

Recommendations for future

Taken from the Action plan.

COMPONENT I

EXPERT : W. van Pelt (Activity 1.5 - 04/2005)

17 Let professionals meet weekly for 1 hr to discuss bottle-neck in the control of CD, actual problems, signals from surveillance and signals from abroad.

EXPERT : M. Otto (Activity 1.9 - 01-02/2006)

44 A reliable internet connection of sufficient bandwidth is crucial for the success of the project !

45 RUVZ Banska Bystrica: here the internet connectivity (minimum bandwidth 512 kBit/s, better 2 MBit/s) should be improved. Switch from radio-based connectivity to cable/dsl connectivity.

EXPERT : W. van Pelt & A. van de Giessen (Extra activity 1.12 - 09/2006)

59 Collaboration between experts from the public health authorities and veterinary and food authorities should be further stimulated and facilitated. Also, collaboration between the national public health and the veterinary national reference laboratory should be realised.

EXPERT : J. de Boer & H. Gotz (Extra activity 1.15 - 09/2006)

60 Training on these subjects should be continued in Slovakia. Ms. Kristufkova is presently giving epidemiological training, an activity which should be continued. It would be preferable to start courses for trainers of trainers (TOT).

63 Give English courses to professionals in public health.

COMPONENT II

EXPERT : J. Galama (Activity 2.2 - 04/2005)

5 Consider to bring the Virology NCRs at the NIPH under a single organisation with a virus isolation laboratory, headed by a classical virologist, a molecular laboratory for all NAT, headed by a molecular biologist and a serology laboratory, headed by a clinical immunologist. Within this organization, reference tasks can still be supervised by reference specialists.

6 Reconsider to bring more PH 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 etc. *See nr. 5*

7 There is need to increase mutual understanding and close collaboration between the fields of epidemiology and microbiological laboratory.

8 Stimulate a climate for development of private diagnostic virology (financed by insurance companies) and in University Hospitals, with virus isolation as well as NAT, performed outside governmental institute.

9 Development of electronic laboratory administration system.

EXPERT : B. Mulder (Activity 2.2 - 04/2005)

10 Monitor improvement of coordination between NRC and clinical laboratories.

12 Implementation of software application for laboratory information system. *See nr. 9*

17 Make computer and software available for data registration in the laboratories. *See nr. 9*

19 Need to increase mutual understanding and close collaboration between the fields of epidemiology and microbiology. *See nr. 7*

22 Reduce vulnerability in continuity by increasing staff and personnel formation.

EXPERT : J. Galama (Activity 2.5 - 02-03/2006)

52 To expand the number of facilities for virus diagnostics (for example in university or teaching hospitals) as to increase the numbers of samples being analysed for viruses which can be a PH threat.

EXPERT : W. Melchers (Activity 2.5 - 04/2006)

54 It is recommended that the potential supervisor will get extensive training possibilities in this area (either by following courses or work-visits in established laboratories).

58 It will be important to establish a Slovakian working group on molecular diagnosis in which open discussions concerning newly acquired experiences will extend the possibilities to introduce these techniques country-wide.

Strengthening the Surveillance and Control of Communicable Diseases

EXPERT : W. Melchers (Activity 2.6 - 06/2006)

- 67 It is recommended that Dr. J. Černická will get extensive training possibilities in this area. Especially an internship in an established laboratory is recommended. By doing so, she can learn all potentials and pitfalls of these technologies in a relative short time period without being confronted with these issues in her own setting from the start.
- 70 As indicated previously, it will be important to establish a Slovakian working group on molecular diagnosis in which open discussions concerning newly acquired experiences will extend the possibilities to introduce these techniques country-wide.

EXPERT : J. Galama (Activity 2.6 - 07/2006)

- 73 Increase attention for clinical virology in the medical curriculum at Universities (Virology, not only within the Science Faculty but also in the Medical Faculty).
- 74 Integrate virology in the clinical diagnostic proces by introduction of viral diagnostic units in the Microbiology Departments of University Hospitals and large Teaching Hospitals.
- 75 Providing training of medical professionals how to apply viral diagnostics.
- 76 Increase number of clinically relevant diagnoses, which will improve sight on the prevalence and incidence of viral infections.

EXPERT : K. De Schipper-Visser (Activity 2.7 - 09/2006)

- 78 Retrieving Quality Manual from former Quality Manager Bratislava.
- 80 Research on a way to implement a Laboratory Information System.

COMPONENT III

EXPERT : K. De Schipper-Visser (Activity 3.3 - 06/2006)

- 5 Evaluate the effort/benefits of organizing EQAS rounds for two regional PHA.

EXPERT : K. De Schipper-Visser (Activity 3.4 - 09/2006)

- 6 Still include SOP's on EQAS in system of document control.
- 8 Research on the possibilities to develop a system for EQAS on a national level that's appropriate for public health laboratories as well as private clinics (as recommended by Dr. Niks).

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
COMPONENT I		Coordinator: Ms Avdicova			
Activity 1.3		Brainstorm session concerning the user requirements of the surveillance and control system of communicable diseases			
M. Otto (04/2005)					
1 The Influenza Reporting system will be integrated into the new database (as an independent module).	Avdicova	Will be integrated to analysis of information system requirements.		31 October 2006	
2 The EWS should provide verbal information on national cases as well as on European cases.	Avdicova	Will be integrated to analysis of information system requirements.		31 October 2006	The current EWS works this way, even manually.
3 The EWS should enable an automated evaluation of the actual influenza situation.	Avdicova	Will be integrated to analysis of information system requirements.		31 October 2006	
4 The EWS should report to the EISS of the EU.	Avdicova	Will be integrated to analysis of information system requirements.		31 October 2006	
5 Ing. Accipiter will prepare a flow chart on the flow of data on infectious diseases as discussed during the brainstorm meeting an April 19 at Banska Bystrica.	Accipiter	Followed.		April 2005	
Activity 1.4		Evaluation of data protection regulations and its implementation			
J. Holvast (04/2005)					
6 Information systems processing: As all this information will almost be the same for all regional centres, it is recommended to make a model which can be used by all of them.	Avdicova	Followed.		finished	The information system works the recommended ways already for many years.
7 Intervene with the Data Protection Office.	Avdicova	Followed. Wording of paragraphs regarding the infectious diseases in the new Law on Public Health were approved by the Data Protection Office.		finished	

