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What Ever Happened to Evidence-Based Practice during COVID-19?

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Abstract

Contemporary medical practice is grounded in rigorous scientific evidence in concert with best clinical practices and informed shared decision making with patients. During these times of uncertainty, disruption, and even anxiety, it becomes especially critical that we engage with our patients and communities in thoughtful dialogue and realistic expectations regarding treatments surrounding COVID-19. The hope for a "miracle" cure and urgency to return back to normal times can stimulate irrational thought, behavior, and even desperate measures by individuals or groups. It becomes especially important that we continue to use reasonable, informed clinical judgment in discussing the various options with patients.

Commentary

There are real and justifiable concerns about the coronavirus pandemic due to the aggressive nature of the virus, high transmission rates, and increasing mortalities. The urgency to develop mechanisms for widespread antibody testing, therapeutics, and vaccinations for COVID-19 on the part of governmental agencies, pharmaceutical companies, private industry, and healthcare institutions is real and time sensitive. However, if there is one thing we should not forget during this pandemic, it is that we do not throw out the core foundation of 21st century medicine, which is grounded in evidence that guides practice recommendations and decisions. The National Academy of Medicine has advocated for the use of clinical practice guidelines by clinicians to improve healthcare quality and outcomes based on best practices and patient preferences that enhance shared decision making.[1] The AAO-HNSF has investigated thousands of dollars, hours of time, and substantial resources developing Clinical Practice Guidelines and Consensus Statements based on evidence to help guide best practices in otolaryngology

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practice and achieve optimal health outcomes for patients, such as the recently revised guideline on tonsillectomy.[2] I can personally attest to the rigorous process adhered to that involves extensive searches of databases, analyses of the literature, peer-review, and public commentary.[3] These evidence-based recommendations help provide guidance to millions of health professionals, institutions, and patients throughout the world.

With the strong push to bring widespread COVID-19 antibody testing to the market, federal regulatory oversight has been minimal. Dozens of manufacturers have released antibody tests for the virus into the marketplace with varied levels of accuracy.[4] There is significant concern regarding high rates of inaccurate results that may provide individuals with incorrect assurances of immunity to the virus and protection from future infection. If we base our clinical decisions on data with questionable accuracy, we run the risk of making recommendations on whom may return to work, school, or social activites when they are still susceptible to acquiring COVID-19. These mixed findings regarding sensitivity and specificity of various antibody testing substantiate the need for clinicians to work closely with patients in providing information and in helping them to understand and interpret the meaning of any test results.

On the other hand, we have all attended meetings where a speaker might offer an anecdotal comment regarding the “off label” use for a medication under certain circumstances. This simply means that the FDA approved drug is being used to treat a symptom or condition for which it was not specifically tested for safety and efficacy. Under certain circumstances, the physician is using the medicine in a specific manner within one’s own practice. This is a very

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different message from the one currently being communicated during the COVID-19 crisis by governmental and non-healthcare public officials. One area that has been extremely controversial and driven by unsubstantiated claims of potential effectiveness is the use of the antimalaria drug hydroxychloroquine to treat patients hospitalized for coronavirus infection. Initial enthusiasm for the antimalaria medication came out of anecdotal findings or small non-randomized controlled studies but has gained unprecedented momentum amidst the rush to find a cure.[5] The first tragedy in the U.S. came after an elderly coupled ingested chloroquine phosphate, a derivative of the antimalaria drug, in an effort to ward off the coronavirus. The couple was hospitalized after taking the drug and subsequently the husband died from respiratory complications.[6] Despite unsubstantiated claims that hydroxychloroquine is safe or effective in treating patients with coronavirus symptoms, state and local governments around the country have been stockpiling the drug.[5] One small retrospective study conducted at a VA hospital found no evidence that hydroxychloroquine administered either with or without azithromycin was effective in reducing the need for mechanical ventilation in 368 hospitalized patients with confirmed COVID-19. However, the researchers did find an increased mortality rate in those patients who had been treated only with hydroxychloroquine.[7] A small clinical study conducted in France, found no clinical benefits in administering hydroxychloroquine combined with azithromycin to hospitalized patients with significant comorbidities.[8] These preliminary studies further illustrate the need for scientists and clinicians to rely on well-designed trials to determine medication safety and efficacy before advocating widespread use in patients. Although federal agencies have been slow to respond, in late April, the Food and Drug Administration (FDA) posted a notice on their website warning against the use of

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hydroxychloroquine to treat COVID-19 outside of the hospital setting[9] and the CDC reiterated the FDA's message that there were no drugs or therapeutics approved at this time for the prevention or treatment of the virus.[10]

We are living and working in unprecedented times where we are faced with many uncertainties about our health, our families, our economy, and our future. We are all desperate for answers, effective treatments, even a cure or perhaps a miracle that will help us return to our normal lives again or better yet bring us back to that time before the coronavirus even entered our lives. But realities tell us that this is not going to occur anytime soon. That is why it is particularly important that health professionals remain grounded in evidence and best practices and maintain open candid dialogue with patients. The search for a miracle to get us out of this pandemic can lead to individuals taking drastic measures that are not beneficial and may even prove to be harmful. The AAO-HNSF's hard work in developing evidence-based clinical practice guidelines for over two decades has been extremely valuable to millions of practicing clinicians around the globe. With strong research and expert clinical reasoning, we will overcome COVID-19 like we have done successfully with so many other diseases.

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