

**INCO-DEV : International Cooperation with Developing Countries
(1998-2002)**

Contract number : ICA2-CT-2002-1005

2nd YEAR REPORT

Start date : Dec. 03

Duration : 12 months

Title : Reducing mortality and long-term disability of TBI victims through research into treatment procedures used in Bosnia-Herzegovina, Macedonia and Croatia. RESEARCH TREAT TBI

Project homepage : http://www.igeh.org/project4_1_1.php

Keywords : (5 maximum) Balkans, CEEC, Brain Injuries, Evidence Based Medicine

Shared-Cost Rtd

Contract number : ICA2-CT -2002-10005

TITLE : Reducing mortality and long-term disability of TBI victims through research into treatment procedures used in Bosnia-Herzegovina, Macedonia and Croatia RESEARCH TREAT TBI

COORDINATOR

Internationale Gesellschaft zur Erforschung
von Hirntraumata (IGEH)
Mölkergasse 4/3
Wien A-1080
Austria

Univ. Doz. Dr. Rusnak Martin, MD,
PhD
E-M : rusnakm@igeh.org
TEL : +43 1 409 0363
FAX : +43 1 409 0363

CONTRACTORS

Internationale Gesellschaft zur Erforschung
von Hirntraumata (IGEH)
Mölkergasse 4/3
Wien A-1080
Austria

Univ. Doz. Dr. Rusnak Martin, MD,
PhD
E-M : rusnakm@igeh.org
TEL : +43 1 409 0363
FAX : +43 1 409 0363

Urazova nemocnice Brno
Spinalni Jednotka
Ponavka 6
662 50 Brno
Czech Republic

Prof. Dr. Peter Wendsche, PhD
E-M : p.wendsche@unbr.cz
TEL.: +420 5 45538394
FAX: +420 5 45538276

Hippokrates
Podlavická cesta 27
975 17 Banská Bystrica
Slovak Republic

Dr. Milan Kanianksy, MD
E-M : mkaniansky@nspbb.sk
TEL.: +421 (48) 441 2157
FAX: +421 (48) 441 2992

The Center for Applied Epidemiology and
Health Policy
Bernardgasse 39
A-1070 Wien
Austria

Dr. Franz Piribauer, M.D. Ph.D
E-M : PIRIBAU1@fagw-n1.stlrg.gv.at
TEL.: +43-1 5246020
FAX: +43 1 5246020

Department of Intensive Care in
Neurosurgery, Clinic of Anesthesiology,
Reanimation and IC
ul. Vondjanska 17
1000 SKOPJE
Former Yugoslav Republic of Macedonia

Profesor Dr. Zorka Todorova
Nikolova
E-M : medfask@mt.net.mk
TEL.: +389 172342
FAX: +389 112502

Osijek University Hospital Division of
Neurosurgery

Dr Bruno Splavski
E-M : splavski.bruno@kbo.hr

Huttlerova 4
31000 Osijek
Croatia

TEL.: +385 31 511383
FAX: + 385-31)512222

University Clinical Center Rijeka
Neurosurgical Dept.of Surgical Clinic
Tome Strizica 3
51000 Rijeka
Croatia

Dr.Med. Dean Giroto, M. Sc.
M.D.
E-M : dean.giroto@ri.hinet.hr
TEL.: +385-51 624140
FAX: +385-51 624140

University Hospital Sestre Milosrdnice
Vinogradska street 29
10000 Zagreb
HR Croatia

Dr. Miroslav Vukic, MD, PhD
E-M : crsm@iskon.hr
TEL.: +385-1 3787522
FAX: +385-1 3768273

Department of Neurosurgery, Clinical Centre
University of Sarejevo
Bolnicka 25
71000 Sarajevo
Bosnia and Herzegovina

Dr. Kemal Dizdarevic
E-M : kemaldiz@uitc.net.ba
TEL.: + 387 33 215 839
FAX: + 387 33 711 340

CONTENTS

1	SUMMARY OF THE FINAL REPORT	7
2	CONSOLIDATED SCIENTIFIC REPORT	11
2.1	OBJECTIVES	11
2.1.1	General objective	11
2.1.2	Specific Objectives for the second year of the project	11
2.2	ACTIVITIES	12
2.3	RESULTS ACHIEVED	13
2.3.1	Guidelines implementation	13
2.3.2	The ITCP dataset	13
2.3.3	Results from interim analysis	13
2.3.4	Hypothesis formulation	14
2.4	PROBLEMS ENCOUNTERED	14
2.5	TECHNOLOGY IMPLEMENTATION PLAN	14
2.6	PUBLICATIONS AND PAPERS	14
2.7	CONCLUSION	15
3.	MANAGEMENT REPORT	16
3.1.	ORGANIZATION OF THE COLLABORATION	16
3.2.	MEETINGS	16
3.2.1.	The 2 nd Workshop	16
3.2.2.	Meeting Participant 7 – CZ Brno	16
3.2.3.	Meeting Participant 7 - HR Rijeka	16
3.2.4.	The 3 rd Workshop	16
3.3.	EXCHANGES	17
3.4.	PROBLEMS	17
4.	INDIVIDUAL PARTNER FINAL REPORT	18
4.1	PARTICIPANT 2 AU VIENNA EPIDEMIOLOGY	18
4.2	Participant 3 CZ Brno	18
4.3	Participant 4 SK Nove Zamky/Banska Bystrica	19
4.4	Participant 5 FYROM Skopje	20
4.5	Participant 6 HR Osijek	24
4.6	Participant 7 HR Rijeka	25
4.7	Participant 8 – HR Zagreb	26
4.8	Participant 9 - BH Sarajevo	28
5.	ANNEXES	29
5.1	SELECTED RESULTS from the INTERIM ANALYSIS	29
5.2	MEETINGS REPORTS	31
5.2.1	Report from the Research-TBI project meeting in Bratislava, November 22nd – 23rd June 2004	31

**5.2.2 Report from the Research-TBI project meeting in Rijeka 19th – 20th
June 2004**

34

6. DATA SHEET FOR FINAL REPORT

43

1 Abstract

Number of death from injuries in Bosnia-Hercegovina, Macedonia and Croatia as reported by WHO in 1998 is very high. Injuries rank number one, number two and number three killer in young population of the region (ages 5 to 44). The broad objectives of RESEARCH-TREAT-TBI project are to save the lives of traumatic brain injury (TBI) victims and to improve the quality of life of survivors through research in factors determining health outcomes of hospital care and through changing current clinical practices to provide better care. The project builds up on experiences with the research in determinants of health outcomes and in implementation of scientific based guidelines for good clinical practice. Planned Project will facilitate the research and subsequent guidelines implementation in concrete clinical settings, and reflecting local situation both clinical and public health.

Research into factors determining the quality of care for victims of severe Traumatic Brain Injuries (TBI) (Glasgow Coma Scale less than 9), accentuating the quality of life after recovery. Dissemination of state-of-the-art knowledge on quality care of Traumatic Brain Injury patients; Practical and participative implementing programs for the introduction into clinical care procedures of Scientific Evidence Based Guidelines (elaborating protocols, practice modification taking local conditions fully into consideration, behavioral change of the staff involved, collecting data on patients in order to monitor the progress so that participants can see the results of their work, and can check and revisit the assumptions on best clinical practice). The implementation of Scientific Evidence Based procedures is followed by a research in efficacy of changed medical practice. To help the countries in preserving and developing their research excellence in the field of public health.

1 SUMMARY OF THE FINAL REPORT

Objectives:

General objective of the project is to research main factors of traumatic brain injury (TBI) in Bosnia-Herzegovina, Macedonia and Croatia. The objectives of the 1st year of the project were to introduce scientific evidence-based guidelines in participating centers, install database for entering patient data, implement the guidelines, monitor TBI management, analyze interim results of patient data and disseminate the interim outcomes.

Materials and Methods:

The web site for the project was developed based on existing IGEH's web site (http://www.igeh.org/project4_1_1.php). The site includes relevant information on the project (plan, members and contacts) and reports. For the launching up of the project an introductory workshop and local workshops in individual centers were organized. Centers were equipped with necessary hardware. As a software ITCP database was installed in all the centers. At least 2 people per each center were trained in using the database.

Retrospective patients' data for 2000 and 2001 were entered into the database. In March 2003 a new version of the database was installed in all the centers. Interim analyses of collected data was performed. The data set was transferred to Excel format. As the first step basic data cleaning was performed. The second step was to convert all measurements to common SI units. Data were analyzed using built in Excel functions as well as XLSTAT statistical package.

In order to monitor guidelines implementation and to discuss the results of the data quality assurance, a workshop was organized in Rijeka (Croatia) in June 2004. In the same meeting hypothesis on the final data analysis to be performed during the next phase of the project were formulated.

Results:

All participating centers were instructed on scientific evidence based guidelines on TBI management, had ITCP database installed and were trained in using it. They all entered their TBI patients in the database during the year. Data set of more than 600 patients was formed until November 2003. The data were cleaned and statistical methods were applied for interim analysis. All the centers started implementing scientific evidence based guidelines on TBI management and continued collecting patients' data. Problems met in these two activities were identified and possible solutions were discussed.

Until November 2004, 502 records from Bosnia, Croatia, and Macedonia were entered in the database. Additional 84 cases of TBI were entered by other participants. An interim analysis provided preliminary results on the epidemiological aspects of severe TBI in the centers.

A set of hypothesis to be investigated during the final data analysis was formulated.

