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Letter to the Editor: The future of immunization policies in Italy and in the European Union: The declaration of Erice

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On December 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 polices, 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 (EVAP[2]- 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

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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.[4]

As a contribution to the ongoing pan-European discussion and to the Italian commitment to stay at the forefront of promoting vaccination polices, 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.[5] Following the European Union guidelines to MS to equip health professionals with better immunology vaccinology and public health knowledge via better training,[1] 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 Organization, 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 discussions 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 stakeholders in Italy and Europe.

1. Immunization programmes should be designed, implemented and regularly updated on the basis of the most recent scientific evidence 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 programmes[2] 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 Immunization 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 vaccination 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 administrated;
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;

9. Effective communication strategies should be carefully identified, planned and implemented with the aim of educating the general public on the benefits of vaccination. In line with that, dedicated resources should be used to train healthcare professionals on risk communication, so as to maximize their role in informed decision making;[17]
10. The growing role of Information and Communication Technologies (ICT) technologies and 'new media' should be leveraged by institutions and the public health community to increase vaccine uptake and ultimately immunization coverage rates.[18] Innovative tools of proven effectiveness, which need to be widely implemented, include: immunization information systems, computerized reminders for providers and electronic remind/recall systems for parents and patients;
11. Efforts should be devoted to the development of wider partnerships between stakeholders involved in the various phases of the immunization process, of enhanced joint efforts and of strengthened cross-program links between health services;
12. As healthcare providers' knowledge and attitudes toward vaccines are identified as crucial components of effective immunization programmes, further resources should be invested in in-service training and continuous education of healthcare professionals;
13. Monitoring of updated and complete data is of fundamental importance to plan, implement and evaluate immunization programs. Additional steps are still needed to improve and harmonize immunization information systems across regions as well as to strengthen national surveillance systems;
14. The potential extension of a non-compulsory vaccination scheme to other Italian regions than Veneto (where already in place) should be envisaged, though only further to an in-depth assessment of the political, cultural and social factors involved.[19] The suspension of compulsory vaccination requires detailed planning of the scientific, administrative, educational and communication processes as well as strict monitoring and evaluation of immunization coverage rates once introduced;
15. Research should be encouraged and further funded (through e.g. European Union and National funding) to support partnership-based research projects aimed at assessing the effectiveness of vaccination programmes in different setting and population targets. In this context, the decision of the Italian National Center for Disease Prevention and Control (CCM) to list research in the field of communicable diseases and immunization as one the 3 priority funding areas of the new annual activities' plan was well received.[20]

The Conclusions of the Employment, Social Policy, Health and Consumer Affairs Council of the European Union have identified vaccinations as a key tool of public health in Europe; they call on Member States and other stakeholders including scientific societies, health professionals' organisations and academia to take action to tackle challenges in immunization polices across Europe. The Declaration of Erice - as an enriching input from the scientific and public health community - identifies actions that should be prioritized at the national level. The recommendations from the European Union combined with national scientific input such as the Declaration of Erice should inform European vaccination polices in the near future. Those polices should be aimed at harmonizing universal coverage across Europe as well as targeting, designing and implementing setting-specific immunization programmes.

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