



The State of Health of Vaccination in the EU

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The State of Health Policy of Vaccination in the EU *first part*

Opening remarks: Sergio Pecorelli, AIFA President, Rome

The key objective of this Conference is to bring together representatives of key public and private stakeholders, to discuss the “state of health of vaccination in Europe” today, and jointly define a vision for future actions to normalize prevention in societal and healthcare practice, securing the role of vaccination as part of it.

The concept of immunization is a cultural one and must be understood by both the caregivers and the civil world, including politicians as well as our citizens.

The regulators feel the responsibility of assuring high quality and an adequate quantity of vaccines, with safety and security as the primary goal; of performing the best vaccine vigilance actions; of offering the best possible communication tools; and of promoting vaccination as one of the most important actions for a sustainable health system.

Introduction to health policy promotion and achievements: Beatrice Lorenzin, Italian Minister of Health, Rome

In a recessionary period like the current one, investing in prevention and promotion of an active and healthy lifestyle and in vaccination practices, is not only ethically correct because health is a universally recognized right, but also because it represents an important contribution towards the creation of a more sustainable and productive society.

Given this perspective, it is essential to define programs for the prevention and control of both non-communicable chronic diseases and communicable ones and to implement strategies to disseminate and facilitate vaccination practices and the choice of a correct lifestyle according to the principle of “health in all policies.”

It is highly desirable therefore that, taking into account the scientific evidence of well-established practices and consolidated primary and secondary prevention in addition to therapeutic approaches, the total investment in prevention, presently very low, must increase significantly. We need to impose a radical change in prevention policies which must include a changed attitude towards our lives from the age of primary school on. Health education should become a normal part of our daily lives and must be included in the school curricula.

This is why, together with the Italian Medicines Agency, the Italian Ministry of Health intends to insert this goal into the Agenda of the Semester of the Italian Presidency and, in agreement with the European Union scientific and political positioning, to incorporate the theme of vaccines into the conclusions of the EU Council of December 2014.

The agenda proposes a mechanism shared by the EU Council members of identification of, and fight against, the risk of epidemics due to new and re-emerging diseases that can spread very quickly, as a result of increased global travel and trade.

In this agenda the threats to health arise from at least five sources are identified:

- the emergence and spread of "new" pathogens;
- the globalization of travel and food consumption;
- the rise of drug-resistant pathogens;
- the risk of accidental or intentional release of pathogens from a number of laboratories for research and development that different countries have implemented; and
- the acquisition by terrorists of practices for the development and use of biological agents as weapons.

It is of note that the European Commission has always paid attention to the prevention of infectious diseases, promoting the exchange of good practices and experiences related to vaccination programs between the Member States. The Italian goal is to put together in the term "One Health" the human and the animal approaches to prevention. It is a firm Italian objective to protect both animals and the nutritional chain. In the current geopolitical commitment the need to have a vision of what is happening in North Africa for foot-and-mouth disease should be underlined. The present Italian health policy represents in the Mediterranean area an instrument of peace and an instrument of health prevention. Geopolitics is strongly linked to health system.

Despite the undeniable benefits of routine vaccination programs, we have seen a gradual increase in the number of parents who show concern about the safety of vaccines and the real need to vaccinate their children who are subject to national recommendations.

These parental doubts, fuelled also by pseudoscience or the inadequacy of some health workers, lead to the decision to postpone the administration of vaccinations or even to reject them, exposing children to an unacceptable risk of contracting preventable diseases, which can cause flare-up epidemics, involving other population groups. One example is measles that, first in the UK and then in Italy, had dangerous peaks. In our agenda for the children the level of vaccination is 90% but our goal is 100%.

These and other aspects have been dealt with the "Conclusions on Childhood Vaccination," adopted by the EU Council on June 2011.

In particular, the themes that have been highly stressed are:

- to maintain a high coverage for childhood vaccinations;
- to improve the monitoring of preventable diseases thanks to vaccines;
- to have the means which enable registration at the national level of the vaccinations implemented;
- and to monitor the coverage rate both at the national and European levels.

Although the autonomy of the Member States in the definition of the Vaccination Calendar has been reaffirmed, it underlines the critical importance of shared objectives and methods for the control, elimination or eradication of infectious diseases that can be prevented by vaccines within the European Union. The Ebola case demonstrates the need to find global and comparable solutions.

Among the key actions, several have been highlighted:

- a) free access to vaccines included into the Vaccination Calendar and covered by the National Health Systems with priority given to the most vulnerable population groups;
- b) request for informed dissent to the parents who refuse the vaccines scheduled in childhood and confirmation of the immunization status at entry in pre-school or primary school (in Italy, this action has not been introduced yet);
- c) availability of new and additional opportunities to be vaccinated with the aim of improving accessibility of this relevant preventive mean, for example: Immunization Days or Vaccine Campaigns in the schools, and in wider terms, the simplification of the access to vaccination, by overcoming bureaucratic, social, and cultural barriers. During a recent national congress on Gender Medicine it was proposed to promote the HPV vaccination not only for the girls but also for the boys because of the diffusion mechanisms of the virus between males and females. Moreover studies are showing the link between HPV and male infertility
- d) efficient information campaigns based on logic and innovative strategies to combat the anti-vaccination lobbies; it is important that when parents receive incorrect information we are there to provide comprehensive, convincing, and correct information as a counterbalance, and to help the new medical doctors, e.g. family doctors and pediatricians, to participate effectively in this campaign.

It is necessary to implement a set of actions:

- to affirm the crucial role of the promotion of health and prevention as features of the development and growth of our society and of welfare sustainability, in particular in light of new demographic dynamics and in line with the "One Health" approach;
- to adopt public health approaches that guarantee equity and a reduction of disparities;

- to express the cultural vision in values, objectives, and methods of public health, based on the experience of past national prevention plans (PNP) that consider populations and individuals at the centre of the interventions to achieve the highest possible level of health.
- • to base the interventions needed for prevention, promotion and protection of health on the best and most efficient practices implemented equally across all strata, and these practices must be set up to reduce inequalities;
- to accept and manage the challenge of cost-effectiveness of interventions, of innovation, and of governance;
- to pursue the development of competences of experts, populations, and individuals for an adequate and responsible use of available resources.

In a landscape so complex and full of challenges as Europe, a cross-cutting approach among policy-makers, industries, non-governmental organizations, associations, and academia, is needed; however, it is also critical to integrate health in such diverse areas as education, environment, tax systems, research, social affairs, and foreign affairs to provide coherent answers for all of our citizens, in light of total transparency. Primary and secondary prevention helps people to live longer and healthier; the goal should be matching or reducing as much as possible the distance between life expectancy and healthy life expectancy : this is the objective that the EU should commit itself to achieve.

In order to provide influential and documented information to our citizens, two primary strategies have been identified: first, the monitoring of websites and social networks, to understand the real worries and concerns about vaccinations in the population, and to provide evidence-based answers, accessible and understandable by people without a medical background; secondly, the use (even at the institutional level) of social media as effective tools to spread the right vaccination culture. Another critical aspect is a continued support of the expertise and skills of the healthcare professionals to improve and assure success of the very important dialogue with the citizenry.

