TWINNING INTERIM QUARTERLY REPORT

No. 1

Strengthening the surveillance and control of Communicable Diseases

Member State Partners

The Netherlands Ministry of Health, Welfare and Sport,
The Netherlands School of Public and Occupational Health (NSPOH)

Beneficiary Country Partners

Ministry of Health of the Slovak Republic
Public Health Authority of the Slovak Republic

30 May 2005

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Section 1. Project data

Twinning Contract No.	SK03/IB/SO/01
Project title	Strengthening the surveillance and control of communicable diseases
Twinning partners	Ministry of Health, Welfare and Sport (NL) Ministry of Health (SK)
Report No.	1
Period covered by the report	14 February – 13 May 2005
Duration of the project	21 months

Rapporteur Member State	Rapporteur Beneficiary Country
Mr Geert van Etten, project leader	Ms Zuzana Škublová, project leader

Section 2. Content

Background

Policy development

The new Act of Public Health including a list of mandatory reported infectious diseases and the draft of a new Directive on surveillance and control of the communicable diseases in the Slovak Republic has been prepared. The mandatory reported Communicable Diseases in the list were divided into 3 groups according the urgency of reporting.

The following EU Directives have been approximated:

- Decision N° **2119/98/EC** of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (Official Journal L 268, 03/10/1998, p.0001 - 0007)
- Commission Decision N° **2000/57/EC** of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C (1999) 4016) (Official Journal L 021, 26/01/2000, p. 0032 – 0035)
- Commission Decision N° **2000/96/EC** of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C (1999) 4015) (Official Journal L 028, 03/02/2000, p. 0050 – 0053)
- Commission Decision N° **2002/253/EC** of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C (2002) 1043) (Official Journal L 086, 03/04/2002, P. 0044 – 0062)
- Commission Decision N° **2003/534/EC** of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (notified under document number C (2003) 2301) (Official Journal L 184, 23/07/2003, P. 0035 – 0039)

Project assumptions

The assumptions as formulated in article 3 of the Work plan are

- The structure of public health service will remain stable
- Access to database of relevant information of Communicable Diseases
- Co-operation with other stakeholders, providing relevant information about Communicable Dideases
- Positive approach of institutions, representing relevant EU networks, towards Slovak integration ambitions
- The accreditation process takes less than three months (if it takes more than three months it will lead to delay in the accreditation of the NRCs)
- EU networks are willing to register BC's experts into their networks
- Dutch or German institutes are prepared to receive interns for two weeks

The assumptions that EU networks are willing to register BC's experts into their networks and a positive approach of institutions, representing relevant EU networks, towards Slovak integration ambitions have been fulfilled. Opinions diverge on the stability of the structure of public health service and the co-operation with other stakeholders, providing relevant information about Communicable Diseases. The assumption that Dutch and German institutes are prepared to receive trainees is likely to be fulfilled soon.

There have not been any developments, which make some of the assumptions impossible to achieve.

Achievements of mandatory results

The following **Benchmarks** were achieved in the reporting period:

Component I

- Members of expert group from the PHA were selected and participated in discussions with NSPOH expert on the assessment and development of the monitoring system of CD harmonised with EU standards
- Within the framework of a training programme, 6 Slovak specialists visited institutions in the Netherlands and Germany to study the surveillance and control system
- Provisional definitions of conditions, outputs, inputs, and functionality of the software for target applications (early warning system, infectious diseases national register, and influenza surveillance) were drafted
- An overview of data protection regulations in Slovakia in comparison with EU requirements and practices was prepared
- An assessment of the reporting system of CD in relation with the Acquis and existing systems in the EU including data protection and an assessment on current membership of Slovak experts in EU networks were performed.

Component II

- Members of expert group from PHA and NRCs were selected and participated in discussions with the NSPOH expert on the assessment and improvement of the internal quality assurance system
- Recommendations on training needs and equipment were drafted and technical specifications on the supply contract developed.

Component III

- Members of expert group from PHA and NRCs were selected and participated in discussions with NSPOH expert on the assessment and improvement of the external quality control system
- An assessment of current Standard Operating Procedures was performed.

The following **Mandatory Results** were completed or are close to completion:

- Definition of the conditions, outputs, inputs, and functionality of the special software for three target applications: Early Warning System, Infectious Diseases National Register, and Influenza Surveillance

Activities in the reporting period

The Twinning project started on 14 February 2005. The Resident Twinning Adviser, Mr Adriaan J.H. Korver arrived in Slovakia on 13 February 2005 and started with his activities on the date of notification. Mr Korver has a temporary assignment until beginning of August 2005.

