TheGMS
The Gazette of Medical Sciences
https://www.thegms.co ISSN 2692-4374 DOI https://www.doi.org/10.46766/thegms

Medical Ethics | Review

FAILURE OF CARE STANDARD IN RELATION TO PFIZER BNT162b2 modRNA

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Submitted: 24 August 2024
Approved: 07 September 2024
Published: 09 September 2024

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How to cite this article: Vella D, FAILURE OF CARE STANDARD IN RELATION TO PFIZER BNT162b2 modRNA. G Med Sci. 2024; 5(1):156-163.
https://www.doi.org/10.46766/thegms.medethics.24082501

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KEYWORDS

benefit-risk, efficacy, safety, ethics, autonomy

1. INTRODUCTION

Most of the general public would agree that a physician, much like a firefighter or police officer, is a designated and long respected protector of the community. Commonly during a time of crisis, a proverbial "snake oil salesman" will appear with a fake cure seeking to profiteer from an unsuspecting and often fearful public. Such unethical behavior is one of the important reasons for the physician's protective role. This article explains two core physician competencies required for licensure, and the recent widespread failure of physicians to provide safe medical care for the communities which they serve.

The two core competencies referred to involve basic interpretation of the medical literature and adherence to medical ethics. These essential skills are so foundational, they are part of the first-year curriculum of every medical school in the United States. This fund of knowledge is tested for with the first part of the U.S. Medical Licensing Exam administered routinely during the second year of medical school [1-4]. Educators do not intend to invest four years training a student who lacks the ethical fortitude required to practice medicine safely. Also, at no time is it assumed that the medical school graduate will possess all knowledge of treatments of all human ailments. Therefore, it is critical for the student to learn the basic skills required to assess the safety and efficacy of any new treatment brought to market after completion of training.

The practicing physician will be required to exercise independent and critical analysis of therapeutics, regardless of the source of any new recommendation. This is specifically so the physician is not inappropriately influenced by predatory business interests (e.g. pharmaceutical companies) or unknowledgeable public officials (e.g. agency regulators), who could intentionally or unwittingly harm the public. Unlike third parties which frequently harbor conflicts of interest, it is the physician who holds the time-honored and trusted relationship with the individual patient.

2. APPLICATION OF SKILLS: BENEFIT-RISK ASSESSMENT

The application of these two critical skills was uniquely straightforward in the case of the experimental BNT162b2 modRNA treatment. The singular scientific information presented to clinicians to assess this genetic prodrug's efficacy and safety was the two-month interim data from the original Pfizer BioNTech trial [5]. The paper was published in the New England Journal of Medicine (NEJM) and readily accessible to practitioners for their review December 10th, 2020 before the treatment became available. Every physician practicing in the United States is familiar with the NEJM. The results of the Pfizer BioNTech study were reported in a fashion that is misinformative to the untrained nonprofessional reader [6]. In contrast, the physician should have immediately recognized the "95% effective" and "95% protection" relative risk-based statements as well-known statistical deception [7]. Similarly, the statement in the abstract results section: "The incidence of serious adverse events was low, and was *similar* in the vaccine and placebo groups" is quite misinformative. In combination, the exaggerated efficacy and dismissive safety concern are termed *mismatched framing*, which again is easily recognizable statistical chicanery. The licensed medical practitioner should have quickly noted these flaws and determined that the risks of the spike protein coding mod RNA actually far outweighed the benefits. Moreover, presentation of the experimental BNT162b2 information in this manner violated best practice standards for communicating risks and benefits to patients. Alternatively utilizing the limited data presented and exercising professional due diligence, every clinician administering or advising the novel treatment could have conducted a simple benefit-risk assessment.

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Basic biostatistics tools introduced during the first year of medical school include: absolute risk, numbers needed to harm (NNH) and numbers needed to treat (NNT). These methods are scientifically supported and used industry wide to arrive at percentages and natural frequency information to be presented to the patient. Using this basic methodology, the physician should have realized that the experimental injection actually caused seventeen times as many adverse event harms compared to benefits. The modRNA biologic prodrug caused nearly twice as many serious harms than the number of serious cases of COVID it prevented. Overall, the treatment posed much greater risk than benefit to the trial participants [8].

