



VENICE project

Contract DGSANCO n. 2004201

1st Annual Report

1st January -31st December 2006

February 28, 2007

Project Leader: Stefania Salmaso



Contents

Project key personnel	pg 5
List of participating Countries	pg 7
Introduction	pg 14
Aims of the project	pg 14
Specific Objectives	pg 15
Methods	pg 15
WP 1: Coordination	
Tasks of the WP1 and expected deliverables for the 1 st year of the project	pg 17
Results of WP1	pg 17
Coordination of the project	pg 17
Creation of a network of public health experts in Europe	pg 18
Collaboration with other networks as EUVAC-NET, VACSACT, POLYMOD, Brighton Collaboration	pg 19
Creation of the VENICE website	pg 20
Survey on Immunisation Programs in Europe	pg 21
WP 2: Dissemination of results	
Tasks of the WP2 and expected deliverables for the 1 st year of the project	pg 22
Results of WP2	pg 22
Organisation of annual workshops	pg 22
Dissemination of results through publications in bulletin and peer-reviewed journals	pg 22
WP 3: Indicators of immunisation programs	
Tasks of the WP3 and expected deliverables for the 1 st year of the project	pg 23
Results of WP3	pg 23
Survey on Immunisation Programs in Europe	pg 23
Survey on methods for measuring vaccine coverage in Europe	pg 25
WP 4: Priority setting and decision making process	
Tasks of the WP4 and expected deliverables for the 1 st year of the project	pg 27
Results of WP4	pg 27
Surveys on the use of Rotavirus and HPV vaccines in MSs	pg 27
WP 5: Capacity building in monitoring, prevention and management of post vaccination Adverse Events	
Tasks of the WP5 and expected deliverables for the 1 st year of the project	pg 29
Results of WP5	pg 29
Survey on AEFI surveillance and management in Europe	pg 29
Problems encountered so far	pg 30
Future activities in the next 2 years of the project	pg 30

Conclusion	pg 31
Appendix 1: Timetable of the project	pg 32
Appendix 2: Agenda and summary of WP leaders meetings and conference calls	pg 33
<i>Annex 2a</i> : meeting May 17 ^{en} 2006	
<i>Annex 2b</i> : meeting July 11 ^{en} 2006	
<i>Annex 2c</i> : conference call October 2 nd 2006	
<i>Annex 2d</i> : conference call January 24 th 2007	
Appendix 3: Communication with national gatekeepers and contact points	pg 34
<i>Annex 3a</i> : letter of invitation to participate to the VENICE project	
<i>Annex 3b</i> : letter of invitation to participate to the survey on IP	
<i>Annex 3c</i> : letters of invitation to participate to the survey on the use of HPV and rotavirus vaccines	
<i>Annex 3d</i> : letter of invitation to participate to the survey on the methods for measuring vaccine coverage	
<i>Annex 3e</i> : letter of invitation to participate to the forum on HPV and rotavirus vaccines	
Appendix 4: home page VENICE website	pg 35
Appendix 5: Agenda of the VENICE workshops	pg 36
<i>Annex 5a</i> : agenda of the 1 st workshop in Malta (April 8 th 2006)	
<i>Annex 5b</i> : agenda of the 2 nd workshop in VENICE (April 11 th -13 ^{en} 2007)	
Appendix 6: publications	pg 37
<i>Annex 6a</i> : launch of the VENICE project on the 1 st issue of V&I ECDC bulletin	
<i>Annex 6b</i> : Immunisation Program (IP) Profile of Ireland and Italy on the 2 nd issue of V&I ECDC bulletin	
<i>Annex 6c</i> : Immunisation Program (IP) Profile of France on the 3 rd issue of V&I ECDC Bulletin	
<i>Annex 6d</i> : Immunisation Program (IP) Profile of Sweden and Luxembourg on the 5 th issue of V&I ECDC Bulletin	
<i>Annex 6e</i> : Immunisation Program (IP) Profile of Germany and Portugal on the 6 th issue of V&I ECDC Bulletin	
<i>Annex 6f</i> : Immunisation Program (IP) Profile of Norway and Bulgaria on the 7 th issue of V&I ECDC Bulletin	
<i>Annex 6g</i> : Immunisation Program (IP) Profile of Poland and Latvia on the 8 th issue of V&I ECDC Bulletin	
<i>Annex 6h</i> : Immunisation Program (IP) Profile of Spain and Romania on the 9 th issue of V&I ECDC Bulletin	
<i>Annex 6i</i> : Immunisation Program (IP) Profile of Czech Republic and Slovakia on the 10 th issue of V&I ECDC Bulletin	
<i>Annex 6l</i> : Immunisation Program (IP) Profile of Denmark and Estonia on the 11 th issue of V&I ECDC Bulletin	
<i>Annex 6m</i> : Immunisation Program (IP) Profile of Belgium and Finland on the 12 th issue of V&I ECDC Bulletin	
<i>Annex 6n</i> : Immunisation Program (IP) Profile of Hungary and Greece on the	

13^{en} issue of V&I ECDC Bulletin

[Annex 6o](#): Immunisation Program (IP) Profile of Lithuania and Cyprus on the 14^{en} issue of V&I ECDC Bulletin

[Annex 6p](#): Immunisation Program (IP) Profile of Austria on the 15^{en} issue of V&I ECDC Bulletin

[Annex 6q](#): Immunisation Program (IP) Profile of The Netherlands on the 16^{en} issue of V&I ECDC Bulletin

[Annex 6r](#): article published in Eurosurveillance weekly on January 18^{en} 2007: VENICE: Europe's new network for vaccination

Appendix 7: Surveys

pg 38

[Annex 7a](#): survey on IP in Europe

[Annex 7b](#): protocol of the survey on Immunisation Programs (IP) in Europe

[Annex 7c](#): report of the survey on IP in Europe

[Annex 7d](#): survey on methods for measuring vaccine coverage in Europe

[Annex 7e](#): survey on use of Rotavirus and papilloma virus (HPV) vaccines in Europe

[Annex 7f](#): survey on surveillance of adverse events following immunisation (AEFI) in Europe