On 30 March 2005, the kick-off meeting for the project took place. Mr. Ottinger, Deputy Minister of Health and Mr. Stokvis, ambassador of The Netherlands in Slovakia were the guests of honour at the meeting. In addition to the speeches by the guests of honour, Mr Lafeber (representative of the Ministry of Health, Welfare and Sport of The Netherlands) and Dr. Rovny, chief hygienist of Slovakia and Director of the National Public Health Authority of Slovakia addressed the audience. After the official opening, speakers of Slovakia, The Netherlands and Latvia informed the audience about “surveillance and control of Communicable Diseases” in their respective countries (annexes I.1 – I.8)

During the first quarter, one Side Letter related to the reduction of the project duration from 24 to 21 months, reallocations in the project budget and the appointment of new experts was submitted to the CFCU (annex II.1).

Component I.

Activity 1.1 Establishment of an expert group on data collection system and Early Warning & Rapid Response system for Communicable Diseases.

No MS experts were involved in this activity. The RTA received the list of participants prepared by the beneficiary institution upon arrival in the country.

The following experts from the Slovak Republic are members of the expert group:

- Ms M. Avdičová, Head Section of Epidemiology, Regional Public Health Authority Banská Bystrica / Co-ordinator component I
- Ms F. Hrubá, Head Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica / Deputy Co-ordinator component I
- Mr K. Accipiter, IT manager Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica
- Mr D. Béreš, Director, Regional Public Health Authority Rimavská Sobota
- Ms H. Hudečková, Head Section of Epidemiology, Regional Public Health Authority Martin
- Ms T. Kašperová, Head Department of Bioterrorism Prevention and Emergency Planning, Public Health Authority of Slovak Republic
- Ms M. Sláčiková, Section of Epidemiology, Public Health Authority of Slovak Republic / Deputy Project Manager (from 6 May 2005)
- Ms M. Štefkovičová, Head Section of Epidemiology, Regional Public Health Authority Trenčín
- Mr P. Truska, Head Section of Epidemiology, Regional Public Health Authority Bratislava

The activity was completed before the actual start of the Twinning project.

Activity 1.2 One-week study visit of 6 BC experts to the Netherlands and Germany

The RTA together with NSPOH organised the study visit to Germany and The Netherlands.

The following experts from the Slovak Republic participated in the study visit:

- Ms M. Avdičová, Head Section of Epidemiology, Regional Public Health Authority Banská Bystrica / Co-ordinator component I
- Ms F. Hrubá, Head Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica / Deputy Co-ordinator component I
- Mr K. Accipiter, IT manager Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica
- Ms T. Kašperová, Head Department of Bioterrorism Prevention and Emergency Planning, Public Health Authority of Slovak Republic
- Ms E. Máderová, Head Section Epidemiology, Public Health Authority of Slovak Republic / Project Manager (until 6 May 2005)
- Ms L. Matuškovičová, Assistant at the Section of Epidemiology, Public Health Authority of Slovak Republic

The visit took place from 3 – 9 April 2005 (annex II.2). The participants drafted a report about their visit (annex II.3). The main conclusions made up after the visit by the participants were:

- They replenished their knowledge about system of public health in the Netherlands and Germany
- They got a picture of the structure and mission of public health services in the Netherlands and Germany, and
- They got new ideas about how the report system and register of infection diseases in the Slovak Republic could be adapted.

The Study Visit programme was completely fulfilled and expectations were met.

Activity 1.3 Brainstorm session concerning the user requirements of the surveillance and control system of communicable diseases
Mr Matthias Otto (NSPOH / KinderUmwelt Germany) was involved in this activity on behalf of the Member State-partner.

The following experts from the Slovak Republic participated in brainstorming session:
- Ms M. Avdičová, Head Section of Epidemiology, Regional Public Health Authority Banská Bystrica / Co-ordinator component 1
- Mr K. Accipiter, IT manager Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica
- Mr D. Béreš, Director, Regional Public Health Authority Rimavská Sobota
- Ms F. Hrubá, Head Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica / Deputy Co-ordinator component I
- Ms D. Komandová, Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica
- Ms Z. Krištúfková, Head Department of Infectious Diseases Control, Public Health Authority of Slovak Republic / Project Manager (from 6 May 2005) / former SPO of the project
- Mr P. Lokša, Section of Epidemiology, Regional Public Health Authority Banská Bystrica

The session took place at the Regional Public Health Authority in Banská Bystrica. The visit took place from 18 - 21 April 2005.

