

Mandatory and recommended vaccination in the EU, Iceland and Norway: results of the VENICE 2010 survey on the ways of implementing national vaccination programmes

M Haverkate¹, F D'Ancona (dancona@iss.it)², C Giambi³, K Johansen³, P L Lopalco³, V Cozza⁴, E Appelgren², on behalf of the VENICE project gatekeepers and contact points⁵

1. Radboud University, Nijmegen, Nijmegen, the Netherlands
2. Istituto Superiore di Sanità, Rome, Italy
3. European Centre for Disease Prevention and Control, Stockholm, Sweden
4. University of Bari "Aldo Moro", Bari, Italy
5. The members of the group are listed at the end of the article

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This report provides an updated overview of recommended and mandatory vaccinations in the European Union (EU), Iceland and Norway, considering the differences in vaccine programme implementation between countries. In 2010, the Vaccine European New Integrated Collaboration Effort (VENICE) network, conducted a survey among the VENICE project gatekeepers to learn more about how national vaccination programmes are implemented, whether recommended or mandatory. Information was collected from all 27 EU Member States, Iceland and Norway. In total 15 countries do not have any mandatory vaccinations; the remaining 14 have at least one mandatory vaccination included in their programme. Vaccination against polio is mandatory for both children and adults in 12 countries; diphtheria and tetanus vaccination in 11 countries and hepatitis B vaccination in 10 countries. For eight of the 15 vaccines considered, some countries have a mixed strategy of recommended and mandatory vaccinations. Mandatory vaccination may be considered as a way of improving compliance to vaccination programmes. However, compliance with many programmes in Europe is high, using only recommendations. More information about the diversity in vaccine offer at European level may help countries to adapt vaccination strategies based on the experience of other countries. However, any proposal on vaccine strategies should be developed taking into consideration the local context habits.

Introduction

Vaccinations are one of the most important tools of primary prevention. All countries in the European Union (EU) have a long tradition of implementing vaccination programmes. The level of control over diphtheria, *Haemophilus influenzae* type b (Hib) infections, hepatitis B, polio and tetanus is excellent in many countries [1].

The burden of measles, mumps, rubella, and pertussis decreased dramatically over the last decades, but there is still room for improvement in those programmes in many EU countries [2]. Strong efforts are being made to accelerate the implementation of newly introduced vaccines against pneumococcal, meningococcal and human papillomavirus disease.

In the presence of such a large variety of vaccines on offer, the way vaccination programmes are organised differs considerably between countries. The vaccines included in the programme, the type of vaccine used, the total number of doses administered, and the timing of the vaccinations vary. Vaccines can also be offered in many different ways: usually, the vaccines included in the routine (childhood) vaccination programme are paid for by the national healthcare system, whereas in some countries other vaccines need to be paid for up front by the recipient [3]. There are also large differences in whether vaccinations included in the national programmes are recommended or mandatory. Mandatory vaccination can be enforced by legislation, even though the term 'mandatory' has to be interpreted differently in different countries.

The Vaccine European New Integrated Collaboration Effort (VENICE) is a European network of experts working in the field of immunisation. All 27 EU Member States plus Iceland and Norway participate in VENICE. In each country a so called gatekeeper for VENICE is identified among the national experts in vaccine-preventable diseases [4]. In 2007, VENICE conducted a survey on immunisation programmes. The survey also included some questions whether vaccinations were recommended or mandatory. Of the 28 participating countries, 10 reported mandatory vaccinations for

different vaccines in their national immunisation programmes [3].

In the meantime, vaccination programmes have changed. New vaccines have been added to the immunisation programmes [5] and legislation about recommended and mandatory vaccinations may have changed. Therefore, the aim of this article is to provide an updated overview of recommended and mandatory vaccinations in the EU countries, Iceland and Norway, considering the differences in the modality of vaccine programme implementation between countries.