Project key personnel

Project Leader

Stefania Salmaso
Centro Nazionale di Epidemiologia,
Sorveglianza e Promozione della Salute
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Rome - Italy
Tel. 0039 06 49904010
Fax 0039 06 49904110
Email: stefania.salmaso@iss.it

Project manager:

Lucia Pastore Celentano
Centro Nazionale di Epidemiologia,
Sorveglianza e Promozione della Salute
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Rome - Italy
Tel. 0039 06 49904270
Fax 0039 06 44232444
Email: lucia.celentano@iss.it

Project Secretary:

Eva Appelgren
Centro Nazionale di Epidemiologia,
Sorveglianza e Promozione della Salute
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Rome - Italy
Tel. 0039 06 49904013
Fax 0039 06 49904110

Workpackage Leaders:

Workpackage 1-2 “Coordination & Dissemination of results”

Stefania Salmaso
Centro Nazionale di Epidemiologia,
Sorveglianza e Promozione della Salute
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Rome - Italy
Tel. 0039 06 49904010
Fax 0039 06 49904110
Email: stefania.salmaso@iss.it

Workpackage 3 “Indicators of immunisation programs”

Darina O’Flanagan
HSE-Health Protection Surveillance Centre
25-27 Middle Gardiner St
Dublin1
Tel 003531 8765336336
Fax 003531 8765333
e-mail: darina.oflanagan@mailx.hse.ie

Niamh Mullins
HSE-Health Protection Surveillance Centre
25-27 Middle Gardiner St
Dublin 1
Tel 003531 8765336336
Fax 003531 8765333
e-mail: niamh.mullins@mailx.hse.ie

Workpackage 4 “Priority Setting and decision making processes”

Daniel Levy Bruhl
Institut de Veille sanitaire
Département des maladie infectieuses
12 rue du Val d’Osne
94415 Saint-Maurice
Tel. 0033 1 41 796741
Fax. 0033 1 41 796872
e-mail: d.levybruhl@invs.sante.fr

Workpackage 5 “Capacity building in monitoring prevention and management of post-vaccination AEs”

Antonio Ferro
Regione Veneto - Segreteria Sanità e Sociale
Palazzo Molin - S.Polo 2513-

30125 Venezia
Tel: 0039 0412791352-3
Fax: 0039 0412791355
e-mail: antonio.ferro@regione.veneto.it;

Piero Berra
(pieroeritrea@libero.it)

Giuseppe Tridente (Workpackage 5)
Green Channel Immunology Unit
Department of Pathology
University of Verona
Policlinico G.B. Rossi
37134 Verona
Tel. 0039 045 8074256
Fax: 0039 045 580900
e-mail: giuseppe.tridente@univr.it

Giovanna Zanoni
Green Channel Immunology Unit
Department of Pathology
University of Verona
Policlinico G.B. Rossi
37134 Verona
Tel. 0039 045 8074256
Fax: 0039 045 580900
e-mail: giovanna.zanoni@univr.it

Partecipating Countries

Austria

Fm For Health And Women
Directorate General Public Health
Radetzkystr 2
1030 Vienna
Gatekeeper:
Robert Muchl
Tel: 0043 664 13 22 163
Fax: 0043 1 715 73 12
e-mail: robert.muchl@bmgf.gv.at

Belgium

University of Antwerp - Campus 3 Eiken
Epidemiology and Social Medecine
Universiteitsplein, 1
2610 Wilrijk
Gatekeeper:
Pierre Van Damme
Tel: 0032 3 820 25 38
Fax: 0032 3 820 26 40
e-mail: pierre.vandamme@ua.ac.be

Bulgaria

National Center of Infectious and Parasitic Diseases
Department Epidemiology and Surveillance of Communicable Diseases
26 Yanko Sakazov Blvd
1504 Sofia
Gatekeeper:
Mira Kojouharova
Tel. +359 2 846 55 17
Moble: +359 887 916 549
Fax: +359 2 846 55 17
e-mail: mkojouharova@ncipd.netbg.com

Czech Republic

**National Institute of Public Health
Centre Epidemiology and Microbiology**
Srobarova, 48
10042 Prague
Gatekeeper:
Bohumir Kriz
e-mail: bohukriz@szu.cz

Cyprus

**Medical and Public Health Services
Surveillance Unit**
Markou Drakou 10, 1449 Pallouriotissa
Nicosia
Gatekeeper:
Dr Chrystalla Hadjianastassiou
Tel.: + 357 22400 146
Fax.: + 357 22400 223
e-mail: cycomnet@cytanet.com.cy

Denmark

**Statens Serum Institut
Department of epidemiology**
5 Artillerivej
DK 2300 - Copenhagen
Gatekeeper:
Glismann Steffen
Tel: 0045 3268 8414
Fax: 0045 3268 3874
e-mail: stg@ssi.dk

Estonia

**Health Protection Inspectorate
Epidemiological Department**
Paldiski road 81,
10617 Tallinn
Estonia
Gatekeeper:
Natalia Kerbo, MD
Tel: 372 6943520
Fax: 372 6943520
e-mail: natalia.kerbo@tervisekaitse.ee

Finland

**National Public Health Institute
Laboratory of Viral Vaccines**
Mannerheimintie 166
00300 Helsinki

Gatekeeper :
Tuija Leino
Phone: +358-9-47448366
Fax: +358-9-47448355
e-mail : tuija.leino@ktl.fi

France

Institut de Veille sanitaire
Département des maladie infectieuses
12 rue du Val d'Osne
94415 Saint-Maurice
Gate keeper:
Daniel Levy Bruhl
Tel. 0033 1 41 796741
Fax. 0033 1 41 796872
e-mail: d.levybruhl@invs.sante.fr

Germany

Robert Koch Institute
Immunization Unit
Seestrasse 10
13353 Berlin
Gatekeeper:
Sabine Reiter
Tel.: +49-30-45473461
Fax: +49-30-45473533
e-mail: reiters@rki.de

Greece

Hellenic Centre for Diseases Control & Prevention
Department of epidemiological Surveillance & Intervention
56 Tritis Septemvriou street
10433 Athens
Greece
Gatekeeper:
Panagiotis Panagiotopoulos
Tel. +30 210 6460 614
Fax +30 210 6412 059
e-mail: tpan@nsph.gr

