Impact of COVID-19 pandemic on HTA

The impact of the COVID-19 pandemic on health technology assessment (HTA) is discussed by Paula Lorgelly, University College of London, and Amanda Adler, University of Oxford, in a commentary published in *Applied Health Economics and Health Policy*.

The impact of the pandemic on health systems and economies has led to a suspension of most clinical trials and research that are not directly related to COVID-19. Guidance has been issued to study sponsors by both the US FDA and the European Medicines Agency (EMA) to ensure patient safety and preserve data integrity if protocol deviations are required. However, the "implications of this situation includes missing real treatment effects for underpowered studies, or erroneously declaring a treatment effective based on a surrogate endpoint". Additional impacts of COVID-19 on research and development arise from the lockdown measures implemented in many areas, as well as prioritisation of COVID-19 research by pharmaceutical and medical technology companies, which means that "[d]elays this year in discoveries and initial experiments may not be evident until a decade later given the length of time to get innovations to market".

Lorgelly and Adler noted that regulators and HTA committees will need to adjust to working remotely, including considerations of being quorate; the need for secure video platforms; under-resourcing due to many members being health professionals; and a potential reduction in patient participation due to technological or medical challenges. Non-essential meetings in April 2020 were cancelled or postponed by the US FDA, whilst the EMA moved to a virtual format for this time, with enforcement of the Medical Device Regulation (European Union) 2017/745 postponed from its planned date of 26 May 2020 due to resourcing and prioritisation considerations. In the UK, rapid guidance and evidence summaries related to COVID-19 have been produced by the National Institute for Health and Care Excellence (NICE), with free scientific fast-track advice offered for companies responding to the pandemic, and only therapeutically critical or COVID-19 related guidance and guidelines being published. On issue of HTA for COVID-19 therapies, the authors cautioned that fast-tracking of these therapies through a HTA process may undermine the cost and clinical effectiveness of approved treatments, and raised the issue of whether usual cost-effectiveness thresholds would be applied in these assessments as "perhaps the middle of a pandemic is not the best time to debate the value of life".

In returning to a "new normal", the authors commented that "[a] well-functioning HTA system . . . will be critical" but it is not clear whether HTA agencies will face government-imposed budget constraints, which could result in lower thresholds of cost effectiveness. Lorgelly and Adler commented that HTA may need to focus on "technology management" rather than "technology adoption" and "evaluate divesting in inefficient services or low-value healthcare". HTA agencies may become more risk adverse in response to financial uncertainty and the potential that disruptions in clinical trials resulted in a more uncertain evidence base. This may lead to a heavier reliance on approaches such as risk sharing arrangements or managed access schemes, possibly accompanied by pricing innovations such as outcome-based payments. They concluded that "[o]ur healthcare systems are changing rapidly, and our means of undertaking assessments of value will also need to change. HTA is not immune to COVID-19, but it can and will adapt".

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