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
8 To prevent that individual consent of the patient is necessary for distributing information from the general practitioner/hospital to the RIPH's it will be tried to put in the new Law on Public Health a paragraph in which it is laid down that this distribution is obligatory, together with a list of personal data, the purpose of their processing, conditions for their acquisition and the group of subjects.		Included in the new Law on Public Health.		finished	
9 In the same Law on Public Health it will be promoted that the National Register of communicable diseases will be seen as a health care facility.		Included in the new Law on Public Health.		finished	<i>3rd St.C.: suggestion for future consultations with other organizations because of overlap</i>
10 Question on data protection and ethnicity.	Avdicova	Information will be collected by another way.		finished	<i>3rd St.C: Meeting Data Protection Office conclusion: data can't be collected</i>
Activity 1.5 Evaluation and recommendations on the: quality and range of the data collected according to the EU network needs; links between NRC data and CD database; output and feedback of the system.					
W. van Pelt (04/2005)					
11 Good moment to improve content of what is registered.	Avdicova	Followed.		finished	
12 Do not tender for completely new software. Make an inventory of systems in use in different countries that fit the needs and routine in Slovakia and that can be easily adapted by Slovak experts.	Avdicova	Not followed. No financial resources dedicated for such inventory.		finished	<i>3rd St.C.: suggestion make inventory of systems from other countries. Conclusion: not needed, have studied 3 systems already</i>
13 Do not tender for software specifically for influenza surveillance.	Avdicova	Followed.		October 2005	
14 Do not tender for an Early-Warning System!!! There is no software company who can understand what you want or has the epidemiologic or scientific knowledge.	Avdicova	Not followed. EWS will be tendered as electronic system for private communication of experts.		finished	<i>3rd St.C.:comment: different approach to originally planned development of SW; answer: decided to stick to original plan after analysis</i>

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
15 Proposition for a Basic System: It is strongly recommended to choose the place where the national CD register is located, in Banska Bystrica. They already have the personnel the routine for data collection, tradition in reporting and analytical and informatics people for this purpose.	Avdicova	Followed. The National CD register will be located in RPHA Banska Bystrica, as written in the new Law on Public Health.		finished	
16 Strengthen, motivate, involve all professionals that have to register. Make clear the purpose of the registration and their role.	Avdicova	Followed. Mentioned action will be applied after evaluation of questionnaire study among GP and other Health professionals.	End 2006		No action yet. Task of all epidemiologists. when development of software is finished, regional meetings will be organised as well as the press conference and articles in Health Newspapers will be published.
17 Let professionals meet weekly for 1 hr to discuss bottleneck in the control of CD, actual problems, signals from surveillance and signals from abroad.	Avdicova	Accepted as a good idea, not applied yet.			
18 Invite professionals to write about all possible topics of interest to Slovakian public health practice. Make them available on the web for all practitioners. Add English abstract to interest for example Euro-surveillance weekly/monthly.	Avdicova	Followed. Mentioned action will be applied after evaluation of questionnaire study among GP and other Health professionals. <i>Related to no. 16.</i>	End 2006		No action yet. Task of all epidemiologists. when development of software is finished, regional meetings will be organised as well as the press conference and articles in Health Newspapers will be published.
19 Protocollise per disease what has to be registered-notified dependent on GP, Lab or PHA. Which disease should be notified if suspected and which when lab-positive. Only report suspected cases if there is a public health threat, define and protocollise this. Otherwise only report positive cases.		Followed. Included in the wording of the new Law on Public Health.		finished	

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
20 Translate and adapt protocols from other EU countries and use the principals of A,B and C diseases		Followed. Included in the wording of the new Law on Public Health.		finished	
21 Investigate underreporting and coverage (oblige labs to make year reports for example)	Avdicova	Accepted, not applied yet.	First half 2007		As soon as new system is installed, this can also take place, but could be evaluated at leats after few months of system running.
22 Look at examples of web-based reporting systems in other countries. Ask them copies of the software involved	Avdicova	Partly followed.		finished	There are language barriers in understanding system from other countries (Web based systems are e.g. in The Netherlands, Sweden, Ireland). Also, the philosophy of the system can be hardly understand from a software (e.g. Ireland has a special terminology).
23 Build in levels of availability of parts of the website dependent on the authority of the web-visitor (for example public, media, GP, Lab, or Ministry of Health)	Avdicova	Is already integrated in design of new system.		finished	
24 Make a questionnaire asking all professionals and authorities what they do with the reports, what they would like to find in the reports	Avdicova / working group	Followed. Data are collected, data will be entered to a computer database and evaluated.		finished	
25 Do not at this moment in time bother the national developments of a Basic System with activities that are mainly laboratory management activities! Automated electronic laboratory surveillance is far future	Avdicova	Accepted.		finished	
26 The server serves all PHA, Standard laboratories, relevant clinicians, Reference laboratories and eventually in the future all GP	Avdicova	Is already integrated in design of new system.		finished	

