PP27 The Private Healthcare Responses Against COVID-19 Emergencies In Brazil

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Introduction: The Corona Virus Disease 2019 (COVID-19) pandemic is the biggest public health crisis of all time. Private health care plays a major role in health globally. We conducted a study to document the engagement of a Brazilian private health care organization to influence decisions to private and public health emergencies of COVID-19.
Methods: This retrospective study evaluated the outputs of the health technology assessment (HTA) group of Unimed-BH, a private Health Maintenance Organization (HMO) with 1.5 million participants in Belo Horizonte, Minas Gerais state. The study evaluated the impacts on the overview of health local decisions in the municipality and the national supplementary health agency (ANS) during the period from March 2020 to December 2022.
Results: During the pandemic, Unimed-BH made all its sanitary decisions based on scientific research, such as the use of masks and appropriate medications. Even though some medicines, such as regdanvimab, were authorized for emergency use by the Brazilian Health Regulatory Agency (ANVISA), Unimed-BH did not recommend their use due to uncertain evidence, and months later, ANVISA withdrew the registration.
Unimed-BH also conducted a systematic review of ivermectin for COVID-19 treatment, which showed no effect, and therefore did not recommend its use. Additionally, Unimed-BH provided weekly updates on COVID-19 data, including suspected and confirmed cases, hospitalizations, and deaths in their customer portfolio. The organization also actively supported the decisions made by ANS and municipal managers using evidence and statistics on the pandemic. The Unimed-BH HTA group produced a total of 167 reports from March 2020 to December 2022.
Conclusions: Belo Horizonte had the lowest in-hospital mortality rates with COVID-19 in Brazil. Unimed-BH's HTA reports provided evidence-based assessments for decision-making, proposed partnership with policymakers, fomented information transparency, and strict follow-up on pandemic numbers, which may have contributed to the lower fatality rate in our city. These findings underscore the importance of private healthcare organizations in responding to COVID-19 emergencies, and their potential to support evidence-based decision-making and minimize the impact of the pandemic.

PP30 The Fast Track In Drug Registration By ANVISA – Brazil And Possible Consequences

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Introduction: The fast track in drug registration by the Brazilian Health Regulatory Agency, ANVISA, began in 2017 and is intended to prioritize analysis related to drugs relevant to public health. This process is appropriate in situations where there are no therapeutic alternative available or for technologies show significant improvement in safety, efficacy, or adherence to treatment.
Methods: The Brazilian public administration has a tool for accessing information called Transparency Portal. Thus, data on the number of drugs approved by fast track between 2018 and 2021 were requested through this tool and evaluated.
Results: The data received by the Brazilian transparency portal shows that the number of requests for fast track had an increase from one in 2018 to 32 in 2021. There is an important increase of registrations, being drugs with phase II trials and with single-arm clinical trials. With registration based on a phase II trial, these patients are in fact receiving drugs in a context similar to clinical trials, but with funding from the healthcare system. Given that phase II studies are conducted in a limited population, there has been an increase in the registration of drugs with suboptimal efficacy and safety concerns. This scenario of uncertainty leads to non-adherence to treatment and a discrepancy in real-world outcomes in comparison to the clinical trial. About 70 percent of phase II trials, show no benefit, and only 30 percent proceed to later phases. It is noteworthy that about 50 percent of the studies that move on to later phases fail to show benefits. Nowadays the number of drugs approved by the fast track has increased, many probably with phase II studies and no comparator group.
Conclusions: Given the uncertainties in the efficacy and safety of a drug registered via fast track, often based on phase II studies, implementing provisional registration with real-world evaluation of outcomes, and coupled with financing based on risk-sharing agreements, may be a sustainable alternative for health systems.

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