It is clear that only through a new alliance between institutions and stakeholders, including scientific societies, and only through a new ethic of communication and relation with the public, will it be possible to ensure that people have access to vaccinations, which are an essential service for public health.

Points to consider and Points to remember in the vaccination state in Europe

The role of vaccines in sustainability of the National Healthcare System: Massimo Scaccabarozzi, Farmindustria President, Rome

Today citizens are becoming more and more informed on health issues, and at the same time dissatisfied with the services provided. In many cases they are flooded by information but paradoxically they risk being very uninformed. That's why it is essential to give them appropriate means to recognize quality and scientifically based information.

A lack of scientific information may generate distrust in health strategies; as a consequence, Europe is experiencing declines in vaccination coverage for preventable diseases along with eroded confidence and lack of trust in the value of vaccines and vaccination, and we all know that, where vaccination coverage is inadequate, diseases return.

We all have the responsibility to reverse this worrying trend and develop targeted and effective communication strategies involving all stakeholders on the value of vaccination, especially those focused on young people who will be the parents of the future when it will be possible to eradicate even more debilitating diseases.

Vaccines are one of the most cost/efficient investments for the National Health Systems (NHS). In a system with limited resources it is not only the amount of the expenditure that determines the state of health of a country, but the way in which it is spent. It is important for the NHS to invest funds in a strategic way, to provide appropriate medical care and improve the quality of life of its patients.

Healthcare systems should be even more focused on disease prevention through vaccinations, because

prevention is a smart investment in terms of individual well-being and the improved efficiency of healthcare systems. For example:

- it reduces the costs arising from diseases and contributes to the sustainability of the National Health Systems and
- it contributes to the growth of the country by decreasing absenteeism at work.

According to both the scientific societies and companies it would be appropriate to commit specific assets and resources to vaccines, as indicated in the Italian Vaccination Calendar, to ensure the achievement of vaccine coverage as requested by the WHO and to allow the introduction of innovative vaccines that may be able to make a real difference in terms of both of public health sustainability and quality of life improvement.

Furthermore secure assets dedicated to vaccines may allow the Italian Regions to plan efficient vaccination policies.

It would be necessary to consider complete vaccination coverage as one of the performance criteria for measuring the success in improving health of the health district General Managers.

The best vaccine in the world has no value if people do not use it. That is why everyone must do his or her part to ensure the success of vaccination policies.

Measles elimination in Europe: will 2015 be a turning point?: Lucia Pastore Celentano, ECDC

Acting Head of Diseases Program VDP, Stockholm

Questions to the European Center for Disease Prevention and Control - ECDC

What is the strategy that could help the European countries in reaching a common approach to measles, mumps, rubella (MMR) vaccination programs? What can be done to help the European countries to increase their efforts toward measles elimination?

Measles is an extremely contagious disease. A person with measles will infect between 12 and 18 people in a non-immune population compared to influenza which infects an average of 1 to 4 people.

The availability of effective and safe vaccines means that measles can be potentially eradicated from the world.

In September 2010, the countries of the WHO European Region unanimously adopted a resolution at the World Health Organization's (WHO) Regional Committee for Europe meeting to renew their commitment and accelerate actions to eliminate measles and rubella from the WHO European Region by 2015. The elimination of measles, understood as the interruption of indigenous measles transmission, is part of the WHO strategic plan for measles and congenital rubella infection in the WHO European Region. In order to stop the spread of the disease, sustained vaccination coverage above 95% with two doses of measles-mumps-rubella (MMR) vaccine is required in all EU Member States, and all imported outbreaks have to be rapidly controlled.

Support Member States in reaching the measles elimination goal in Europe represents one of the main activities of The European Centre for Disease Prevention and Control (ECDC). The EU agency developed a 'Strategy for measles and rubella elimination 2012–2015;' five key areas of intervention were identified: a thorough analysis of the problem, data for action, strengthening of public health capacities, evidence-based communication, and regional and international collaboration.

Although many efforts have been made by the Member States in developing and implementing a national measles action plan, in the last five years Europe has experienced a dramatic resurgence of measles and rubella, and several countries reported large outbreaks (e.g. in 2010 Bulgaria reported more than 24,000 cases with 24 deaths, in 2011 France reported 15,000 cases, in 2012 Romania reported 6,000 cases, in 2013 The Netherlands reported 2,600 cases, and in 2014 Italy reported 1,500 cases).

The reasons behind this resurgence are multiple and complex, but the root cause of the continued measles and rubella transmission in the EU is the sub-optimal uptake of MMR vaccine, leading to an accumulation of susceptible individuals. ECDC estimates that 4.9 million children born between 1998 and 2008 missed the first dose of measles vaccine. The number of children who did not receive a second dose is even higher.

Because measles spreads so easily, MMR vaccination uptake must be very high (i.e. above 95%) to interrupt the transmission of the virus.

Points to consider

Measles is still endemic in many EU countries. The 2014 statistics show that in the last 12-month period (October 2013-September 2014), 4,735 cases of measles were reported in the EU. Eighty-five percent of cases reported in the last 12 months were unvaccinated. Among children aged 1-4 years, the age group targeted by routine childhood vaccination programmes, 77% of cases were unvaccinated.

Infants and children are often believed to be the only age group affected by measles. In reality in the last 10 years, on average 40% of measles cases reported in the EU were above 14 years old. Moreover, in the last year in several EU countries 70% of cases occurred among adolescents and young adults. Very high notification rates were also reported in infants below 1 year of age, too young to be vaccinated.

Nosocomial transmission was also observed in a number of outbreaks in the EU in 2014. Factors that negatively impact on the chances of reaching the elimination goal by 2015 include: perceptions by the general population and healthcare workers that measles is a mild disease; a decline in public confidence in vaccines; the existence of pockets of under-vaccinated populations (e.g. those who have taken an active decision not to vaccinate and those that the national immunization programmes have failed to reach); strained public health budgets, and various health system factors.

Points to remember

Measles can be potentially eradicated from the world because there are very effective vaccines. We need to vaccinate with two doses of vaccine and reach 95% coverage for both doses. Advocacy at the political level and transparent information to public will be expected to: facilitate access to health care; increase financial and human resources for MMR vaccine programmes; increase awareness among healthcare workers; increase catch-up among adolescents; and control of nosocomial transmission.

A strategic ECDC Multi Annual Programme by 2020 will have programmes to monitor vaccinations: to contribute to the 2015 measles and rubella elimination targets by providing technical support to increase vaccine coverage; to identify underserved groups; to help member states to increase vaccination coverage up to recommended levels by providing technical support; and to facilitate the proposal of a life-long vaccination calendar at the EU level, by providing evidence for comparative cost-effectiveness.

Vaccination: prevention and health literacy, a patient's view: Peter Wiessner, EPHA Board Member, Brussels

Questions to European Public Health Activity - EPHA

Which communication approach can, or could, combine the expectations of the many institutions involved in the vaccination issues? What is the on-going evaluation of the vaccine program management by stakeholders in Europe?

The mission of EPHA is to bring together the public health community to provide thought leadership and facilitate change; to build public health capacity to deliver equitable solutions to European public health challenges; and to improve health and reduce health inequalities.