Strengthening the Surveillance and Control of Communicable Diseases

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27 The Basic System should know: The personal identity number of the patient entered in the system which has to be unique. Each PHA, each Lab, each GP each specialist or recording person needs to have a unique identifier and must be made to know and asked for allowance on the system at some moment to the Basic System (i.e. on the server). The names addresses and telephones, e-mail of the institutes must be known in the Basic System.		Included in the data structure required by the new Law on Public Health.		finished	
Activity 1.6 Second brainstorming session concerning the design of the surveillance and control system of communicable diseases					
<i>M. Otto (05/2005)</i>					
No recommendations					
Activity 1.7 Development of a communication architecture which will be the conceptual framework of the new information system					
<i>M. Otto (08/2005)</i>					
28 STE (possibly supported by the RTA) will contact the Dutch authorities at RIVM to obtain details related to the Dutch reporting system ISIS.	RTA / Otto	RTA/NSPOH has asked RIVM for more information on this issue (28/03)			Waiting for reply from RIVM; see also nr. 40
29 The members of working group establish separated working group for evaluation of existing data for 7 groups of diseases a definition need for new software.	Avdicova / working group	Followed. The task is still running and working groups are still continuing with their work.		Running from December 2005	
30 To realize questionnaire study with reps of GP and other professionals within all regions of Slovakia	Avdicova / working group	Followed. The questionnaire was created, data were collected, the evaluation is completed.		finished	See also 4th Q.R., p.9
Activity 1.8 Development of a specification of the information system(s), including the mechanisms for generating, distributing, updating and evaluating information within the identified areas and taking SOP, QA/QC principles into account. Defining the links between NRC laboratory data and CD database. Preparation of ToR (including the technical specifications for the web-site and the implementation of the new systems throughout the country) for TA & training (service contract)					
<i>M. Otto (12/2005)</i>					

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
31 The data in the now outdated EPIS-System are of high quality. Thus they should be preserved and made available in the new system, e.g. for future analyses of long term trends.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
32 The envisaged architecture of a central data base accessed via a web module will overcome shortcomings of the present EPIS-System which relies on (numerous) distributed local data bases.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
33 The data fields in the forthcoming electronic register of communicable diseases should correspond as closely as possible to the data fields used in the paper-based blanks (e.g. name of responsible official, measures taken, contact, case management/version).	Avdicova / Hrubá	Data fields in the paper-based blanks are also under process of revision.		end of 2006	
34 A web-based flexible analysis and presentation of data according to different criteria, e.g. disease, aetiology, age and gender distribution as well as spatial (GIS) and temporal patterns is a top priority matter. To the general public, only aggregated data should be made available.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
35 The register should be flexible enough to accommodate new medical knowledge. Appropriately qualified operators should - up to a certain extent - be able to modify menus and/or static information.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
36 The system should enable a flexible data export to EU-networks.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
37 The identification of reporting subjects (connected with classification of cases into 3 categories and handling of related cases) should be based on the National Register of Physicians and Hospitals (including hospital departments) etc.	Avdicova / Hrubá	Already implemented in the design of the new system		finished	
38 With respect to the storage and processing of data at the local (GGD) level, it was learned that a duplicate data entry may be necessary (information provided by RIVM).	Avdicova / Hrubá	All data will be stored and processed at the central level, which excludes the option of duplicate data entry.		finished	
39 Dutch system: it is advisable to seek information on the module used at the GGD for the local case management	Avdicova / Hrubá	Local case management is included now in the central database in the design of the new system		finished	

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
40 The (informal) offer of RIVM to share ISIS/OSIRIS software and know-how with their Slovak colleagues should be kept in mind.	Avdicova / Hrubá	RTA/NSPOH have asked RIVM for more information on this issue (28/3). The offer still stands according to Marja Esveld, RIVM (email 5/4/06). The system at the moment is not ready yet to be implemented in other countries.		still open offer, might be interesting for CC in the future, currently not	RIVM/Marja Esveld said (email 5/4/06) that in the e.g at the end of 2006, the CC can email her about the system again to see if it is ready yet.
41 German system: if considered to be necessary, a contact to the SurvNet Developer Team can be established.	Avdicova / Hrubá	Not used.		finished	
Activity 1.9 Development of a technical framework, including recommendations on hardware (Technical specifications for Supply contract), software, data-format, issues of security, accessibility, access control, availability and technical management					
M. Otto (01-02/2006)					
42 Involve a broad(er) group of future users in the revision of the analysis report and later also in the pilot testing phase	Avdicova / Hrubá	5-6 RUVZ plus UVZ SR Bratislava and RUVZ Banská Bystrica are proposed to test the system.		finished	Broader group now involved
43 In addition to criteria for the "lean client technology" (see SOFTEC Report, chapter 13.1, p.112), web design criteria from the viewpoint of computer workplace ergonomics should be observed, too (i.e. usability, accessibility, didactics, cf. www.w3c.org, www.afgis.de)	Avdicova / Hrubá	Followed. Web design for the system will be developed by a specialized web design company.		Autumn 2006	After the testing of the system this will also happen.
44 A reliable internet connection of sufficient bandwidth is crucial for the success of the project !	Avdicova / Hrubá	The idea is accepted and it is estimated to be solved by PHA SR in Bratislava.	End of October 2006		
45 RUVZ Banská Bystrica: here the internet connectivity (minimum bandwidth 512 kBit/s, better 2 MBit/s) should be improved. Switch from radio-based connectivity to cable/dsl connectivity.	Avdicova / Hrubá	The idea is accepted and it is estimated to be solved by PHA SR in Bratislava.	End of October 2006		
46 All RUVZ's should agree preferentially on one and the same Internet provider. This would facilitate the construction of a Virtual Private Network and thus enable also remote diagnosis and maintenance.	Avdicova / Hrubá	Out of the project scope.		finished	Not possible to negotiate about this and for the success of this project this is not crucial.

