

Workshop on Joint Procurement of Medical Countermeasures (MCM) and a High-Level Hearing on the Implementation of the Council Recommendation on Seasonal Influenza Vaccination

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Lale Ozisik, MD
Hacettepe University Faculty of Medicine
Department of Internal Medicine
Ankara, TURKEY

EFIM Adult Vaccination Working Group

As you know, I have attended the workshop on the joint procurement of medical countermeasures/ High-level hearing on the implementation of the Council Recommendation on seasonal influenza vaccination as a representative of ADVICE group in the name of EFIM. Here is a brief report of the meeting and some remarks that I would like to share with you.

The workshop on the joint procurement was especially about on new developments in pandemic vaccine production and research.

John F Ryan, acting Director Directorate C- Public health, Directorate General for Health and Food Safety, European Commission (EC), reported that the European parliament in its resolution of March 2011 and the Council in its conclusions of September 2010 stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases e. g. by obtaining advantageous prices and order flexibility with regard to a given product. With regard to pandemic vaccines, the context of limited production capacities at global level, such a procedure would be undertaken with the aim of enabling more equitable access to vaccines for the Member States involved, to help them to better meet the vaccination needs to their citizens, in the line with vaccination policies in the Member States. They give the definition of medical

countermeasures and examples as vaccines, other categories of treatments irrespective of classification, diagnostic kits and protective equipment.

Dr. Cornelius Schmaltz Deputy Head of Unit E.3, from the EC that European Union (EU) presented the innovations in vaccine research/production/administration with a particular attention to progresses made that could affect vaccines against pandemic influenza. He stated that Horizon 2020 is a funding for research and he gave some examples of projects in H2020: I-MOVE+, TBVAC2020, EMI-TB. I-MOVE+ is scientific public health platform designing studies to measure the effectiveness and the impact of influenza and pneumococcal vaccines against clinical and laboratory confirmed outcomes in the elderly population and making cost analysis in 13 countries for influenza and in 6 countries for pneumococcal diseases. He said that there is 2 ongoing Tb vaccine research project in H2020: TBVAC2020 in which they are advancing novel and promising Tb vaccine candidates from discovery to preclinical and early clinical development and EMI-TB in which they are eliciting mucosal immunity in tuberculosis. Dr. Cornelius Schmaltz also emphasized that The Innovative Medicines Initiative's (IMI) research agenda included vaccines and announced for future IMI calls.

Another issue was marketing authorization procedures for pandemic vaccines.

Agnes Mathieu, SANTA D5, from the EC reported that the authorization procedure was taking 210 days and that in case of major interest from the public health's point of view, period of scientific assessment could be reduced to 150 days (accelerated assessment procedure). That would be the pathway for pandemic vaccines.

Representatives of European Medicines Agency (EMA) reported that mock up vaccines were better for pandemics than emergency procedures. The other issues that were discussed by representatives were packaging, labeling and liability issues.

On the second day, there was the High-level hearing on the implementation of the Council Recommendation on seasonal influenza vaccination in which ideas to improve vaccination coverage rates were shared.

Martin Seychell, Deputy Director General for Health made a keynote speech about the benefits and challenges of seasonal influenza vaccination. He reported that they are bringing back vaccination on health agenda and seasonal epidemics of influenza is still important in the means of mortality, morbidity, healthcare costs and productivity loss (work absenteeism). He reported that in the last season it's reported that 5-10 % of the adults and 20-30 % of the children got flu and most of them due to Influenza H3N2. He reported that vaccination reduces hospitalizations and healthcare costs. Especially it reduces hospitalizations in diabetic patients. He reported that EU encouraged adopting to implement action plan and policies. He said that in January 2014 it is reported that only two countries have reached to the target coverage rates. He concluded that monitoring of coverage rates and encouraging healthcare workers to advocate are very important.

Pasi Penttinen from European Centre for Disease Prevention and Control (ECDC), gave a brief overview on national immunization programs in the EU- covering influenza and reported an update on the latest Vaccine European New Integrated Collaboration Effort (VENICE III) project on seasonal influenza vaccination.

He stated that, very recently Kare Molbaek and the EuroMoMo network highlighted in Eurosurveillance that the excess winter mortality in Europe had reached very high levels. Mortality in older population was about 40000 between 43rd week of 2014 and 3rd week of 2015. Over 90 000 excess winter deaths were recorded in 17 European countries. It is tempting to postulate that this excess mortality is due to the drifted AH3N2 subtype and the corresponding lack of vaccine effectiveness this season. Effectiveness was low not only against H3N2, but also against H1N1 and only slightly better against B-Viruses. When we look at the 9th week of 2015, in adults older than 60 years old for Influenza AH1N1 it was in negative values, for Influenza AH3N2 it was 29 % and for Influenza B it was 51 %. The only really positive signal was the good effectiveness against H1N1 among children. So one could argue that the severe impact of influenza during the past season is due to suboptimal vaccine effectiveness. However, we should keep in mind that such an effect is to be expected

only if the vaccines are used routinely in the first place. He also presented the situation in European countries.