The vision of EPHA is: one Europe with universal good health and well-being, where all have access to a sustainable and high quality health system; one Europe whose policies and practices contribute to health, both within and beyond its borders. The values are equity, sustainability, diversity, solidarity, universality, and good governance.

Points to consider

Vaccinations represent a public health challenge that underlines the relationship between an individual and the population. Structural and environmental barriers to prevention and vaccination can produce health inequalities. Low levels of communication in every situation are the basis of perceptual and behavioural barriers. Low health literacy is associated with reduced use of preventive services and management of chronic conditions, and higher mortality.

Points to remember

Concerns over safety and effectiveness increase a need for a continuous and inclusive dialogue to address common misconceptions, apprehensions, and suspicions. Diverse social and cultural perspectives to ensure the widest possible vaccination coverage must be understood by health professionals.

Improving communications and health literacy can help healthcare providers to enhance childhood vaccination uptake; underline the importance of explaining and emphasising benefits of vaccination by being protected; and focus on the approach of protecting others, rather than focusing on potential side effects of vaccination. The reasons and numbers for health inequalities must be continuously evaluated. Negative or misleading media reports and studies require an immediate and clear response. Viewing health threats emanating from communicable diseases as civil emergencies rather than merely health threats, puts everyone's health at risk.

Veterinary policy on vaccination: Stefano Cinotti, IZS Brescia Director General, Brescia

Questions to the veterinary health world

How many vaccination programs in animals are protecting humans from the same infection? What are the limitations on the development of vaccine protection in animals?

Vaccinations brought about dramatic improvements of livestock health worldwide: foot-and-mouth disease, classical swine fever, rabies, Rinderpest are the major examples of success. Rinderpest has been eradicated as a result of vaccination policies. The most prominent example of a major failure is African swine fever because no effective vaccine has yet been developed.

The following diseases have no vaccines or vaccines have not been successfully used to improve animal health in the EU: no state vaccination campaigns are available for Newcastle disease, rabies, Aujeszky's disease, blue-tongue, brucellosis; only an emergency vaccination program is followed for classical swine fever, Avian influenza, and foot-and-mouth disease; and there is no vaccination at all for bovine spongiform encephalopathy (BSE), African swine fever, and bovine tuberculosis.

Points to consider

From the early 1980's EU health policy impeded state-driven vaccination campaigns preferring to control animal infectious diseases through mass slaughter of infected animals. Such decisions resulted in the destruction of an extremely high number of animals, eliciting protests from the public.

From the early 2000's attention was directed one more time to the use of "emergency vaccination" campaigns because of the introduction of DIVA (Differentiating Infected from Vaccinated Animals) methodology which allowed differentiation between vaccinated and unvaccinated animals.

Points to remember

For ethical, ecological, and economic reasons, it is no longer acceptable to control and eradicate disease outbreaks mainly through the mass slaughter of animals.

Whenever feasible, World Organization for Animal Health (OIE) should formulate vaccination policies as alternatives to the mass slaughter of animals.

As for animal diseases outside international rules and trade agreements, vaccinations on a farm, or regional basis, are still valuable and cost/effective options in the framework of a wider number of disease control measures.

Health & Growth: the industry's contribution to a healthier Europe: Andrea Rappagliosi, Vaccines Europe President, Brussels

Questions to Vaccine Europe

What is the opinion of industry on a coherent vaccination strategy in Europe, such as "prevent the preventable"? Should there be increased cooperation between political decision makers and all vaccine stakeholders?

Recently, the Organisation for Economic Co-operation and Development (OECD) confirmed that in Europe health expenditure in prevention has dramatically decreased in the last few years. The prevention growth rates in real terms, public and total, from 2000 to 2010, have registered a reduction of -3.2% in the period 2010-11. And this negative trend was confirmed in 2012 and 2013 as well.

Points to consider

Reducing funding in prevention and vaccination leads to lower public health standards on one hand and on the other hand increased mortality and morbidity risk exposure for the European citizens of all ages. Using

influenza as an example, only two countries (NL and UK) in Europe met the EU vaccination target coverage rates of 75% for the elderly; however, there is no data on chronic patients and healthcare workers as a result of insufficient monitoring of these key targets. Reaching the 75% target in all the European countries would have a tangible and measurable impact: it would avoid the death every year of between 9,000 to 14,000 people for influenza. The effect of not reaching the 75% target not only demonstrates a disinvestment from the societal perspective, but also would also have an impact on the industry business model (“low incentives - low investment”). Today, we are losing investment, know-how, and talent. We need to learn from what we did right: diphtheria, small pox, and polio are examples of the high impact of vaccinations in the 20th century. Unfortunately, today cases of measles, pertussis, and rubella keep increasing due to the lack of a proper communication campaign on the value of vaccination and the difficulties in addressing vaccination hesitancy. We have progressed in understanding the value of active and healthy aging, but we have yet to capture the full benefit of senior vaccination. The models run in some countries indicate a fiscal savings of >4€ for every 1€ spent on adult vaccination (tangible economic revenues for governments and an opportunity to free resources in other sectors of healthcare).

Points to remember

Investing in prevention is an opportunity to free resources, and vaccination is a smart investment in health, growth, and health system efficiency. Prevention is an investment in people’s health and human capital acting in societal, economic, health systems, and individual areas. It reduces disease burden, and contributes to the sustainability of health systems, keeps seniors healthy, and reduces inequalities. There is a need for appropriate economic modelling capable of capturing the full value of immunisation. Unfortunately the health systems are still built on illness and not health promotion. Immunization should be put at the centre of our public health agenda: vaccines are a key tool for spending smarter and they contribute to freeing resources for medical innovation. We have to set policies to double the investment in immunisation by 2016. To re-set the “True North” in vaccination programs we need stronger interactions and inclusive partnerships with all stakeholders. A new model from R&D to immunization programmes in Europe is needed to secure and to maintain leadership in immunization for the benefit of patients and citizens in Europe.

Fostering good health through EU action to fight vaccine-preventable diseases: John Ryan, DG SANCO Acting Director Public Health, Luxembourg

Questions to DG SANCO

What is the position of the DG SANCO in the development of a European cooperation in the infection diseases management? What is the European position in developing a European vaccination program

Vaccination is a competence of the member states. The Commission supports member states in maintaining or increasing vaccination coverage against a range of vaccine-preventable diseases. Collaboration focuses on diseases with elimination and eradication targets.

Points to consider

Currently, the area of immunization is characterized by a lack of political commitment in several Member States. There is insufficient understanding of the value of immunization, both among healthcare workers and the general public. Inaccurate perception of the safety and effectiveness of vaccines, on the one hand, and underestimated risks of communicable diseases, on the other hand, result in vaccine hesitancy in the general public and insufficient engagement of healthcare workers to advocate vaccination. Furthermore, national immunization programs are insufficiently addressing demographic ageing that is linked to epidemiological shift in the EU population.