Strengthening the Surveillance and Control of Communicable Diseases

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47 With respect to the expected server housing at RUVZ Banska Bystrica, location-specific guidelines (in Slovak language) for access control, operation, safety, updates, backup procedures and emergency training should be developed, taking discussions with the STE and own experience into account.	Avdicova / Hrubá	It is not planned for implementation within this project.			
48 Start preparing a training concept (i.e. a train-the-trainer approach) for the future users of EPIS – in line with the progress of the project and in close collaboration with SOFTEC	Avdicova / Hrubá	Followed. Training of users was organized partly by company SOFTEC in August 2006 and partly by RPHA in Banska Bystrica in September 2006.		Aug & Sept 2006	
Activity 1.10 Formulation of Slovak specific general guidelines for outbreak management Activity 1.11 Two days workshop on outbreak management for regional staff with exercise on case control and cohort studies					
A. Timen (02/2006)					
49 Assess the goals of this project component on short and long term; formulate the content of the remaining activities on the basis of this assessment. The development of the new software requires a great deal of energy and it is my feeling that other activities in this component are subordinated to the software development.	Avdicova / Hrubá	Aware of this. However, all activities under Comp. I are interrelated and not 1 is more important than another.	Oct 2006		The 2- days that were left over for act. 1.11 and the extension of act. 1.15 paid attention to this recommendation.
50 Organize an in depth training for a small group in methodology of outbreak investigation: - lecture on basic epidemiological principles and statistic significance (RR, OR, AR, CI, p, confounding and bias) - interactive training with a case – control study Profile expert: epidemiologist working in the field of surveillance of infectious diseases at the national level (possible topics: salmonellosis, legionellosis)	Avdicova / Hrubá	Accepted.		Sept 2006	The extension of act. 1.15 was used for this.
W-A. van Stiphout (07/2006)					

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
51 More training on the subjects discussed, with a lot of examples and exercises, will be needed. It is therefore recommended to repeat the issues on data analysis (validity) during the next training in September by way of some exercises.	Avdicova / RTA office	Followed. It was communicated through RTA office with STEs in order to include this in the next training in September 2006.		Training took place: 19 - 22 Sept 2006	
52 It should also be considered whether simultaneous translation would be helpful or not.	Avdicova / RTA office	Followed. It was communicated to RTA office and the interpretation was arranged for the next training in September 2006.		Training took place: 19 - 22 Sept 2006	
Activity 1.13 Implementation, testing and evaluation of the new systems on data collection in 5 selected pilot regions					
M. Otto (07/2006) 1st part					
53 Install a help desk / hotline to answer emerging problems (preferentially at RPHA Banská Bystrica)	Avdicova / Hrubá	Followed. This is involved in the software project (discussion forum).		October 2006	
54 Consider a "train-the trainer" approach to educate well-experienced people at each RPHA which in turn may help in the case of local problems.	Avdicova / Hrubá	Followed. This was involved in software project and now it is finished.		27-28 Sept 2006	
55 Create a discussion forum on technical issues on the portal.	Hrubá	Followed. This is involved in the software project (discussion forum).		October 2006	
56 Put a FAQ-list on the portal	Hrubá	Followed. This is involved in the software project (discussion forum).		October 2006	
57 Consider an evaluation of the training course (e.g. by means of a questionnaire)	Avdicova	Not followed. Training course was evaluated by discussion by now.			
M. Otto (08/2006) 2nd part					
58 In August 2005, workgroups on groups of diseases (virus hepatitis, foodborne diseases, nosocomial infections, STD, zoonoses, diseases preventable by vaccination) had been established. It is strongly recommended to make these workgroups permanent. They should care for a high data quality in their respective field and also for updates in the EPIS menus according to the "state of the art".	Avdicova	Accepted. In the process.	End of October 2006		The list of members for workgroups which will be nominated by PHA SR was prepared.
Extra activity 1.12 1 day workshop for Salmonella (EU-legislation, early-warning, control, international obligations and collaboration).					
W. van Pelt & A. van de Giessen (09/2006)					

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
59 Collaboration between experts from the public health authorities and veterinary and food authorities should be further stimulated and facilitated. Also, collaboration between the national public health and the veterinary national reference laboratory should be realised.					
Extra activity 1.15		3 day training on risk assessment and -management, and different aspects of outbreak investigation (cohort and case control study), followed by a final conference on the same subject.			
J. de Boer & H. Gotz (09/2006)					
60 Training on these subjects should be continued in Slovakia. Ms. Kristufkova is presently giving epidemiological training, an activity which should be continued. It would be preferable to start courses for trainers of trainers (TOT).					
61 Training of trainers is preferable in order to achieve sustainable results.	Avdicova	Followed. Trainings of epidemiologists will take place.			
62 Training parts should be followed by a continuous group of participants.	Avdicova	Trainings of epidemiologists would be enough to organize in the future.			
63 Give English courses to professionals in public health.		Language knowledge is recommended for all public health professionals, but it is not requirement from the employer.			

