

COVID-19 and the Evolution to Checklist/Worklist Medicine

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Abstract

The excess mortality of COVID-19 in the US; over 800,000 lives appear inconsistent with the state of the US health care system both in terms of funding, access to technology, research and development. While “individual freedom” has been advanced for failures to control the spread of infection, the total number of deaths remains unexplained. This paper introduces the concept that the devolution of healthcare delivery to any “provider” armed with a checklist based on guideline-based medicine was inadequate to impact the pandemic. When checklists become worklists, their lack of specificity fails to compensate for the complexity inherent in the pandemic.

1. Introduction

The COVID-19 pandemic is currently associated with the loss of more than 800,000 lives in the US in the past two years with the largest number of both cases and fatalities in the developed world (Johns Hopkins Coronavirus Resource Center, n.d.), in the context of a medical system which spends twice as much per capita as comparable countries. That this occurred in the context of record numbers of healthcare organizations being ranked by organizations such as JD Power as superior quality institutions (presumably based on care delivery) is an apparent further contradiction.

Individual patient exposure to SARS-CoV2 would seem to be random and while risks for the development of mild or severe infection have been published; the question remains a about what accounts for our inability to prevent those infected from dying and is that inability due to structural deficits within the US healthcare system that can be defined and modified. Alternatively, is the excess mortality inherent in a society where individual freedoms prevent the draconian measures necessary to prevent viral spread and persistence. Problematic is the racial and socio-economic distribution of both infection and death were not evenly distributed and represented both risk factor distribution increasing infection rates and inequality in access to healthcare [12]. The severity of disease onset and widely published symptoms would not

seem to explain cultural bias as contributing to recognition of infection but may have impacted early arrival to healthcare. The pandemic highlighted the urban-rural healthcare divide in unexpected ways, the early high death rate in New York City, associated with enhanced transmission in a crowded landscape, together with lack of familiarity with both the infection, the availability of testing and treatments contrasts with the winter 2020/2021 outbreak in rural areas associated perhaps more with complacency and lack of access to tertiary care, but modified by rapid advances in treatment and disease modification therapies. This perspective does not address the factors which led to infection, but to the inability of the healthcare system to respond which may have contributed to increased mortality. It is not appropriate to assess fatality rate since testing leading to discovery evolved rapidly over time and at differing rates around the world so the actual number of infections may never be fully known. The defining difference with this pandemic, compared to prior pandemics or other disasters is the speed and intensity with which it consumed medical resources. It disrupted healthcare on an international scale, unlike local disasters, or even national disasters when other entities, including international entities like WHO or Red Cross/Crescent can relocate supplies across borders in a timely manner. COVID-19 overwhelmed all healthcare everywhere and within weeks. Supply chains were disrupted by national embargoes, “just-in-time” economic principles suddenly became not only irrelevant but disastrous, and every person, hospital and government were left often to fend for themselves. No-where was this more apparent than in the US when states competed for scarce supplies sold to the highest bidder.

We perspective investigates the hypothesis that the COVID-19 pandemic was the perfect storm due to the misalignment of three competing elements of the US healthcare system; the economic commoditization of disease, the economic commoditization of healthcare delivery, which were both overwhelmed in the face of inadequate data to inform medical decision making on a mass scale. The culmination of these decades long devolutions away from patient care to health care or more

appropriately sick-care created a system which was unable to quickly find the common ground needed to deal with the pandemic known as COVID-19.