During the first brainstorm session, the present data flow between all relevant stakeholders (GP´s, hospitals, laboratories, regional institutes of Public Health and National Reference Centres [NRC] etc) was analysed. Particular attention was paid to evaluating the individual reporting routes with respect to reporting compliance, frequency and completeness of data. The administrative level at which case management of individual cases should take place was also discussed. The working group agreed that case management will take place at local level (local Regional Institute of Public Health). The ability to see a case history will be a very important feature of the new reporting system. Moreover, the experts agreed that the new central database will comprise 3 components, i. e. a Register on Communicable Diseases, an Early Warning System and a Influenza Reporting System. An open and frank discussion on the role and position of the National Reference Centres also occurred. National Reference Centres serve a dual purpose, both as specialised laboratories and as well as a guiding/counselling institution in case management. This will have implications on the data flow in the forthcoming Register on Communicable Diseases.
Finally, a draft ToR for the tender prepared by the Slovak experts was discussed and (provisional) criteria for the selection of an appropriate IT company defined.

Mr Otto's mission report can be found in annex II.4.

Activity 1.4 Evaluation of data protection regulations and its implementation
Mr Jan Holvast (NSPOH) was involved in this activity on behalf of the Member State-partner.

The following experts from the Slovak Republic participated in meetings with Mr Holvast:
- Ms M. Avdičová, Head Section of Epidemiology, Regional Public Health Authority Banská Bystrica / Co-ordinator component I
- Mr K. Accipiter, IT manager Section of Informatics and Health Statistics, Regional Public Health Authority Banska Bystrica
- Ms F. Hrubá, Head Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica / Deputy Co-ordinator component I
- Ms Z. Krištúfková, Head Department of Infectious Diseases Control, Public Health Authority of Slovak Republic / Project Manager (from 6 May 2005)

- Ms E. Máderová, Head Section of Epidemiology, Public Health Authority of Slovak Republic / Project Manager (until 6 May 2005)
- Mr M. Otto, Expert Activity 1.3

The meetings took mainly place at the Regional Public Health Authority in Banská Bystrica. The Data Protection Office in Bratislava was also visited. The visit took place from 17 – 21 April 2005.

During the visit of the Dutch expert, several issues on data protection were discussed. A major issue was to clarify the flow of information from patient to National Register of Communicable Diseases.This issue was extensively discussed during and after the brainstorming session (activity 1.3). The Data Protection Act is applicable on the processing of these data. The possibility of using the national identification number in the registration of communicable diseases is allowed. Once the purposes are clearly formulated, it can be defended that also the processing of ethnic data is necessary.
The expert extensively discussed the operational aspects of the National Register in the light of the Data protection Act. Expert agreed to draft a letter to the Data Protection Office in order to clarify some issues.

Mr Holvast's mission report can be found in annex II.5.

Activity 1.5 Evaluation and recommendations on the quality and range of the data collected according to the EU networks needs, links between NRC data and CD database, output and feedback of the system and memberships in EU networks
Mr Wilfrid van Pelt (NSPOH / RIVM) was involved in this activity on behalf of the Member State-partner. The RTA prepared a tentative inventory on membership in EU networks (annex II.6).

The following experts from the Slovak Republic participated in meetings with Mr van Pelt:
- Ms M. Avdičová, Head Section of Epidemiology, Regional Public Health Authority Banská Bystrica / Co-ordinator component I
- Ms F. Hrubá, Head Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica / Deputy Co-ordinator component I
- Mr K. Accipiter, IT manager Section of Informatics and Health Statistics, Regional Public Health Authority Banská Bystrica
- Ms E. Böhmová, Section of Epidemiology, Regional Public Health Authority Bratislava
- Ms J. Bosá, Head Section of Medical Microbiology, Public Health Authority of Slovak Republic / Co-ordinator component II
- Ms D. Gavačová, Head NRC for Salmonelloses, Public Health Authority of Slovak Republic
- Ms Z. Krištúfková, Head Department of Infectious Diseases Control, Public Health Authority of Slovak Republic / Project Manager (from 6 May 2005) / former SPO of the project
- Ms E. Máderová, Head Section of Epidemiology, Public Health Authority of Slovak Republic / Project Manager (until 6 May 2005)
- Ms J. Pertináčová, Head Department of Epidemiology, Regional Public Health Authority Bratislava
- Ms Z. Sobotová, Head NRC for Poliomyelitis, Public Health Authority of Slovak Republic
- Mr J. Strhársky, Section of Medical Microbiology / Head Department of Medical Parasitology, Regional Public Health Authority Banská Bystrica
- Mr P. Truska, Head Section of Epidemiology, Regional Public Health Authority Bratislava

The visit took place from 24 – 29 April.