recommendations for future

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
COMPONENT II					
Coordinator: Ms Bosa					
Activity 2.2					
Evaluation of existing knowledge and experience on quality assurance systems and progressive detection methods of NRC staff and analysis of available equipment and material at the different NRC's. Development of technical specifications for supply contract					
J. Galama (04/2005)					
1 Equipments, as listed in Annex 6 of report FICHE_2003-004-995.03.07. Surveillance, will strengthen the position of the NRCs in the NIPH.	Bosa	Followed. Tender for supply of equipment and HW took place.		30 Nov 2005	
2 Priority for establishment of BSL-3 facility, which are mandatory for pandemic flu, poliovirus, SARS, hemorrhagic fevers, highly pathogenic agents (bio-terrorism) etc.	Bosa / Gavacova	Followed. Existing BSL3 lab doesn't fulfil all requirements (WHO Biosafety Manual, EU standards, national law) for BSL3 lab. The request was forwarded to management of PHA SR. The progress depends on the financial capacities.			Related Act 2.3 visiting BSL3 lab in the Netherlands.
3 Next June, Dr. J. Adamčáková will visit the NRC for Influenza in Rotterdam.	RTA / NSPOH	The internship of Dr. Adamcakova took place as part of Act 2.3 .	end of influenza season	2-15 April 2006	
4 Next June, Dr. J. Tietzová will visit the NRC for MMR in Berlin.	RTA / NSPOH	The internship of Dr. Tietzova took place as part of Act 2.3		5-18 June 2005	
5 Consider to bring the Virology NCRs at the NIPH under a single organisation with a virus isolation laboratory, headed by a classical virologist, a molecular laboratory for all NAT, headed by a molecular biologist and a serology laboratory, headed by a clinical immunologist. Within this organization, reference tasks can still be supervised by reference specialists.		Not followed. This issue was discussed. At the moment there is no possibility to implement this system of management. Not possible to implement.			
6 Reconsider to bring more PH 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 etc.		Not followed.			See nr. 5

Strengthening the Surveillance and Control of Communicable Diseases

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7 There is need to increase mutual understanding and close collaboration between the fields of epidemiology and microbiological laboratory.		No comment. Not related to the aim of the project.			
8 Stimulate a climate for development of private diagnostic virology (financed by insurance companies) and in University Hospitals, with virus isolation as well as NAT, performed outside governmental institute.		No comment. Not related to the aim of the project.			
9 Development of electronic laboratory administration system.	Bosa	Followed. The request for LIS (Laboratory information system) has been followed to the management of PHA SR. The progress depends on financial capacities.			Suggestion: to finance LIS with spare money for SW development Comp I. <i>3rd St.C.: this is not possible: further discussion suggested St.C.: LIS will be developed partially as a part of epidemiology software</i>
B. Mulder (04/2005)					
10 Monitor improvement of coordination between NRC and clinical laboratories.	Bosa				
11 Implementation of laboratory equipment for NRC's (annex 6, see above).	Bosa	See <u>Act 2.2</u> Mr Galama / nr. 1		finished	
12 Implementation of software application for laboratory information system.	Bosa	See <u>Act 2.2</u> Mr Galama / nr. 9			
13 Extension of bacteriological NRC's with broader range of related bacterial pathogens.	Bosa	Followed. Planned extension with <i>Streptococcus pneumoniae</i> , <i>EHEC</i> diagnostic.	2007		Depends on financial capacities and laboratory facilities.
14 Implementation of molecular biology unit for bacterial pathogens.	Bosa	Followed. Proposed establishment of the Laboratory for Molecular Diagnostic. The laboratory is provided with technical and staff capacities.		July 2006	See also nr. 26 and act. 2.5 (Mr. Galama).
15 Improve internal quality control of susceptibility testing by using reference strains.	Bosa	Followed. The reference strains were ensured: partly bought from international institution and partly provided by NRCs from the Netherlands		Sept-Oct 2005	

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
16 Implement participation in an external quality control system (for bacterial testing).	Bosa	Followed. External control of NRC for Meningococci was realised by interlaboratory comparison.		October 2005	Acceptable results.
17 Make computer and software available for data registration in the laboratories.	Bosa	See <u>Act 2.2</u> Mr Galama / nr. 9			
18 Arrange complete sending of strains from clinical laboratories to NRC.	Bosa	All clinical labs are obliged to send samples to related NRCs according to conditions stated in Regulation of Chief Hygienist of SR.		finished	
19 Need to increase mutual understanding and close collaboration between the fields of epidemiology and microbiology.		See <u>Act 2.2</u> Mr Galama / nr. 7			
20 Strengthen infrastructure of NRC's by providing laboratory equipment (see above).	Bosa	See <u>Act 2.2</u> Mr Galama / nr. 1		finished	
21 Provide epidemiological data by introduction of Pulse Field Gel Electrophoresis (PFGE) technology.	Gavacova	Followed. PFGE technology is planned to be implemented for <i>Salmonella</i> spp.		finished	Related to <u>Act 2.3</u> , internship of Dr Gavacova
22 Reduce vulnerability in continuity by increasing staff and personel formation.					
23 Strengthening the NRC of Salmonellosis by simultaneous development of reference for other enteric pathogens (Enterohemorrhagic E. coli, Campylobacter spp.).	Gavacova	Followed. Planned extension with <i>EHEC</i> , <i>Capmylobacter</i> spp. diagnostic.	2007	finished	Related to <u>Act 2.3</u> , internship of Dr Gavacova
24 Strengthening the NRC of Meningococci by simultaneous development of reference for other bacterial pathogens (<i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>Listeria monocytogenes</i>) in view of the extension to a national reference laboratory for bacterial meningitis.	Bosa / Svejnochova	Followed. Planned extension with <i>Streptococcus pneumoniae</i> diagnostic. Other pathogens will follow in the future.	2007	finished	Related to <u>Act 2.3</u> , internship of Dr Bosa.
25 Priority for establishment of Bio Safety Level 3 laboratory (BSL3) conditions for the implementation of Antrax detection.	Bosa / Gavacova	Followed. Existing BSL3 lab doesn't fulfil all requirements (WHO Biosafety Manual, EU standards, national law) for BSL3 lab. The request was forwarded to management of PHA SR. The progress depends on the financial capacities. The project of the BSL 3 lab is in preparation.		finished	Related <u>Act 2.3</u> visiting BSL3 lab in the Netherlands.