He gave information about latest vaccination recommendations: In December 2009 European Council of ministers recommended to achieve 75% vaccination coverage by influenza season 2014-15 in older age groups (often defined as those aged 65 and over), those with chronic medical conditions; To protect vulnerable individuals and reduce transmission vaccine also is recommended to improve vaccination coverage in health care workers (HCWs).

WHO in 2012 recommended vaccination of pregnant women, children aged <5 years, elderly (older age groups), individuals with chronic medical conditions and HCWs. WHO position paper SAGE (Strategic Advisory Group of Experts on immunization) Chronic medical conditions include those with chronic cardiovascular, respiratory, renal and hepatic diseases, diabetes mellitus, immunosuppression due to disease or treatment, obesity, children and teenagers on long-term aspirin therapy and individuals older than 65 years.

He reported that; the ECDC supported VENICE surveys that have been identified as being the most effective way to monitor implementation of the EC recommendation as several surveys were already conducted before Council Recommendation was issued. From 2008 VENICE has conducted annual surveys to follow up changes and to identify compliance with the European Commission recommendation to achieve the European Union (EU) goal of 75% vaccination coverage in older age and risk groups by 2014-15.

Then he gave some important results of the survey:

All countries recommend vaccination of the older age groups; however the age specified differs between countries. Twenty-two member states recommend seasonal influenza vaccination for individuals 65 years and older. Vaccine is recommended for those aged 60 years and older in four members; in Malta and Poland vaccine is recommended for those aged over 55 years; In Ireland vaccine is recommended for

those over 50 years. Slovakia recommends seasonal influenza vaccination for those aged 59 years and over. There were no significant changes in vaccination recommendation for older age groups, children and adolescents across countries in comparison to previous 2011-12 influenza season.

All countries recommend seasonal influenza vaccine for those with chronic medical conditions (Respiratory (pulmonary) disease, cardiovascular disease, renal disease, immunosuppression due to disease or treatment, hepatic diseases hematologic /metabolic disorders, HIV/AIDS, children on long-term aspirin therapy, morbid obesity). The changes in recommendations were seen for morbid obesity and hepatic diseases. Seasonal influenza vaccine was recommended for those with morbid obesity in 15 countries in 2012-13. Such recommendation in influenza season 2011-12 had 10 countries. In addition, hepatic diseases were added to the list of clinical risk conditions in four countries.

7 EU/EEA countries reported seasonal influenza vaccination coverage rates among those with chronic medical conditions. The vaccination coverage (VC) rates varied from 28% in Portugal to 80.2% in UK-Northern Ireland (median 50%) in 2012-13 season. EU target for 2014-15 achieved or almost achieved in Northern Ireland and Netherlands. The highest reported VC rates were in Netherlands, Northern Ireland, Scotland and England that achieved or almost achieved EU target in 2012-13.

27 countries recommended seasonal influenza vaccine for pregnant women in 2012-13: 25 of them to all pregnant women; 2 of them only for those with chronic medical condition; 9 countries recommended seasonal influenza vaccine in the 2nd and 3rd trimester; 18 countries recommended vaccine at any pregnancy trimester. Number of countries that recommend seasonal influenza vaccine for pregnant women increased over time if we compare 2008-09 and 2012-13 (from 10 to 27 countries). Only six Member States (including all countries of UK) monitor vaccination coverage among them. Three countries (Ireland, Hungary Lithuania) provided vaccination coverage data for first time for 2012-13 influenza season in comparison to previous season. Vaccination coverage varied between countries with range from 0.2% in Lithuania to

64.6% in UK- Northern Ireland (median 16%) and is low in all countries except UK. (Median 16%).

29 countries recommended seasonal influenza vaccine for HCWs in 2012-13; however only 15 were able to report vaccination coverage results for this specific group. The reported vaccination coverage varied from lowest of 9.5% in Poland to the highest 45.6% in UK-England in 2012-13 (median 28%).

In conclusion, results of their surveys indicate that recommendations for influenza vaccination exist in most of the countries for the main clinical and occupational risk groups in addition to the elderly. The recommendations comply with EC and WHO recommendations and implementation varies across countries. Additionally, large discrepancies between recommendations and vaccination coverage monitoring exist for clinical risk groups, pregnant women and HCWs.