Methods

The national VENICE gatekeepers from the participating countries, the 27 EU countries plus Iceland and Norway, were sent a survey by email and asked to fill it out. The survey addressed the question whether the different childhood vaccinations were recommended (i.e. voluntary) or mandatory. A definition of 'recommended' and 'mandatory' was provided in order to avoid misinterpretation. The following definitions were used:

- Recommended: vaccination included in the national immunisation programme for all or some specific groups independent of being funded or not.
- Mandatory: a vaccination that every child must receive by law without the possibility for the parent to choose to accept the uptake or not, independent of whether a legal or economical implication exists for the refusal.

The gatekeepers were asked to provide information about childhood vaccinations against: diphtheria, Hib, hepatitis A, hepatitis B, human papillomavirus (HPV), influenza, invasive disease caused by *Neisseria meningitidis* serogroup C, invasive pneumococcal disease, measles-mumps-rubella, (MMR), pertussis, polio, rotavirus, tetanus, tuberculosis (with Bacillus Calmette-Guérin, BCG) and varicella. The reply options were (i) recommended (for all or for people at risk), (ii) mandatory (for all or for people at risk), or (iii) absence of recommendation. Data were collected in November 2010. Data from all countries were sent to the VENICE gatekeepers who were asked to validate them in April 2011.

Results

In total 28 of the 29 participating countries responded to the survey. For four countries (Estonia, Germany, Luxembourg and the Netherlands) additional information was found on the websites of the respective national public health institutes, which allowed the table for all 29 countries to be completed [6-10]. Data were validated from 19 countries. The results per country can be found in table 1.

The results according to vaccine are shown in Table 2.

All 29 countries include vaccination against diphtheria, hepatitis B, Hib, influenza, MMR, pertussis, polio

and tetanus in their programme. In total 28 countries include vaccination against invasive pneumococcal disease in their recommendation or legislation, some countries only for children and others also for adults or risk groups. Most other vaccinations (against hepatitis A, HPV, invasive disease caused by *Neisseria meningitidis* serogroup C, tuberculosis (with BCG) and varicella) are considered by at least 20 of the participating countries. An exception is observed for rotavirus vaccination, which is only included in the national immunisation programme for nine of the 29 countries.

In total 15 countries do not have any mandatory vaccinations; the remaining 14 countries have at least one mandatory vaccination included in their programme. Vaccination against polio is mandatory for all children in 12 countries; diphtheria and tetanus vaccination is mandatory in 11 countries, and hepatitis B vaccination in 10 countries. For eight of the 15 vaccines considered here, some countries have a mixed strategy of recommended and mandatory vaccinations. Usually this means that the vaccination is recommended for the whole population, but that it is mandatory for some risk groups.

Discussion

Mandatory vaccination may be considered as a way of improving the compliance to vaccination programmes. However, many programmes in Europe are effective even though voluntary, just with recommendations.

In the vaccination field, legal consequences can be very different: they can be very strong – including pecuniary penalties, difficulty to attend public schools, or even penal consequences for the parents – or can be much milder with the possibility of choosing to 'opt-out'. Moreover, the enforcement varies in practice. It is possible that in some cases penalties are only theoretical and never applied. This information was not collected in this survey because it is difficult to evaluate the national context and differences could exist in different regions of each country.

Opinions on recommended or mandatory vaccinations are divided, because several ethical issues are related to the subject [11,12]. Furthermore, at first sight there seems to be no striking difference in vaccination coverage between countries that only recommend certain vaccinations and countries that oblige them [1,12], although from studies it is known that making influenza vaccination mandatory for healthcare workers can increase the vaccination coverage rates in this particular group [13]. On the other hand, in 2008 the Veneto region in Italy, with a population of five million, abolished all mandatory vaccination, and the coverage trend was carefully monitored. A vaccine coverage evaluation, performed in the region during 2010 for the 2008 birth cohort (the first cohort concerned by the change), revealed a slight decline of immunisation coverage rates for all the vaccinations mandatory prior to 2008 (diphtheria, hepatitis B, polio, tetanus) though levels remain well above the objective of 95%, as aimed for by the Italian National Immunisation Plan

