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Issue/problem:

Italy was one of the four European countries that started to join forces to accelerate access and distribution of a muchneeded vaccine against COVID-19. When the first vaccine was approved, a National Strategic Plan for COVID-19 vaccination, examining the most relevant domains for Health Technology Assessment (HTA), has just been issued in Italy. **Description of the problem:**

Considering the possible provision of COVID-19 vaccines in the short time, in Autumn 2020 the necessity for a comprehensive assessment came up. In Italy HTA has been identified as the method for assessing the broad value of existing and new vaccines by the last two National Immunization Plans. However, the pandemic highlighted the need for a quick introduction and distribution of COVID-19 vaccines. A multidisciplinary Steering Group was therefore appointed by the Ministry of Health, in order to define vaccination strategies, organizational models, economic aspects, communication and social issues.

Results:

Taking into account plans already released by other countries, a National Strategic Plan for COVID-19 vaccination was issued in December 2020. Main topics covered were: epidemiology and priority groups to be immunized, logistic and organization, efficacy and safety monitoring, economic and burden of disease assessments, communication. The application of these recommendations has finally proven to be difficult, because of vaccines procurement delays, suspected adverse events, inequalities in the different Regional settings.

Lessons:

Given the concerns and difficulties faced by Italy and other European countries in the appraisal and management of COVID-19 vaccines, a HTA adapted framework could be an option for guiding the definition of National Strategic Plans. This could offer a common structured approach, make decision-making process more transparent, and be significant for a timely, convenient, and affordable access to new vaccines against SARS-CoV-2.

The role of HTA in COVID-19 vaccination campaign: the Italian experience Chiara Cadeddu

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