Comments and Conclusions:

Few minor organizational changes took place within the implementation of the project. First workshop was organized in Vienna instead of planned Zagreb, which allowed participants to visit the Europe leading trauma centre – Lorenz Bohler Unfall Krankenhaus.

The second workshop was organized in Slovakia where it was easier to obtain visa for the participants.

Use of TBI_trac™ database for data collection was originally planned. However, over time, the IGEH developed new version of this database under new label: ITCP - International Traumatic Coma Program. The ITCP is more research oriented, it allows for international cooperation (language versions), supports different measurement units, follows patients outcome up to 180 days.

The project exceeded the set of indicators stated by individual work packages in number of trauma cases collected, in quality of data and in activities of all members of the project.

In 2004 the project continued according the plan. Because of the leave of Dr. Urbansky the center in Banska Bystrica resumed his activity.

The project will be continued according to schedule and with every achievement foreseen in the organization and methodology.

Basic assumption is that all participants will continue their roles and that enough data will be collected to start the explorations and policy development. If this assumption is kept, the project will continue without a need for major changes.

Main publications:

Rusnak, M.: Traumatic Brain Injuries – EU Balkan Project. BIT conference, Wien, Jan. 2003.

Mauritz, W., Rusnak, M., and Janciak, I.: Implementing Scientific Evidence-Based Guidelines: Case Study of Severe Traumatic Brain Injuries. *Clinical Research and Regulatory Affairs* Vol. 20(1), 2003, 81-87

P. Brezany, A.M. Tjoa, M. Rusnak, J. Brezanyova, I. Janciak: Knowledge Grid Support for Treatment of Traumatic Brain Injury Victims. In: *Computational Science and Its Applications – ICCSA 2003 International Conference Montreal, Canada, May 18-21, 2003. Proceedings, Part II* Springer-Verlag Berlin Heidelberg 2003, pp. 446 – 455.

Rusnak, M., Mauritz, W., Urbansky, M.: Evidence based medicine in brain trauma care. Presentation given at the Regional Meeting of Young Anesthesiologists, Skopje, March 2003.

M.Rusnák: Evidence based medicine and neurotrauma (Medicina bazirna na činjenicama i neurotrauma) . First B&H Meeting on Neurotrauma wirth International Participation, September 20, 2003, Sarajevo

K. Dizdarevic: B&H and The International project of neurotrauma (BiH i internacionalni projekt za neurotraumu). First B&H Meeting on Neurotrauma wirth International Participation, September 20, 2003, Sarajevo

Brazinova, A., Mauritz, W., Rusnak,M., Janciak, I., I.Wilbacher, P.Dado, L.Lenartova, J.Leitgeb, F.Chmelizek, G.Clarici, K. Dizdarevic, M. Soljakova, Z. Todorova-Nikolova: Brain Trauma Risk Factors in selected Regions of Austria, Bosnia and Herzegovina and Macedonian. Abstract submitted to conference Safety 2004, June 6-9, Vienna, Austria

Soljakova M., Nikolova –Todorova Z., Stojanova S: The influence of the level of blood lactate on the outcome of trauma patients. Abstract submitted to conference Safety 2004, June 6-9, Vienna, Austria

Dizdarevic, K.: Two articles on new treatment options in head injured patients are in press (Med journal; Med Voice- Bosnian Journals). Sarajevo, Bosna-Hercegovina

M. Soljakova, Z. Todorova-Nikolova: The effects of hypotensive anaesthesia to the BTI victims ; Ministry of science, report, Skopje, March 2004

Z. Todorova-Nikolova, M. Soljakova: Management of fluid balance in Brain trauma injuries, DIGI-print, Skopje, 2004 ISBN 9989-2188-46 (COBISS.MK-ID 57959690)

M.Soljakova, B. Kuzmanovska: Syndrom of lost of sodium, Acta anesthesiologica Macedonica, :22, 2004

Z. Todorova-Nikolova, B. Kuzmanovska: Resuscitaion of brain trauma victims, I workshop of MSCCM, Skopje, 2004

J.Nanceva, M. Soljakova, E Stoickovski: Anaesthesia for geriatric patients, MSA FEEA VI, :9-18, 2004, ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)

Z. Todorova-Nikolova: TIVA, MSA FEEA VI, :117-120, 2004 ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)

Splavski B, Ivić D, Saftić R, Mužević D, Kčira-Fideršek V. Most important early predictors of outcome following severe traumatic brain injury.ations: an international focus meeting, September 19-20, 2003, Rimini, Italy, p 28.

K Dizdarevic, I.Omerhodžić, N Iblizović. B Jahić: Neurosurgical intensive care unit as a prerequisite of current approach to neuropatients. Med Journal, in press.

K. Dizdarević: Cerebral microdialysis and prevention of cerebral ischemia after neurotrauma and aneurysmal hemorrhage. Med Arch, in press

Rusnak, M., Janciak, I., Brazinova, A., Mauritz, W., Project Research Team (Dr. Miroslav Vukic, Dr. Bruno Splavski, Dr. Dean Giroto, Dr. Kemal Dizdarevic, Dr. Maria Soljakova): **Epidemic and Clinical Characteristics of TBI situation in three Balkan countries: case study of Croatia, Macedonia and Bosnia.** Proceedings of the 7th World Conference on Injury Prevention and Safety Promotion, Wien, June 06th – 09th, 2004.

Leitgeb J., Lenartova L., Dado P., Mauritz W., Rusnak M., Vécsei V.; **Trauma systems in Middle Europe.** 6th European Trauma Congress, Prague, 16-19 May, 2004

Martin Rusnak, Walter Mauritz, Ivan Janciak, Ingrid Wilbacher, Alexandra Brazinova, and Traumatic Brain Injury Study: **Epidemic of Severe TBI in Selected Regions of Austria and Balkan.** Proceedings of the third International Conference on Healthcare Systems, Charleston, West Virginia, USA, October 14-17, 2004

Doc. MUDr. Martin Rusnák, CSc a prof. Dr. Med. Walter Mauritz: **Kvalita zdravotníckej starostlivosti a znalostná medicína. Klinická epidemiológia ťažkých úrazov mozgu.** Červenkové dni preventívnej medicíny, Banská Bystrica, Slovak Republic, June 2003

Wilbacher I., Brazinova A., Janciak I., Leitgeb J., Lenartova L., Mauritz W., Rosso A., Rusnak M.: **Brain Injury – a short Epidemiology of TBI and presentation of a new European database.** Proceedings of the 11th International Mondsee Medical Meeting, Unterach, Austria, September 9–12, 2004

Rusnak M., Brazinova A., Janciak I., Leitgeb J., Lenartova L., Mauritz W., Rosso A., Wilbacher I.: **Perspectives on Guidelines and Standards. Do They Make a Difference in Outcomes?** Proceedings of the 11th International Mondsee Medical Meeting, Unterach, Austria, September 9–12, 2004

2 CONSOLIDATED SCIENTIFIC REPORT

2.1 OBJECTIVES

2.1.1 General objective

Improvements in care of Traumatic Brain Injury victims will lead to lower health costs and lower burden on society by decreasing mortality and morbidity. The disintegration of the Balkans due to war has created a specific regional problem with regard to Traumatic Brain Injuries for two main reasons: Direct and Indirect impacts of war. Direct impacts of the war – war wounds, have created a higher than average burden on the Balkan region in terms of costs of care of victims of war-related Brain Injuries. Indirect impacts are those resulting from accidents due to undetonated mines (mostly landmines), severe state of roads leading to higher rates of car accidents, and under funded and poor public health systems leading to costs related to the higher incidence of such Traumatic Brain Injury cases, and the long-term disabilities created by the Secondary Brain Insults (which are preventable), caused by the poor state of roads, poor system of post impact and in-hospital care, and poor public health policy.

- Research into factors in the Balkan region, which determine the quality of care for victims of severe Traumatic Brain Injuries (TBI) (Glasgow Coma Scale less than 9), accentuating the quality of life after recovery.
- Dissemination of state-of-the-art knowledge on quality care of Traumatic Brain Injury patients; Practical and participative implementing programs for the introduction into clinical care procedures of Scientific Evidence Based Guidelines
- Specific scientific and technological objectives
- Research the factors determining health outcomes of Traumatic Brain Injury Victims in the three Balkan countries prior to project (Control Group 1 – quantitative and qualitative analyses)
- Implementation of Scientific Evidence Based guidelines for the treatment of Traumatic Brain Injury victims
- Research the extent of implementation of the Scientific Evidence Based guidelines in the three Balkan countries after the project (Control Group 2 – quantitative and qualitative analyses)
- Comparative analysis of results of patient outcomes for Control Group 1 VS Control Group 2
- Dissemination of results to all involved parties

2.1.2 Specific Objectives for the second year of the project

The main objective for the 2nd year of the project was the implementation of scientific evidence-based guidelines on severe TBI management in the participating centers. In order to monitor guidelines implementation and its effect on patients' outcome, also the following objectives were defined:

- Continuous retrospective and prospective data collection with follow up of patients;

- Data quality assurance;
- Interim analysis of the TBI epidemics in the centers;
- Research hypothesis formulation.

2.2 ACTIVITIES

During the second year of the project activities carried out were oriented to implement the objectives of the Project.

The second year of the project was launched after the workshop that took place in Bratislava in November 2003, where evidence based guidelines on the management of severe TBI were introduced to participating centers. The guidelines contained scientific indications for the management of severe TBI, including recommendations on Trauma Systems' structure, initial management of TBI victims, resuscitation of blood pressure and oxygenation, indications for Intracranial Pressure management, Cerebral Perfusion Pressure management, use of hyperventilation, and indications on the use of medicaments such as mannitol, barbiturates, steroids and antiseizure prophylaxis. Each participating center started implementing the guidelines, under the supervision of the project contact person. Continuous contact between the centers and the coordinator was kept in order to help the centers in adopting the new standards, and consultations were provided when needed.