Hungary

National Center for Epidemiology
Department for Communicable Disease Epidemiology
Gyali Ut 2-6
1097 Budapest
Gatekeeper:
Zsuzsanna Molnár
Tel: 003612151792
Fax: 0036121517920

e-mail: molnarzs@oek.antsz.hu

Iceland

Directorate of Health
Centre for Infectious Disease Control
Austurstrond 5
170 Seltjarnarnes
Gatekeeper:
Thorolfur Gudnason
Tel: 003545101900
Fax: 003545101920
e-mail: thorolfur@landlaeknir.is

Ireland

HSE-Health Protection Surveillance Centre
25-27 Middle Gardiner St
Dublin 1
Gatekeeper:
Suzanne Cotter
Dublin 1
e-mail: suzanne.cotter@mailx.hse.ie
Tel 003531 876533
Fax 003531 876533

Italy

**Centro Nazionale di Epidemiologia,
Sorveglianza e Promozione della Salute**
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Rome - Italy
Gatekeeper:
Marta Luisa Ciofi degli Atti
Tel. 0039 06 49904263
Fax 0039 06 49904110
e-mail: marta.ciofi@iss.it

Latvia

Public Health Agency
Department of epidemiological Surveillance of Infectious Diseases
7 Klijanu Street
1012 Riga
Gatekeeper:
Perevoscikovs Jurijs
Tel: 003717081521
Fax: 003717375490
e-mail: Jurijs.perevoscikovs@sva.lv

Lithuania

**Centre for Communicable Diseases Prevention and Control
Immunization Department**

Kalvariju 153

08221 Vilnius

Gatekeeper:

Kupreviciene Nerja

Tel: 00370 5 2159273

Fax: 0037052778761

e-mail: n.kupreviciene@ulpkc.lt

Luxemburg

Ministère de la Santé

Direction de la Santé - Division de l'Inspection Sanitaire

Rue de Prague 5°

L-2348 Lussemburgo

Gatekeeper:

Danielle Hansen-Koenig (Policy decisions)

Tel: 003524785650

Fax: 00352480323

e-mail: danielle.hansen-koenig@ms.etat.lu

Norway

Norwegian Institute of Public Health

Department of Vaccination and Immunity

Geimyrsveien 75

PO Box 4404 Nydalen

N-0403 Oslo

Gatekeeper:

Feiring Berit

Tel. 004722042261

Fax: 004722042301

e-mail: berit.feiring@fhi.no

Poland

National Institute of Public Health

Division of Microbiology

Chelmska 30/34

Warsaw

Gatekeeper:

Hryniewicz Waleria

Tel. 0048228413367

Fax: 0048228412949

e-mail: waleria@cls.edu.pl

Portugal

Communicable Diseases Division
Directorate General of Health
Alameda D. Afonso Henriques, 45
1049-005 Lisboa Portugal

Gatekeeper:

Teresa Fernandes

Tel: +351 21 843 06 03

Fax: +351 21 843 06 20

e-mail: teresafernandes@dgsaude.min-saude.pt

Romania

Institute of Public Health
Epidemiology Institute of Public Health
Bv. Dr. Victor Babes 16-18
300226 Timisoara

Gatekeeper:

Chichin Gratiana

Tel: 00256492102

Fa: 00256 494101

e-mail: grati2ro@yahoo.com

Slovakia

Public Health Authority of the Slovak Republic
Section of Epidemiology

Trnavska 52

826 45 Bratislava

Gatekeeper:

Eva Maderova

Tel: 00421249284385

Fax: 00421244372641

e-mail: maderova@uvzsr.sk

Slovenia

Institute of Public Health of the Republic of Slovenia
Centre for Communicable Diseases

Trubarjeva 2

1000 Ljubljana

Gatekeeper:

Kraigher Alenka

Tel: 0038612441412

Fax: 0038612441471

e-mail: alenka.kraigher@ivz-rs.si

Spain

**Instituto de Salud Carlos III
Centro Nacional de Epidemiologia**

Sinesio Delgado, 6
28029 Madrid

Gatekeeper:

Martinez de Aragon y Esquivias Maria Victoria
e-mail: vmartinz@isciii.es

Sweden

Smittskyddsinstitutet-Department of epidemiology

Nobels Väg 18
SE 17182 Solna

Gatekeeper:

Annika Linde

Tel: 00468

Fax: 004683006 26

e-mail: annika.linde@smi.ki.se

The Netherlands

**National Institute of Public Health and the Environment
Department Public Health**

A. Van Leewenhoeklaan 9
3721 Bilthoven

Gatekeeper:

De Melker Hester

Tel: 0031 30 2744409

Fax. 0031 302744409

e-mail: h.de.melker@rivm.nl

United Kingdom

**Health Protection Agency
Communicable Disease Surveillance Centre**

61 Colindale Avenue
NW9 5EQ London

Gatekeeper:

Richard Pebody

Tel: 0044 208 200 6868

Fax: 0044 208 200 7868

e-mail: richard.pebody@hpa.org.uk

The VENICE Project

Introduction

As the most important tool of primary prevention, vaccination targets large numbers of healthy individuals in each Member State with the aim of preventing specific infections and having an impact on the epidemiology of certain diseases.

New vaccines are introduced according to common European Union (EU)-wide regulatory procedures, which implies that they are licensed with common indications for their use across the European countries.

However the type of products used, the recommended schedule for their administration and the organization of immunisation programs are usually set at national level and can vary across EU.

Many countries use similar childhood vaccination schedules and also the same commercial products, but concurrently administer different vaccines, measure vaccine coverage in different ways or in different age groups and have different systems for monitoring adverse events following immunisation (AEFI).

Observations obtained at national level are not collected in order to be systematically comparable neither are made available to others countries and there is no attempt to pool experience or tools on a systematic basis at European level.

On the other hand, effects of Immunisation Programs (IP) are expected to have an impact beyond political borders especially in the EU context of free circulation of persons and potential infectious vehicles.

Furthermore the enlargement of the EU from 15 to 27 member states (MS) is increasing the variability of the already heterogeneous picture and the demand for knowledge about the systems in place.

The development of common tools for improving vaccination programs and responding in a coordinated way to challenges is therefore a European priority.

