Patient and citizen engagement, and deliberative processes in COVID-19 vaccine assessment

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Examining the health technology assessment (HTA) landscape in Europe and globally, the limited involvement of HTA bodies in vaccine assessment becomes evident. To a large extent this is because of the role the National Immunization Technical Advisory Groups in providing recommendations for vaccines and immunisation. The role of patients and citizens, given the fact they are important stakeholders in HTA, is well acknowledged, but their involvement remains limited. Issues on how vaccines are developed, including the lack of patient-reported outcomes (PROs) in vaccine research and development, prevent the clearer benefit/risk information to reduce uncertainty. Given the fast-paced approach in comparison to traditional trials and the high level of uncertainty for different population groups, a comprehensive risk communication strategy, is key both for evidence-informed deliberative processes, as well as to ensure the success of vaccination programmes with the best possible outcomes and to overcome vaccine hesitancy. The impact of vaccination or non vaccination extends to families, communities and also has potential psychological consequences of alternative non-vaccine interventions such as lockdowns. Inclusion of such broader impacts may alter both acceptance and willingness-to-pay thresholds for COVID-19 vaccines. Given the lack of a specific legal framework to allow interaction between patients and other stakeholders at both institutional and individual levels, with respect to GDPR, it is vital to ensure interaction and engagement. In a democratic society, it is also important to assure general engagement that will be inclusive and transparent, without exclusion of vulnerable societal groups, that can only be assured by means of communication of scientific advice and regulatory decisions in a language accessible to all, with readily understood terms.