In meetings with several Slovak experts, the Dutch expert evaluated the current system of registring communicable diseases. According to the Dutch expert, Slovakia did a remarkable good job with regard to the CD-registration considering the means and the workload. The historical data are a goldmine for supporting health policy, contribution to EU-scientific-networks and future implementation of automated EW-algorithms and sensible feedback to health-practitioners within the country and abroad. Despite this positive evaluation, there are several shortcomings (e.g. participation of stakeholders, number of diseases to be registered, labour-intensive registration and unclearness about what is done with the collected information). Particular attention was paid to the Early Warning System (EWS). It should provide information on national cases as well as on European cases. Moreover, it should enable an automated evaluation of the actual influenza situation and it should report to the "European Influenza Surveillance Scheme" (EISS) network of the EU. EWS has nothing to do with software. It concerns – inter alia – contingency planning (e.g. for large cross-national problems with food or an influenza pandemic or major national outbreaks like avian influenza), relationships and communication with professionals, leadership and professional training.
One of the recommendations of the expert was "do not tender for completely new software". He suggested making an inventory of systems in use in different countries that fit the needs and routine of Slovakia and that can be easily adapted by your Slovak experts in the future. In particular, the expert suggested not tendering specifically for software for influenza surveillance.

Mr van Pelt's mission report can be found in annex II.7.

Component II.
Activity 2.1 Establishment of an expert group on internal quality assurance within National Reference Centres
No MS experts were involved in this activity. The RTA received the list of participants prepared by the beneficiary institution upon arrival in the country.

The following experts from the Slovak Republic are members of the expert group:
- Ms J. Bosá, Head Section of Medical Microbiology, Public Health Authority of Slovak Republic / Co-ordinator component II
- Ms M. Švejnochová, Head NRC for Meningococci, Public Health Authority of Slovak Republic / Deputy Co-ordinator component II, III
- Ms H. Blaškovičová, Head NRC for Influenza, Public Health Authority of Slovak Republic
- Ms D. Gavačová, Head NRC for Salmonelloses, Public Health Authority of Slovak Republic
- Mr C. Klement, Chief Specialist Ministry of Health of Slovak Republic for Medical Microbiology / Head Section of Medical Microbiology, Regional Public Health Authority Banská Bystrica
- Mr M. Nikš, Head NRC for monitoring the resistance of micro-organisms on antibiotics, Public Health Authority of Slovak Republic / Co-ordinator component III
- Ms Z. Sobotová, Head NRC for Poliomyelitis, Public Health Authority of Slovak Republic
- Ms Z. Majláthová, Quality Manager, Regional Public Health Authority Banská Bystrica

The activity was completed before the actual start of the Twinning project.

Activity 2.2 Evaluation of existing knowledge and experience on quality control systems and progressive detection methods of NRC staff and analysis of available equipment and material at the different NRCs, and Development of technical specifications for supply contract.
Ms Wendy Waijboer and Mrs Joep Galama and Bert Mulder (NSPOH) were involved in this activity on behalf of the Member State-partner.

The following experts from the Slovak Republic from Public Health Authority of Slovak Republic participated in meetings with Mrs Galama and Mulder:

- Ms J. Bosá, Head Section of Medical Microbiology, Public Health Authority of Slovak Republic / Co-ordinator component II
- Ms J. Adamčáková, Staff member NRC for Influenza
- Ms Š. Bláhová, Staff member NRC for Poliomyelitis
- Ms H. Blaškovičová, Head NRC for Influenza
- Ms D. Gavačová, Head NRC for Salmonelloses
- Ms Z. Sobotová, Head NRC for Poliomyelitis
- Ms M. Švejnochová, Head NRC for Meningococci /Deputy Co-ordinator component II/III
- Ms J. Tietzová, Head NCR for MMR / Head of cell-culture laboratory

The following experts from the Slovak Republic participated in meetings with Ms Waijboer:

- Ms J. Bosá, Head Section of Medical Microbiology, Public Health Authority of Slovak Republic / Co-ordinator component II
- Mr M. Nikš, Head NRC for monitoring the resistance of micro-organisms on antibiotics, Public Health Authority of Slovak Republic / Co-ordinator component III
- Mr Bakoš, Quality manager - measuring accuracy technique, Regional Public Health Authority Košice
- Ms H. Blaškovičová, Head NRC for Influenza, Public Health Authority of Slovak Republic
- Ms D. Gavačová, Head NRC for Salmonelloses, Public Health Authority of Slovak Republic
- Mr C. Klement, Head of NRC for Pertussis and Parapertussis / Head Section of Medical Microbiology, Regional Public Health Authority Banská Bystrica
- Ms Z. Majláthová, Quality Manager, Regional Public Health Authority Banská Bystrica
- Ms Miková, Head NRC for Diphtheria, Regional Public Health Authority Košice
- Ms Z. Sobotová, Head NRC for Poliomyelitis, Public Health Authority of Slovak Republic
- Ms M. Švejnochová, Head NRC for Meningococci, Public Health Authority of Slovak Republic / Deputy Co-ordinator component II/III
- Ms J. Tietzová, Head NCR for MMR / Head of cell-culture laboratory, Public Health Authority of Slovak Republic