TABLE 1

Modality of implementation of childhood vaccination programme by country, the European Union countries, Iceland and Norway, 2010 (n=29)

A Country	Diphtheria	<i>Haemophilus influenzae</i> type B	Hepatitis A	Hepatitis B	Human papillomavirus ^a	Influenza	Invasive disease caused by <i>Neisseria meningitidis</i> group C
Austria	RA	RA	RR	RA	R	RR	RA
Belgium	RA	RA	RR	MR/RA ^{b)}	R	RR	RA
Bulgaria	MA	MA	RR	MA	R	RR	A
Cyprus	RA	RA	RR	RA	A	RR	RA
Czech Republic	MA	MA	MR	MA	R	RR	RR
Denmark	RA	RA	RR	RR	R	RR	RR
Estonia [6]	RA	RA	RA ^e	RA	R ^e	RA ^e	RR ^e
Finland	RA	RA	RR	RR	A	RA	A
France	MA/MR/RA ^f	RA	RR	MR/RA ^{b)}	R	RR	RA
Germany [7]	RA	RA	RR	RA	R	RR	RA
Greece	MA	RA	RA	MA ^{h)}	R	RR	RA
Hungary	MA	MA	MR	MA	A	RR	A
Iceland	RA	RA	RR	RR	A	RR	RA
Ireland	RA	RA	RR	RA	R	RR	RA
Italy	MA ⁱ⁾	RA	A ^{l)}	MA	R	RR	RA/RR ^{k)}
Latvia	MA	MA	RR	MA	MA	RR	RR
Lithuania	RA	RA	RR	RA	A	RR	RR
Luxembourg [8]	RA	RA	RR	RA	R	RR	RA
Malta	MA	RA	RR	RA	A	RA	A
The Netherlands [9]	RA	RA	RR	RR	R	RR	RA
Norway	RA	RA	A	RR	R	RR	A
Poland	MA	MA	RR	MA	R	RR	RR
Portugal	RA/MR	RA	A	RA	R	RR	RA
Romania	MA	MA	RR	MA	R	RR	A
Slovakia	MA	MA	MR/RR ^{p)}	MA	R	MR/RR ^{o)}	RR
Slovenia	MA	MA	RR	MA	R	RR	RR
Spain	RA	RA	RR/RA ^{k)}	RA	R	RR	RA
Sweden	RA	RA	A	RR	R	RR	A
United Kingdom	RA	RA	RR	RR	R	RR	RA

A: absence of recommendation, MA: mandatory for all; MR: mandatory for people at risk; R: recommended; RA: recommended for all; RR: recommended for people at risk.

^b Mandatory for healthcare workers.

^d RA: conjugated vaccine to children younger than two years of age.

RR: polysaccharide vaccine to older persons.

^e Not included in the national immunisation programme, but recommended by the Ministry of Social Affairs [10].

^f MA: children up to 18 months of age.

MR: healthcare workers.

RA: bolder than 13 years of age.

^g MA: children up to 13 years of age.

MR: healthcare workers.

RA: older than 13 years of age.

^h No penalty exists for non-compliance.

^j One of 20 regions does not have any mandatory vaccination as of 2008.

^k Regional variability.

^m Rubella: mandatory for girls by the age of 14.

TABLE 1

Modality of implementation of childhood vaccination programme by country, the European Union countries, Iceland and Norway, 2010 (n=29)