This well-established methodology for conducting benefit-risk assessments regarding any newly available therapeutic has been advocated for many decades by medical educators (as referenced above) and continues to be supported by many professional societies such as the American College of Physicians (ACP) and American Academy of Family Physicians [9, 10]. The concepts are re-presented routinely in post graduate study materials such as the Medical Knowledge Self-Assessment Program (MKSAP). This continuing educational program is promoted by the ACP and is reissued regularly for the purpose of ongoing board certification testing. Certification is now frequently required for physician employment and now being advocated for reimbursement from third party payers. Importantly, these standards are also currently promoted by public health experts and regulatory agencies. The FDA published an evidence based best practice guide specifically on this subject in 2011 [11]. The fund of knowledge discussed here is acquired very early in medical training, reaffirmed throughout a physician's career and represents an extremely low bar for professional competency.

3. COMMUNICATING RISKS AND BENEFITS

Physician core competency requires the ability to convey information in numerical terms that can be best understood by the patient. Using natural frequencies is the most appropriate approach for less numerate patients. Based on the BioNTech trial design, the obvious net harm could and should have been applied to the general public. With the scientific evidence provided, the physician should have advised any patient of the following facts: "119 people need to be injected to prevent one case of COVID, but 1 in every 7 persons treated reported a significant adverse reaction. That is, you have a 1 in 119 chance of benefiting from the gene-based injection, and you are 17 times more likely to be harmed in some way than prevented from contracting COVID. Also, you are much more likely to be hospitalized for any reason after the treatment than prevented from hospitalization due to COVID." Based on the trial results, no patient in the community should have been advised to receive the experimental modRNA prodrug.

Failure to arrive at the correct benefit-risk assessment and to appropriately relay that information to patients seeking advice, in this unique situation, represents rudimentary incompetence and grossly unsafe medical practice. Specifically, overestimating the benefit of the treatment by acknowledging only relative risk, ignoring the harms to patients which were much more frequent, misrepresenting those benefits and harms to patients, and then administering or advising the injection all constitute serious medical negligence. In chapter seven of Communicating Risks and Benefits: An Evidence-Based User's Guide, the FDA advises: "Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an *absolute risk* format should be used". Similarly, the Agency for Healthcare Research and Quality actively promotes

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The SHARE Approach advising: "Give *absolute risk* instead of relative risk. Absolute risk estimates the number of health events among individuals in a group, and gives a better sense of personal or individual risk" [12]. It is this style of communication that is optimal for informed consent.

4. ADHERENCE TO MEDICAL ETHICS: RESPECT FOR PATIENT AUTONOMY

Professional training and judgement would preclude a physician from choosing to follow a new and demonstrably harmful recommendation while ignoring all long-established standards for safe medical practice [13]. That is, new and ever-changing recommendations and guidelines, which can be based on faulty literature, do not simply supersede exercising core competences required for medical licensure. It is well known that promoters of guidelines often have conflicts of interest (COIs) which may be contrary to the patients' best interests. These COIs include cost containment pressures, maximizing profits for medical product and pharmaceutical companies, and promoting nefarious political agendas.

The physician has an ethical duty to act in the patient's best interest with one's professional assessment, advice and practice. This is regardless of any coercion the physician may be under by third parties including financial pressure from employers. The foundational ethical principles of *patient autonomy* and *informed consent* are inextricably entwined. The physician, by failing to disclose appropriate information regarding or misrepresenting the modRNA treatment, denied the patient the inalienable right to exercise autonomy through true informed consent to or refusal of the experimental treatment [14]. Moreover, when failing to uphold ethical standards, the physician failed to protect the patient from unethical medical intervention. Finally in this circumstance, the physician violated the industry standard fiduciary relationship with the patient by accepting reimbursement for professional service rendered and then failing to act in the best interest of the patient.

5. POSSIBLE LEGAL IMPLICATIONS

Based on the available scientific evidence, a physician's judgment to administer or advise a patient to receive the COVID modRNA injection is flawed. These actions demonstrate substandard care and increased risk of harm to the patient. Moreover, the physician's failure to interpret the available safety and efficacy data and present that information to the patient to allow for informed consent early in the chain of events may be the root cause of injury. This line of argumentation might be helpful to circumvent the Public Readiness and Emergency Preparedness (PREP) Act [15] *limited* liability protections. If the physician's action was to protect self-interests, including financial or emotional (e.g.- fear of COVID infection), then the malpractice described here could escalate to intentional malfeasance or harm [16]. This intentionality could constitute "willful misconduct" possibly piercing the PREP Act as well. Consider physician complicity as the lynch pin in Operation Warp Speed. A line of questioning during deposition or trial testimony could lead a physician to admit to negligence or admit to complicity due to duress, such as from practice interference by *administrators practicing corporate medicine*. Either admission would be tremendously advantageous for injured plaintiffs.