The visit of Mrs Galama and Mulder took place from 17 – 21 April 2005. Mr Galama evaluated the situation at the NRCs for respectively MMR, Influenza and Poliomyelitis, and the cell-culture laboratory; Mr Mulder on the NRCs for respectively Meningitis and Salmonellosis. Their main findings/conclusions were:

- The NRCs are small, have little staff and personnel (vulnerable regarding continuity and progress of work). In addition, these NRCs have many techniques in common but do not cooperate or benefit from an infrastructure to be used by all (except for the TC facility).
- Priority for establishing BSL3 conditions for the implementation of Anthrax detection.
- Consider bringing the virological NRCs at the PHA under a single organisation with a virus isolation laboratory, headed by a classical virologist, a molecular laboratory for all Nucleic Acid Techniques, headed by a molecular biologist and a serology laboratory, headed by a clinical immunologist. Within this organisation, reference tasks can still be supervised by reference specialists.
- Reconsider bringing more Public Health reference activities under a single umbrella, whether or not to be concentrated at one single place, for example, hepatitis, candidate emerging viruses (zoonoses), viral STD (including HIV), food-related viruses, meningitis, etc.
- Implement participation in an external quality control system.
- Strengthen infrastructure of NRCs by providing laboratory equipment and by introducing Pulse Field Gel Electrophoresis (PFGE) technology.
- Develop an electronic laboratory administration system.

The mission reports of Mrs Galama and Mulder can be found in respectively annex II.8 & II.9.

The visit of Ms Waijboer took place from 10 – 22 April 2005.
Recommendations were formulated in relation to training needs for heads of NRC (internship & internal auditing), and to general training needs for all staff of NRC (e.g. information on quality assurance in general, on complain management, on the control of non-conforming testing and/or calibration work, corrective and preventive actions, and on internal and external auditing). Moreover, she formulated recommendations in relation to e.g. SOPs and a Quality Manual.
Her general remark was that creating and implementing a quality system in a medical laboratory in one year is very ambitious. It took most laboratories in the Netherlands at least two years. To show the SNAS that the quality system really works, one needs to have some history (internal audit reports and follow-up, complain management system, etc.).

Ms Waijboer's mission report can be found in annex II.10.

Component III.
Activity 3.1 Establishment of an expert group on external quality assurance within National Reference Centres
No MS experts were involved in this activity. The RTA received the list of participants, prepared by the beneficiary institution upon arrival in the country.

The following experts from the Slovak Republic are members of the expert group:
- Mr M. Nikš, Head NRC for monitoring the resistance of micro-organisms on antibiotics, Public Health Authority of Slovak Republic / Co-ordinator component III
- Ms M. Švejnochová, Head NRC for Meningococci, Public Health Authority of Slovak Republic / Deputy Co-ordinator component II, III
- Ms H. Blaškovičová, Head NRC for Influenza, Public Health Authority of Slovak Republic
- Ms D. Gavačová, Head NRC for Salmonelloses, Public Health Authority of Slovak Republic
- Mr C. Klement, Chief Specialist Ministry of Health of Slovak Republic for Clinical Microbiology / Head Section of Medical Microbiology, Regional Public Health Authority Banská Bystrica
- Ms Z. Sobotová, Head NRC for Poliomyelitis, Public Health Authority of Slovak Republic
- Ms J. Tietzová, Head NCR for MMR / Head of cell-culture laboratory, Public Health Authority of Slovak Republic

The activity was completed before the actual start of the Twinning project.

Activity 3.2 Analysis of current Standard Operating Procedures for external quality assurance
Ms Wendy Waijboer (NSPOH) was involved in this activity on behalf of the Member State-partner.

The following experts from the Slovak Republic participated in meetings with Ms Waijboer:
- Ms J. Bosá, Head Section of Medical Microbiology, Public Health Authority of Slovak Republic / Co-ordinator component II
- Mr M. Nikš, Head NRC for monitoring the resistance of micro-organisms on antibiotics, Public Health Authority of Slovak Republic / Co-ordinator component III
- Mr Bakoš, Quality manager - measuring accuracy technique, Regional Public Health Authority Košice
- Ms H. Blaškovičová, Head NRC for Influenza, Public Health Authority of Slovak Republic
- Ms D. Gavačová, Head NRC for Salmonelloses, Public Health Authority of Slovak Republic