In June 2004 a meeting of all participating institutions was organized in Rijeka, where difficulties met in guidelines implementation were discussed. Each center exposed local problems which limited the possibility of following the indications. Possible solutions to overcome those problems were discussed with the coordinator (see ANNEX).

Retrospective data collection in the database was continued by the centers, covering the years 2002 and 2003. Furthermore, prospective collection of new cases admitted in 2004 was started. The collection of data regarding the long term outcome of registered cases was started; every center autonomously decided the method to use to obtain those data.

All entered material was sent to the central server, based in the coordinating organization.

Regular maintenance of data (back-ups, copying, antivirus protection, reporting) was provided by IGEH staff. Regular reports were sent to the centers informing them on the current status of data collection.

Data quality assurance of all recorded material was performed in June 2004 by IGEH staff. All information entered into the database before June 2004 was reviewed, and all erroneous and missing data were identified. The most frequent missing and errors were presented to all participants of the meeting in Rijeka. Furthermore, every representative received a detailed list of incomplete data from its center. Problems met in data collection and possible solutions were discussed with the coordinator.

Interim analyses were performed on collected data, focusing on the description of TBI epidemics in the centers. As the first step basic data cleaning was performed. The second step was to convert all measurements to common SI units. Data were analyzed using built in Excel functions as well as XLSTAT statistical package.

As an introduction to the following phase of the project, which will be the data analysis, participating centers were asked to make suggestions on the hypothesis to be tested. The goals of the analysis were defined, and research hypothesis to better

understand the factors improving the outcome of TBI were formulated during the meeting of Rijeka (see ANNEX).

2.3 RESULTS ACHIEVED

2.3.1 Guidelines implementation

All the participating centers started implementing scientific evidence based guidelines on severe TBI management.

2.3.2 The ITCP dataset

Through the retrospective data collection of patients admitted in 2002-2003, and the prospective collection of new patients admitted in 2004, a dataset of 502 records was formed until November 2004. Data collected with ITCP database in the second year of the Project formed the retrospective data set. This set will be used as the baseline data for further analysis.

TBI CASES by CENTERS		
CENTER	TOTAL	%
Osijek	29	5.8
Sarajevo	143	28.5
Skopje	242	48.2
Zagreb	57	11.4
Rijeka	31	6.2
TOTAL	502	100

Most of the cases are from Sarajevo and Skopje, what complies with local situation.

2.3.3 Results from interim analysis

An interim analysis was provided with the aim to evaluate the characteristics of the TBI epidemics in the participating centers. It was chosen to focus on the epidemiology of TBI to describe the population of TBI patients and to analyze the most frequent risk factors associated with severe TBI , trying to identify significant differences between centers.

These results can provide a background to understand the extent and the characteristics of severe TBI in the centers. Anyway, further investigations will be needed to better investigate the existence of inter- center differences. More detailed analysis will be provided later on.

Selected results are displayed in ANNEX.

2.3.4 Hypothesis formulation

A set of hypotheses to be tested with the collected data analysis was developed. Aim of the analysis will be identifying the factors that can improve the outcome of severe TBI victims. The list of hypothesis is included into the report from the meeting in Rijeka.

2.4 PROBLEMS ENCOUNTERED

There were no major problems encountered during the execution of activities in the second year of the project.

The timing of work packages was not significantly changed. Surprisingly more data was collected then it has been expected.

Resource Schedule - there were no changes to the resources schedule as it applies to the entire duration of the project.

Work packages - there were no changes to work packages required.

2.5 TECHNOLOGY IMPLEMENTATION PLAN

This is not relevant for this stage of the project

2.6 PUBLICATIONS AND PAPERS

- 2.6.1 M. Soljakova, Z. Todorova-Nikolova: The effects of hypotensive anaesthesia to the BTI victims ; Ministry of science, report, Skopje, March 2004
- 2.6.2 Z. Todorova-Nikolova, M. Soljakova: Management of fluid balance in Brain trauma injuries, DIGI-print, Skopje, 2004 ISBN 9989-2188-46 (COBISS.MK-ID 57959690)
- 2.6.3 M.Soljakova, B. Kuzmanovska: Syndrom of lost of sodium, Acta anesthesiologica Macedonica, :22, 2004
- 2.6.4 Z. Todorova-Nikolova, B. Kuzmanovska: Resuscitaion of brain trauma victims, I workshop of MSCCM, Skopje, 2004
- 2.6.5 J.Nanceva, M. Soljakova, E Stoickovski: Anaesthesia for geriatric patients, MSA FEEA VI, :9-18, 2004, ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)
- 2.6.6 Z. Todorova-Nikolova: TIVA, MSA FEEA VI, :117-120, 2004 ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)
- 2.6.7 Splavski B, Ivić D, Saftić R, Mužević D, Kčira-Fideršek V. Most important early predictors of outcome following severe traumatic brain injury.ations: an international focus meeting, September 19-20, 2003, Rimini, Italy, p 28.
- 2.6.8 K Dizdarevic, I.Omerhodžić, N Iblizović. B Jahić: Neurosurgical intensive care unit as a prerequisite of current approach to neuropatients. Med Journal, in press.
- 2.6.9 K. Dizdarević: Cerebral microdialysis and prevention of cerebral ischemia after neurotrauma and aneurysmal hemorrhage. Med Arch, in press
- 2.6.10 Rusnak,M., Janciak, I., Brazinova, A., Mauritz, W., Project Research Team (Dr. Miroslav Vukic, Dr. Bruno Splavski, Dr. Dean Giroto, Dr. Kemal Dizdarevic, Dr. Maria Soljakova): **Epidemic and Clinical Characteristics of TBI situation in three Balkan countries: case study of Croatia, Macedonia and Bosnia.**

- Proceedings of the 7th World Conference on Injury Prevention and Safety Promotion, Wien, June 06th – 09th, 2004.
- 2.6.11** Leitgeb J., Lenartova L., Dado P., Mauritz W., Rusnak M., Vécsei V.; **Trauma systems in Middle Europe.** 6th European Trauma Congress, Prague, 16-19 May, 2004
- 2.6.12** Martin Rusnak, Walter Mauritz, Ivan Janciak, Ingrid Wilbacher, Alexandra Brazinova, and Traumatic Brain Injury Study: **Epidemic of Severe TBI in Selected Regions of Austria and Balkan.** Proceedings of the third International Conference on Healthcare Systems, Charleston, West Virginia, USA, October 14-17, 2004
- 2.6.13** Doc. MUDr. Martin Rusnák, CSc a prof. Dr.Med. Walter Mauritz: **Kvalita zdravotníckej starostlivosti a znalostná medicína. Klinická epidemiológia ťažkých úrazov mozgu.** Červenkové dni preventívnej medicíny, Banská Bystrica, Slovak Republic, June 2003
- 2.6.14** Wilbacher I., Brazinova A., Janciak I., Leitgeb J., Lenartova L., Mauritz W., Rosso A., Rusnak M.: **Brain Injury – a short Epidemiology of TBI and presentation of a new European database.** Proceedings of the 11th International Mondsee Medical Meeting, Unterach, Austria, September 9–12, 2004
- 2.6.15** Rusnak M., Brazinova A., Janciak I., Leitgeb J., Lenartova L., Mauritz W., Rosso A., Wilbacher I.: **Perspectives on Guidelines and Standards. Do They Make a Difference in Outcomes?** Proceedings of the 11th International Mondsee Medical Meeting, Unterach, Austria, September 9–12, 2004

2.7 CONCLUSION

The project exceeded the set of indicators stated by individual work packages in number of trauma cases collected, in quality of data and in activities of all members of the project.

Changes and justifications as described above will not affect the quality of the research or the successful implementation of the project. The project will be continued according to schedule and with every achievement foreseen in the organization and methodology.

Basic assumption is that all participants will continue their roles and that enough data will be collected to start the explorations and policy development. If this assumption is kept, the project will continue without a need for major changes.

3. MANAGEMENT REPORT

3.1. ORGANIZATION OF THE COLLABORATION

The cooperation among partners was kept on very good level by combination of frequent electronic contacts, web based sharing of information, newsletters, and regular circulation of information on the data set. Naturally the best results were achieved through direct personal communication arranged during the meeting in Rieka and other mostly bilateral meetings. Also conferences proved to be useful for exchange of experiences and results. The major problem observed was in delivering cost statements and annual reports due to certain misunderstandings. However, partners worked hard to overcome the problems with mutual respect.

3.2. MEETINGS

3.2.1. The 2nd Workshop

Date: 22nd-23rd November, 2004, in Bratislava, Slovak Republic

See the details of the meeting in ANNEX.

3.2.2. Meeting Participant 7 – CZ Brno

Date: Monday, April 5th, 2004, Trauma Hospital Brno – Dr. Wendsche and Dr. Pavel Hude

Meeting prof. Peter Wendsche to discuss possibilities of having presentations of our group at the forthcoming conference in Prague. Meeting Dr. Hude to discuss continuation of the ITCP database.