Aims of the project

The Vaccine European New Integrated Collaboration Effort (VENICE) project was designed in 2004, approved in late 2005 and launched in January 2006 with the aim of establishing a European network of experts with experience of working in national IP.

The Venice project aims to encourage collection and dissemination of knowledge and best practice relating to vaccination and to further develop collaboration and partnership between member states.

The aims of the project are:

- 1) to address the need to improve knowledge on how vaccinations are performed across the EU as to integrate available information and identify gaps;

- 2) to agree on common indicators for monitoring vaccination programs;
- 3) to define models of decision making processes;
- 4) to share expertise on surveillance and case management of AEFI.

Indeed, careful comparison of national vaccine schedules would enable experts to assess the performance of various administration schedules for a specific vaccine, or the effect of co-administration of different vaccines, or the frequency and management of certain adverse events following immunisation for each vaccine.

In addition, through the VENICE network, it is possible to monitor in real time the introduction at national level of new vaccines as the human papilloma virus (HPV) vaccines and rotavirus vaccines recently licensed in EU.

Specific Objectives

1. To create an EU vaccination network able to collect and collate information on vaccination programs in each MS.
2. To create a resource able to provide advice and support to single member states by integrating available tools and knowledge on various vaccine-related issues
3. To create a network able to provide support in the development of preparedness strategies (including immunisation programs)
4. To define common indicators for monitoring, in a comparable way, the immunisation programs across MSs and their constituent regions.
5. To encourage a rational approach to vaccination policy decision-making processes by providing standardized tools.
6. To provide MSs with the necessary information regarding safe vaccination and support capacity building in areas dealing with contraindication and the management of Adverse Events following vaccination.

Methods

The methods used fall into two categories

1. Management outputs: co-ordination of the communication process between participating member states, identification and co-ordination of the working groups, developing and managing the process for bringing together documentation from member states, overseeing the development and maintenance of the website.
2. Technical outputs:
 - o Epidemiological: to provide the skills and knowledge required to complete the work packages activities, to ensure the quality control of the contents of the website as of information collected from member states.

- Information technology: to provide the skills and knowledge required to develop and maintain the website.

Twenty-six EU member states (all except Malta) and two EEA/EFTA countries (Iceland and Norway) participate to the project. In each country, several people in public health institutions have been identified and are involved: a gatekeeper responsible for the project at national level and three contact points, one for each “technical WP”.

An executive board of the 4 Work Package Leaders (WPsL) have been established to ensure that the aims and objectives of the project are met. They are responsible for the performance management of the project during the three years. This board meets regularly also via telephonic conferences. The discussion is usually opened to major collaborators also of other institutions (e.g. ECDC, Brighton collaboration).

The day-to-day management of the project is undertaken by the project co-ordinator in Italy at Istituto Superiore di Sanità (ISS)

Description of Work packages

The project is organised in 5 work packages (WPs).

WP 1 focuses on the administration, management and coordination of the project, the development and maintenance of the website; WP 2 deals with the dissemination of results and communications.

WPs 3 to 5 focus on the program outputs. The main themes are development of indicators of immunisation programmes, vaccination policy and decision making processes, surveillance and management of AEFI and contraindications.

Each of the WPs participates in the design and implementation of the survey across the EU MSs and uses the relevant results as the starting point for developing their toolkits and reports. Each work package has a team leader who is responsible for feeding back information during the annual progress review meetings.

Names of the WPs

WP 1: Coordination

WP 2: Dissemination

WP 3: Indicators of immunisation programs

WP 4 : Priority setting and decision-making processes

WP 5: Capacity building in monitoring, prevention and management of Adverse Events Following Immunisation (AEFI)

WP 1: Coordination

Tasks of the WP1 and expected deliverables for the 1st year of the project

This work package is linked to the specific objectives 1, 2 and 3 and includes the work needed to coordinate the creation of the vaccination network for ongoing immunisation programmes, the related web site and the creation of a pool of experts to be able to support national preparedness plans, including immunisations.

Specific tasks of WP1 are:

- 1) undertaking the performance management of the project: ensuring that timetables for the completion of work are respected and the aims as the objectives of the project are met within the timeframe specified in this document in the Appendix 1;
- 2) providing an information hub through which general exchanges of information from MSs can be coordinated;
- 3) overseeing the development of the website, ensuring that the tools are adequate and that an ongoing process of data renewal is in place. The development and maintenance of the website has been subcontracted to the Interuniversity Consortium (CINECA);
- 4) coordinating the survey to be carried out, jointly designed with the WP3, WP4, WP5 leaders;
- 5) Establish links with appropriate international resources on vaccines and vaccinations as the European Agency for medical Products (EMA), WHO, Brighton Collaboration as with other European networks on vaccines and immunisation as EUVACNET and VACSACT

Expected deliverables in the 1st year of the project are:

- 1) the creation of the VENICE website;
- 2) a survey on IP in MSs;
- 3) the annual report

Results of WP1

Coordination of the project

WP1 plans the activities jointly with WP 3-5 leaders, working in close collaboration with them. WP1 continuously oversees and coordinates the work in progress , ensuring respect of deadline and fulfilment of the objectives.

A meeting with WP leaders , ECDC and Brighton Collaboration counter parts has been organised in Rome in May 2006.

Many issues have been discussed in that occasion(see Annex 2a). First of all, there was a general agreement on the importance to avoid overlapping activities with WHO-CISID and EUVACNET as with EUVAX and EUREPI projects.

A project, funded by DG research on Mathematical Models to support Policy-Making (POLYMOD) was presented; a possible future collaboration between VENICE and POLYMOD was envisaged by channelling to the VENICE gatekeepers the results of POLYMOD and by asking public data to VENICE counterparts to feed the mathematical models developed in POLYMOD (currently available for rotavirus, varicella).

A presentation of the Brighton collaboration group was done by Ian Bonhoeffer.

Collaboration between VENICE and the Brighton collaboration was envisaged by the spreading of the already developed case definitions and by the potential use of “experts” on adverse reaction management. As ECDC has also expressed interest in establishing working contact with the BC, VENICE participates to this common interest.

