

VACCINATION PLANNING IN ITALY: INCREASING VACCINES WHILE REDUCING COVERAGE?

Vaccination protects both individuals and the community, reducing the risk of transmission and circulation of pathogens and thus preventing many diseases. Although vaccines may be potentially very cost-effective, the most recent are very expensive indeed [1].

Italy has a strong tradition in public health and vaccination planning, although the regionalization of the Italian National Health Service led to a decade of planning blight [2]. However a national vaccine plan (NVP) was approved in 2012 [3] and the new agreement (for the period 2016-2018) is awaiting final approval from the Ministry of Treasury [4].

Unexpectedly, the forthcoming NVP raised a fierce debate among Italian experts [5]. In an attempt to assess critically whether this debate was justified, we consider the main contents of the document and discuss its potential implications, mainly from an economic perspective.

The new NVP

In line with the (much shorter) previous plan, the general objective of the new NVP is the harmonization of regional vaccination strategies across Italy. Then, in the light of the generalized decreasing coverage for 'historical' vaccinations and the increasing risk factors due to immigration, several specific goals are stated, such as the preservation of polio-free status and the elimination of measles and rubella.

The new NVP reaffirms the paradigm of health technology assessment (HTA) as the most suitable and transparent approach for decision makers to inform the introduction of new vaccinations. The main novelty is the inclusion of five new vaccination cycles in the national calendar: rotavirus, meningococcal B and HPV male extension, for youth population; anti-pneumococcal (PCV13 followed by PPV23) and anti-*herpes zoster* vaccines, for older adults.

Intermediate vaccination targets aiming for the 'gold standard' of 95% coverage for each vaccination schedule are set, and as yet unspecified sanctions are envisaged for regions that do not achieve them. The yearly cost of vaccines at full coverage is estimated at €620 million (3.4% of total public pharmaceutical expenditure).

Policy Implications

The forthcoming NVP includes some elements of novelty, although with arguably scant evidence to support the most important innovations. HTA is still claimed to be a crucial tool for supporting the introduction of a new treatment, however there is no sign of it to justify the inclusion of the five new vaccinations. In particular, an epidemiological evaluation of the burden of preventable diseases in Italy would have been very useful to support the most controversial new vaccines, i.e. rotavirus for infants and *herpes zoster* for elderly people. We may have expected that the decreasing coverage for traditional vaccinations in infants would have led to reverse this trend as an urgent priority before

adding two further vaccination programmes for older adults. Investment in national computerized information registries would have been welcomed by all experts, since their piecemeal and uneven regional distribution is a well recognized obstacle to monitoring national coverage rates accurately [6], as the NVP acknowledges itself.

Focusing on the economic implications of new vaccinations, the NVP foresees a doubling of vaccine spending according to the current prices in the (unlikely) situation of ideal coverage for all vaccinations. However, this forecast does not address the potential for price reductions as a result of competitive regional tenders [7]. As recently underlined by the national Antitrust Authority (*Autorità Garante della Concorrenza e del Mercato, AGCM*) [8], potential competition may be exploited further for traditional vaccinations, owing to new multivalent vaccines being marketed (two hexavalent for diphtheria-hepatitisB-pertussis-polio-tetanus-*haemophilus influenza b* and two quadrivalent for measles-rubella-parotitis-varicella), for HPV and PCV vaccinations, although with very uneven results for the two last ones so far - impressive for HPV [9] and negligible for PCV [2]. While the male extension for HPV could contribute to a further decrease of the prices awarded in regional tenders (€28.60 per dose [10] the lowest at present), the combined schedule of PCV13 and PPV23 foreseen for the extension of pneumococcal vaccination to older adults will preclude any kind of price competition in practice, although the difference between the two vaccines is less relevant for this target population [11,12]. There is little potential competition for *herpes zoster* and meningococcal vaccines, since only one manufacturer markets them, while two vaccines are available against rotavirus.

Comment

Public health experts are expected to advise decision makers on whether to adopt new public health interventions such as vaccinations. However, their advice should be strongly evidence based, particularly in the context of requests for universal coverage. When the advice is encouraging, a second question that health authorities should address is whether the vaccination is economically worthwhile. Even though vaccination is generally perceived as a cost-effective strategy, a thorough systematic assessment of the new costly vaccines is a priority in this period of economic difficulties and limited public expenditure. Rather than seeking support in simulated economic models, a more appropriate economic approach to make vaccines that have adequate evidence of effectiveness more sustainable may be to recur to competitive tenders whenever at least two vaccines are available as alternatives and choose the cheapest [7]. If health authorities do not consider these vaccines fully equivalent, a 'quality score' could be added in tender clauses so as not to consider only the best price offered. Since any manufacturer tries to stress the difference between its product and the 'competitor', the crucial issue is where to 'draw the line' of substantial equivalence between similar vaccines for tendering.

To conclude, we contend that health authorities striving to achieve sustainable prices through competitive tendering are very likely to sustain an acceptable cost-effectiveness ratio. Although this

strategy may not always maximize individual efficacy in the short term, we believe it will warrant the economic sustainability of vaccinations for society in the long run. If competition between vaccine manufacturers were exploited to the full, there may be also less scope for ‘outcries for conflicts of interest’ among experts [5], which can undermine the credibility of vaccinations among the public when amplified in the mass media.

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