Most attorneys believe that the PREP Act and additional state enacted protections provide a significant hurdle to corrective action within the COVID narrative. However unlike "agent 007", government cannot simply issue to a physician a license to do harm. This completely undermines the very purpose of granting a medical license to ensure safe practice in the community. Consequently, many resourceful attorneys have already filed numerous

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medical countermeasure injury cases. Remdesivir malpractice cases are currently proceeding and circumventing the PREP Act via essentially medical abuse laws. The facts presented here showing medical negligence by misinforming and deceiving patients can also be used to show violations of numerous state and federal advertising and sales statutes. As misrepresentation and fraud are also not protected by PREP, multiple state Attorneys General have filed suit against Pfizer using these same arguments [17, 18]. Despite these initiatives, motivated plaintiffs are experiencing major difficulty in seeking restitution for COVID gene product injury. Factors include the sheer number of injured patients seeking counsel, the limited number of attorneys available for this emerging arena and ongoing litigation challenges. The only option for some is to file pro se, which desperate remdesivir injured patients are resorting to.

6. ALTERNATIVE CORRECTIVE ACTION

Four years into Operation Warp Speed, negligence and injury continue as the wheels of justice turn ever so slowly. Given the political and legal forces surrounding the experimental gene-based *countermeasure*, court action and its cost are simply too daunting to consider for many of those suffering harm. Despite some progress mentioned, civil litigation does not yet offer an overly reassuring or expedient path toward restitution, even though damages caused by BNT162b2 modRNA are estimated to be at least an order of magnitude greater than remdesivir. An alternative to pursuing legal counsel and proceedings for those injured may involve a regulatory pathway. Mechanisms are currently available to register patient complaints regarding inappropriate medical care. These systems serve as an early warning signal to mitigate potential harms. State licensing boards are responsible for oversight of licensed practitioners and routinely investigate concerns regarding incompetent and potentially dangerous practice behavior. Filing a complaint with the state licensing agency may provide an effective alternative for those mistreated to warn and protect others from sustaining similar injuries.

If the injections were administered under the direction of or were obtained as a result of advice from a physician, injured patients could utilize a brief template delineating failure to uphold the core competencies described here. Chief medical officers (CMOs) of health systems recommending the injections would be among the negligent physicians. The template could be easily accessed and personalized with a statement of injury along with a request for investigation. Connecting this template with a readily available link to state licensing boards would simplify and accelerate the process for plaintiffs. Many advocacy organizations currently use this software for their initiatives. The innovation is particularly common for sending letters en masse to educate and inform legislators about an issue of concern and its degree of public support. If agencies fail to respond to the potential large number of petitions, government watchdog and investigative media groups would bring further scrutiny to this issue. In addition, consideration should also be given to combining this strategy with preplanned litigation if licensing boards fail to fulfill their regulatory mandate as determined by state law.

In an era of aggressive scientific censorship by the medical establishment, consider that the effect of this additional strategy to empower victims is manifold in the following ways. First and foremost, would be to catalyze wider public attention to the problems associated with this gene-based treatment. Second, in a cascading fashion, increased awareness is likely to expand funding for nonprofit organizations attempting to assist those in need. The third effect will be to help finance more civil litigation for badly needed restitution. The fourth consequence is to decelerate the ongoing morbidity

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and mortality associated with this negligence. Fifth is to foster physician reeducation of the scientific method and ethical conduct for the general benefit of public health. Ultimately, the longer-term goal is to prevent another sudden mass iatrogenic event in the future [19, 20].

7. CONCLUSION

The COVID debacle ushered in a pernicious neglect of two core competencies required for medical licensure and safe medical practice in the community. These breaches involve basic interpretation of the medical literature and adherence to medical ethics. More specifically, these essential physician skills are identified as benefit-risk assessment, effective patient communication, respect for autonomy, and allowance for informed consent or refusal. There are two material explanations for physician failure to deliver adequate care in this situation. The first is fundamental incompetence, and the second is simply "following orders" from administrators to protect one's own livelihood. Both of these factors, easily account for the precipitous loss of public trust in the medical profession during the COVID era [21]. Moreover, without physician buy-in, far fewer patients would have submitted to the medical experiment even under the duress caused by the unprecedented mandates. Physicians neglected their ethical duty to advocate for patients when they failed to oppose medical coercion. Despite some positive initiatives mentioned here, the limited protections provided by the PREP Act still present a significant hindrance to correcting aberrant physician conduct in this arena. However, an underutilized but powerful auxiliary mechanism for corrective action is currently in place. As long as practitioners believe that they are immune to any consequences, negligent behavior is unlikely to cease. Accordingly, in absence of counterbalance, stakeholders can expect the outcome of Operation Warp Speed to be far surpassed by *Project NextGen* [22].

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