- Mr C. Klement, Head of NRC for Pertussis and Parapertussis / Head Section of Medical Microbiology, Regional Public Health Authority Banská Bystrica
- Ms Z. Majláthová, Quality Manager, Regional Public Health Authority Banská Bystrica
- Ms Miková, Head NRC for Diphtheria, Regional Public Health Authority Košice
- Ms Z. Sobotová, Head NRC for Poliomyelitis, Public Health Authority of Slovak Republic
- Ms M. Švejnochová, Head NRC for Meningococci, Public Health Authority of Slovak Republic / Deputy Co-ordinator component II/III
- Ms J. Tietzová, Head NCR for MMR / Head of cell-culture laboratory, Public Health Authority of Slovak Republic

The visit of Ms Waijboer took place from 10 – 22 April 2005. The experts agreed that during Dr. Bosá's internship in The Netherlands, Dr. Bosá and Ms Waijboer will discuss with the Dutch Foundation on Quality Control of Medical Laboratory Diagnostics the possibilities to improve external quality.

Ms Waijboer's mission report can be found in annex II.10.

Timing & Delays

Adherence to time schedule[1]

The adherence to the time schedule is expressed in the following table:

[1]

Activity planned
Activity implemented
Activity delayed by more than 3 months

Activity \ Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Component 1																					
Activity 1.1																					
Activity 1.2																					
Activity 1.3																					
Activity 1.4																					
Activity 1.5																					
Activity 1.6																					
Activity 1.7																					
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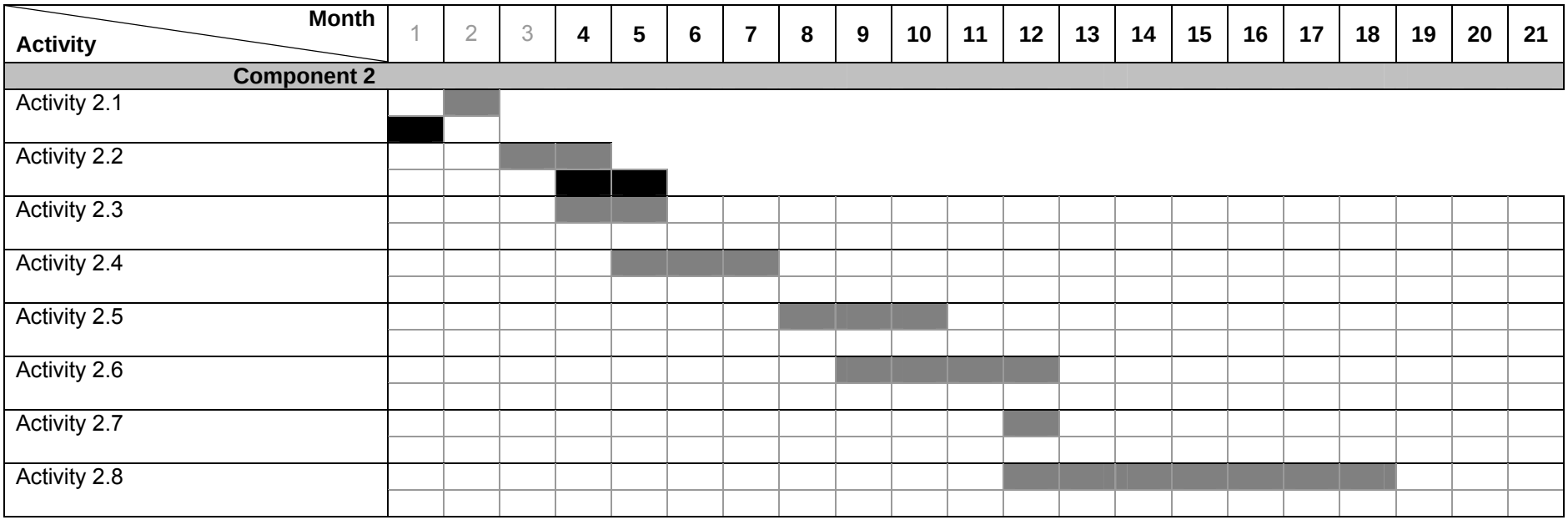
Month
Activity
1
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20
21
Component 2
Activity 2.1
Activity 2.2
Activity 2.3
Activity 2.4
Activity 2.5
Activity 2.6
Activity 2.7
Activity 2.8

Activity \ Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Component 3																					
Activity 3.1																					
Activity 3.2																					
Activity 3.3																					
Activity 3.4																					

Recuperation of delays
There were no delays of more than three months.