Points to remember

Under the Italian Presidency, EU Council conclusions on vaccination as an effective tool in public health will be adopted in December 2014. These Council conclusions provide an opportunity to bring vaccination back on the political agenda and provide a basic element for developing a future EU vaccination policy, addressing all current shortcomings and underlining the need for strengthened collaboration. Strategic objectives and strategies formulated in the WHO Vaccine Action Plan 2015-2020 for the European Region, will focus on strengthening political commitment, increasing the understanding of the value of

immunization services and vaccines, and integrating immunization systems into health systems. A possible future EU vaccination approach is expected to improve the education and training of health care workers, and to enhance the collaboration among Member States with regard to funding, surveillance, and monitoring of immunisation programmes. Electronic immunisation records should be introduced across Europe. A stakeholders consultation in the spring of 2015 will help and guide the ideas of stakeholders and professionals of Member States on European policy in vaccination.

The European regulators' agenda to foster prevention and immunization: Guido Rasi, EMA Executive Director, London

The current clinical requirements for vaccine approval (EMEA/CHMP/VWP/164653/2005) in immunogenicity, efficacy, and safety studies, necessitate special considerations on immune interference, cross-reacting immune responses, lot-to-lot consistency studies, and bridging studies and can only be conducted under the auspices of a Correlate of Protection (CoP).

Points to consider

The concept of immuno-bridging allows the extrapolation of efficacy in a specific population or age group to other age groups or other populations based on comparable immune response.

The proposal is to follow a vaccine's classification in: historical vaccines (such as HBV, measles, polio); recurrent vaccines (such as influenza) with a large media impact and societal responsibilities; and pandemic vaccines, such as Ebola, with even a larger immediate media impact due to the pressures of emotion, expectations, and failures. The agency is committed to provide up-to-date regulatory support to developers via its guidance documents developed mainly by the Vaccine Working Party and via a scientific advice framework, such as in the revision of influenza guidelines, or in the way to employ human challenge studies (such as malaria), or in the revision of the phases of development for new innovative vaccines to encourage optimization and efficiency.

Points to remember

It is critical to assure EU citizens that there is constant vigilance, and that the vaccines we are all using are safe and effective. Effectiveness of vaccines in real life use is relevant as it also measures the herd effect on the population. The Agency understands that there is a need for good collaboration with public health authorities, as industry alone might have problems in conducting such studies.

Safety has to be thoroughly scrutinised since the tolerance for safety issues is particularly low for vaccines. Apart from continuous surveillance, special safety studies to investigate specific potential adverse reactions post authorization (PASS) are expected in many cases. Cases of adverse events happening concomitantly with vaccination will always occur and it is very important to be able to determine the association. Only large studies would be able to assess if a vaccine is causing an increase in certain safety issues. It is important to act rapidly and proactively to avoid loss of public confidence.

There is a need to be constantly aware of the different expectations of political organizations and institutions, local, national and international governments, NGO's and other international entities, as well as the individual because vaccines cannot afford a failure.

Discussion between audience and speakers on what can be done in the future in immunization and vaccination

Paolo Rossi, Delegate Paediatric Committee (PDCO) EMA, London: three questions:

a) *Focus on:* the vaccination of chronic diseases in special populations: what do we know about this general and special growing population? Is there evidence as to how vaccines work and the immunologic end-work of vaccines? Is there currently any kind of research to develop this knowledge?;

b) *European calendar:* we all do need a European calendar and not a combination of different local calendars;

c) *Introduction of immigrants* in various countries: this is a major problem for Italy and other European countries; what can we do for children in combining their rights within the hosting state? Without a solid approach we will see many outbreaks.

Discussion on Paolo Rossi's issues

John Ryan:

a) On chronic diseases there is no mention of vaccination in the policy draft document the Commission has prepared. There is some mechanism in the 20/20 program. It would be good to organize in the Commission a meeting on the topic;

b) On the European calendar, some years ago, it was tried to organize a recommendation on the calendar for children deriving from a common European record of vaccination, and the harmonization of the calendar; it was a presentation in a meeting in Hungary but was refused; in Austria there is a large electronic record for vaccination. Furthermore, there is the necessity to understand where to produce a common vaccine;

c) There was a discussion on migration by the working group on screening of diseases and health issues; but the development of Ebola stopped the discussion; some countries are applying TB screening; Italy has a good acceptance system; the challenge is to check when immigrants are going from Lampedusa to other European sites.

Andrea Rappagliosi: on the European calendar John Ryan explained very well the concepts of subsidiarity and public health. The question is not to have only one European calendar which would be challengeable from a subsidiarity principle standpoint. The real question is how to work together to have a harmonization of calendars linked with the free circulation of people in Europe based on the scientific harmonization already in place in the regulatory assessment of vaccines. The EU Commission and Member States *coalition of the willing* can trigger the necessary reflection on a harmonized assessment of the medical value of vaccines.

Lucia Pastore Celentano: in the last few years we have seen a progressive attempt to harmonize different schedules of vaccinations; we are moving towards an aligned schedule. Also aspects of administration play a role in vaccine harmonization.

Further Discussion

Hildrun Sundseth, President, European Institute of Women's Health Institute on Women Health, Brussels: Congratulations to the Italian Ministry of Health and AIFA for highlighting vaccination during Italy's EU Presidency and including representatives of civil society in such an important discussion. Immunization is one of the most effective public health measures, yet is underused as our society has become vaccination hesitant. Today patients are actively advocating in most chronic disease areas for best treatment and care. Yet when it comes to advocacy for immunization there is a lack of positive communication. This has allowed negative media stories to capture the public mind and the need for immunization to protect people from infections is not high on society's agenda. Our organization, a health NGO, is grateful that the Italian EU Presidency has shown political leadership in putting immunization on the European health agenda. We have a major interest in the prevention of diseases - chronic and infectious. Sometimes the two interact. We feel that is time for Member States to develop a comprehensive European strategy for vaccination across the life-course that includes young and old. By involving civil society organizations and health NGOs we can work together with national health authorities and experts to improve health literacy about vaccination in the general population to make vaccination once more the norm.

Stefania Salmaso, National Health Institute, Rome: Most of the speakers so far have highlighted that the current major issue in promoting vaccination is related to the need of a cultural change in the knowledge and attitude of different population groups, including health staff, whose perceptions often are not dissimilar from that of the general population (as shown by the low vaccination coverage during the last

influenza pandemic). Such issue has to be addressed with an inter-sectorial approach, starting from school education and including the medical community. There is limited knowledge of those scientific studies supporting vaccination outside of the specialized community. Moreover to build up the people's confidence in vaccination offer as a public health effort, promotion of independent studies is very much needed. We need strong public research on this, and unfortunately this is not the case at the moment.

Pamela Logan: (from Ireland, representing the Pharmaceutical Group of the European Union (PGEU) which represents over 400,000 community pharmacists across Europe). In her speech this morning, the Italian Minister of Health said that we must look at new and additional opportunities for vaccination. In 2011, the Irish Minister for Health did just that by introducing legislation to allow pharmacists to supply and administer the seasonal influenza vaccine. In the first season, pharmacists vaccinated 9,000 patients, in the second season they vaccinated 18,000 and last season they vaccinated over 40,000 patients. We collected information from pharmacists about who they vaccinated and we know that last season, 25% of patients vaccinated in pharmacies had never been vaccinated before and, of those, 85% were in an at risk group. This shows the true value of pharmacists being involved in vaccination as pharmacists see their patients with chronic diseases every month. In Europe, only Ireland, Portugal, and the UK currently facilitate pharmacy vaccination. If we are looking for new and additional opportunities for vaccination, the community pharmacy can certainly deliver.