3.2.3. Meeting Participant 7 - HR Rijeka

Date: Friday, April 9th, 2004, Clinical Hospital Rijeka, Rijeka Croatia – Department of Neurosurgery

Meeting Dr. Giroto to discuss problems with inputting the data into ITCP database. The problem was evidently caused by slow connection to the internet. Also possibilities to organize the group meeting in Rijeka were discussed. Dr. Giroto promised to find adequate place with good accommodation and reasonable price for the meeting. He also suggested to develop relations to Dr. Fred Zeidler, who is responsible for ambulance services in the region. The visit to Participant 7: HR Rijeka was adjourned to the satisfaction of all parties.

3.2.4. The 3rd Workshop

See the details of the meeting in ANNEX.

3.3. EXCHANGES

No exchanges were planned and/or realized during this phase

3.4. PROBLEMS

Give details of any problems with management, administrative and financial aspects of the contract.

4. INDIVIDUAL PARTNER FINAL REPORT

4.1 PARTICIPANT 2 AU VIENNA EPIDEMIOLOGY

Dr. Franz Piribauer, MD, MPH, The Centre for Applied Epidemiology and Health Policy, Wien, Austria

4.1.1 Activities

The role for the center planned for the 2nd year of the project was to support the project in data processing and preliminary statistical analysis of collected data. The interim analysis of data with a focus on quality of collected data was carried out by Dr. Brazinova. The results were presented at the 3rd meeting of the project. During the meeting in Rijeka, Dr. Brazinova took an active role in facilitating a discussion among centers preparing a background for further policy development.

4.1.2 Results Achieved

Updated descriptive statistical analysis (tabulations, frequencies, descriptive statistical parameters and charts) of collected data from centers was performed and results were discussed during the meeting along with indicators of data quality. The results were also displayed at the web site of the project.

4.1.3 Problems encountered

There were no major problems encountered during this activity. Data collected were in sufficient quality and export the ITCP database to an Excell file was performed with no major difficulties.

4.1.4 Technology implementation plan

Not relevant for this activity

4.1.5 Publications and papers

No papers and/or publications were produced

4.1.6 Conclusion

The second year of the project proved feasibility of the project approach. Interim data analysis demonstrated existing differences among centers. The final analysis will be largely dependent on quality of data and availability of long term outcome data.

4.2 Participant 3 CZ Brno

Prof. MUDr. Peter Wendsche, CSc, Urazova nemocnice Brno, Spinalni Jednotka, Brno, Czech Republic

4.2.1 Activities

Prof. Wendsche and Dr. Hude took an active role in communicating their experiences with intensive care of TBI patients within their hospital. They also facilitated active participation of the Project members at the conference in Prague. Dr. Hude actively participated at the meeting in Rijeka contributing to general debate about outcomes and indicators.

4.2.2 Results Achieved

Results were consistent with planning.

4.2.3 Problems encountered

There were no major problems encountered during this activity.

4.2.4 Technology implementation plan

Not relevant for this activity

4.2.5 Publications and papers

Please add any papers or publications which might be relevant

4.2.6 Conclusion

The second year of the project proved feasibility of the project approach.

4.3 Participant 4 SK Nove Zamky/Banska Bystrica

Dr. Milan Urbansky, President of Obcianske zdruzenie pre urazy hlavy (Civic Association for Head Trauma), Nove Zamky, Slovak Republic

Dr. Milan Kaniansky, Obcianske zdruzenie Hippocrates, Banska Bystrica, Slovak Republic

4.3.1 Activities

The activities of the center in Nove Zamky had to be replaced with those of (Civic Association Hippocrates), We have started with data collection, too. During the last meeting in Rijeka we were able to start consulting our colleagues in Slovak Republic as well as in Balkan countries.

4.3.2 Results Achieved

The team in Banska Bystrica collected 59 TBI patients, while the number for entire Slovak Republic is 84.

4.3.3 Problems encountered

The major problem dealt with was to find a replacement for the center which will coordinate activities within Slovakia and cooperate with the project members. Based on a support from Dr. Milan Urbansky the organization in Banska Bystrica has taken over all the activities and responsibilities.

4.3.4 Technology implementation plan

Not relevant for this activity

4.3.5 Publications and papers

No papers and/or publications were produced

4.3.6 Conclusions

The center started with dissemination of results and will help other project members in their activities locally.

4.4 Participant 5 FYROM Skopje

Skopje, 14.02.2004

The team:

Prof. d-r. Marija Soljakova

Prof. d-r. Zorka Nikolova-Todorova

d-r. Ivica Stefanovski

d-r. Nikola Sikov

4.4.1 Activities

In this period of time the undertaken activities were focused and correlated with the main objectives of this project. The activities were divided in several phases:

1. Establishment of a time table of the future activities
2. Review of the collected data
3. Improvement of the quality of the collected data (to complete the outcomes)
4. Evidence of the treatment protocols of the new coming patients with traumatic brain injuries
5. The implementation of the new treatment methods in the other centres in the Country
6. Preparation of the web research for articles: hypotensive anaesthesia in brain trauma patients, fluid balance of the surgical patients, establishment of the scoring systems in NS patients, minimal nursing, novelty as possibilities in the therapy of TBI, establishment of the Association for Critical care medicine, secondary brain injury and the hypothalamic-pituitary-adrenal function in the patients with traumatic brain injuries.
7. Impact of the obtained results in Public health in the Country
8. Impact of the obtained results in traffics regulations of the Country.

Our first activity was the establishment of a time table of the future activities. The team which was consisted from two specialists and two young fellows was changed. Because of the rotation of one of the young fellows, he was substitute with other. Additionally explanations of the objectives of the project was performed and the duties of each member of the team were specified. Every member of the team was responsible for one or two point of the Project proposals. The second step of this activity was the review

of the collected data. The main activity was to establish a directory with the data of the discharged patient, this was necessary to follow up of the outcomes. An evidence of the treatment protocols of the new coming patients according the evidence base treatment of TBI was done. We performed a meeting with the colleagues from the EMS and the anaesthesiologists from Strumica. The task of the meeting was prehospital care of the patients with traumatic brain injuries. We discussed the guidelines and the necessary steps to improve the prehospital care of brain trauma patients. The implementation of the guidelines and protocols for the management of Trauma Brain Injury patients, is a process that will improve the quality of patients' outcomes.

Our next activity was the regular entry of the data of the new coming patients and the continuous training of new collaborators on how to use the software program was necessary. The preparation of the data for the coming meeting in Rijeka was done (two members of the team joint the meeting). An additional training of the co-workers about the collecting and keeping the data and the outcomes, there insertion and transfer of the data was performed.

To accept the updated guidelines for the treatment of the traumatic brain injuries, the team was obliged to work in the library and using the Web. Every member was forced to work on one problem connected with the brain trauma. So, the problem of sodium and electrolytes changes in brain trauma patients was solved. We made guidelines for pre-hospital and peri-operative fluid therapy.

The results of the research for hypotensive anaesthesia in brain trauma patients was reffered ,in front of the audience of the professors of the Medical Faculty in Skopje. A representative from the ministry of the science was presented. The second research was dedicated to the fluid balance of the surgical patients. The researche was finished and the data of the resent research was publish in a booklet. The establishment of the scoring systems in NS patients, and the most often used scoring systems in the ICU were done. A young fellow started to work on the use of the SOFA scores in our ICU. The practical work with the nurses for minimal nursing of the TBI patients was performed. A workshop about the use of PK-Merz in TBI in Ohrid was organized by the a pharmaceutical firm; the team of our Project attended this workshop. The novelties in the therapeutic approach in the therapy of TBI were discussed. The representatives of our team joint the meeting in Rijeka. In the begening of September our team established a multidisciplinary Association for Critical care medicine. The first meeting was dedicated to the secondary brain injury. The problem of hypothalamic-pituitary-adrenal function in the patients with traumatic brain injuries was a challenge. The young fellows of our team made a research about this problem in the literature and in the webs. We made a meeting with the responsible doctors from endocrinology and we discussed this matter. A protocol for further research was done.

4.4.2 Results Achieved

The second year of the project started December 01, 2003 until November 2004. The collecting of the data of the patients with BTI continued with the new entries of 62 patients during this period. The data were exported to the Project Centre. From this date till to day we collected the data of 262 patients.

There are presented the results that are analyzed during the second year of the Project from 1st of December 2003 until 1st of December 2004.

The following results are achieved from the second series of data

Tab.1. Demographics of the patients with TBI during 2003/2004 (n=158) (M±SD) %

	SEX		AGE	WEIGHT	HEIGHT
	M	F			
Total	51	11	46.53±22.41	81.2±11	174±8
%	82.25	18.75			

During this analyze of the data about the age and the genders, was found that there is a difference between the previous data (first year) and the last data. The majority of the victims are male 82.25% out of 76.6 respectively.

In the recent results we did not analyzed the mechanisms of the injury, that will be statistically account in the future. But following the data it is obvious that the main reasons for head and brain injuries still are road traffic accidents

We made an analysis of the rate of the mortality of the new entry data. It was found that the number of dead is still high (25 out of 62), or the rate of the mortality is 40.32 %.

Main reason for such high rate of mortality is the high number of politrauma patient. One third of the entries are patients, TBI victims with multiple trauma. Also 4 of them died in the first 24 hours.

It was difficult to collect the outcome records. The number of the missing patients and data is still too high.

The data obtained shows that the majority of the patients are directly transported from the field of the accidents to our centre and the others received prime resuscitation in other medical centres. The possibility for resuscitation in the field is still very low. The data implicate for very basic monitoring during the transportation.

The transportation from the high distance posts leads to the losing time for proper treatment of the TBI. The patients are not treated or operated very quickly.

The ICP measurement and its' use as routine is still missing.