The criteria underlying the identification of VENICE counter parts, who are experts in IP in each MSs and who work in public health institutions, were established.

Method to be applied to conduct the first survey and its content, were discussed in depth.

A 2nd meeting with the coordinator of VACSATC project (Vaccine Safety Attitudes, Training and Communication) was organised in July 2006 in order to integrate the activities done by VENICE with those of VACSACT and to ensure complementarity between the 2 projects. For more details see the Annex 2b.

A conference call with WP leaders, ECDC and Brighton Collaboration Counterparts, was organised in October 2006 to point out the need of conducting a survey on the use of rotavirus and HPV vaccines in each MSs, due to the recent availability of these vaccines on the European market (see Annex 2c). This topic has been considered a priority to explore within the VENICE network and two surveys have been launched after that conference call. The timetable of the other activities has been consequently rescheduled.

The last conference call of this 1st year was organised in January 2007 to decide a tentative agenda of the 2nd workshop as the outputs to present during it. The restyling and the content of the VENICE website have been deeply discussed.(see Annex 2d)

Creation of a network of public health experts in Europe

Before starting the project, collaboration from the epidemiologists on the field of communicable disease in Europe was sought. At the time the application had been submitted to DG SANCO (January 2006), a formal statement of interest was obtained from 21 MSs. However, during this first year of activities, other MSs asked to participate and the statement of interest has been collected from other 7 countries. An amendment in the contract was requested to DG SANCO in January 2007.

There are 28 European countries participating in the network: 26 EU member states (all except Malta) and two EEA/EFTA countries (Iceland and Norway).

VENICE is intended as a common platform where qualified users can exchange information and share expertise in immunisation and vaccines field.

National gatekeepers have been identified on the basis of their participation in other ongoing European vaccination networks (e.g. EUVACNET) as well as through the sponsor (DG SANCO) and the ECDC advisory forum EU members (see Annex 3a).

Given the broad approach of VENICE to cover different aspects of the immunisation programs - with the aim of linking all them together - it seemed unlikely that a single contact point would have been in the position of following the various activities of each specific work package, therefore gatekeepers were requested to identify additional colleagues in each country, at least one for each work package topic (1) immunisation registries and coverage, 2) policy decisions, 3) surveillance and management of adverse events) able and willing to actively take part in the project.

Such further contact points are contacted and asked to collaborate on the collection of specific information needed. The national gatekeeper in any case are informed about the requests and is expected to act as a coordinator when needed and as a facilitator for the surveys to be carried out.

WP1 is responsible for maintaining a constant and appropriate flow of information and for facilitating the development of relationships between national gatekeeper and contact points in order to create a network of european experts in vaccine and immunisation .

As an example of the constant flow of information, letters sent to gatekeepers on the main issues covered in the project so far, are attached (see Annex 3b-3f)

Collaboration with other networks as EUVAC-NET, VACSATC, POLYMOD, Brighton Collaboration

The ECDC has been invited to play a major role in the VENICE project considering that ,once the project finishes, the results should be taken over by the ECDC as the coordinating scientific body which will maintain and sustain the network across national immunization programs.

Beside its links with the ECDC, VENICE is collaborating with other European networks and organisations on vaccine-preventable diseases and immunisation issues, including Commission-funded projects like EUVAC.NET (<http://www.euvac.net>), VACSATC and the Brighton Collaboration (<http://www.brightoncollaboration.org>), in order to be complementary, to avoid overlapping activities and to facilitate dissemination of relevant data to the vaccination network.

Staff of WP1 also participated to the VACSATC steering board telephone meeting in July.

A member of the Brighton collaboration is usually invited to the VENICE conference calls and he is also involved in the organisation of the 2nd workshop.

As a further example of such collaboration, the first VENICE workshop was held in Malta in April 2006, together with the EUVAC.NET annual workshop; the next one will be organised in spring 2007 and will also include a session dedicated to presenting the results of the DG Research-funded project POLYMOD.

A POLYMOD members area has been created in the VENICE website for facilitating the exchange of documents and discussion among POLYMOD gatekeepers.

Creation of the VENICE website

The website (<http://venice.cineca.org/>), has been created taking advantage of the experience gained during the development of the DGSANCO sponsored project IRIDE (Inventory of Resources for Infectious Disease in Europe <http://iride.cineca.org>), which had also been developed by CINECA.

The website (see Appendix 4) is one of the most important sub-projects within VENICE and aims to provide information and recommendations in order to encourage the use of standard approaches (common case definition, common indicators to evaluate European immunisation programmes) to vaccination surveillance and data collection in participating countries. The website intends to be a platform for the collection and dissemination of information relating to vaccinations and is enabling the development of a European network of people working within the vaccination field.

The website provides regularly updated information on national and regional immunisation programmes, including schedules, vaccines used, vaccine coverage, methods for calculating coverage, systems for adverse event surveillance and management.

The area with the information above is at the moment restricted to national gatekeepers and contact point.

The VENICE project activities concerning the set-up of the VENICE web-site and the related web-based Information Technology tools have been the following:

1. Set-up of the web server on a high-availability web farm with a special user access and ssl based data security management
2. Study and set-up of the web site structure.
3. Set-up of an easy-to-use content management system
4. Set-up of a tool for the secure exchange of documents and information among VENICE project participants. The information flows are organized according to the structure and the hierarchy of the work group

5. Set-up of a web-based discussion forum among the participants. Access to the forum is granted on the basis of the structure of the work group
6. Set-up of a web-based tool for the conduction of surveys among project participants
7. Set-up of five web-based surveys
8. Set up of the function “download the database” which allow to have a database in excel format containing data from surveys in the electronic format conducted so far

After having implemented a first version of the site, mostly oriented to support the work of the project participants, a second version is being implemented.