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
26 The creation of a centralised molecular biology unit for bacteriological typing to extend diagnostic and epidemiological activities.	Bosa	Followed. Proposed establishment of the Laboratory for Molecular Diagnostic. The laboratory is provided with technical and staff capacities.		July 2006	Started. See also nr. 14
W. Waijboer (04/2005)					
27 Internal auditor course (RPHA Banska Bystrica).	Bosa	Not relevant for this project.		finished	<i>3rd ST.C.: financed by external sources as part of accreditation process (SNAS is provider)</i>
28 Quality assurance/control training for Mr Bakos, specific for medical laboratories (ISO 17025) (RPHA Kosice).	Bosa	Not relevant for this project.		finished	<i>idem: see nr. 27</i>
29 Internal auditor course for Mr Bakos and some other employees (RPHA Kosice).	Bosa	Not relevant for this project.		finished	<i>idem: see nr. 27</i>
30 One week internship J. Bosa: with a focus on the translation of the theory of the ISO 17025 standard into a practical and efficient quality assurance/control system (PHA SR Bratislava).	RTA / NSPOH	The internship of Dr. Bosa took place as part of <u>Act 2.3</u> . 3rd week of the three-weeks internship was focused on ISO 17025 standard.		4-8 July 2005	See programme and mission report of Dr. Bosa in the 2nd QR.
31 Information sessions for NRC heads about internal control and validation by the quality manager (Ms Waijboer will send info by e-mail) (PHA SR Bratislava).	Bosa	Followed. The session took place at PHA SR.		Sept 2005	
32 Internal auditor course (PHA SR Bratislava).	Bosa	Followed. The course was given by the Quality Manager.		May 2004	
33 General recommendations/agreements on training needs for all NRC staff, lab-technicians etc. can be given by the quality manager (PowerPoint presentations) after the internships and implementation of relevant documents (quality manual and SOP's) together	Bosa	Followed. The session took place at PHA SR. All staff at the Section of Medical Microbiology were briefed with documents of system of quality (quality manual, SOPs etc.)		October 2005	
34 Make a list of needed general SOP's for each selected NRC before 1 June (J. Bosa and other quality managers).	Bosa	Followed. The list of needed methods was made and translated into English and forwarded to Ms Waijboer.		July 2005	
35 Make a list of needed method SOP's and equipment SOP's for each selected NRC before 1 June (NRC heads, J. Bosa and other quality managers).	Bosa	Followed. The list of needed methods was made and translated into English and forwarded to Ms Waijboer.		July 2005	

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
36 Make a list of the missing chapters of the quality manual before 1 June (J. Bosa).	Bosa	Followed.		Sept 2005	
37 Make a framework for an actionplan before 15 June (Ms Waijboer (and J. Bosa)).	Bosa / working group /	Followed. All essential documents for system of quality control were finalised step by step.		October 2005	
38 Make an actionplan for the implementation of the quality system for each NRC before 1 July (J. Bosa and other quality managers (and Ms Waijboer)).	Quality Managers RPHA				
39 Write missing chapters quality manual, start immediately (J. Bosa and other quality managers).	Banska Bystrica &				
40 Write missing general SOP's, start immediately (J. Bosa and other quality managers).	RPHA Kosice				
41 Write missing method and equipment SOP's, start immediately (lab-technicians and NRC heads).					
42 Sending a printed version of ISO 15189 (Eng) to the quality managers of Banska Bystrica and Kosice (J. Bosa).	Bosa	Followed.		May 2005	
43 Sending specific criteria for accreditation of medical microbiology laboratories, of molecular biology in medical laboratories and virology by e-mail to the quality managers of Banska Bystrica and Kosice (J. Bosa).	Bosa	Followed.		May 2005	
44 Reconstruction of the buildings (electricity, new windows with sunshields, air-conditioning and washable walls) is necessary for accreditation.	Bosa / PHA SR	Followed. Reconstructions in RPHA Kosice is finished. Reconstruction in PHA SR in Bratislava was completed in mid October 2006.		October 2006	
45 Audit SNAS.	Bosa	Followed. The successful assessment on place has been done in RPHA Banská Bystrica. The certificate was given in March 2006.		20 December 2005	
		Followed. The successful assessment on place has been done in RPHAs Košice. The certificate was given in Sept 2006.		29 March 2006	

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
		Followed partly. The assessment on place has been done in PHA SR in Bratislava. The SNAS report showed 30 non-conformities. The deadline for solving most of them: 30 June. Next SNAS visit planned on Dec 2006.		1st SNAS visit: 11-12 April 2006	
Activity 2.4 Set up of a unit for Quality Assurance / Quality Control within the Public Health Authority					
W. Waijboer (09/2005)					
46 Wait with the application for accreditation. First: - validate all the methods; - finalise all the draft versions (quality documents); - implement/introduce all the quality documents in the laboratories; - work with the quality documents; - perform internal audits; - improve the quality system (solve nonconformity's internal audits); - write management review.	Bosa	Not followed. The application form with requested documentation of system of quality was sent to SNAS.		18 October 2005	The issue with reasons were discussed at the 2nd meeting of the Steering Committee. See Minutes of the 2nd Stc meeting (included in the 3rd QR).
47 Translate important quality documents (for example the quality manual) to get a good picture of the status of the quality system.	Bosa	Followed. The Quality Manual was translated for Mrs. De Schipper in April 2006 (act. 2.5).		April 2006	The translation would be useful for future collaboration with international institutions.
48 We think it will be very useful to translate a Dutch quality document (SOP) about validation into Slovak because validation is the base of the ISO 17025 standard and thus a very important part of the accreditation.	Bosa / Gavacova	Followed. Two Dutch SOPs were translated into Slovak language in May 2006.		May 2006	The translated document can help quality manager with implementation of other methods.
Activity 2.5 Training of staff of 9 selected NRC's in quality control systems and progressive detection methods					
J. Galama (02-03/2006)					
49 PCR for mumpsvirus, parvovirus B19 and mycoplasma contamination of TC soon be implemented.	Tietzova	Planned. Start in November 2006.	Autumn 2007		
50 Providing of the PHL's in Banska and Kosice with Vero-SLAM-, and RK13 cell lines as to spread the capacity for MMR surveillance over the country.	Tietzova	Planned. Started in June 2005.	Autumn 2007		