4.4.3 Problems encountered

1. The main problem was the disability to measure and control the ICP by a ventriculostomy. The lack of the devices for this purpose still exists. There are some effort to provide it, but it takes too long.
2. Second problem was the shifts of the collaborators. It was necessary to provide additional learning for the new collaborators.
3. Next problem was with the computer. It was several times attacked from the viruses, that made the data collecting slower.
4. The completion of the outcome of the patients was very difficult. We were not able to collect the data of the majority of discharged patients. Even that we made a directory with the addresses and telephone numbers of discharged patients, they are not responded. All those patients rest with unknown outcome so the severity of the disability could not be accounting.

4.4.4 Technology implementation plan

According to the results achieved from the project the implementation should be stratified on three divisions: development of the human resources, improvement of the health care and the improvement of the community policies.

1. Potentials- development of the human resources: M1, M2, M3

M1 The results of the TBI project will be presented to the qualified doctors- neurosurgeons, EMS professionals and anaesthesiologists.

M2 A workshop: Evidence based Medicine - the implementation of the TBI guidelines.

M3 Spread of the knowledge to three main centres in the country- Visit with lectures
All the participants will be encouraged to visit the IGEH web site. An interactive learning will be provide

2. Second action to improve the health care:

Technology: improvement of the health care : M4, M5, M6, M7

Volunteers to use the TBI-Trac database

Education on evidence based treatment of the TBI

Introduction of the invasive methods of monitoring, ICP measurement

The results to be presented to the health Authorities

3. Third Action

Community policies: M8, M9, M10, M11, M12

Improvement of the regulations on the roads/ improvement of the quality of the driving

Policies for driving under alcohol

Presenting the data to the NGO-as to the organization: save the children

Involvement of the local WHO organization for support of short schedules

Information's in mass media

CME Courses for Staff employed in the EMS

Promotion of the use of generic technology and IGEH web side for self education

4.4.5 Publications and papers

M. Soljakova, Z. Todorova-Nikolova: The effects of hypotensive anaesthesia to the BTI victims ; Ministry of science, report, Skopje, March 2004.

Z. Todorova-Nikolova, M. Soljakova: Management of fluid balance in Brain trauma injuries, DIGI-print, Skopje, 2004 ISBN 9989-2188-46 (COBISS.MK-ID 57959690)

M.Soljakova, B. Kuzmanovska: Syndrom of lost of sodium, Acta anesthesiologica Macedonica, :22, 2004

Z. Todorova-Nikolova, B. Kuzmanovska: Resuscitaion of brain trauma victims, I workshop of MSCCM, Skopje, 2004

J.Nanceva, M. Soljakova, E Stoickovski: Anaesthesia for geriatric patients, MSA FEEA VI, :9-18, 2004, ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)

Z. Todorova-Nikolova: TIVA, MSA FEEA VI, :117-120, 2004 ISBN 9989-2018-3-8 (COBISS.MK-ID 56383754)

4.4.6 Conclusion

TBI causes significant mortality, morbidity, and contributes substantially health care costs. Accepting of the guidelines is essential for the improvement of the treatment of the victims of the traumatic brain injuries. To force and improve the normal cerebral physiology is essential to alter the track of the poor out come. Despite acute reductions in ICP and improvements in CBF with mannitol therapy, there are insufficient data to preclude either a harmful or beneficial effect on mortality. Hyperventilation may acutely control ICP; Anticonvulsant prophylaxis has been shown to prevent early seizures after TBI. Evidence based medicine have failed to show a beneficial effect on mortality or neurological outcome in TBI patients treated with corticosteroids; however, a small but important beneficial effect of corticosteroids cannot be ruled out.

According the TBI guidelines we will use the following recommendations:

-to control the ICP less than 20-25 mm Hg;

-in the absence of an ICP monitor we will maintain the CPP \square 70 mm Hg; MAP above 90 mm

- to optimize the cerebral oxygenation we will provide a normocapnia

The improvement of the social and economic conditions of the country will improve the state of the roads in the country that will decrease the number of the victim injured in the road traffics.

The policies of the country would be to improve the health care and to decrease the number of the accidents that lead to brain injuries.

The obtained results at the end of the first year, that the severity of the brain injuries are due to traffic accidents, made an Impact in the Country traffics regulations. The low to use the seats belt and to drive with the lights-on is appreciated by the drivers.

Report prepared by prof.Dr. Marija Soljakova

4.5 Participant 6 HR Osijek

4.5.1 Activities

In 2004 the data for other 9 patients suffering severe brain injury was gathered. All patients' data were entered into the database designed by IGEH and on a weekly basis sent over the Internet to the IGEH, Vienna, for further statistical and technical processing. The database was daily updated.

In June 2004 we all met in Rijeka-Omisalj, Croatia, for annual review of our work, according to the project plan established at the project start.

4.5.2 Results achieved

In 2004, 9 patients with severe brain injury were treated at Department of Neurosurgery. The management protocol in accordance with the Guidelines for the management of severe head injury was strictly followed. Four out of nine patients who suffered severe brain injury died, with overall mortality rate of 44.4%. In all five (55.6%) patients who survived severe brain injury satisfactory outcome was recorded (GOS 4 and

5). The results showed improvement of the outcome, as well as reduction of morbidity when compared to our results achieved in the previous years.

4.5.3 Problems encountered

There is still a permanent minor problem related to the quality of ambulance data but we hope with more education the problem can also be solved.

4.5.4 Technology implementation plan

According to the Guidelines for the management of severe head injury, a state-of-the-art treatment for patients suffering severe brain was successfully implemented at our Department as a daily routine due to cooperation between the neurosurgeons and the anesthesiologists involved.

4.5.5 Publications and papers

In 2004 we didn't publish any new paper regarding this project in indexed scientific journals. There is intention to publish the paper concerned with the topics on severe brain injury and database from this conjoined project in 2005.

In the past years a paper on this topic by authors involved with the project appeared as a poster at The 1st Croatian Congress of Neurological Rehabilitation and Restoration Neurology held in Osijek, Croatia in November 2004.:

Splavski B, Ivić D, Saftić R, Mužević D, Kčira-Fideršek V. Most important early predictors of outcome following severe traumatic brain injury.ations: an international focus meeting, September 19-20, 2003, Rimini, Italy, p 28.

4.5.6 Conclusion

As far as our experiences are concerned, this project has met the expectations regarding the benefit of the treatment of severe head injured patients according to the Guidelines for the management of severe head injury. At the project end, it will be interesting to learn the difference of outcomes among the three countries involved in the project and compare the results achieved to the EU experience.

We believe that this project when completed will determine the main problems facing the management of severe brain injury and will offer possible variety of solutions in overcoming the encountered problems.

**Bruno Splavski, MD, MS
Head, Department of Neurosurgery,
Osijek University Hospital**

4.6 Participant 7 HR Rijeka

----- Original Message -----

Subject:
(no subject)

Date:

Thu, 03 Feb 2005 20:13:00 +0100

From:

Dean Girotto <dean.girotto@ri.htnet.hr>

To:

annalisa.rosso@igeh.org

Finally in the period November 2003 to November 2004 i don't have problem like last year with my PC and virus attack.

At all period collections data of patients and input for retrospective study of TBI cases, reporting and synchronizing with ITCP database.

Problems: in my Clinical hospital is not get routine alcohol profile.

In this year period I get promise of clinical laboratory that start with alcohol profile routine.

With regards

Dean Girotto

4.7 Participant 8 – HR Zagreb

Miroslav Vukic, MD, PhD, University Hospital Sestre Milosrdnice, Vinogradska street 29, 10000 Zagreb, HR Croatia, **Zagreb, February 28th 2005**

4.7.1 Activities

In the year 2004 we gathered data of another 23 patients who sustained severe head injury and were treated in our Neurosurgical ICU. According to our project intention all patients' demographic and clinical data were entered into the database designed by International Brain Trauma Foundation. Database was weekly reviewed for updates and upon updating database was electronically sent to Vienna.

There was a meeting organized by the Project Managing Board in Omisalj, Croatia, June 2004. At that particular meeting all coordinator and local project leaders reported upon their activities related to the project and stressing importance of that project to public health in each participating country, in general. Croatia has served as an example of high incidence of ICP monitoring in severely brain injured patients and appropriate compliance with the Guidelines for the Management of Severe Head Injury.

4.7.2 Results achieved

In the year 2004 we treated 23 patients with severe brain injury in our Neurosurgical Department. Overall results of the year 2004 showed worsening of the outcome as compared to that achieved year before.

There was one month mortality rate of 44%. Out of 56% of patients who survived severe brain injury, 61% had good outcome. Reasons for achieving worse results in outcome as compared to the last year were: lower GCS score on admission, higher percentage of transfer patients and rather late treatment, especially surgical one. The incidence of ICP monitoring was over 85 %, predominantly ventriculostomy was used.

4.7.3 Problems encountered

In the year 2004 we had some minor problems with our hardware in the ICU, basically missing the Internet connection. But at the end of the 2004 that particular problem was solved.

There were permanent minor problems related to the quality of ambulance data and missing data of the transferred patients. We hope that broader education for all those involved in emergence service and treatment can solve the problem in the future. In that respect there will be a meeting organized in Zagreb, June 2005, where all Croatians participants in this project will try to do the best to overcome such troubles.

4.7.4 Technology implementation plan

The treatment of severely head injured patients is in our institution, in particular, based on continuity of neuromonitoring.

According to the Guidelines for the management of severe head injury, we have implemented a state-of-the-art treatment for patients with severe head injury as a daily routine. With a good cooperation between the neurosurgeons and intensivists at our Department, the implementation of modern treatment of severe head injury was in general, very successful.