Major differences with the current VENICE web site include:

- Area for link to other European networks on vaccine preventable diseases as EUVACNET, and link to ECDC, EMEA, WHO, Brighton Collaboration, Eurosurveillance, VACSATC
- Public pages containing selected information on Vaccines and vaccination programs, as a result of the work of the VENICE participants
- A public section of useful documents (e.g. text of surveys, ...)
- A function “search the website”, using relevant key words on vaccines and immunisation
- A function “search the database”, with semi structured queries that allow simple analysis of the database
- A section ‘contact the experts’ with a maintained list of European experts in the field of vaccination and AEFI management
- A fast method of disseminating important information, for example regular news emails to people who register for this service
- An electronic newsletter on vaccines

In the next couple of months, the website will also publish updates on scientific evidence concerning the effectiveness of vaccines against rotavirus, human papillomavirus, pneumococci, meningococci and varicella/VZV. It will provide access to information about vaccine products from national and European regulatory bodies such as the European Agency for the Evaluation of Medicinal Products and to relevant information on vaccination from international organisations such as the World Health Organization and the European Centre for Disease Prevention and Control (ECDC).

This area will be of public domain.

[Survey on Immunisation Programs in Europe](#)

This survey has been conducted in collaboration with WP3. Please see the section “[Survey on IP in Europe](#)” described in WP3 for details and the annex [7a,7b,7c](#) attached.

WP 2: Dissemination of results

Tasks of the WP2 and expected deliverables for the 1st year of the project

This work package is linked to the specific objective 1, 3 and the main task is the organisation of 3 workshops that will provide guidance and direction to the evolution of the network and of the specific subprojects undertaken by the technical work packages.

The dissemination of the interim findings, final results, and the method of dissemination of the specific projects is also coordinated within this work package

Expected Deliverables in the first year of the project

1. Month 4 Initial workshop
2. Month 12 Workshop on decision taking process

Results of WP2

Organisation of annual workshops

The 1st workshop was held in Malta in April 2006 (see Annex 5a) jointly with the EUVACNET annual meeting, as many gatekeepers of the VENICE project are also the EUVACNET contact points. This workshop was mainly oriented to illustrate the aims and objectives of VENICE as well as to begin the creation of a network of experts working in the national public health institutes. In that workshop the basis of the future strategies and activities of the project have been made. The 2nd workshop will be held in Venice next April and it is devoted to present the results of the subprojects after one year of activity as to discuss with national gatekeepers the gaps and the urgent issues to address (see Annex 5b).

Dissemination of results through publications in bulletin and peer-reviewed journals

A description of the immunisation program in each MS of the participating countries is regularly published on the ECDC biweekly newsletter. (see Annexes 6a-6q)

In the future, in each number of the ECDC bulletin, we will have a VENICE section where the advancement of the project and the related relevant news will be reported.

The activities of the VENICE project have been also illustrated in a short article published in *eurosurveillance* in January 2007 (see Annex 6r)

WP 3: Indicators of immunisation programs

Tasks of the WP3 and expected deliverables for the 1st year of the project

This work package is linked to the specific objective 4: to define common indicators for monitoring in a comparable way the immunisation programs across member states as well as their constituent regions.

To achieve this objective the participating MSs have agreed to provide information on immunisation schedules, immunisation vaccine coverage and vaccine coverage assessment through completed questionnaires, summaries of current national immunisation programs and information via national immunisation websites where applicable.

The feasibility of collecting immunisation uptake data using computerised immunisation registries in each member state is under examination.

Specific tasks of WP3 are:

- 1) to conduct a survey on IP in Europe;
- 2) to compare the methods used in each member state to measure immunisation uptake;
- 3) to review standards for the development of immunisation registries and capabilities of current systems assessed against these standards;
- 4) to develop technical protocols for measurement of immunisation uptake at agreed age intervals;
- 5) to describe barriers to comparability of data.

Expected Deliverables in the first year of the project

1. Month 6 Survey on immunisation programs in MSs
2. Month 10 Report on current methods on monitoring

Results of WP3

Survey on Immunisation Programs in Europe

This survey has been conducted and organised by WP1 and WP3.

According to the original outline of Venice, at least 3 surveys have to be conducted; one on immunisation programs indicators, one on vaccine policy and the 3rd one on AEFI following immunisation.

A preliminary survey on general organisation of the immunisation programs and vaccination delivery system in each country was carried out among national gatekeepers between July and September 2006. (see Annex 7a)

The survey has been piloted among 3 countries (Italy, Ireland, France) before launching it among all gatekeepers.

The survey was focused on obtaining general information on the context where vaccinations are systematically provided. Each country was therefore asked to assemble a narrative short report of the immunisation program in place and to respond to a list of specific questions.

The objectives of this survey were:

- 1) To have a structured description of national immunisation programs according to basic variables to allow comparison across different countries.
- 2) To identify similarities and differences of immunisation programs across European countries
- 3) To identify heterogeneities of the immunisation program at subnational level in each Country
- 4) To Collect background information on immunisation programs indicators, vaccine policy and decision making process, surveillance and management of AEFI that could have been used for the development of the specific surveys planned as part of the WP3, WP4, WP5.

The survey was divided in two parts (for details see the protocol attached, Annex 7b) .

In the first part, gatekeepers were asked to write a two page summary on how the immunisation program works in each country. This was a structured description, according to the specific issues as the presence of dedicated infrastructures for vaccine administration, information on vaccine purchase, vaccination schedules for childhood and adults, heterogeneity of the system at subnational level in terms of schedules and diseases targeted, vaccine coverage measurement, surveillance of AEFI.

The second part of the survey was including multiple choice questions and open answer questions to understand in depth the IP in each MSs.

The description of the immunisation programs of the participating countries is regularly being published on the ECDC biweekly bulletin .

A general report have been also produced and have been attached to this report (see Annex 7c).

Twenty seven out 28 countries returned back the questionnaire. Iceland is missing.

Results from the first survey on immunisation programs, indicated that National Vaccination Committees exist in 22 /27 MSs.

Vaccination schedules (mandatory and recommended) are followed by 23/27 member states at sub national national level except in Austria, Germany, Spain and Sweden.

Sub national administrative areas are present in 17/27 of the countries.

Mandatory vaccines are governed by legislation, recommended vaccinations are voluntary.

Those that are routine generally are paid for by the government whereas those that are recommended for at risk groups need to be paid for by the patient in certain countries.

In some cases there are charges both for the vaccine and the administration of the vaccine.

The ten commonest diseases that vaccinations are provided against are diphtheria, tetanus, pertussis, polio, Haemophilus influenza B, measles, mumps, rubella, meningococcal disease, and pneumococcal disease.