2. Virtual Professionalism

Bryan re-interprets the doctor patient relationship from the modern perspective (Generation X) and quotes Gourevitch in predicting that physicians will be replaced by healthcare technicians [1]. Physician “professionalism” and the emotional art of medicine to put the patient first is both costly and unpredictable with regard to cost of care and ultimately for the payors, shareholder returns. It is widely known that each and every practicing physician in the US has at least 10 independent individuals tasked with their professional oversight and regulation. While the true corporate ownership of physicians is banned in many states, almost 85% of physicians (and their associated mid-levels) are “employed”, often through arm’s length 401©3 corporations. The employment of “midlevels” such as physician assistants or nurse practitioners (with the same prescribing power) is not constrained by such historically anachronisms such as the Hippocratic Oath; neither physician assistants or nurse practitioners have defined or published articles of professionalism to this date. If the delivery of medicine is to be placed in the hands of the most cost-effective provider (aka the value-driven proposition), the fundamental question becomes “How much knowledge is required to practice medicine?” In a personal conversation with the developers of Google glass, the fundamental question arose, “with so much information available so easily on the internet, how much knowledge does a practitioner need to safely practice”. The constraint on internet based medical knowledge becomes not so much the generation of data, but the ability to determine its veracity and applicability. The seemingly world-wide suspension of the belief and trust in science (evident prior to COVID in the climate change controversy) was rapidly introduced into COVID-19 “science”, with every provider and news “expert” entitled to their own personal interpretation of the data and because the information was being generated at such a furious rate, with no seeming cohesion, each provider was entitled to interpret information to suit their own personal application to their patients. It appears that 50 years of evidence-based medicine was discarded, precisely because there was no evidence. This however was incorrect; there was a significant body of evidence developed from the 5000+ deaths from SARS CoV1 and MERS that should have rapidly informed the present pandemic. There is no evidence to date that the effects of SARS-CoV2 is any different in its pathological effects than either of the prior two coronaviruses.

The efficient use of human capital in medicine is to put the creation of value in the hands of the least

expensive “provider” supported by corporate guidelines, flowcharts and checklists. An OpEd in the prestigious New England Journal of Medicine during the prequel to Obamacare stated specifically that legal exposure resulted from not following the determined checklist whereas following an incorrect checklist was defensible. As we speak payors are closing this “loophole” by insisting that nurse practitioners bill under their own National Provider Identifier (at their assigned lower reimbursement rates) rather than continuing to bill under the more lucrative physician NPI number (TMA 5/4/2021). Not only has the delivery of medicine become a commodity, each and every diagnosis is a commodity with its own re-imbursement. Note that checklist medicine is not to produce excellence in any way other than to reduce error. The diversity in healthcare delivery was attributed humanistic bias which became replaced by human influenced computer algorithms which administer care with less clearly defined but more harshly delivered biases in both diagnosis and care options; your procedure or medication is either approved or denied. Thus, the economics of medicine as a consumer (or producer) of 16% of GDP placed medical decision making in the hands of the least experienced defended by guidelines and checklists.

COVID-19 disrupted the system in ways not previously imagined by closing physician practices and any non-urgent hospital visits through government mandate. Some 37 million patients became unemployed and many lost both their employer mandated health insurance and access to care. Many patients were lost to regular follow-up and patients were seen virtually, predominantly by telephone by providers they did not know. The relaxation of the rules for telemedicine unraveled the provider-patient relationship even further. A large percentage of telemedicine visits were performed by providers who had no prior knowledge or relationship with the patient. Virtual medicine unilaterally documents symptoms with no ability to verify the time-intensity relationship which is so critical to any assessment of pathology or functional capacity. The adage that 75% of communication is non-verbal further exacerbated the ability to collect accurate data, fundamental to the commoditization process. This is further exacerbated by the inability of patients to see ongoing providers, their appearance at acute care clinical and ER is further devoid of contextual information that may elucidate that many of the symptoms attributed to COVID-19 infection and more specifically the new so-called “long hauler” status existed for months or years prior to COVID-19 infection. Those conversations were not recorded by the participating provider but often a designated “scribe” who may not even be in the US. This raises serious issues related to the assignment of liability in such circumstances. If a medical record is written by a scribe in another country paid for by the employer of the

physician assistant who is overseen by a provider who is also not on-site, where does accountability lie? In the era of electronic medical records, the ability of computers to generate unsubstantiated medical information ensnared one large provider [2] the cut-and-paste insertion of incorrect information makes the current medical record as a transmitter of meaningful information dubious. In a recent example, two visits to a hospital emergency room generated 128 pages of medical records. The inaccuracy of computer-generated medical records has led to the imposition of so called “meaningful use” criteria, the purpose of medical records having devolved so far from being either meaningful or useful.