Petra Falb, *Austrian Agency for Health & Food Safety / Federal Office for Safety in Health Care, Vienna:*

- a) Comment to Paolo Rossi: vaccinations for special populations as cancer patients, immuno-compromised people, or pregnant women are indeed a challenging issue. The Medical University in Vienna (Institute for Specific Prophylaxis and Tropical Medicine) established a special vaccination ambulance for these patients and works there in close connection with the respective attending doctors as gynecologists or oncologists.
- b) Considering the issue of growing skepticism regarding vaccines, it could be a good idea to increase transparency regarding the medicines authorities and also the EMA – a big part of the general public is not aware of the important impact of their work and responsibilities.
- c) Comment to Stefano Cinotti's presentation: veterinary vaccination is an important issue regarding health of animals and humans as well. Since vaccinations in emergency situations have been mentioned (e.g. foot-and-mouth disease, blue tongue disease) and also the danger of new diseases emerging in the future, using unapproved products may be an issue of extensive discussions and also may cause some risks. Appropriate working groups of EMA are developing guidance documents and can offer any decision makers, such as ministries for health, a helpful basis for benefit- risk considerations.

Robb Butler, *Vaccine-Preventable Diseases and Immunization, WHO Regional Office-Europe, Copenhagen:* The more we know about vaccination in Europe, the more we understand that while some people do make individual informed choices on vaccination, the majority vaccinate because others in their community vaccinate – they copy the behaviours of others. This social copying makes each and every immunization programme vulnerable to "swings" in public opinion and sentiment. When a large enough group is formed through this copying of behaviour we can see herd immunity is threatened as fewer people are vaccinated and the pocket of susceptibles is enlarged. I would like to stress the importance of a point that Minister of Health Lorenzin made regarding vaccination education in schools and the importance of anchoring the next generations with a positive opinion and perspective on vaccination. I would prompt the Italian Presidency to pursue this further, following the success of tobacco, sexual reproduction health, and alcohol abuse education in the schools and in the classrooms. The second point to be made here concerns the convenience of vaccination. At the WHO regional Office for Europe we talk about complacency, confidence, and convenience (as the 3 Cs) as determining factors affecting vaccine hesitancy. Much has been said about complacency and confidence in vaccines and the services that administer them, but we must also pay due attention to the convenience of getting vaccinated. The vaccination we offer to parents today is not the most convenient one. I would like to stress attention on how we can offer easier means of vaccination, at times and locations that are more appealing and accessible and to the public, and that we go forward and develop and use new technologies that are less evasive and easier to administer.

Conclusion remarks of the first part

Guido Rasi, EMA Executive Director, London:

Important issues have been raised by civil society in terms of advocacy of vaccines; the voice of patients and civil society is the most powerful, and one of the few credible today. Transparency is one of the main values of EMA: the culture is there but it is not yet consulted as a primary source of information. The risk is that we can be perceived as being too close to industry when we approve new innovative medicines. At the same time, we can be seen as overly bureaucratic if we don't approve something highly expected by patients but insufficiently proven with regard to safety and efficacy. Another important note refers to the tradition of independent studies: we hope that Europe can encourage, support, and enjoy this approach for independent research. Most of the questions on regulatory issues are post-marketing regulatory specific questions: they might have quite an easy answer but it is difficult to have them sponsored. Vaccination is not a prescription, as remarked by WHO. It depends on the health environment. We have to learn from the experience and hard work to improve our work.

The State of Health Policy of Vaccination in the EU

second part

Points to consider and Points to remember in the vaccination state in Europe

The case of influenza: implementing the 2009 Council recommendation: John Ryan

Questions to DG SANCO

What European policies will improve vaccination coverage rates for all risk groups? How can the DG SANCO help improve the approach to influenza prevention for the general population?

On the basis of a European Center for Disease Prevention and Control (ECDC) technical report, in January 2014 the Commission issued a progress report on the implementation of the Council recommendations on seasonal influenza vaccination, which aims to support the development of respective vaccination policies in the Member States. Children, chronic CVD patients, pulmonary patients, and people with metabolic disorders represent risk groups, together with pregnant women and older age groups (aged 65 and older). Health workers must also be protected. Education and training represent an open opportunity to interact with the population.

Points to consider

Unfortunately, in the last few years, just two countries reached the target of 75% vaccination coverage; today the coverage is low. The next steps involve encouraging and increasing implementation of effective vaccination policies.

The report revealed a number of shortcomings, such as low perception of disease risk, fear of possible side effects from vaccination, perceived low effectiveness of the influenza vaccine, broader anti-vaccine sentiments, issues of cost, availability, misleading reports in the mainstream media, and a general lack of accurate information about influenza and vaccination. In almost all EU Member States, the vaccination coverage rate for older people does not meet the target of 75%. For all other risk groups, there are limited data available and insufficient monitoring, and the assessment of vaccination coverage rates is thus difficult.

Points to remember

At the Member State level it is suggested that the following to be implemented: strengthen political commitment, strengthen efforts in collecting and monitoring vaccination coverage data, engage with healthcare workers, develop data on the socioeconomic impact of vaccination, and strengthen efforts in evaluating the effectiveness of communication activities. At the EU level it is suggested that lessons learned be shared, guidance developed for program management, coordination of research initiatives be strengthened in order to identify reasons for vaccination refusal and initiatives be strengthened to improve the quality of the seasonal influenza vaccine. In the spring of 2015, the Commission will organize a high-level hearing on the implementation of the Council recommendation with all stakeholders involved to improve vaccination coverage rates for all risk groups. The goal is to discuss findings of the interim report on the implementation of the Council recommendation; to share best practices how to improve vaccination coverage rates; to discuss the added-value of cooperation at EU level; and to identify respective measures to be taken. A more general reflection on the value of vaccination is also proposed as part of this conference.

Surveillance and Immunization Strategies: Robert Linkins, Chief, Accelerated Disease Control and Vaccine Preventable Disease Surveillance Branch, Global Immunization Division, US CDC, Atlanta, GA

Questions on adverse events following immunization

What is the achievable safety goal of a vaccine? What is being done to have a correct surveillance program in a vaccination project?

Comprehensive surveillance is a critical strategy for controlling, preventing, and eliminating vaccine preventable diseases. It is very difficult to compare surveillance data between countries if case definitions and reporting requirements vary. Without accurate data, trends cannot be accurately monitored, unusual occurrences might be missed, and intervention effectiveness cannot be easily evaluated. The experience of the Regional Committee Guidance on Eliminating Measles & Rubella by 2015 offers a basis for evaluation. All regions now have measles elimination goals; the Americas and Europe also have rubella elimination goals. Methods and technologies are described to reach such goals.

Points to consider

Surveillance data are needed to document and monitor the impact of a vaccination program on disease incidence, morbidity and mortality; evaluate vaccine effectiveness under conditions of routine use; and monitor the changes in disease epidemiology. It is very difficult to compare countries in their activities without accurate data: trends cannot be accurately monitored, unusual occurrences might be missed, and intervention effectiveness cannot be easily evaluated. Important data collected during case investigations include demographic information, reporting source, clinical data, laboratory data (serology, virus isolation, genotyping), vaccine history, travel history, and potential source of exposure.

