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A National Standard for Diagnosing COVID-19

— Accurate statistics should guide America's re-opening

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It's been more than a month since most states issued shelter-in-place mandates and ordered businesses to close. These actions were crucial -- and they've saved lives. Now most Americans are eager to see the country re-open, but we have to be smart about how we do it. One of the big challenges is that re-opening criteria are dependent on the data of new diagnoses and deaths attributable to COVID-19. But the numbers that are often reported are based on the subset of people who were tested and tested positive. In reality, most people with the infection and some who even die from it are never tested. That results in skewed infection and fatality rates.

Based on a few limited population antibody testing studies, it is estimated that approximately 10-85 times more people have been infected than are entered into most public health tracking systems. In addition, some doctors and hospitals were observing spikes in influenza-like illnesses in March, before testing was widely available, likely causing many early cases to be missed in the reporting. Another reason for under-diagnosing patients is that a patient may present to a hospital late in their illness or have a rapid decline too urgent to make testing a priority since it had minimal impact on patient management prior to the remdesivir trial.

We should also remember that not everyone goes to a hospital to die. Consider that when New York had approximately 500 confirmed COVID-19 deaths per day, the medical examiner's office reported that approximately 200 people were found dead at home per day. That's much higher than the state's usual pre-COVID rate of 20-30 deaths at home per day. This substantial increase begs the question, are people dying at home from COVID-19 or because they are avoiding medical care for other ailments and dying from lack of proper medical attention?

Both reasons can and should be counted as "excess deaths" due to the COVID-19 pandemic. In other words, while the deaths may stem from a variety of contributing conditions, the patient would not have died at that given time were we not in the midst of an outbreak.

Some reviews suggest that deaths over the last few months may have been due directly or indirectly to COVID-19. In Colorado, the state's department of public health reclassified three deaths at a nursing home as COVID-19 deaths last week, after physicians ruled that all three were not related to coronavirus. Similarly, New York's death count nearly doubled overnight as the state began counting the "probable COVID-19" cases in its official reporting.

While under-diagnosing COVID-19 deaths suggests that the true death toll is higher than reported, there is a possibility of the opposite error of inappropriately attributing a death to COVID-19. While this is rare, its incidence may be increasing because of the new higher reimbursement for any patient admitted to a hospital for "COVID-19 suspected illness." Stemming from provisions under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the government will pay more to hospitals for COVID-19 cases in two ways:

- Paying an additional 20% on top of traditional Medicare rates for COVID-19 patients during the public health emergency

- Reimbursing hospitals for treating uninsured patients with the disease at the higher Medicare rate

Additionally, the U.S. Department of Health and Human Services announced that an additional $10 billion would be earmarked for hospitals in areas particularly impacted by COVID-19. This targeted-approach to funding addresses concerns raised by hospitals in the hardest-hit areas that they had received significantly less funding per COVID-19 patient compared with other hospitals with fewer COVID-19 patients.

Other concerns have been raised that billions are going to wealthy hospitals while poor hospitals struggle to survive. Banner Health, a non-profit hospital where the CEO was paid $21.6 million in one year, received $200 million in the bailout. At the same time, many hospitals were operating pre-COVID on razor-thin margins and many rural hospitals have been on the brink of closure. In order to determine which facilities could qualify for this targeted distribution, each hospital is now required to submit the number of ICU beds it has and its total COVID-19 admissions as of April 10, 2020, as well as deaths due to COVID-19.

The updated CDC guidance says officials should record deaths in which the patient tested positive for COVID-19 or, if a test was not performed, "if the circumstances are compelling within a reasonable degree of certainty," then it is acceptable to report COVID-19 on a death certificate as "probable" or "presumed." This caveat is spurring intense concern as to whether health officials are inflating their COVID-19 deaths to receive higher funding allotments in an effort to offset the losses from canceling "elective" procedures and increased personal protective equipment and staffing expenses.

While perverse financial incentives to "up-code" in medicine are well-established, the vast majority of medical doctors do the right thing and are making personal sacrifices to heed the call to help patients at this critical time. In reality, hospitals and physicians also have disincentives for up-charging, which can result in not only civil but criminal liability. However, it is critical that we physicians code patient conditions accurately to empower public health officials with reliable statistics and guard against middlemen interjecting themselves into coding authorship.

The ICD-10-CM Official Coding and Reporting Guidelines were established April 1, 2020, separating confirmed and presumptive positive COVID-19 cases. Thus, coding with the ICD-10-CM code U07.1 should be reserved for a patient with a confirmed COVID-19 diagnosis. However, as it is written, "for a confirmed diagnosis of COVID-19, documentation of the type of test performed is not required; the provider's documentation that the individual has COVID-19 is sufficient." Unfortunately, this may have introduced a loophole leaving many "possible" cases to be over-reported, skewing data and leading to conspiracy theories of hospitals up-coding for financial remuneration.

If the clinician documents "suspected," "possible," "probable," or "inconclusive" COVID- 19, do not assign code U07.1. Assign a code(s) explaining the reason for the encounter (such as fever) or Z20.828, Contact with and (suspected) exposure to other viral communicable diseases.

We propose principles to guide the appropriate use of the COVID-19 diagnoses codes:

- Limit utilization of the ICD-10-CM code U07.1 for patients with a confirmed COVID-19 diagnosis via molecular or serological testing

- If laboratory testing is negative, or testing is not available, do not assign code U07.1. Assign a code(s) explaining the reason for the encounter (such as fever) or Z20.828, Contact with and (suspected) exposure to other viral communicable diseases

In contrast to the Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19) on the CDC.gov site, we propose in cases where a definite diagnosis of COVID–19 cannot be made, but is suspected or likely, then "probable COVID–19" should be listed secondary on the death certificate rather than the primary cause.

For example, consider a patient with known end-stage renal disease (ESRD) who dies from a myocardial infarction with hyperkalemia. Given the current precautions across the country, a COVID-19 test may be performed to determine need for possible airborne precautions upon arrival. If the test was positive, this case should be coded as ESRD as the primary cause of death, cardiovascular disease as the second line, and COVID-19 may be added to the third line if there could be a link between the patient's hyperkalemia and the pandemic. Such a delineation in listing the cause of death would enable a more accurate tally of regional and national health statistics at this critical time.

In the same way that health data inform our country's research and funding priorities, an accurate count of the number of deaths due to COVID-19 infection is central to ongoing public health surveillance, prevention, and response efforts. Precise and transparent reporting is equally vital to maintaining public trust and the integrity of our healthcare system.

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