4.7.5 Publications and papers

There is one written paper that is going to be published in a national surgical publication in 2005 with the topic of severe brain injury and the results coming from that multinational conjoined trauma project.

Dr Miroslav Vukic was invited speaker at the Fourth International Congress of Croatian Pharmacological Society (held in Split, July 2004) reporting the current pharmacological therapy of severe head injury and reporting about this particular project and its perspectives

4.7.6 Conclusion

This project has so far met all our expectations regarding the benefit of the treatment of severely head injured patients according to the Guidelines for the management of severe head injury. At the end of the project it will be interesting to see the difference in the treatment patients as well as the outcome between the three Balkan countries. We hope that sharing our data and consequently knowledge, will eventually have significant influence on current treatment modalities of severe head injury patients across the South East Europe.

**Assistant Professor Miroslav Vukic, MD, PhD
National Project Coordinator**

4.8 Participant 9 - BH Sarajevo

Dr. Kemal Dizdarevic Department of Neurosurgery, Clinical Centre University of Sarajevo, Bosnia and Herzegovina

4.8.1 Activities

Over the year 2004 we focused our activities to collect the data and to implement the TBI guidelines in practice. We checked the quality of data against the indicators discussed during the meeting in Rijeka.

4.8.2 Results Achieved

We have collected 143 patients so far.

4.8.3 Problems encountered

As in other centers the major problem encountered was with the follow up of patients within a year interval.

4.8.4 Technology implementation plan

Not relevant for this activity

4.8.5 Publications and papers

K Dizdarevic, I.Omerhodžić, N Iblizović. B Jahić: Neurosurgical intensive care unit as a prerequisite of current approach to neuropatients. Med Journal, in press.

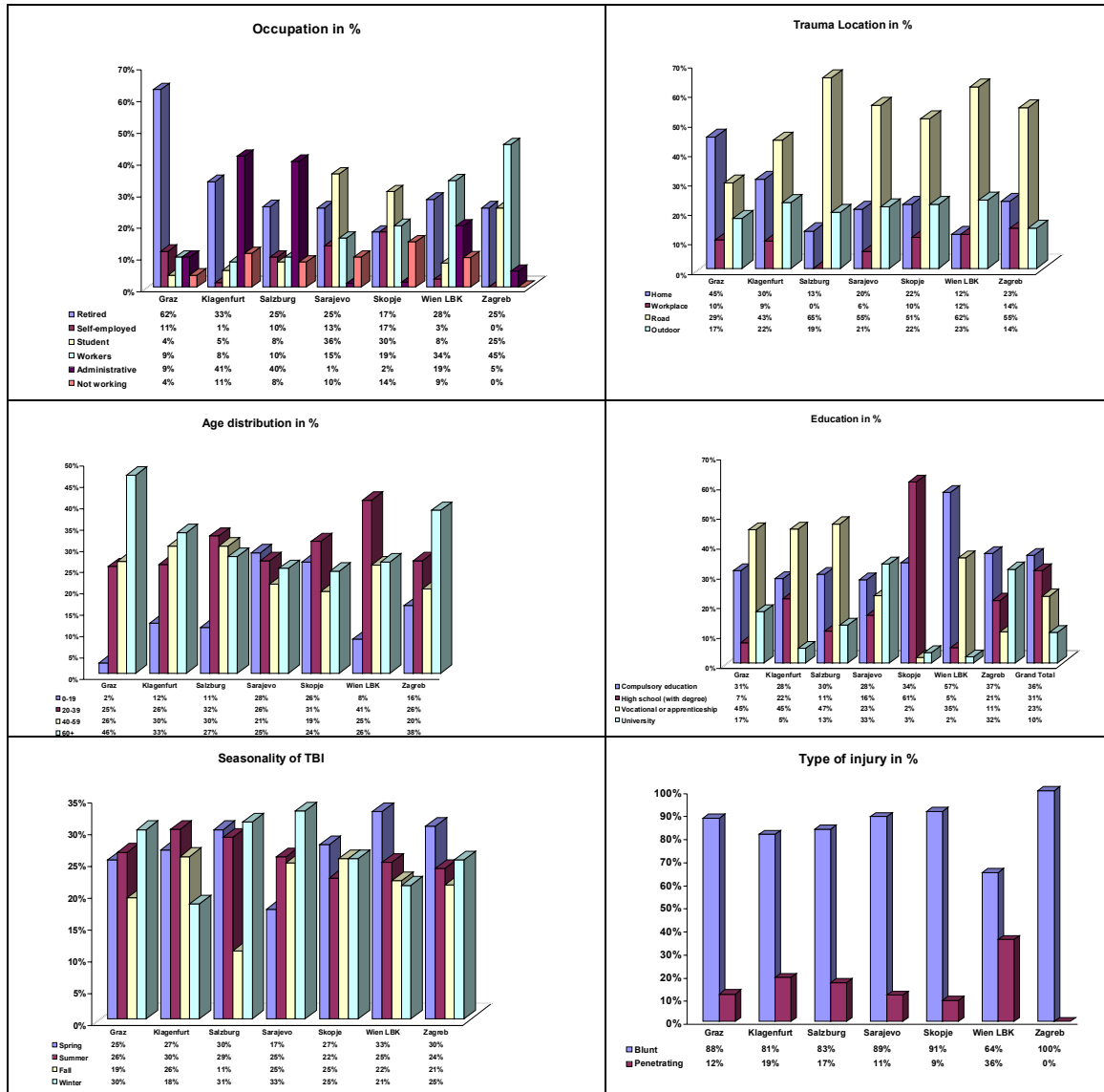
K. Dizdarević: Cerebral microdialysis and prevention of cerebral ischemia after neurotrauma and aneurysmal hemorrhage. Med Arch, in press

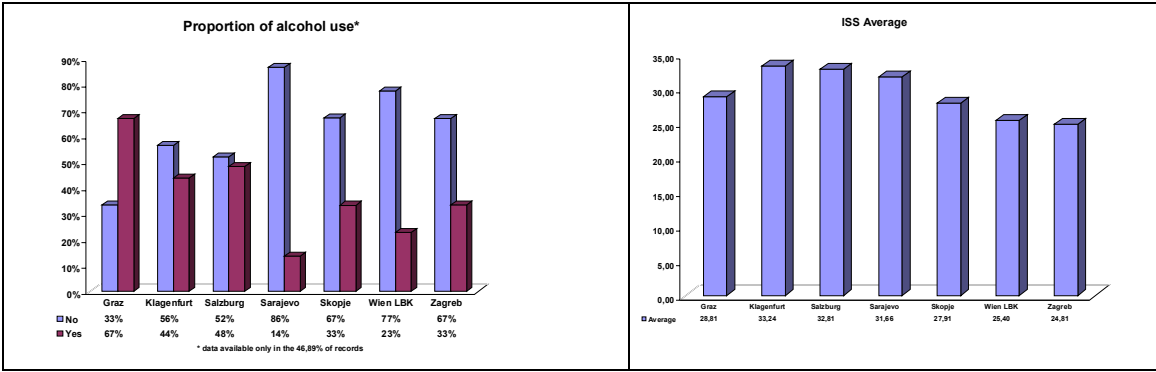
4.8.6 Conclusion

We have successfully prepared ourselves to continue the project and we have enough data to be subjected for final data analysis.

5. ANNEXES

5.1 SELECTED RESULTS from the INTERIM ANALYSIS





5.2 MEETINGS REPORTS

5.2.1 Report from the Research-TBI project meeting in Bratislava, November 22nd – 23rd June 2004

The workshop was held with several **objectives**:

- To review current state of the project and to evaluate results reached in the 1st year;
- To initiate quality control of data collected;
- To introduce and discuss individual procedures of TBI treatment based on TBI Guidelines.

List of Documents each participant received:

Agenda

Address list

TBI Guidelines

Guidelines and Management of the patient with traumatic brain injury: State of the Art –

Walter Mauritz

Data Description

Presentations:

Trauma Systems – Lucia Lenartova

Epidemiology of TBI – Alexandra Brazinova

Intracranial Hypertension – Petra Dado

International Neurotrauma Research Organization Scale (INROS) – Johannes Leitgeb

Nursing aspects of TBI care – Ingrid Wilbacher

Short history of Bratislava

Results:

1. Welcoming remarks and introductions – M. Rusnak

Dr. Rusnak asked all the participants to introduce themselves. Participants were asked to update their contact information, too.

2. Overview of the project – M. Rusnak and reports from centers with a discussion

Dr. Rusnak gave a presentation on the project between the kick off meeting and today. He also outlined major challenges for the coming second year of the project. The discussion was mostly concerned with issues of data collection, quality of data and problems of patient selection.

3. Guidelines and Management of the patient with traumatic brain injury: State of the Art – Walter Mauritz

The presentation of guidelines and clinical protocols was followed by an extensive discussion.

4. Discussion

Q: Who monitors SjO₂ routinely. A: M.Vukic : 80% of our patients have jugular bulb monitoring, average of SjO₂ in our patients is 50, we take samples every 12 hours.

Q: Does anyone use PA catheters? A: No.

Q: Does anyone use hypothermia? Prof. Soljakova: Sometimes.

Q: Does anyone use minimal nursing? No.

Q: Tris buffer – is expensive for us (M.Skoljakova)

Q: Do you do decompressive craniotomy? A: M.Soljakova – sometimes. M.Vukic – it's a problem. Indications: blood mass, GCS < 5, diffusiv edema, age < 40, ICP > 30, under barbiturates and cooling.