Points to remember

Accurate surveillance information is particularly important for personnel at the local health departments, and also for Ministries of Health in determining potential changes needed to the vaccination program. Activities for enhancing surveillance are supported by: regular training on standardized case definitions and reporting requirements to encourage complete and timely provider reporting, ensuring adequate case investigation including collection of specimens to enable laboratory confirmation, using surveillance performance indicators to monitor performance and make course corrections, and strengthening both paper-based and electronic surveillance infrastructures.

Comments on the presentation of Robert Linkins

From Sergio Pecorelli: 2015 is in two months. I am really worried about this goal for 2015. Do you think it is realistic?

Robert Linkins: the question should be put to my colleagues at WHO/EURO

From Robb Butler: 2015 is around the corner. We are still identifying the target. We are waiting to receive clarification by the Commission. In ten days the Commission will deliberate and discuss what the next step is: there is a block of countries that has eliminated measles. We are not using advocacy messages on what we could. The remaining countries' performance should be revised. There is a matrix to evaluate 8 to 10 countries and the attention should be on those countries. We should be harder in placing more political pressure on the performance of those countries, not just in terms of commitment or in terms of resolution, but also in terms of protecting the budget, as well as building a project. The decision makers of those countries are not in the same department, but in several departments. Our intent is not to attack them, but to construct jointly a solution.

Robert Linkins: the example of polio should be taken into consideration. Many polio eradication targets have been set and missed. Among the important lessons learned from this experience, I believe, is that as long as the virus is circulating anywhere, countries are at risk everywhere. So even when the European Region becomes measles-free, whether by 2015 or not, it will be critical to continue the momentum to eliminate measles globally, and to ensure that the Region maintains high population immunity from two doses of measles-containing vaccine, and that laboratory-based surveillance remains strong.

“Calendario per la vita” Vaccines for adults and children: instructions for physicians and pediatricians: Paolo Bonanni, Director, Post Graduate School in Hygiene and Preventive Medicine, University of Florence, Italy

Questions to Scientific Medical Societies

How can different experts develop vaccines programs that would be successful in the lives of different individuals? Which indicators should be used to determine health and economic returns of such an approach in the life of a single individual?

The “Calendario per la vita” Lifetime Vaccination Calendar is a consolidated approach by national medical societies in Italy (Italian Society of Hygiene, Preventive Medicine and Public Health (SItI), Italian Society of Paediatrics (SIP), Italian Federation of Family Paediatricians (FIMP), and Italian Federation of General Practitioners (FIMMG)), is used in the management of vaccines for adults and children, and contains instructions for physicians and pediatricians. More than 20,000 practitioners are involved in the use of the Calendar. The goal is structured and continuous cooperation among the mentioned societies to help the people throughout their lives, from birth to old age, with a proposed calendar of vaccines to protect their health. Vaccines are “the more important medical discovery in the human history” (WHO). It is clear that investment in the use of vaccines can be improved in Italy. We are happy to stress that, as already mentioned by the Italian Minister in her remarks, Italy has received a commitment from the international community in the field of vaccination strategies. WHO-Euro requests the presence of a National Immunization Technical Advisory Group (NITAG) in every country to make the European Vaccine Action Plan (EVAP) operational and monitored. We do hope that a National Vaccination Commission (discontinued in 2008) will be soon re-instituted in Italy.

Points to consider

There is a need to increase the vaccine culture among health professionals, without any distinction among roles, services, and ages of people, from 0 to 100 years old. The Lifetime Vaccination Calendar is meant to bring together the scientific world and healthcare practitioners (public health, paediatricians, GPs) to propose the best possible and regularly updated immunization schedule, based on the most recent discoveries and scientific evidence. This is not intended to replace public health decision makers but it is important to guide doctors and nurses on what and how to inform the general population about the best available choices for the individual in the interest of public health.

Points to remember

The document represents a commitment of several national societies to support the national, regional, and local institutions, to establish the basis for new deliberations of regional vaccination plans. Healthcare workers (HCWs) who follow the indications of the Lifetime Vaccination Calendar, if found professionally responsible, are only responsible for serious negligence. Such indication represents a further prompt from the scientific societies that, while defining good practices, also provide an effective preventive and judicial support for all professionals involved in the vaccination system.

Keeping fit through vaccination: building the A,B,C’s of a healthy lifestyle – an Italian experience to strengthen cross-sector collaboration: Gaia Pecorelli, Italian Healthy Foundation Initiative, Milan

Questions to Healthy Foundation

What kind of help could be expected from the educational approach towards young people with regard to a vaccination strategy? What kind of commitment could be expected from high schools and universities?

The main objective of the Italian Healthy Foundation is health promotion through training and education on lifestyles, including vaccinations. By including vaccinations in an integrated concept of prevention and lifestyles, as part of the health and welfare of its citizens, this important message can be delivered both to the young and to the adult population. To make vaccination appealing it should be combined with healthy food and a favorable environment.

Points to consider

In public schools, vaccinations were presented as a milestone in the history of public health, their history was explained as a curious and intriguing story that would catch adolescents’ attention, and, going through the vaccination calendar, the concept of the best timing to perform a vaccination was described.

Vaccinations, which should be given to elementary and high school students and should be discussed in the classroom, are: rubella which allows a discussion about the possibility of a virus causing malformations during pregnancy and the HPV vaccine that opens a discussion about sexually transmitted diseases, stressing that this vaccination is not only for girls but for boys as well, thus presenting the concept of universal vaccination.

The influenza vaccination and the population clusters that could highly benefit from it could allow the introduction of concepts like frailty, sarcopenia, and ageing of the population.

Points to remember

The goal of involving young medical doctors is a double-win since the doctors become the educators of the young and the students gain empowerment through their knowledge of health literacy, which is one of the main goals of the European Commission. The project is called 10+ and promotes the commitment of young students in the schools.

The expected results from this approach are increasing interest in and appreciation of a healthy lifestyle, including the important role of vaccinations by both students and young medical doctors; excellent feedback by teachers; an appreciation by the families; and an increase in vaccination rates for influenza and HPV vaccines.

The educational challenge: the role of universities in promoting public health: Stefano Paleari, Rector, University of Bergamo

Prof. Pecorelli discussed the core messages by Stefano Paleari who could not attend the meeting due to unplanned institutional commitments.

Achieving the full potential of vaccination: understanding and addressing barriers to vaccine acceptance: Bruce Gellin, US Deputy Assistant Secretary for Health and Director at National Vaccine Program Office, Washington, DC

Questions to the US Vaccine Program Office

What are the considerations and strategies needed to coordinate the US National Vaccine Plan to ensure that all who can benefit from vaccines receive them, and, more specifically, how are you approaching the issue of vaccine acceptance?

The National Vaccine Plan is the strategy guiding the National Vaccine Program, which was created in 1988 by the Public Health Service Act in the US. The first National Vaccine Plan was issued in 1994, and updated in 2010 to reflect the new opportunities and challenges of the 21st century immunization landscape.

The US National Vaccine Plan has five broad goals:

- develop new and improved vaccines;
- enhance the vaccine safety system;
- support communications to enhance informed vaccine decision-making;
- ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability, and death in the United States; and
- increase global prevention of death and disease through safe and effective vaccination.