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
51 To establish with the epidemiologists a more tight cooperation on Improvement of the MMR surveillance by raising the numbers of adequate samples reaching the lab.B63	Tietzova	Followed. Started in 2006. It is not optimal yet but it functions.		continuously	
52 To expand the number of facilities for virus diagnostics (for example in university or teaching hospitals) as to increase the numbers of samples being analysed for viruses which can be a PH threat.		Not to be followed within this project.			
<i>(D. Van Soolingen) W. Melchers (04/2006)</i>					
53 The NCR is now establishing the infrastructure for reliable molecular diagnosis. This point will influence all further developments in this area and I therefore consider this aspect as a major break-point for future work. At this point I highly recommend to bring all molecular diagnostics work in a single unit under the supervision of full-area over-viewing head. This means that both molecular diagnosis and typing should be concentrated in the separate laboratories (clean-lab, clinical lab and analysing lab). In the analysis lab all available and new equipment (PCR, Light Cycler, PFGE) should be brought together, accessible for every assay.	Bosa / Cernicka	The lab for molecular diagnostics has been established. Ms Cernicka, the responsible person, suggested after the consultation with Mr Melchers the organization and workflow. Some methods have been already implemented into this lab but the full functioning will come after the reconstruction work and purchase of lab facility. Recommended separate labs and accessibility of the new equipment in analysis lab will be followed.		finished	
54 It is recommended that the potential supervisor will get extensive training possibilities in this area (either by following courses or work-visits in established laboratories).		Accepted but it depends on the future cooperation with other laboratories.			
55 It is recommended to implement RAPD and PFGE as molecular tools for outbreak and epidemiological analysis in the laboratory setting.	Bosa / Gavacova	Followed. Next steps to speed-up the implementation of this process were agreed.	December 2006	finalizing stage	
56 It is recommended to incorporate the molecular diagnosis of parvovirus by PCR and enterovirus by real-time PCR (LightCycler)	Tietzova / Sobotova	Followed. Parvovirus - cooperation with Mr Melchers continues. Enteroviruses - object of the other TW light project (at Slovak Medical University).	December 2006	finalizing stage	

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
57 It is recommended to incorporate gene-targeted detection as an addition for non serological typable Salmonella strains.	Gavacova	Followed. Testing diagnostics have started after receiving the primers from Mr Melchers. This will be a basis for other methods in the future.	December 2006	finalizing stage	
58 It will be important to establish a Slovakian working group on molecular diagnosis in which open discussions concerning newly acquired experiences will extend the possibilities to introduce these techniques country-wide.		Accepted but it is an issue for the future.			
59 It will be important to establish a net-work for proficiency-panels to quarantine quality assessments.	Bosa / Head NRCs	Followed in all NRCs except the NRC for Meningococci.	for NRC Mening. 2007	other NRC finished	
<i>(W. Waijboer) K. De Schipper-Visser (04/2006)</i>					
60 Reconstruction of the building especially climate control should be implemented asap.	PHA SR	Followed.	2007		
61 Active involvement of the top management towards the management system has to be described and implemented (ref: ISO 17025;2005, 4.1.6, 4.2.3, 4.2.4, 4.2.7).	Bosa	Followed. Will be described and incorporated into management system of labs of the Section of Medical Microbiology.	Oct-Dec 2006		
62 A system of seeking active feedback from the institutes sending the samples should be described and implemented. (ref: ISO 17025;2005, 4.7.2).	Bosa	See nr. 61	Oct-Dec 2006		
63 The instruments for continually improvement (ISO 17025;2005, 4.10) should be described and implemented (e.g. management of complaints, checklists for training of employees, vertical audits and management review).	Bosa	See nr. 61	Oct-Dec 2006		
64 Although Ms Bosa is doing a tremendous good job it would be helpful for her to appoint a independent quality officer for document control and review and follow-up of corrective and preventive actions (metrology and internal auditing is already partly delegated).		Accepted. New organzational structure provides for a new quality manager.	Oct-Dec 2006		
Activity 2.6 Development and implementation of the quality control systems and progressive detection methods					
<i>(D. Van Soolingen) W. Melchers (06/2006)</i>					

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
65 As stated also in the previous Mission report, the NCR is now establishing the infrastructure for reliable molecular diagnosis. This point will influence all further developments in this area and I therefore consider this aspect as a major break-point for future work. At this point I still highly recommend to bring all molecular diagnostics work in a single unit under the supervision of full-area over-viewing head. This means that both molecular diagnosis and typing should be concentrated in the separate laboratories (clean-lab, clinical lab and analysing lab). In the analysis lab all available and new equipment (PCR, LightCycler, PFGE) should be brought together, accessible for every assay.	Bosa / Cernicka	Followed. The laboratory for molecular diagnostics was established. Responsible person is Mgr. Cernicka. Recommended design of the laboratory area and the workflow were accepted.		after reconstruction is finished (mid Oct 2006)	
66 I would recommend Dr. J. Černická to be the Head of this new molecular unit, with full responsibility and power to implement these new technologies.	Bosa	Followed.		April 2006	
67 It is recommended that Dr. J. Černická will get extensive training possibilities in this area. Especially an internship in an established laboratory is recommended. By doing so, she can learn all potentials and pitfalls of these technologies in a relative short time period without being confronted with these issues in her own setting from the start.	Bosa / Cernicka	Accepted. Recommendation was followed to the director of PHA. The result depends on his final decision.	Jan/Feb 2007 planned intersnhip		
68 It is recommended to implement RAPD and PFGE as molecular tools for outbreak and epidemiological analysis in the laboratory setting in a broad perspective.	Bosa / Gavacova / Cernicka	Followed.			
69 It is recommended to incorporate the molecular diagnosis of parvovirus by PCR and enterovirus and meningococci genotypes by real-time PCR (LightCycler)	Bosa /Cernicka	Followed.			