Q: What forms of antithrombotic treatment do you use. A: M.Soljakova – we use in early stage (2nd day) low dose heparin, from the first moment ranitidine, proton pump.

Q: antibiotics shouldn't be used as prophylaxis. A: B.Splavski: we don't use it in traumatic patients, only if there is subarachnoidal hemorage.

Q: what is the best time to operate on other than head trauma in multiple trauma patients? A: M.Soljakova: we do it after 24 hours. W.Mauritz: we try to do all operations in one session. There are no good comparative data for this.

Other comments and suggestions: Check the pathways in your handouts and send us all ideas by email; M.Rusnak: we will put all information on our website; W.Mauritz: insert your own clinical pathways and mail them back to us. Final product of this project will be a book on TBI treatment written by this group.

5. Presentation of data from centers – M.Rusnak and I.Janciak

The data were sorted and displayed to start a discussion on their quality. (See below) M.Vukic commented that his center has at least 30% of isolated trauma.

Q:W.Mauritz: does anybody use algorithm for estimating alcohol by osmolality? A: No.

Participants felt that there is a need for detailed quality of data verification process.

Mr. Janciak will prepare an algorithm to check missing and erroneous data and will send the results to all centers.

6. Suggestions of particular research items by members IGEH team

a. Trauma Systems – Lucia Lenartova

Prof. Wendsche suggested to submit this paper for the conference on trauma care to be held in Prague next year.

b. Epidemiology of TBI – Alexandra Brazinova

The data from ITCP already allow for

c. Intracranial Hypertension – Petra Dado

d. International Neurotrauma Research Organization Scale (INROS) – Johannes Leitgeb

e. Nursing aspects of TBI care – Ingrid Wilbacher

7. Discussion on next steps

Discussion:

- o

IGEH team presentations.

- Discussion: W.Mauritz: a paper should be written on the course of ICP in TBI patients.

List of participants

- **MUDr. Miriam Bartošová**, Anesteziolog Dpt. Anestheziology and Intensive Care NsP Michalovce 071 01 Michalovce Slovakia bartosova@hotmail.com
- **MUDr Alexandra Bražinová**, PhD, MPH Research Fellow IGEH Mülkergasse 4/3 A-1080 Wien Austria abrazinova@igeh.org
- **Dr.Med. Petra Dado** Research Fellow IGEH Mülkergasse 4/5 A-1080 Wien Austria petra.dado@chello.at
- **Dr Kemal Dizdarevic**, MD neurosurgeon Dpt. Neurosurgery Clinical centre University of Sarajevo Bolnicka 25 71000 Sarajevo Bosnia & Herzegovina kemaldiz@bih.net.ba
- **Dr Dean Giroto**, M.Sc. Neurosurgeon Dpt. Neurosurgery University Hospital Rijeka Tome Strizica 3 HS-1000 Rijeka Croatia dean.giroto@ri.hinet.hr
- **Dipl. Ing. Ivan Janciak** IT Specialist Universität Wien Institut für Softwarewissenschaft Liechtensteinstrasse 22 A-1090 Wien Österreich ijanciak@igeh.org
- **Dr. Hrvoje Jednacek** Hospital Osijek Josipa Hutlera 4 31 000 Osijek Croatia
- **MUDr Milan Kaniansky** Primár Dpt. Traumatology F.D.Roosevelt Nemocnica nám. L. Svobodu 1 975 17 Banská Bystrica Slovakia mkaniansky@nspbb.sk
- **Dr. Vieceslav Kcirj**, Dpt. Neurosurgery Hospital Osijek Josipa Hutlera 4 31 000 Osijek Croatia
- **Dr.Med. Johannes Leitgeb** Assistentarzt Trauma Surgery Allgemeines Krankenhaus der Stadt Wien Währinger Gürtel 18-20 A - 1090 Wien Austria johannes.leitgeb@akh-wien.ac.at
- **Mag. Lucia Lenartova** Research Fellow IGEH Mülkergasse 4/3 A-1080 Wien Austria lucial13@hotmail.com
- **Prof. Dr.Med. Walter Mauritz** universitatsprofessor primarius Fachartz für Anaesthesiologie und Intensivmedizin Unfallkrankenhaus "Lorenz Bohler" Donaueschingenstrasse 13 A-1200 Wien Austria Walter.Mauritz@igeh.org
- **Prof. Zorka Nikolova Todorova** Head Clinic of Anesth., Reanimation and Intensive Care Medicine Clinical Center at Medical Faculty ul. Vondjanska 17 1000 Skopje Macedonia drniktod@yahoo.com
- **prim. MUDr. Dagmar Řehořková** vedoucí lékař ARO Úrazová nemocnice Brno Ponávka 6 662 50 Brno Ceska Republika
- **Univ.Dož. Dr.Med. Martin Rusnak, CSc**, IGEH, Mülkergasse 4/4, A-1080 Wien, Austria, rusnakm@igeh.org
- **Prof. Marija Soljakova** Clinic of Anaesthesiology and Intensive Care KARIL Vodnjanska 17 MKD-1000 Skopje Macedonia soljakm@ukim.edu.mk
- **Dr. Bruno Splavski**, Ph.D. Head Dpt. Neurosurgery Hospital Osijek Josipa Hutlera 4 31 000 Osijek Croatia splavski.bruno@kbo.hr
- **Dr. Ivica Stefanovski** Clinic of Anesth., Reanimation and Intensive Care Medicine Clinical Center at Medical Faculty ul. Vondjanska 17 1000 Skopje Macedonia
- **Dr. Duje Vukas**, Dpt. Neurosurgery University Hospital Rijeka Tome Strizica 3 HS-1000 Rijeka Croatia
- **Dr. Miroslav Vukic**, PhD neurosurgeon Dpt. Neurosurgery Medical School, University Clinical Center Zagreb Kispaticeva 12 10000 Zagreb Croatia crsm@iskon.hr

- **Univ.Prof.Dr.Med. Petr Wendsche**, CSc Spinální jednotka Úrazová nemocnice Brno Ponávka 6 662 50 Brno Ceska Republika p.wendsche@unbr.cz
- **Mrs. Ingrid Wilbacher**, RN, IGEH, Mülkergasse 4/4, A-1080 Wien, Austria, iwilbacher@igeh.org

5.2.2 Report from the Research-TBI project meeting in Rijeka 19th – 20th June 2004

Participants

- Project Members:** Dr. Dean Giroto (Rijeka)
 Dr. Fred Zeidler (Rijeka)
 Dr. Miroslav Vukic (Zagreb)
 Dr. Bruno Splavskji (Osijek)
 Dr. Marija Soljakova (Skopje)
 Dr. Zorka Nikolova-Todorova (Skopje)
 Dr. Kemal Dizdarevic (Sarajevo)
 Dr. Pavel Hude (Brno)
 Dr. Miriam Bartosova (Slovakia)
 Dr. Milan Kaniansky (Slovakia)
 Dr. Martin Rusnak (IGEH)
 Dr. Alexandra Brazinova (IGEH)
 Dr. Johannes Leitgreb (IGEH)
 Dr. Lucia Lenartova (IGEH)
 Dr. Annalisa Rosso (IGEH)
 Mag. Ingrid Wilbacher (IGEH)
- Observers:** Dr. Fiona Lecky (Research Director from the Eurotarn Network)
 Mr. Friz Hochwimmer (representant of the Schwandner Klinikprodukte)

Review of the state of the project. Dr. Martin Rusnak

As an introduction to the meeting Dr. Rusnak reviewed the evolution of the project from 1999, where the first proposal has been written, and the contents of the previous meetings.

The first phase of the project started after the meeting of January 2003 in Vienna, consisting in the retrospective data collection from severe TBI patients hospitalized in the previous years.

In the meeting of November 2003 in Bratislava the guidelines for the treatment of Severe TBI were introduced, and the guidelines implementation phase started.

The meeting of Rijeka has the proposal to start a new phase of the project: the data analysis. The contents of this meeting were defined as a preliminary discussion concerning the problems met so far in data collection and guidelines implementation, the identification of possible solutions to overcome such problems, and finally suggestions for the data analysis.

Data Quality Assurance. Mag. Ingrid Wilbacher

Being responsible for the Data Quality Assurance, Mag. Wilbacher has reviewed all the data collected by the different centers and has identified frequent missings and imprecisions.

General recommendations for the most evident problems have been given, and then Mag. Wilbacher discussed her findings personally with the members from each center (see Wilbacher's personal Report).

The first recommendation was to not leave data without being filled when information are not available, but always to select "unknown" in these cases. The second one was to include all the patients admitted to the hospital with a $GSC \leq 8$, also the ones dying just after the arrival

A debate about the Outcome collection was then started, since the outcome data showed to be very often incomplete. All the centers discussed their way to get those information, and most of them declared to have problems getting the long term ones. The comments from every center are here reported:

Skopje: Dr. Soljakova declared to have difficulties in the collection of the outcome for the historical records (retrospective ones), since they usually don't have the addresses of those patients. For the new records they created a register of addresses and they send postcards to the patients' families asking about the outcome, but they often don't get answers.

Austrian Centers: Mag. Wilbacher explained the way she uses to collect outcomes in Austria: she sends a questionnaire to the patients via mail asking whether they are working or not, whether they have disabilities and in which percentage, and if they have the need of support. She stated that the feed back is quite high in Austria, in contrary to Macedonia, and this difference could probably be due to cultural reasons.