The evolution of the recommended childhood immunization schedule tells a story of progress (research and development) and public health impact (<http://www.cdc.gov/vaccines/schedules/past.html>)

In one way, the success of our efforts can be demonstrated by some of the facts. In the US, between 1994 and 2013, more than 322 million cases of infectious diseases have been prevented in children. This was in large part due to the creation and implementation of our Vaccines for Children Program, a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay (<http://www.cdc.gov/vaccines/programs/vfc/index.html>). Yet it is critically important to distinguish vaccine availability and access from vaccine acceptance. The latter is about a behavior (to receive, delay or refuse a vaccine that is otherwise available and offered). Vaccine coverage data may not sufficiently distinguish the reasons why a vaccination did not occur so other data may be necessary to clarify the root cause(s) of low vaccination rates in a community. A closer look at the recommended

schedules shows the increasing number of serious infectious diseases that are now safely and effectively prevented by vaccines, but also a story of complexity (as revealed in the footnotes that accompany the schedule as well as the many detailed guidance documents that are developed by the Centers for Disease Control and Prevention with its Advisory Committee for Immunization Practice (ACIP)) (<http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>).

The science behind vaccine development is complex and with the increased number of vaccines that are routinely recommended there is an ongoing challenge for health care providers to ensure that all get the vaccines they need, as well as all get the information they want to inform their decision about vaccination. With ready access to all sorts of information – some reliable, others not – it is easy to see why some parents and patients have many questions about vaccines. The ability of healthcare providers to knowledgeably answer patients' questions, and address their concerns, with the scientific evidence, has a direct impact on vaccine acceptance. This can go a long way to reinforce the value of vaccines and to improve vaccine acceptance for the benefit of both the vaccine recipient and the larger community.

Points to consider

Vaccines and the vaccination programs in which they are delivered have changed the face of society. But despite their power and their promise, vaccines can only achieve their full impact when they are used. Unlike other medicines, vaccines work at both the individual and community level so their full impact is achieved only when both individual and community immunity is optimized.

Recognizing that there are some who choose to delay or refuse a vaccine that is offered: there is a growing field of research on “vaccine hesitancy” – and it is an issue that has been explored by the World Health Organization's Strategic Advisory Group of Experts (SAGE). In developing a fuller understanding of the many factors that influence vaccine decision making a vaccine hesitancy model has been developed. This model acknowledges that vaccine hesitancy is complex and context specific, varying across time, place, and vaccines, and is influenced by factors such as complacency, convenience, and confidence. The Vaccine Hesitancy Model is based on confidence (trust in vaccines, delivery system, and policy makers), convenience (physical access, geographical access, and appeal of immunization services), complacency (low perceived risks, vaccination not deemed a necessary preventive action). (See also http://www.who.int/immunization/sage/meetings/2014/october/2_tracking_sheet_Oct_2014.pdf).

Points to remember

The availability of affordable vaccines that are safe and effective is a prerequisite for vaccination programs, but at the end of the day, it is the decision about whether to accept a vaccine that is offered, that will determine whether individuals and the communities in which they live are protected from serious infectious diseases.

Understanding and addressing the factors that lead to a decision to accept, not accept, or delay a recommended vaccine, are increasingly important if we are able to continue to protect our communities from serious infectious diseases and their consequences. Routine immunization coverage surveys are not designed to assess vaccine delay or refusal, and therefore cannot be the only measure of vaccine hesitancy in a community. Rather, new tools need to be developed to better assess vaccine hesitancy in order to design and direct more specific remedies. For example, the Guide to Tailoring Immunization Programmes (TIP), developed by the World Health Organization's regional office for Europe, provides an approach to this with tools to identify susceptible populations, determine barriers to vaccination, and implement evidence-based interventions (<http://www.euro.who.int/en/health-topics/communicable-diseases/poliomyelitis/publications/2013/guide-to-tailoring-immunization-programmes>). Beyond this, sharing our collective experiences with addressing vaccine hesitancy will help to better define the nature of the problem and how we are addressing it so that all can benefit from the promise of vaccines.

Michael Sulzner, DG SANCO European Commission, Luxemburg: The Commission is presently working on preliminary proposals for a policy framework for a strategic and lifelong approach to immunization. One of the ideas is to support the cooperation of technical policy advisers who are developing national vaccination programs. This should allow addressing the improvement of national vaccination programmes and strengthening the capacity for carrying out evidence-based and cost-effective vaccinations. In this regard it will be important to develop initiatives to share best practices and exchange information with regard to monitoring the impact of vaccination programmes or developing communication strategies.

Discussion between audience and speakers on what can be done in the future in the immunization and vaccination arenas

Some of the comments made during the Q&A could not be understood.

Andrea Rappagliosi: We heard this morning a strong call from the Italian Minister of Health Ms. Lorenzini on the value of vaccination. Similar statements are echoed by other European Ministries of Health, as Ms Touraine in France. How the Commission plans to take concrete actions in coordinated the effort in developing a European life-long immunization strategy?

Michael Sulzner: We should be aware that vaccination is a competence of the Member States. However, as independent advisory bodies are already in the process of strengthening their cooperation, I would see some added-value in supporting national immunisation advisory groups in their efforts to establish a formal mechanism of working together.

Luca Pani: What could have been done at the national level we have done...we can ask prof Pecorelli...or turn the question to WHO.

Robb Butler: Let me comment on the presentations of the afternoon: very interesting. I have a question to Dr Gellin, very brave of you showing the importation from Europe. Have you contacts tracing the cost stabilization, the indirect/direct costs of the importation, of importation of leading outbreaks. My second question is to Ms Pecorelli: the Healthy Foundation has a very fantastic project. I would like to discuss how you interact with the school system and educational authorities.

Gaia Pecorelli: Most authorities at the moment are not collaborating. Obviously in going forward, obtaining the help of authorities is essential.

Paolo Durando, Associate Professor and Coordinator of the Post Graduate School in Occupational Medicine, University of Genoa, Italy and Vaccines and Clinical Trials Unit, IRCCS AOU San Martino IST of Genoa, Italy: Healthcare workers, when susceptible, are at increased risk of acquiring and transmitting some relevant vaccine-preventable diseases, such as measles, mumps, rubella, varicella, pertussis, viral hepatitis types A and B, and influenza. However, in many European countries, including Italy, vaccination coverage rates for some of the above-mentioned diseases are suboptimal in this group, both for physicians and nurses. It is the case of influenza for which immunization is recommended in > 40 countries including many countries of the European Union and the United States: vaccine uptake shows significant differences between most of the EU countries (generally less than 30%) and the US (ranging between 70% and more than 90%). It is clear that this is the “momentum” to share experiences between the EU countries in order to move on with novel immunization strategies/policies to fill this gap, starting from the high-risk areas and critical wards. How can we convince our patients at high-risk for some vaccine-preventable diseases to get vaccines if we, as healthcare workers, are not immunized as recommended?