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
70 As indicated previously, it will be important to establish a Slovakian working group on molecular diagnosis in which open discussions concerning newly acquired experiences will extend the possibilities to introduce these techniques country-wide.	Bosa	Accepted but the realization could be somewhere in the future.			
71 It will be important to establish a net-work for proficiency-panels to quarantine quality assessments, the NCR can be leading in this issue.	Bosa / Head NRCs	Followed in all NRCs except the NRC for Meningococci.	for NRC Mening. 2007	other NRC finished	see no. 59
<i>(W. Waijboer) K. De Schipper-Visser (06/2006)</i>					
72 Make a strict time-schedule up for solving of NCF's before evaluating mission (activity 2.7) in September and make use of mailcontact with expert in preparation for verification visit of SNAS.	Bosa / Pastuchova	Followed. Responsible persons for solving the non-conformities (NCF's) were appointed.	Dec 2006 - Jan 2007	Have started after SNAS accepted the proposal for solving NCF's	Mid Oct 2006 - planned finish of the reconstruction. Afterwards, delivery and installation of the last lab equipment. Therefore the day of the second inspection of solved NCF's by the SNAS is postponed to Dec 2006.
<i>J. Galama (07/2006)</i>					
73 Increase attention for clinical virology in the medical curriculum at Universities (Virology, not only within the Science Faculty but also in the Medical Faculty).		Not to be followed within this project.			
74 Integrate virology in the clinical diagnostic proces by introduction of viral diagnostic units in the Microbiology Departments of University Hospitals and large Teaching Hospitals.		Not to be followed within this project.			
75 Providing training of medical professionals how to apply viral diagnostics.		Not to be followed within this project.			
76 Increase number of clinically relevant diagnoses, which will improve sight on the prevalence and incidence of viral infections.		It is a question of change in the present conception of clinical microbiology.			

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realization	Remarks
77 A separate recommendation is to organize post-graduate training and accreditation of professionals in the 3 Public Health Laboratories, which should, as far as not already achieved, become integral part of the quality system.	Bosa	Followed. Each NRC is also a training workplace for cooperating laboratories with the aim to achieve the standadization of methods. Cooperating laboratories are parts of the quality external control.		continuously	
Activity 2.7 Final assessment of the implementation of the new quality control system (W. Waijboer) K. De Schipper-Visser (09/2006)					
78 Retrieving Quality Manual from former Quality Manager Bratislava.		Director PHA SR should try to get this document back from former CC II.			
79 Appoint a new Quality Manager Bratislava.		Accepted. New organzational structure provides for a new quality manager.	Oct-Dec 2006		
80 Research on a way to implement a Laboratory Information System.					

 recommendations for future

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realisation	Remarks
COMPONENT III					
Coordinator: Mr Niks					
Activity 3.2					
Analysis of current Standard Operating Procedures for external quality assurance					
<i>(W. Waijboer (04/2005))</i>					
1 Visit SKML (foundation quality control medical laboratory diagnostic) during the internship of J. Bosa in the Netherlands (OLVG) together with Ms Waijboer (activity 2.3) to look if the system can be improved.	Bosa	Followed. Dr Bosa visited OLVG with Ms Waijboer during the 3rd week of her three-weeks internship in the Netherlands as part of <u>Act 2.3</u>		4-8 July 2005	See programme and mission report of Dr. Bosa in the 2nd QR.
2 Briefing Prof. Niks about the visit to the SKML in the Netherlands as soon as possible after returning to Slovakia (J. Bosa).	Bosa	Followed.		July 2005	
3 Start writing the SOP's as soon as possible after the briefing (Prof. Niks).	Niks	Followed.		2005	
Activity 3.3					
Development of Standard Operating Procedures for external quality assurance based on the new-implemented quality assurance system					
<i>(W. Waijboer) K. De Schipper-Visser (06/2006)</i>					
...after finish project:					
4 Include SOP's in system of document control. Eventhough the EQAS is not accredited it will be good for evaluating and monitoring the EQAS.	Bosa	Followed.	Sept 2006		
5 Evaluate the effort/benefits of organizing EQAS rounds for two regional PHA.		Not clear. Probably cannot be solved within the project.			
Activity 3.4					
Implementation and testing in 5 selected pilot workplaces of Standard Operating Procedures for external quality assurance					
<i>(W. Waijboer) K. De Schipper-Visser (09/2006)</i>					
6 Still include SOP's on EQAS in system of document control.		To be done by Dr. Bosa or somebody who continues her job.			

Action plan

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

Activity / Recommendations, conclusions	Responsible person	Action / Status	Deadline	Date of realisation	Remarks
7 The results of the EQAS PHASK-MMR run No 01/2006 RPHA Banska Bystrica are alarming. The risks of reporting false negative results should be investigated and if necessary appropriate measurements for improvement should be taken.	Niks	The aim of the project was to develop and test EQAS PHASK. Negative results in B.Bystrica confirm effectivity of the system and its usefulness. Correcting action in B.Bystrica, whatever urgent - require more time and cannot be a part of EQAS testing as proposed by the project. According to me, our task is just to evaluate the run and to report results to the tested laboratory.			
8 Research on the possibilities to develop a system for EQAS on a national level that's appropriate for public health laboratories as well as private clinics (as recommended by Dr. Niks).	Niks	I don't understand. There are no EQAS requirements shared by both regional public health institutes and clinical microbiology laboratories (private clinics?). EQAS for the two laboratories at regional PHA has shown serious problems in one of them, but EQAS is not the effective way how to solve them.			

8 recommendations for future