3. Commoditization of Disease

Simultaneously with the commoditization of the healthcare delivery process the patient, their disease and complexity became increasingly codified and so called “relative value units” assigned. These units became the currency of payment under the diagnosis related groups (DRGs) which form the basis of hospital reimbursement. With the progressive consolidation of healthcare providers and payors, why is there not a typical supply and demand relationship? Supply and demand to create value requires price transparency; despite many efforts to encourage and legislate price transparency, this remains an illusion. Ironically the published Medicare re-imbursement rates for more than 10,000 procedures are readily available and indexed by county. The authority of Medicare to both assess the viability of procedures and assign a CPT code generally determines if the procedure will be reimbursable. While not readily accessible, payor contracts typically trigger off this list and pay (a small amount) above Medicare rates and sometimes below. It is generally accepted that these are the reasonable and customary rates for any procedure. Conversely, any procedure for which Medicare fails to allocate a specific billable code is generally condemned to oblivion. In a fashion Medicare (which by law must pay the lowest price for services) sets the lower limit of reimbursement for any procedure. The upper limit has no bounds and the burden of the (unpublished and unknown) upper limit falls primarily on the uninsured who are billed at multiples of the Medicare floor rate. Private payors add both outcomes and value-based criteria to procedures before determining authorization strategies.

The alignment of providers with large shareholder entities who have no vested interest in curbing demand, and through the promotion of screening programs seek to increase the number of asymptomatic people accessing healthcare. The decades long controversy surrounding coronary calcification and calcium scoring is testament to this struggle between early detection and the costs of early intervention.

The widespread use of electronic medical and health records with data mining of existing patients to find more valuable diagnoses further dehumanizes the patient under the guise of population-based health or “big data”. The use of IBM Watson Big Blue by hospital systems is well known [3]. The spin-off Watson Healthcare now has its own hospital quality awards.

A significant constraint on data mining is the factual basis of the underlying data which is subject to documentation errors. The system rewards the assessment of many diagnoses even if incorrect, rather than a fewer number of correct ones. There are cases where insurers, perhaps inadvertently based on improper documentation, up charged Medicare for complex care [4]. A medical coding company was held liable. Both hospital systems, medical coding companies and insurers have been subject to the legal ramifications of such “upcoding” and “over-utilization. The declaration of a disaster by either local or federal authorities requires an immediate cessation of prior authorization requirements for medical procedures and medications, in the case of COVID-19 at a federal level. Oftentimes this creates an immediate avenue for exploitation so that experimental procedures which had previously been banned or limited can be performed without pre-authorization. Payors early in the pandemic petitioned for ongoing control over the “medication supply” under the guise of preventing hoarding of medications such as hydroxychloroquine, and in return, maintained control over the most expensive medicines including biologics and generated record profits during the pandemic. To their credit, they relaxed payments for diagnosis, care and treatment for COVID related illness, but were more than compensated by the abolition of elective procedures for weeks or months. The loss of 37 million employee/employer premiums appears not to have had a significant on cash-flow.

4. Science, Statistics and Guideline Based Medicine

The so-called “science of medicine” providing the basis by which technicians become decision makers results from the adoption of “checklist medicine” [5] formulated by guideline-based practices, citing evidence-based medicine derived from scientifically conducted clinical trials. The patient decision is therefore at least three steps removed from the original data upon which the decision is made. Clinical trials are graded in guidelines using a Class I (best evidence) to Class IV (studies that are non-comparative, unrepresentative of the population of interest, with major biases or confounding, lacking useful measures of effect, or lacking measures of effect estimate stability [6]. In everyday practice the class of evidence supporting a