Bruce Gellin: As one of the most contagious infectious diseases that we know, measles serves as a litmus test for many of the problems with our immunization programs. A safe and effective measles vaccine has been available for more than 50 years, but understanding the ongoing occurrence of measles provides an understanding of the root of the problem. For many in the developing world, it is a question of access and affordability. Efforts by the World Health Organization, UNICEF, and the Gavi Alliance are addressing that part of the problem. But in other parts of the world, the occurrence and spread of measles, despite the availability of an affordable vaccine, provides deeper insights into vaccine hesitancy. Of course, this includes patients who may decline a vaccine but also includes health professionals who may not be recommending measles-containing vaccines for their patients and immunization programs who have not addressed this issue within their communities.

Influenza vaccine also provides additional insights into this problem – and towards solutions. One example is the use of influenza vaccines by healthcare workers. Last year, over 75% of all healthcare workers received a seasonal influenza vaccine and in healthcare settings, where vaccination was required in order to care for patients, almost 98% of healthcare workers were vaccinated (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm>). And, despite longstanding recommendations for seasonal influenza vaccine for pregnant women, their vaccination rate was low until the influenza pandemic in 2009. At that time, when it was clear that pregnant women were at highest risk of 2009 H1N1 influenza and its complications, vaccine was in high demand by pregnant women. That routine has persisted. We continue to recommend influenza vaccines for all pregnant women and over 50% of pregnant women are being vaccinated each year. And the important message that doctors are giving their pregnant patients now is: this is important for you, and it is safe and important for your baby.

Paolo Bonanni: Comment on the number of antigens. Too many antigens and adjuvants. We do not have communication on the overload. Now you are giving more than 100 thousand proteins in comparison to the past. We do not have an issue on danger on this enlarged vaccination. There is a need of information that there is no danger for over stimulation.

Bruce Gellin: I agree on that and we have to understand better how to communicate the science on this important topic. As I mentioned previously, the return on our many investments in research is the development of a number of vaccines for diseases that were not previously vaccine preventable. This is real progress. However, if we are not clear about communicating the message that this is safe and that we do a lot to understand the safety and effectiveness of our childhood immunization schedules, our patients and our communities will continue to have diseases and their complications that are preventable. Surveys of the public routinely find that this is a concern, so we have to redouble our efforts to address those concerns. Fortunately, there is a robust scientific basis we can point to. To address this for our healthcare community we wrote a special article several years ago: *Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?* (<http://pediatrics.aappublications.org/content/109/1/124.full>). As others are faced with these questions, this might be helpful in developing an approach that helps parents better understand why these vaccines – and an increasing number of vaccines – are routinely recommended.

Conclusion remarks of the second part

Luca Pani AIFA Director General, Rome:

Pasteur was a chemist with a chemical mind and his lab is where all vaccinology started to become what it is now. Vaccination is the most effective medical intervention ever introduced: so far it has saved more than 3 billion disease cases, and more than 500 million deaths. Between 2011 and 2020 it is expected to save 25 million deaths, 2.5 million/year, 7,000/day, 300/hour, 5/minute.

The fortunate combination of a chemical mind with a medical strategy led Pasteur to develop a product unlike any other, which would change the face of health protection worldwide. Let me ask you how many have already got a flu vaccination? Not too many. We should be the examples. The influenza is the mother of all, a true paradigm for vaccination. Vaccine culture is not only a mixing of biology, genetics, and adjuvants. Vaccine is also a concept, an idea. Like all ideas it has people who support it and some who fiercely oppose it.

In a seminal book of 1976 by Richard Dawkin "The Selfish Gene" it was described how a gene is the final unit of hereditary transmission, but another unit of transmission was defined: the MEME. MEMEs are concepts, contaminating ideas if you wish, that behave like parasites—they will spread in and out of the brain, they will circulate in society, and they will be inherited. That means that in order to provide useful and truthful information about vaccines it should be expressed not only in biological terms but also in logical, theoretical, and semantic grounds. MEMEs should spread throughout our civil society highlighting how good vaccines are and replacing the anti-vaccine movement which says how bad vaccines are. This is

also a battle among ideas. We need to build better concepts around the value on vaccination and this is why meetings like today are important. We need to address all stakeholders in the field: researchers, developers, regulators, industry, payers; they all are building the history of vaccines. Vaccines and vaccination is a system linking biology, epidemiology, communication, and research shedding potential light on immune and autoimmune disorders.

During the last 30 years, several new technologies have made vaccines possible that were previously thought impossible and many vaccines are now recent breakthroughs. If in conclusion, to use a fashionable term, vaccines hashtags include:

- #vaccineconcepts
- #vaccinestakeholders
- #vaccinehistory
- #vaccinesystem
- #vaccineresearch
- #vaccinetrust
- #vaccinecomplexity
- #vaccinesingularity
- #vaccinefuture

Communications should be targeted not to the patients, but to possible future patients, and they are not, unfortunately, all PhDs. The internet, for instance, is an example on how a lot of information, not necessarily controlled and certified information, can spread and vaccine knowledge is a complex analogue to that.

Finally what is the future of vaccinations? The level of complexity of innovation in this field is very high as seen in hepatitis B, HIV, and immunotherapy for cancer, all of which are advancing very rapidly.

See you next year: you all are invited!

Sergio Pecorelli: Final comments and thanks to the participants in the Conference. We should pay attention to the global picture of health and not only to some selected parts. We had in this room policy, philosophy, civil society. We can be satisfied as we look at what has been launched today: proactive, responsible, and positive attention paid to vaccination from all stakeholders. We thank all of you on behalf of Minister Lorenzin. Thanks to all those who helped. We hope that this meeting will be of help, not just to all of us, but to European citizens and world citizens, for better health and a better life.

Speakers and discussants (in alphabetical order)

Paolo Bonanni, Director, Post Graduate School in Hygiene and Preventive Medicine, University of Florence, Italy

Robb Butler, Vaccine-Preventable Diseases and Immunization, WHO Regional Office for Europe, Copenhagen

Stefano Cinotti, IZS Brescia Director General, Brescia

Paolo Durando, Associate Professor and Coordinator of the Post Graduate School in Occupational Medicine, University of Genoa, Italy and Vaccines and Clinical Trials Unit, IRCCS AOU San Martino IST of Genoa, Italy

Petra Falb, Austrian Agency for Health & Food Safety / Federal Office for Safety in Health Care, Vienna

Bruce Gellin, US Deputy Assistant Secretary for Health and Director, US National Vaccine Program Office, Department of Health and Human Services, Washington, DC

Ranieri Guerra, Director General of Preventive Health and Chief Medical Officer at the Ministry of Health of Italy, Rome

Robert Linkins, Chief, Accelerated Disease Control and Vaccine Preventable Disease Surveillance Branch, Global Immunization Division, US CDC, Atlanta, GA

Pamela Logan, Irish Pharmacy Union, Dublin

Beatrice Lorenzin, Italian Minister of Health, Rome

Stefano Paleari, Rector, University of Bergamo

Luca Pani, AIFA Director General, Rome

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Andrea Rappagliosi, *Vaccines Europe President, Brussels*
Guido Rasi, *EMA Executive Director, London*
Paolo Rossi, *Delegate Paediatric Committee (PDCO) EMA, London*
John Ryan, *DG SANCO Acting Director Public Health, Luxembourg*
Stefania Salmaso, *National Health Institute, Rome*
Massimo Scaccabarozzi, *Farindustria President, Rome*
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The State of Health of Vaccination in the EU

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