On December 1st 2014 the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) of the EU adopted the Council Conclusions on “Vaccinations as an effective tool in public health,” a crucial step to strengthen EU action supporting Member States (MS) to implement effective immunization policies and programs. As a contribution to the ongoing pan-European discussion and to the Italian commitment to stay at the forefront of promoting vaccination policies, the Erice Declaration was drafted by Italy’s best experts in the field of immunization to transpose to the national level the goals set by the EPSCO Conclusions. The aim of the current letter is to present to the broader international audience the Italian perspective as a case study to assess different immunization policy models, challenges and priorities.

Main text

On December 1st 2014 the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) of the EU adopted the Council Conclusions on “Vaccinations as an effective tool in public health.”1 The adopted Conclusions are a milestone in the EU political agenda for public health and represent a crucial step to strengthen EU action supporting Member States (MS) to implement effective immunization policies and programs. Importantly, the Council of the EU recognizes immunization programs as key prevention tools to reduce the burden of infectious diseases and control related morbidity, mortality and healthcare costs.1

The EPSCO prompts the European Commission (EC) to ensure that sufficient EU funding is channeled to foster vaccine research. Furthermore, the EPSCO l invites the EC to make the technical and scientific expertise of the Union agencies more accessible to MS and to facilitate their collaboration with the European Center for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the World Health Organization (WHO).1 While the EPSCO l fully acknowledges the MS’s competence to organize and deliver national healthcare services, including immunization programmes, MSs are strongly encouraged to cooperate, collaborate and exchange good practices and experiences on vaccination programmes.

Along the same lines, the WHO European Region Vaccine Action Plan 2015–2020 (EVAP2- approved by MSs and the European Technical Advisory Group of Experts on Immunization and adopted at the 64th session of the Regional Committee for Europe in September 2014 - defines immunization priority action areas and targets while taking into account country-specific needs and challenges.

Both the Council Conclusions and the WHO-EVAP 2015–2020 were adopted during the Italian Presidency of the European Union (EU). In the 6 months of the EU Presidency, the Italian Ministry of Health engaged in a number of key initiatives aimed at promoting immunization strategies at the international and European level. In September 2014 Italy was appointed by the Global Health security Agenda (GHSA) to lead the GHSA Immunization Action Package for the next 5 years.3 The GHSA is an initiative coordinated by the United States, with the involvement of 40 countries, institutions and specialized agencies such as the EU, the WHO, the United Nations Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE) with the aim to accelerate progress toward a world safe and secure from infectious disease threats.3 In this context, the Italian Ministry of
Health organized in November 2014 in Rome the high-level ‘The state of health of vaccination’ Conference where key speakers from
the US, EU and Italian institutions, public and private stakeholders, the academia and the civil society were brought together to
jointly define a vision for future actions to normalize prevention in societal and healthcare practice, securing the role of vaccination as
part of it.3

As a contribution to the ongoing pan-European discussion and to the Italian commitment to stay at the forefront of promoting
vaccination policies, the Erice Declaration was drafted by Italy’s best experts in the field of immunization to transpose to the national
level the goals set by the EPSCO Conclusions, the WHO-EVAP 2015–2020, the Global Health Security Agenda and the other
above-described initiatives. A further objective of this endeavor was to nail down those principles into country-specific measures.

The Erice Declaration arose out of an intensive residential – non sponsored – 4-day workshop on the priorities and challenges of
the Italian immunization system. Fully endorsing the EPSCO indication to MSs to share experiences and best practices, we aim to
present to the broader international audience the Italian perspective as a case study to assess different immunization policy models,
challenges and priorities. As demonstrated with the publication of issue 11, volume 1 of Human Vaccines & Immunotherapeutics, a
consistent body of research work on immunization and immunotherapy is currently ongoing in Italy.3 Following the European Union
guidelines to MS to equip health professionals with better immunology vaccinology and public health knowledge via better training,3
the workshop was organized in Erice - Sicily by the International School of Epidemiology and Preventive Medicine “Giuseppe
d’Alessandro” in collaboration with the Italian Society of Public Health Faculty included representatives of the World Health Organiza-
tion, the ECDC, the Italian Ministry of Health and its technical agency (Italian Institute of Health), the Italian Society of Public
Health, and the academia. Relevant contributions came also from the regional health authorities and local public health units directly
involved in the implementation of immunization programs. During the workshop, participants engaged in enriching debates and dis-
cussions on vaccination strategies, immunization schedules and programmes, current challenges and possible ways to overcome them.

The Erice Declaration summarizes the workshop’s conclusions; it has been endorsed by all participants and circulated to key stake-
holders in Italy and Europe.

1. Immunization programmes should be designed, implemented and regularly updated on the basis of the most recent scientific evi-
dence available. They should be adequately funded at national and regional level so as to ensure equity in access to vaccination
and quality supply. This is in line with the goals set in the WHO-EVAP 2015–2020 that stresses the importance of evidence-
based immunization policies in further improving good governance of immunization programmes2 and as integral parts of well-
functioning health systems.1

2. It is of fundamental importance to re-establish a National Immunization Technical Advisory Group (NITAG), existing in most
EU countries,6,8 to support policy decision making. Scientific societies active in the field of human immunization should be
involved in the process. The NITAG would be composed by recognized experts to provide policy and strategy guidance to
national immunization programmes and would participate in a European platform- envisaged by the WHO-EVAP 2015–2020 -
to exchange information, best practices and tools between other countries’ NITAGs.2

3. In the context of on-going epidemiologic transition and changing demographic structure, there must be a greater focus on a ‘life-
course’ approach to vaccination. Immunization schedules should include vaccines targeting children, adolescents, adults and the
elderly. As the share of elder subjects is increasing, with more severe and frequent infections and a declined immune function,9
vaccination of the adult population should be a key component of a healthy aging strategy.10 The new Italian National Immuniza-
tion Prevention Plan should consider the growing body of evidence on the positive impact that this approach have on outcomes
such as morbidity, mortality and quality of life.

4. The introduction of new vaccines needs to follow transparent criteria of efficacy, safety, economic sustainability and public health
prioritization. As WHO-EVAP 2015–2020 and the Council Conclusions stress the need of making evidence-based decisions on the
introduction of new vaccines,1,2 efforts should be put in defining a framework of evidence-based criteria to guide decision
making. In such context, Health Technology Assessment (HTA) is identified as a valuable tool.11

5. Accreditation of immunization services should be prioritized where not already in place. In particular, immunization services
should rely on adequate human, technical and organizational resources and should be assessed through a set of quality indicators.
Number, role and activities of healthcare workers including physicians, nurses and healthcare assistants should be defined as per
the accreditation guidelines.12,13

6. Access to vaccination should be enhanced. As there is evidence that subjects – when given the possibility – tend to get vaccinated
off-traditional clinic hours,14 this could be achieved through longer opening hours of the immunization centers (including late
evenings and weekends), more efficient booking systems and availability of flexible and trained staff;

7. Primary care physicians and pediatricians should be more actively involved and be given greater responsibilities in increasing vac-
cination coverage rates. Incentives to primary care physicians and pediatricians, when deemed strategic,15 should be conditional
to population-level coverage targets rather than to the number of vaccines administered;

8. It is of fundamental importance to address the growing phenomenon of the ‘vaccine hesitancy’.16 This should be achieved through:
effective tailor-made communication campaigns, school entry vaccination requirements, compulsory and recorded
informed dissent, moral suasion by health professionals and other forms of incentives;
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