decision point is often ignored. Most providers can find some guideline (or published paper) somewhere which supports their personal mode of practice, and when all else fails, “guidelines are just that, guidelines”. The use of hydroxy-chloroquine in the treatment of COVID-19 was a stark reminder of treatment decisions being made ahead of the science which was subsequently interpreted “as needed”. While rarely acknowledged, clinical trials provide the answer to what is the average outcome of the intervention in the average patient. This is an unacceptable standard in practice when patients and payors demand 95% success rates or better. No hospital, practitioner or insurance company would be rewarded for the delivery of “average”. Therefore, the guidelines upon which check-list medicine is practiced are themselves inimical to the quality demanded, even by governmental authorities such as the Center for Medicare Services. There is further lay confusion when clinical trial data do not translate to reality: for example, COVID vaccine efficacy of 90+% in clinical trials, when associated with 50% vaccine resistance among a large portion of the US population will likely not get to herd immunity. As in other efficacious therapies the total clinical efficacy is diluted by the ability to implement. While clinician scientists report intention to treat, this is not the outcomes measure patients want, they want absolute risk assessments, like the risk of getting COVID with any specific activity; a guideline not published to this day. The recent stand-off between Dr Fauci and Rep Jim Jordan in Congress highlighted this disconnect between science and the day-to-day reality in which decisions must be made. Decisions cannot be made on relative risk; for example, am I more likely to die skydiving or hang-gliding has no relationship to knowing the absolute risk of death in commercial airline travel. In practice, extrapolation from clinical trials is rampant and only egregious violations are exposed [7]. The retraction of COVID-19 related data from prestigious medical journals early in the pandemic harmed the legitimacy of both the science and the role of peer-review [8], in providing accurate information to allow effective decision making. Since much of the data related to COVID-19 has not been peer-reviewed, a common response is “who has the experience to peer review anything to do with COVID-19” The lack of scientific comparison to prior coronavirus outbreaks SARS and MERS is noteworthy. Many observations are published primarily in the media referencing impending publication on pay-for-publish sites like MedRxiv.org.

Patients then have access to vast amounts of conflicting information on the internet with which inform their side of the conversation. Social media has become a major arbiter of information/fact/truth? in COVID-19, so much so that the CDC guidelines on “long haulers” reference social media studies or sites in 17 of their 30 quoted references [9]. No attention appears to

have been made to the fact that more than 500,000 social media websites are fictitious people/patients rented by pharmaceutical companies [10] (Oxford University 2018).

Checklist based care was developed from the airline industry and the safety record derived from such practices. Checklists are generated by the airplane manufacturer; most physicians don’t believe there is a manufacturer for the human body which humorously makes the application of checklists at its best bootstrapping and at its worst ludicrous. The Boeing 737max debacle is evidence that checklists are only as good as the disclosure and understanding of the underlying system. In both 737max and COVID-19 a few lines/bases of malicious code produced catastrophic results. Checklists work safely and efficiently in common conditions for which decades of research have clearly defined the central determinants of both survival and quality of life, and clearly defined (often in case law) the outer boundaries of acceptable medical practice and resource utilization. What happens when there is no data, there is no experience, and specifically in COVID-19 the data being published is incomplete and redacted as quickly. News reports document checklists placed in the hands of 2nd year medical students tasked with delivering care as their first taste of “medical practice”. The failure of the check-list guru to create the promised revolutionary medical system (Haven) pioneered by financial giants, Berkshire Hathaway, Chase and Amazon is testament to the fact that check lists, do as their name suggests, they check existing systems, they do not create new information. What about when the evidence is correct, and the patient data is manipulated to fit the guideline to affect an economic outcome? A recent settlement documented stated that 457 hospitals were found to have implanted defibrillator inappropriately with respect to the published guideline [11].

5. Conclusion

Our perspective seeks to provide an overview of the tension and dysfunction in the US healthcare system that contributed to the excess mortality resulting from the COVID-19 pandemic. Three intersecting factors were discussed; the relentless pursuit of value at the cost of the physician-patient relationship, the economic valuation of disease and procedures more than the patient, and inability of science to quickly develop outcomes-based interventions which were uniformly implemented. While the development of treatment strategies occurred at a historic pace related to the development and implementation of effective vaccines, many lives were lost needlessly in the first year. The pandemic is clearly not resolved, the failure to achieve herd immunity will produce ongoing infection over the next few years.

It is a noteworthy to compare the COVID-19 pandemic to the disruption seen with the appearance of HIV in the 1980s; it has taken two decades to make the disease compatible with long term survival, though no cure is yet available. When sick-care is less an altruistic endeavor and merely another, albeit very high-priced commodity, free-markets become the arbiter in how and where investments of time and resources are deployed. The contemporaneous suspension in belief of generic benevolence, the altruistic nature of science and the ability of government were additional complications impeding both control of the infection and remediation of the consequences.

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