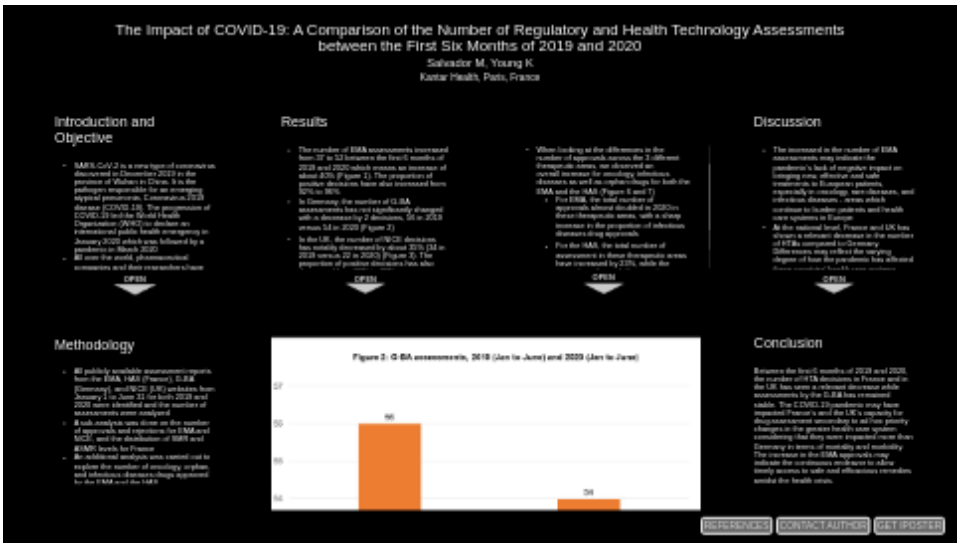
The Impact of COVID-19: A Comparison of the Number of Regulatory and Health Technology Assessments between the First Six Months of 2019 and 2020



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INTRODUCTION AND OBJECTIVE

- SARS-CoV-2 is a new type of coronavirus discovered in December 2019 in the province of Wuhan in China. It is the pathogen responsible for an emerging atypical pneumonia, Coronavirus 2019 disease (COVID-19). The progression of COVID-19 led the World Health Organization (WHO) to declare an international public health emergency in January 2020 which was followed by a pandemic in March 2020
- All over the world, pharmaceutical companies and their researchers have been looking for a vaccine or drug solutions to address the health crisis. In the interim, health care systems are struggling to uphold public health and safety while facing burgeoing budget and resource constraints
- The objective of this study was to explore the possible consequences of COVID-19 on the number of European Medicines Agency (EMA) and health technology drug assessments in France, Germany, and the UK. This research aimed to compare the number of decisions between the first six months of 2019 and 2020

RESULTS

- The number of EMA assessments increased from 37 to 52 between the first 6 months of 2019 and 2020 which means an increase of about 40% (Figure 1). The proportion of positive decisions have also increased from 92% to 96%
- In Germany, the number of G-BA assessments has not significantly changed with a decrease by 2 decisions, 56 in 2019 versus 54 in 2020 (Figure 2)
- In the UK, the number of NICE decisions has notably decreased by about 35% (34 in 2019 versus 22 in 2020) (Figure 3). The proportion of positive decisions has also decreased from 82% to 73%
- In France, the number of HAS SMR decisions has notably decreased by almost a third (248 in 2019 versus 181 in 2020) (Figure 4).
    - The distribution of SMR decisions has seen a slight change between 2019 and 2020, with a decrease in the proportion of major or important SMRs, an increase in the proportion of moderate or weak SMRs, and a decrease in the proportion of insufficient SMRs
    - For ASMR, the proportion of ASMR V decisions has increased while there a slight decrease in the proportion of ASMR III and ASMR IV decisions (Figure 5)

- When looking at the differences in the number of approvals across the 3 different therapeutic areas, we observed an overall increase for oncology, infectious diseases as well as orphan drugs for both the EMA and the HAS (Figure 6 and 7)
  - For EMA, the total number of approvals almost doubled in 2020 in these therapeutic areas, with a sharp increase in the proportion of infectious diseases drug approvals
  - For the HAS, the total number of assessment in these therapeutic areas have increased by 23%, while the proportions for each therapeutic area remained almost the same between 2019 and 2020 as the total number of decisions increased in 2020

DISCUSSION

- The increased in the number of EMA assessments may indicate the pandemic's lack of negative impact on bringing new, effective and safe treatments to European patients, especially in oncology, rare diseases, and infectious diseases - areas which continue to burden patients and health care systems in Europe
- At the national level, France and UK has shown a relevant decrease in the number of HTAs compared to Germany. Differences may reflect the varying degree of how the pandemic has affected these countries' health care systems during the observed timeframe. France and the UK have been more affected compared to Germany in terms of COVID-19 prevalence, hospitalisations, and mortality. The increased pressure in the health care systems of France and the UK may explain the resulting decrease in assessments as resources may have been shifted to address the urgent crisis
- The proportion of positive and negative decisions in France and the UK has shown an increased proportion of negative decisions in the UK and an increased proportion of lower benefit rating scores in France. This may indicate that regardless of the pressures of the health crisis, payers have maintained their strict criteria of only granting access to safe, effective, and cost-effective drugs in these markets
- As organizations have been slow to adapt to the pandemic, the first 6 months may not be the most representative when assessing the sustained impact of the current health crisis. It would be interesting to extend the timeframe of the research considering that the pandemic is foreseen to continue to surge in waves as Europe awaits a safe and effective vaccine like the rest of the world
- It would also be interesting to analyse data at the global level to assess what the consequences have been for the health sector

METHODOLOGY

- All publicly available assessment reports from the EMA, HAS (France), G-BA (Germany), and NICE (UK) websites from January 1 to June 31 for both 2019 and 2020 were identified and the number of assessments were analyzed
- A sub-analysis was done on the number of approvals and rejections for EMA and NICE, and the distribution of SMR and ASMR levels for France
- An additional analysis was carried out to explore the number of oncology, orphan, and infectious diseases drugs approved by the EMA and the HAS

CONCLUSION

Between the first 6 months of 2019 and 2020, the number of HTA decisions in France and in the UK has seen a relevant decrease while assessments by the G-BA has remained stable. The COVID-19 pandemic may have impacted France's and the UK's capacity for drug assessment secondary to ad hoc priority changes in the greater health care system considering that they were impacted more than Germany in terms of mortality and morbidity. The increase in the EMA approvals may indicate the continuous endeavor to allow timely access to safe and efficacious remedies amidst the health crisis.

REFERENCES

EMA. https://www.ema.europa.eu/en

HAS. https://www.has-sante.fr/

G-BA. https://www.g-ba.de/

NICE. https://www.nice.org.uk/