Assessment

Overall assessment of progress
The overall objective of the Twinning project is to strengthen the surveillance and control of Communicable Diseases by increasing the Communicable Disease detection and response rate and by upgrading administrative and implementing structures concerning the epidemiological and laboratory control of Communicable Disease upgraded and integrated into EU networks. In order to achieve this objective, the implementation will focus on three aspects, notably

- Harmonising the Slovak monitoring system of Communicable Disease with EU standards, upgrading the Early Warning System (EWS) and training the concerned staff;
- Extending the National Reference Centres' (NRC) network by establishing a Bio Safety Level 3 laboratory (BSL3) with conditions for the implementation of Anthrax rapid detection), strengthening the existing NRCs, and implementing a Laboratory Assurance Quality System in the NRCs, and
- Implementing Standard Operating Procedures (SOP) in selected microbiology laboratories based on the newly implemented quality assurance system.

The progress of the project is in line with the revised work schedule. The first (Analysis) phase of project was almost completed.
However, the CFCU requested to have all tender documents (Technical specification for hardware and laboratory equipment together with Terms of Reference for Software) at its disposal on 31 May 2005 at the latest, due to the contracting deadline for this project, which is 30 of November 2005. Therefore, the Slovak partner started to work on activity 1.8 and together with the Twinning partner on activity 1.7 during this reporting period, even though they were planned on 7 – 8 month of project implementation.
According to the current situation, all activities are to be completed within a time frame of 21 months.

However, there is one concern related to additional national financing of the accreditation process. In component 2 of the Twinning project, Slovak and Dutch experts will work on improving internal quality by e.g. implementing a Laboratory Assurance Quality System in the NRCs, which may (hopefully) result in accrediting the facilities. In order to get the accreditation, procedures and facilities will be judged. According to the building standards, the concerned laboratory facilities have to be renovated. In case not enough funding for the renovation will be available, it may result in not becoming accredited. This means that one of the benchmarks of component 2 (activity 2.8.) will not be achieved.

There is good progress of the project in terms of content, time schedule and budgetary framework. Different levels within the Slovak Public Health Authority (director of the PHA SR, Project Manager, component co-ordinators and staff members at the PHA SR and regional PHAs) support the implementation of the project in a positive way.

Issues
The up-graded version of the General Coordinating Directive for Foreign Assistance was approved in April by Slovak Government. According to it, Mrs. Kristufkova, former SPO was appointed as a project manager on behalf of the beneficiary institution and replaced Mrs. Maderova.

Ms Daina Toleikyte, project manager of the Netherlands School of Public and Occupational Health visited Slovakia on 7 and 8 April 2005. In order to improve the communication between the Twinning partners, Ms Toleikyte took the initiative to have a meeting with the Slo-

vak project leader. This meeting, in presence of the RTA took place on 8 April. The main conclusions of this meeting were:

- All Side letters, prepared by TW partner will be consulted with the CFCU in the terms of the eligibility of proposed changes prior to submission to MoH for approval.
- Side letters will include the reasons, explanation of proposed changes. In particular cases when the CFCU will not require this explanation to be included in the Side letter, explanation will be given in mail to MoH accompanying the Side letters.
- MoH will be more flexible in communication with TW partner regarding additional requests for information and regarding the approval of Side letters
- Every mission certificate will be signed by the expert, the RTA, the relevant Component coordinator prior to Slovak PL signature.

The minutes of the meeting can be found in annex II.11.

A major problem in the project implementation, that should be mentioned, is the communication problem between the Slovak project leader and the RTA. The Slovak project leader is not satisfied with the RTA regarding the provision of information related to project. BC PL does not receive any information about the short-term expert's mission in the Slovak Republic, dates of particular activities, changes in the Twinning work plan prior to receiving the side letter and the mission reports. On the other hand, the Dutch Twinning partner (project leader and RTA) are not satisfied about the feedback given by the project leader, not or very late replying to e-mails sent by RTA, lack of spirit of co-operation characteristic of Twinning projects and being too much involved in the details of the daily work ("micromanagement"). After some meetings on which these problems were discussed, and also some mail communication between RTA and BC PL, the official meeting on clarifying the communication problems was organized by the National Contact Point on 9 May 2005 The meeting was attended by the project leaders, the RTA and representatives of the Ministry of Health and the Government Office of the Slovak Republic (annex II.12).

Recommendations

General

Several Slovak as well as Dutch experts expressed that there should be much closer collaboration between the section of Epidemiology and of Microbiology. For instance, the two groups could meet once a week for 1-2 hours to discuss bottlenecks in the control of Communicable Diseases, actual problems, and signals from domestic surveillance and from abroad

Component I

The system of collecting and evaluating data on communicable diseases changed from manual tabulation of individual notification cards to a data collection system working on PC in 1991. Since then, the same computer platform is used. Maintenance, support, further development of this system is not more effective, because the currently used system was designed for the MS DOS environment. It is unable to run under Windows environment, and it has limited support for networking. The ability to see a case history will be a very important feature of the new reporting system. This is not possible in the current system. Moreover, the existing central register does not allow the continuous analyses of reported data but only monthly and yearly analyses of epidemiological data on occurrence of infectious diseases in the Slovak Republic. The experts propose to create a web-based system with defined inputs rights, outputs for public and involved stakeholders.