All MSs give three doses of diphtheria, tetanus and pertussis (acellular or whole, DTa/wP) vaccines by twelve months of age.

All MSs administer polio vaccine with oral polio used in 4 countries for all doses on the schedule (BG,CZ,EE,RO,).

Haemophilus influenza B vaccine is routinely given in 25/28 member states.

The Men C vaccine is given routinely in nine countries (DE,ES,GR,IE,IS, LU, NL,PT,UK) of which Ireland administers three doses by 6 months of age and United Kingdom by 12 months of age.

The vaccine used in childhood vaccinations is the pneumococcal conjugate PnV7, which is given routinely in nine of the member states(AT,BE,DE,FR,GR,LU,NL,NO,UK).

Hepatitis B vaccine is currently routinely given in 20 member states (AT,BE,BG,CY,CZ,DE,EE,ES,FR,GR,HU,IT,LT,LU,LV,PL.PT,RO,SK,SL).

eighteen countries administer BCG

(BG,CY,CZ,EE,FI,FR,GR,HU,IE,LT,LV,NO,PL,PT,RO,SE,SI,SK,UK). BCG is given at different times ranging from within 12 hours of birth to 6 weeks of age.

Measles mumps rubella (MMR) vaccine is included in the routine childhood immunisation schedule of all twenty eight member states. Catch up programs are in place in Austria, Cyprus, France, Poland and Italy.

Varicella is listed as a routine childhood vaccination in four countries AT,DE,ES,GR.

Information on four countries with regard to influenza vaccine was not available (AT,BG,CZ,IS,)

Of the remaining 24 countries, all would recommend influenza in at risk groups i.e. children with underlying medical conditions which places them at increased risk of developing potentially fatal complications. Influenza is the commonest adult vaccination with annual campaigns in all member states. Pneumococcal vaccination with the covalent pneumococcal vaccine pn23 is offered to at risk groups in 14 member states (AT, BE,CY,DE,DK,FR,GR, IE,LV,NO,PO,SI,SE,UK).

Tetanus toxoid plus adult diphtheria toxoid (Td) is recommended every 10 years in BG,CY,EE,GR,PT,RO in adults and tetanus toxoid (T) is recommended in The Czech Republic every 10-15 years.

[Survey on method for measuring vaccine coverage in Europe](#)

The main objective of this survey was to collect information on what vaccines are assessed, the age groups targeted, the frequency of vaccine coverage assessment, the methods of assessment, the use of performance indicators, as well as the use of immunisation registries is required.

The final aim is to determine common indicators for monitoring in a comparable way the immunisation programs across member states as well as their constituent regions.

This survey has been created in a electronic format and launched on the private area of the VENICE website. (see the paper format attached as Annex 7d).

Gatekeepers and contact point have been requested to fill in the questionnaire directly on the website.

Once all countries have completed the survey, a database in excel format will be automatically available for WP leaders, using the function “download the database”.

The survey was prepared in November 2006 and has undergone piloting within the Health Protection Surveillance Centre in Ireland.

Further editing and adapting of the questionnaire occurred over December 2006 and January 2007 and most recently from a teleconference involving the work package leaders, with subsequent comments being incorporated into the document.

The agreed changes meant that the questionnaire has now been presented to the IT department in VENICE WP1 and the testing has begun on February 15th in six countries (Italy, Ireland, France, Slovenia, Sweden and UK) with the intention of going live to other member states by end of February.

The final version of the survey was finalised also with the contribution of the project leader of the VACSATC project.

Results from this questionnaire will be analysed and a preliminary report will be available at the annual conference on VENICE in April 11-13th.

The structure of the database and the plan of analysis is ongoing.

Another collateral activity ongoing is Pub med search of relevant articles on immunisation registries currently in use in United States of America, Canada and Australia and elsewhere.

Activities planned in the next months are a manuscript describing obstacles to comparability of uptake data and a technical protocols for measuring immunisation coverage suitable for the EU.

WP 4: Priority setting and decision-making process

Tasks of the WP4 and expected deliverables for the 1st year of the project

This work package is linked to the specific objective 5: to encourage a rational approach to vaccination policy decision-making processes by promoting the exchange of experience and expertise through :

- 1) sharing of information about recent and current studies performed, the methodologies used and the outcomes of the expertise for vaccination policy decisions;
- 2) increasing the efficiency of work by reducing redundant analysis and sharing the tasks when the various MS are faced with similar issues such as integration of a new vaccine in the immunisation schedule;
- 3) increasing the level of expertise to a common high standard within the enlarged UE, including on public perception on vaccinations and techniques and methods to gauge such perceptions, e.g. by suitable questions in surveys;
- 4) setting the basis for European immunisation schedules through ensuring common scientific background for future vaccination decisions;

Specific tasks of WP4 are:

- A review of tools used and analysis performed in the recent years for vaccination decision making process through a survey in the participating countries;
- 2 workshops where discussing the results of the survey and the modalities of an on-going exchange of information about analysis being carried out, methodologies of analysis used and recommendations decided;
- On going posting on the secure website of scientific information including both expertise being carried out in the various MSs and outcomes of other collaborating projects aimed to standardise the framework of analysis for economic evaluation and modelling such as POLYMOD

Expected Deliverables in the first year of activity

1. Month 9: Report of the survey on analysis recently carried out, methodologies used, expertise available in the various MS, in the frame of vaccination policy decision making process
2. Month 12: Workshop on modalities of real-time sharing of expertise between MS including agreement on a chart regarding use of unpublished information shared

Results of WP4

Surveys on the use of rotavirus and HPV vaccines in MSs

With regard to the WP4, during the first meeting with all WP leaders in Rome (see Annex 2a), we decided to focus the activity on the point 2 of the specific tasks described above: “*increasing*

the efficiency of work by reducing redundant analysis and sharing the tasks when the various MS are faced with similar issues such as integration of a new vaccine in the immunisation schedule”.

Indeed this issue was considered to be a priority in order to compare and harmonise the decision making process in each Ms in vaccination policy .

During the meeting, it has been decided to monitor the introduction of Rotavirus as an infant immunisation and HPV vaccines as adolescents one.