B Country	Invasive pneumococcal disease	Measles-mumps-rubella	Pertussis	Polio	Rotavirus	Tetanus	Tuberculosis (with Bacillus Calmette-Guérin)	Varicella
Austria	RA	RA	RA	RA	RA	RA	A	RR
Belgium	RA	RA	RA	MA	RA	RA	A	RR
Bulgaria	MA/RA ^c	MA	MA	MA	RA	MA	MA	A
Cyprus	RA	RA	RA	RA	A	RA	RR	RA/RR
Czech Republic	MR	MA	MA	MA	A	MA	MR	RR
Denmark	RA/RR ^d	RA	RA	RA	A	RA	A	RR
Estonia [6]	RR ^e	RA	RA	RA	RR ^e	RA	RA	RR ^e
Finland	RA	RA	RA	RA	RA	RA	RR	A
France	RA	RA	RA	MA/MR/RA ^g	A	MA/MR/RA ^f	MR/RR ^b	RR
Germany [7]	RA	RA	RA	RA	A	RA	A	RA
Greece	RA	RA	RA	MA ^h	A	MA	RA	RA
Hungary	RA	MA	MA	MA	A	MA	MA	A
Iceland	RR/RA ⁱ	RA	RA	RA	A	RA	A	RR
Ireland	RA	RA	RA	RA	A	RA	RA	RR
Italy	RA/RR ^k	RA	RA	MA	A	MA	RR	RA/RR ^k
Latvia	MA	MA	MA	MA	MA ⁱ	MA	MA	MA
Lithuania	RR	RA	RA	RA	A	RA	RA	RR
Luxembourg [8]	RA	RA	RA	RA	RA	RA	RR	RA
Malta	RR ⁿ	RA ^m	RA	MA	A	MA	RA	RR
The Netherlands [9]	RA	RA	RA	RA	A	RA	RR	A
Norway	RA	RA	RA	RA	A	RA	RR	A
Poland	MR	MA	MA	MA	RA	MA	MA	RR
Portugal	RR	RA	RA	RA	A	RA/MR	RA	A
Romania	A	MA	MA	MA	A	MA	MA	A
Slovakia	MA	MA	MA	MA	A	MA	MA	A
Slovenia	RR	MA	MA	MA	RA	MA	RR	RR
Spain	RA/RR ^k	RA	RA	RA	A	RA	A ^l	RA/RR ^k
Sweden	RA	RA	RA	RA	A	RA	RR	A
United Kingdom	RA	RA	RA	RA	A	RA	RR	RR

A: absence of recommendation, MA: mandatory for all; MR: mandatory for people at risk; R: recommended; RA: recommended for all; RR: recommended for people at risk.

^a Mostly recommended for girls 10-17 years of age.

^b Mandatory for healthcare workers.

^c RA: children born prior to 2010 and younger than five years of age.

^d RA: conjugated vaccine to children younger than two years of age.

RR: polysaccharide vaccine to older persons.

^e Not included in the national immunisation programme, but recommended by the Ministry of Social Affairs [10].

ⁱ RA: from 2011.

^k Regional variability.

^l RA: only in one region.

ⁿ RR: for children under two years of age.

^o MR: social care facilities.

RR: children six months to 12 years of age, elderly, for some diagnoses, for some professions.

^p MR: direct contact with infectious person, some professions.

RR: chronic liver disease, children two years of age living in bad conditions, some professions.

TABLE 2

Modality of implementation of childhood vaccination programme by vaccine in the European Union countries, Iceland and Norway, 2010

Vaccination	Considering vaccination	Recommended (RA or RR)	Mandatory (MA or MR)	Mixed
Diphtheria	29	16	11	2
<i>Haemophilus influenzae</i> type B	29	21	8	0
Hepatitis A	25	22	2	1
Hepatitis B	29	17	10	2
Human papillomavirus	23	22	1	0
Influenza	29	28	NM	1
Invasive disease caused by <i>Neisseria meningitidis</i> serogroup C	22	22	NM	0
Invasive pneumococcal disease	28	23	4	1
Measles-mumps-rubella	29	21	8	0
Polio	29	16	12	1
Pertussis	29	21	8	0
Rotavirus	9	8	1	0
Tetanus	29	16	11	2
Tuberculosis (with Bacillus Calmette-Guérin)	23	15	7	1
Varicella	20	19	1	0

MA: mandatory for all; MR: mandatory for people at risk; NM: not mandatory in any of the countries in the study; RA: recommended for all; RR: recommended for people at risk.

