was 1.7% in our starting material (533,291 deaths of 31,642,996 infected).

Our results indicate that the official number of COVID fatality is strongly inflated by “hearsay cases” [laboratory confirmation is missing] and “pseudo-cases [COVID had no pathogenic effect]. We corrected the official fatality estimate, [CD]=533,291 deaths, by subtracting [PSE-CD]=245,205 “pseudo cases” and reducing the remaining [V-CD]=288,085 cases with 40.3% corresponding to the calculated [CD?]=116,098 “hearsay” based COVID deaths. Our opinion is that the final number, [CD+]=171,987 deaths, is the correct estimate of cases there the UCOD is the COVID virus with reasonable certainty. Consequently, the corrected average fatality rate of the epidemic is [FA]=0.54% and mortality rate, [MO]=52.5/100K.

Fatality, FA is defined as the number of deaths per 100 cases of a given disease.

Mortality, MO is defined as deaths (for a given illness)/ unit of population (100,000 sick and well).

Overestimation of the mortality rate of a pandemic is a very serious error even if we pursue maximal tolerance for accidental mistakes in the medical profession. Too many people lost the quality of their life and the considerable costs of the epidemic is also rather obvious. It is difficult to understand how two relatively simple errors could occur today in the USA, in one of the most developed and sophisticated countries of the world.

- The necessity of evidence to support the diagnosis of a doctor is elementary requirement in the USA and the evidence-based medicine is an established concept in this country. However, a doctor's evidence-based approach to a sick patient or to a dead person can be very different [13]. It wouldn't be surprising to find some degree of nonchalance in determining the UCOD. "Dead is dead".

[Evidence-based medicine (EBM) is defined as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"]

- The CDC instructions are-or supposed to be-clear regarding the determination of COVID death and the specific use of the U07.1 code for reporting

these deaths. The Table 4, illustrates the doctor's dilemma when determining COVID deaths.

There are 3 kinds of information available for a physician who is diagnosing COVID disease or determining that COVID disease was the UCOD. [A+B+C=D].

- A) Clinical signs: flu-like symptoms, highly unspecific-useless if the patient has complex symptomatology (other diseases).
- B) Contact with others having or suspected for COVID infection. This is the classical "hearsay" information, highly unreliable.
- C) Specific COVID laboratory viral test: this is the best evidence we have to confirm the presence of virus in the examined person. Misleading if confused with the antibody test [it detects past, no longer present infection]. The causality between virus and the actual disease has to be established by other methods, like chest X-ray.
- D) The use of U07.1 code for reporting compliance with the CDC recommendation/order is motivated only in viral-test positive cases.

The statistically significant positive correlation between the calculated number of COVID deaths, there the UCOD hadn't been supported by the only available objective "evidence" (viral test) "hearsay" COVID cases and the D/R ratio of the states is especially disturbing. This finding certainly motivates serious attention and confirmation by other independent scientists.

Table 4. Possible scenarios when determining 'COVID' as UCOD.

	A	B	C	D	Comment
	Signs	Contact	Test	U07.1 code	
1	NO	NO	NO	NO	UCOD: Not COVID
2	YES	YES	YES	YES	UCOD: COVID
3	YES	NO	NO	NO	UCOD: NOT COVID
4	NO	YES	NO	[NO]	UCOD: NOT COVID-["HEARSAY" IF YES]
5	NO	NO	YES	YES	UCOD: COVID-FULFILS CDC TEST CRITERIA
6	YES	YES	NO	[NO]	UCOD: NOT COVID-["HEARSAY" IF YES]
7	YES	NO	YES	YES	UCOD: COVID-FULFILS CDC TEST CRITERIA
8	NO	YES	YES	YES	UCOD: COVID-FULFILS CDC TEST CRITERIA

Conclusion

In COVID data is seriously tainted, the number of supposedly COVID related deaths are more than 300% inflated. Consequently, the real average fatality of the COVID disease is less than a 1/3rd of the officially stated (i.e. ~0.54%). This strong overestimation of COVID fatality and its consequences on the economy and life quality of American peoples could have been avoided or at least mitigated if the country follows the WHO recommendation for separating the viral test confirmed and COVID deaths (U07.1) from those there the UCOD was not supported by viral test by using distinctive U07.1 vs. U07.2 diagnostic codes for reporting.

We believe that even better understanding of the fundamental rules of biological life would be beneficial to avoid diagnosing the death of very old people as disease.

Conflict of Interest

The author declare that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Disclaimer

The first draft of this manuscript was already completed in May 2021 but no attempt was made to publish it. The outcome of a pandemic is always uncertain and it is necessary to execute a single and strict policy to protect the people, as the USA certainly did even if that policy turns out to be imperfect. However, 3 years later, when the pandemic is over, publication of our critical notes is necessary. The author's intention is to encourage the responsible doctors, scientists, politicians to critically

review their actions, honestly recognize their mistakes and learn from it. COVID is certainly not the last pandemic the mankind was facing.

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