The new central database will comprise 3 components, i. e. the Register of Communicable diseases, the Early Warning System and the Influenza reporting system. Developing and implementing new software is one of the issues to be addressed in this component. However, before being able to develop any software, the system of data collection and evaluation

should be clear. “Software” is not a goal in itself, but a tool in the registration of communicable diseases.

One of the recommendations is “do not tender for completely new software”. The suggestion is making an inventory of systems in use in different countries that fit the needs and routine of Slovakia and that can be easily adapted by your Slovak experts in the future. In particular, the expert suggested not tendering specifically for software for influenza surveillance. This is a simple component in the Basic System. Different software may irritate people who have to do the registration.

During the brainstorming sessions, particular attention was paid to this issue. A number of experts did not share the same vision on the position of the National Reference Centre in the Communicable Disease surveillance system. National Reference Centres serve a dual purpose, both as a specialised laboratory (National Reference Laboratory) and as a guiding/counselling institution in case management (Epidemiological Department / “Centre of Expertise”). This will have implications on the data flow in the forthcoming Register of Communicable Disease.

Moreover, issues on data protection, usage of personal identification numbers and monitoring of ethnic group have to be clarified, either in forthcoming brainstorming sessions or in communications with other Slovak Ministries and other governmental institutions.

In addition, a legal framework may have to be developed. To prevent that individual consent of the patient is necessary for distributing information from the general practitioner/hospital to the Regional Public Health Authorities, a paragraph may be added to the new Law on Public Health. In this paragraph, it is laid down that the distribution of information is mandatory, together with for instance, a list of personal data, the purpose of processing, and the conditions for their acquisition.

The Early Warning System (EWS) should provide information on national cases as well as on European cases. Moreover, it should enable an automated evaluation of the actual influenza situation and it should report to the “European Influenza Surveillance Scheme” (EISS) network of the EU. EWS has nothing to do with software. It concerns – inter alia – contingency planning (e.g. for large cross-national problems with food or an influenza pandemic or major national outbreaks like avian influenza), relationships and communication with professionals, leadership and professional training.

A rapid, good functioning electronic surveillance system and well-trained epidemiologists, microbiologists and supporting personnel to cope with these changes are crucial. This may need extra investments by the government. Moreover, it is recommended to locate the national CD-register in Banska Bystrica. They already have the personnel, the routine for data collection, and the tradition in reporting and analysing the data.

Component II
The virological NRCs are small and have little staff and personnel. Consequently, they are vulnerable regarding continuity and progress of work. In addition, these NRCs have many techniques in common but do not co-operate or benefit from an infrastructure to be used by all except for the Tissue Culture facility. Therefore, the recommendation is bringing the virology NRCs at the Public Health Authority of the Slovak Republic under a single organisation with a virus isolation laboratory, headed by a classical virologist, a molecular laboratory, headed by a molecular biologist and a serology laboratory, headed by a clinical immunologist. Within this organisation, reference tasks can still be supervised by reference specialists.

Moreover, consider bringing more reference activities under a single umbrella, whether or not to concentrated at one single place, for example viral STDs (including HIV), bacterial meningitis (including S. pneumoniae, H. influenzae, Listeria monocytogenes) and enteric pathogens (including salmonellosis, Enterohemorragic E. coli, Campylobacter spp.).

The Slovak Republic has 38 National Reference Centres (23 under the Ministry of Health, 9 under the Ministry of Education [6 at Comenius University, Faculty of Medicine and 3 at the Slovak Academy of Science] and 6 under the Ministry of Culture). The Dutch experts recommend stimulating closer co-operation between the NRCs under the Ministry of Health and Reference Centre outside this system.

The establishment of Bio Safety Level 3 laboratory (BSL3) conditions for the implementation of Anthrax detection has a high priority.

Section 3. Expenditure

According to the Twinning manual (revision 2004), the total figures of disbursement for key groups of costs are described in this section of the quarterly report. A detailed financial report following the format for financial invoice report is submitted separately to the CFCU.

Total figures of disbursement for key groups of costs

Project management	€ 53.100,38
Activities component I	€ 22.850,90
Activities component II	€ 18.950,20
Activities component III	€ 3.393,25
Total budget	€ 505.816,98
Spent 1st quarter	€ 98.294,73
Total spent	€ 98.294,73

It is expected that all activities will be completed within the duration of the project and within the approved project budget. Moreover, it is expected that a very substantial part of the total budget will have been used by the end of the project.