At this regard, it has to be pointed out that two new vaccines against rotavirus (RV) and human papillomavirus (HPV) have been recently available on the European market, according to common European Union (EU)-wide regulatory procedures .

In order to decide about their inclusion in the national or regional immunisation schedules different issues are to be considered most of them of general interest.

Single experts and institutions involved in providing advice to the health authorities in the EU Member States on vaccination policy are working, producing data to support the decision making process.

This situation has been regarded as a unique opportunity for the VENICE project and the ECDC, according to their respective objectives and missions, to support the networking and the efforts of the involved institutions and to facilitate a synergist approach by sharing information and tools across EU.

National gatekeepers and contact point were invited to collaborate by providing information about the activities carried out in your country to support the vaccination policy on rotavirus and HPV.

In order to gather comparable information from all the EU MS a questionnaire has been developed in an electronic format and launched on the private area of the VENICE website in January 2007. (see the paper format attached as Annex 7e).

Gatekeepers and contact point have been requested to fill in the questionnaire directly on the website.

The survey was prepared in October 2006 and has undergone piloting within 5 MSs: Italy, Ireland, France, Hungary and Greece. The pilot phase ended the first week of February, then all the other MSs completed the survey in the 2nd week of February.

A database in excel format is available for WP leaders, using the function “download the database” on the website.

The statistical analysis is currently ongoing and a short summary of the situation in Europe with regard to the use of these two vaccines will be available in the first half of March.

WP 5: Capacity building in monitoring, prevention and management of post vaccination Adverse Events

Tasks of the WP5 and expected deliverables for the 1st year of the project

This work package is linked to the specific objective 6: to provide MSs with relevant informations on Adverse Events Following Immunisation (AEFI) issues, develop best practice models and contribute to capacity building in dealing with monitoring, preventing and managing of AEFI.

The expected results are:

- 1) the availability of common criteria of case definition and classification of AEFI
- 2) promoting a better knowledge of AEFI related issues

Specific tasks of WP5 are:

- a. collection on information on systems in place for monitoring of AEFI;
- b. development of AEFI case studies, focused on their prevention and management;
- c. development of recommended common case definitions, protocol for investigating etiology, contraindications;
- d. suggesting models for AEFI monitoring, information storage and retrieval and relation with official sources on each pharmaceutical product;
- e. development of material for training modules on:
 - Vaccination best practices, precautions, contraindications
 - AEFI identification and treatment
 - Provision and settling of needed equipment and drugs
 - Emergency co-ordination

Expected Deliverables in the 1st year of the project

1. Month 3 Identification of appropriate MS counterparts
2. Month 9 Survey on the adverse events monitoring system in MSs

The activities of WP5 are conducted in collaboration with the Brighton Collaboration and VACSATC in order to share the expertise on AEFI management, common to all these projects and to ensure complementarity.

In order to gather comparable information from all the EU MS on AEFI surveillance and management, a questionnaire has been developing in a electronic format and it will be launched on the private area of the VENICE website in March 2007. (see the paper format attached as Annex 7f).

Gatekeepers and contact point will be requested to fill in the questionnaire directly on the website.

The survey will be pre tested in 5 MSs in the 1st week of March and the other MSs will be invited to participate in the in the 2nd week of March.

After the launch of the survey, a database in excel format will be available for WP leaders, using the function “download the database” on the website.

Preliminary results of the survey will be presented at the annual workshop in Venice, in April 2007.

Other collateral activities of WP5 are selection of literature on AEFIs and case definition, meaningful and structured case studies, prevention and treatment of AEFIs.

Problems encountered so far

The project is proceeding in a satisfactory way, however the start of the activities had to face additional challenges due to the delays in the approval and signing of the contract. In fact compared to the initial proposal submitted to DGSANCO in 2004 the context of activity at the beginning of 2006 was changed. The major change in the external setting has been the establishment of the European Centre for Disease Control where vaccines and vaccine-preventable diseases are a relevant part of the work plan. The ECDC has instituted a formal Advisory Forum with representatives from each EU Member States. The VENICE project had therefore take into account the new setting and the additional workload of activities requested by ECDC to candidate project gatekeepers. However VENICE has been quite successful in establishing very good collaboration with the ECDC (as demonstrated by the section devoted to VENICE in the ECDC newsletter on Vaccines and Immunisations) and with the MS representatives at various level.

As the major aim of the project is to establish a European network of personnel involved in various aspects of immunisations the current activity has been organised with a strong coordination effort, trying to link together staff working on political decisions with those working on adverse events and those working on vaccine coverage. All the activities performed in VENICE in the various WPs are discussed by the entire group of WP leaders and collaborators. The need to avoid multiple simultaneous requests to the same gatekeepers from different WPs has led to a sequential organisation of the planned surveys.

Future activities in the next 2 years of the project

The first year of activities has been aimed to set up the network and to develop of technical tools for maintaining collaborations, collecting and communicating pertinent information. In the next two years we plan to reinforce and expand the network and the collaboration at international level. Most of these objectives will be pursued by development of the web-site which will be the primary tool for collection on-line of

relevant data, exchanging documents and opinion and including a sort of directory of relevant staff on immunisation across Europe.

Conclusions

The topic of vaccines and vaccinations is becoming always more important across EU and the world and public health has a prominent role in this field.

Although many initiatives had been already launched on vaccine-related issues VENICE has been welcomed by all the partners as its aim is to provide a link between different aspects of the topics and to offer a service to the network participants, by means of facilitating communications and share of experience. The project is conducted with the plan of handing over to ECDC the entire network and therefore with a long-term perspective of collaboration.

Appendix 1: Timetable of the project

Appendix 2: Agenda and summary of WP leaders meetings and conference calls

Appendix 3: Communication with national gatekeepers and contact points

Appendix 4: home page VENICE website

Appendix 5: Agenda of the VENICE workshops

Appendix 6: Publications

Appendix 7: Surveys

This report was produced by a contractor for Health & Consumer Protection Directorate General and represents the views of the contractor or author. These views have not been adopted or in any way approved by the Commission and do not necessarily represent the view of the Commission or the Directorate General for Health and Consumer Protection. The European Commission does not guarantee the accuracy of the data included in this study, nor does it accept responsibility for any use made thereof.