Implementation of seasonal influenza immunization programme in the MS.

Joost Timmermans, from the National Institute for Public Health and the Environment, explained the vaccination practice of The Netherlands. He gave information about the organization that; with the ministry of health decision, the health council prepares the recommendations. Committee National Programme Influenza Prevention was responsible for implementation. He reported that direct communication with the target groups is important for the successful coverage rates. Target groups provide information enabling receivers to make a balanced choice with respect to the provided free vaccination. Professionals (GP, assistants, HCWs) are empowered and facilitated to inform the target group. Much info is communicated, via a special website designed for this programme, including e-learning for professionals covering a lot of topics.

The reported reasons for the declining trend were:

- Negative publicity, press/TV questioning the efficacy of vaccine

- Age 60-65 year was added recently and quite few of them don't think that they are at high risk
- Part of the persons at age 60-65 year got their vaccine at work and these vaccinations doesn't included in the monitor
- Pandemic 2009; still negative feelings related to the high purchase levels of pandemic vaccines
- Pandemic 2009; possible side effects (narcolepsy)

The reported reasons for their success were:

- Vaccination free of charge for the target groups
- GP's receive remuneration per vaccination
- Many providers spread over the country
- Majority target groups receive invitation for annual vaccination
- Excellent infrastructure ordering and supply
- Uniform communication campaign
- Central coordination of the Programme

Richard Pebody, from Public Health England (PHE) gave information of the vaccination practice of United Kingdom. He emphasized the importance of making vaccination campaigns, monitoring and reporting of key indicators related to flu, including flu activity, vaccine uptake and vaccine effectiveness. He said that, they were monitoring delivery of programme in real time by web-based surveillance.

The reported reasons for their success were:

- Influenza vaccination was central component of national flu prevention and control programme
- On-going evolution of programme based on best available evidence
- Introduction of universal childhood flu vaccine programme with newly licensed LAIV
- Central organization in delivery and management of programme
- Near real time vaccine uptake and effectiveness monitoring each year

- Pro-active communication as an integral part of the programme

Marc Jit, from PHE, made a presentation on cost-effectiveness of influenza immunization programmes. He mentioned the importance of productivity loss and health related quality of life issues.

Manuela Mura from European Medicines Agency (EMA), gave information about the new EMA guideline for influenza vaccines that is going to be published at the end of 2015. She reported that public consultation was closed in January 2015 and it is currently under revision based on comments received.

Cornelius Remschmidt from Robert Koch Institute, Germany talked about the role of national immunization technical advisory groups (NITAG) in the national immunization policy making process. He reported that NITAG should ideally be independent from the government, eliminate real or apparent personal conflict of interest and minimize pressure from outside interest groups. He stated that NITAG should advise the Ministry or National Program on optimal immunization policies and strategies, vaccine introduction decisions, monitoring immunization program impact. The NITAG should conduct the best possible review of scientific evidence, should provide timely, evidence based recommendations and vaccine policy. He also emphasized the importance of identifying need for additional data or research for evidence based decision and policy making.

Pernille Jorgensen from WHO Europe, made a presentation about tailoring influenza immunization programmes for HCWs. She reported that influenza vaccination uptake among HCWs was very low and the reasons for non-vaccination are complex and multiple. Monitoring of vaccination uptake is lacking. HCWs have higher infection rates than other adults. Transmission to patients and home residents (because they are dedicated people that still work while they are ill and subclinical infections) and lost work days are important issues. Vaccinated HCWs are more likely to offer vaccine to their patients.

WHO started a programme called Tailoring Immunization Programmes (TIP) to increase influenza vaccination and made an application of it in Montenegro, a pilot study for HCWs. And they found out that 1 in 5 HCWs vaccinated against seasonal influenza. Vaccination rates are similar across departments, gender, seniority, education etc. In the study the key component was to diagnose the barriers and motivators. The reported barriers for vaccination were:

- That they think there is no risk
- Acquire immunity through work
- Thinks natural infection derive better immunity
- Vaccine side effects
- Other reasons
- Thinks vaccine is not effective
- Time access issues

The reported incentives for vaccination were:

- Protect self, protect family, protect patients
- Afraid of flu
- Flu in the past
- Serious disease
- Other
- Encouraged by media, by family
- Received by employer
- Received by colleague

WHO is now planning activities to improve vaccination programs, these include publication of TIP FLU for HCWs and Montenegro case study, development of TIP FLU for pregnant women, annual influenza Awareness Campaigns in collaboration with Member States.