[14]. The evaluation of this experience, over time, may lead to legislative changes at national level [15]. Further research and reports of experiences are needed to see if a relation exists between voluntary or mandatory vaccination programmes, and vaccination coverage.

In countries where both recommended and mandatory vaccinations are part of the national immunisation plan (i.e. France, Greece, Italy, Malta) vaccines against pertussis, measles-containing vaccines and vaccines against Hib are recommended, not mandatory, and the coverage is still very high [16]. Thus the label 'mandatory' is not the only driver behind achieving a high vaccination coverage in these countries and many other factors can play a role such as the use of combined vaccines, prices for the recipient, kind of offer, information and promotional campaigns. The results of our survey show that there are several differences among participating countries. Immunisation strategies range from only voluntary vaccinations in the programme to an almost completely mandatory vaccination programme, and everything in between. The reasons behind such wide differences are probably both historical and cultural rather than evidence-based. Differences in costs for recipients and the kind of vaccination offer, whether active or passive, also exist. These aspects have been explored through other, disease-specific, surveys performed by VENICE [4].

The issue of mandatory versus recommended vaccinations has been widely discussed in Europe. The

situation might change over the coming years following the example of countries where high coverage is achieved, taking advantage of communication strategies and the awareness of the citizen for public health problems and relative solutions.

In conclusion, a national healthcare system should promote and actively offer those vaccines that have been proven to be safe, effective, and with a positive public health impact. In a world where people trust health authorities, more compliance with national recommendations can be established. This would not only benefit the health of citizens, but also support the overall effectiveness of a vaccination programme through the herd immunity effect.

However, communication of the risks and of advantages and disadvantages resulting from large immunisation programmes is a very sensitive issue and any decision about a proposal for vaccine strategies should be elaborated in agreement with tradition and cultural habits.

In this quick survey a recommended vaccination was considered to be a 'vaccine included in the national immunisation plan but not mandatory'. Some countries may not have a unique official document for recommended vaccinations and therefore it may not be straightforward to categorise a vaccine as recommended or not. A different use of the term 'recommended' could also explain some differences to the

programme reported on the World Health Organization website [17].

Meanwhile more information about the diversity in vaccine offer at European level may help countries to adapt vaccination strategies based on the experience of other countries. In this way it is possible also to improve the vaccine offer to the citizen and to increase the awareness of European citizens about the importance of vaccination for public health and the underlying evidence for the strategies chosen. The availability of comparable vaccination coverage data for all the Member States will help this process.

The VENICE project gatekeepers group:

Austria: Jean-Paul Klein. Belgium: Martine Sabbe, Pierre Van Damme. Bulgaria: Mira Kojouharova. Cyprus: Soteroulla Soteriou, Chrystalla Hadjianastassiou. Czech Republic: Bohumir Kriz. Denmark: Steffen Glismann. Estonia: Natalia Kerbo, Irina Filippova. Finland: Tuija Leino. France: Daniel Levy-Bruhl. Germany: Sabine Reiter. Greece: Theodora Stavrou. Hungary: Zsuzsanna Molnár. Iceland: Thorolfur Gudnason. Ireland: Suzanne Cotter. Italy: Fortunato D'Ancona, Maria Cristina Rota. Latvia: Jurijs Perevoscikovs. Lithuania: Egle Valikonienė. Luxembourg: Françoise Berthet. Malta: Charmaine Gauci, Tanya Melillo. The Netherlands: Hester de Melker, Alies van Lier. Norway: Berit Feiring. Poland: Pawel Stefanoff. Portugal: Teresa Fernandes, Paula Valente. Romania: Chicin Gratiana. Slovakia: Helena Hudecova, Jarmila Lancova. Slovenia: Alenka Kraigher. Spain: Josefa Masa-Calles, Isabel Pachón del Amo. Sweden: Annika Linde. United Kingdom: Richard Pebody.

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