Zagreb: the department where Dr. Vukic works only treats a few trauma patients per year (around 40/year), so they probably have less problems collecting outcomes. It is easy for them to collect the 30 days one, and also the 90 days outcome if the patient died or if he went to some rehabilitation center. In this case they usually enter in contact with the doctor responsible for the patient in that center, and they discuss the outcome. The only problem in this situation is that GOS is a "personal" scale, and every doctor can interpret it at his way. Dr Vukic said then to have problems in the collection of the 6 months outcome for the old patients, since he was working in another center at that time, and it is difficult to get addresses from those patients. There are no problems instead for the new patients.

Osijek: Dr. Splavski claimed that it is very difficult for his center to get informations about outcomes, because the patients and their families don't want or don't care for responding a questionnaire.

Brno: this center just started the data collection, so they didn't face the problem about outcome information yet

Banska Bystrica: Dr. Kaniansky said there are usually no problems collecting the outcomes while the patient is still in the hospital, while it is difficult after he left

Mihalovce: Dr. Bartosova explained her personal strategy to get information about the outcomes, consisting in asking relatives for their telephone numbers while the patients are still in the hospital, in order to contact them later.

Sarajevo: also for this center it is difficult to collect the outcomes after the patients left the hospital

Rijeka: it is difficult to collect outcomes because they don't have addresses neither telephone numbers of the patients to contact them after they left the hospitals. In general Dr. Zeidler spoke about problems in the data collection due to the lack of connection between ICU and surgery. He told about the specific problem of registering the alcohol level, because that exam is realized by the department of forensic medicine of the hospital, and they don't get the results (only if they ask to see them). Another problem is the poor education of the physicians, who only have a basic training and are not specialized in trauma.

Some possible solutions to these problems were discussed:

Dr. Rusnak suggested insisting in sending cards to the families until they answer (there can be up to 80% success of response)

Dr. Soljakova proposed to use the family doctor for the connection after the patient left the hospital

Dr. Zeidler suggested speaking with the relatives already when the patients are in the hospital, informing them that they will be contacted in 3- 6 months and asked about the status of the patients, also explaining them the reason why those information need to be collected.

What major limitations you have to face in Guidelines Implementation - discussion facilitated by Dr. Johannes Leitgeb

Problems met in the implementation of the guidelines have been exposed by every center. They appeared to be mainly financial matters and organization problems due to lack of cooperation between medical specialists or with colleagues who don't accept the guidelines. Comments are here reported:

Zagreb: Dr. Vukic started implementing the guidelines already in 1997 or earlier, and at the beginning ('98-'99) they had some troubles with the implementation. Now the guidelines are very well accepted in Croatia, they have been discussed in Workshops and national congresses of the Neurosurgical Society, and the compliance is around 80%. He stated that they don't follow always the guidelines at 100%, they may make some shortcuts according to the general condition and associated problems of the patients; anyway they generally do for the ICP monitoring, also thanks to the collaboration of anesthesiologists. But there would be the need of more intensivists caring for the guidelines, since most of them don't follow them strictly.

There are in general problems of financial restriction from the Ministry of Health in Croatia, but this doesn't affect the hospital of Zagreb, which is the biggest in the country. Anyway there is the need to fight in the hospital to spread the use of guidelines: the chiefs of the neurosurgical departments and intensive care have to agree, and this may not be easy.

Brno: the trauma center of Brno has a concrete problem: they don't have a neurosurgeon. Also they have problems in performing ICP monitoring, considered risky because of the patients' coagulopathy.

Skopje: there were no problems among the intensivists in accepting the guidelines, but in implementing them. They have the concrete limit of not having ICP monitoring devices in the ICU. In contrary the neurosurgeons didn't accept the guidelines, and they have different approaches, for example to the use of steroids (intensivists don't use them, surgeons do). They took the initiative for a joint meeting between intensivists and surgeons to discuss guidelines implementation. A limit in the implementation also comes from the financial restriction: now there is a "budget" that has to be respected.

Osijek: Dr. Splavski said that in Osijek the situation is more complicated than in Zagreb. In general in Croatia 2-3 years were needed to implement the guidelines. According to his opinion, the biggest problem in the implementation is the ICP- monitoring, because it is an expensive procedure. Anyway he sees the problem not really in the compliance of guidelines, but in the organization of treatment: man at field and transportation are out of the control of the hospital physicians, so they can't influence the pre- hospital treatment.

Rijeka: in response to Dr. Splavski, Dr. Zeidler said that he could influence the pre-hospital treatment, being the director of the emergency service of Rijeka, but on the other hand he doesn't have the guidelines. He added that their budget was cut from the Ministry.

Sarajevo: they had financial problems with the director of the hospital, but now they solved them. Anyway they don't follow strictly all the recommendation, for example they don't use steroids if there is no associated spinal injury, they take the CPP value of 60 as limit, and they use anti- epileptic drugs only anti- seizures.

Banska Bystrica: also for this center the main problem is in the ICP monitoring. It is too expensive, and for this reason they use parenchymal devices which are cheaper. The pre-hospital management is not a problem for them, because the hospital has its own helicopter.

Mihalovce: a part from having financial complications, like almost all the other hospitals, the big problem of this center is the implementation of the pre-hospital management. Dr. Bartosova explained that they cover a very big area, and for some patients it takes hours before they arrive at the hospitals. A part from that, the pre-hospital care is often inadequate, i.e. patients arrive without I.V. Another difficulty is the absence of a CT in their building, which forces to transport patients by car to other parts of the hospital.

In addition, there are also problems with the chief of Department for implementing the guidelines.

Austria: Dr. Leitgeb said that his main problems come from the ignorance of the colleagues, who don't accept the guidelines.

UK: also Dr. Lecky shared her experience with the project members. In her hospital they have a team of intensivists, radiologists and neurosurgeons working together for the management of TBI. They were convinced that implementing guidelines would have not cost too much, and would have saved money in hospital admissions. After adopting guidelines they had a first evaluation period. Also nurses have been trained for using guidelines.

At the end of this discussion, two main problems for the implementation of the guidelines have been identified: the requirement of cooperation between different areas of health care (i.e. pre-hospital and hospital care) and financial limitations.

What are the Policies to be Developed and Implemented to overcome those Limitations - discussion facilitated by Dr. Sasha Brazinova

Possible solutions for these and the other obstacles which were met, like the ignorance of colleagues, have been discussed by each center. Dr. Brazinova facilitated a group exercise, defining the main problem for each center in guideline implementation, trying to imagine making a "war" to solve it, identifying which would be the "enemies", the "allies", and what could be the "weapon" to be used to win this "war".

Rijeka: According to Dr. Girotto the main problem is the Hospital System, in particular the lack of communication between departments (especially between ER and neurosurgery). A possible solution could be to find a "contact person" in every department. Also the budget represents a problem, because of the differences in money distribution between the centers.

Dr. Zeidler's biggest problem is time, which means the slow motion of the system (the enemy). The implementation of a new software would solve the problem of data collection, and he sees in the data resulting from this study a possible "weapon" to overcome the problem.

Skopje: they analyzed the concrete problem of not having ICP monitoring in their ICU. The "enemy" in this case would be money, which they don't have, and the weapon could be showing arguments demonstrating the importance of ICP monitoring in saving lives, and the cost-effectiveness of the instrument.

Dr. Brazinova underlined the important role played by the public in these situations. It can be useful to use the media to inform people about such problems: publish in ordinary newspapers, not only scientific papers, realize small booklets, etc. The public would force regional government to change the system. Also the support of NGOs can help

Slovakia: the main problem is the financial limitations, and the enemy is the Ministry of Health. Also in this case the data could be used as a weapon.

Brno: also in this center financial limitations create problems, for example in providing ICP monitoring which is considered too expensive. It is also difficult for them not having a neurosurgeon working in the hospital: complains were already made but without response, so it was suggested from Dr. Zeidler to write an official letter of complain to the director of the hospital, in order to have a “witness“ of the situation.

Osijek: the main difficulty comes from the ignorance of the colleagues and the organization of the hospital. Enemies in this case are the other doctors. Dr. Zeidler proposed the need of changing people’s way of thinking on a local, regional and national level, and the important role of data presentation for this aim.

Dr. Lecky stressed the importance of data to change the mind of people. Change of leadership can help. Collect data and evaluate the implications of the use of guidelines. In the UK system of hospital management they have to demonstrate the quality of care provided in order to get funding.

Zagreb: according to Dr. Vukic the main problem is not financial: it is true that ICP monitoring costs, but only when you buy the machine. The main problem is to change people’s mind, to convince them that you cannot deal with people in coma without monitoring ICP. For this purpose data are important.

Sarajevo: the main problem in Sarajevo is the lack of a professional approach treatment because of not appropriate education and training.

Summarizing the discussion, it emerged the importance of involving other people in the hospital, regional and national administrations, professional organizations and general public as possible allies, and to use data and evidence against the problems, in particular the outcome of this project and the experience of other countries can be valid tools. To overcome the main difficulty of the financial limitation, it was suggested by Dr. Zeidler to look for other sources: during the socialism people were used that money from hospital management came directly from the state, but now in the Western countries money can also come from other sources. Dr. Rusnak in particular proposed to create suggestions for projects in the area of development, rather than in science, by active visits of the institutions.

Defining goals of the Analysis and Hypothesis Formulation, facilitated by Mag. Ingrid Wilbacher

Mag. Wilbacher facilitated a discussion about information which the members of the project would like to get from the data collected so far. The following hypothesis and topics were suggested:

- It was suggested to make a comparison between the Balkan countries, and between Balkan and Austrian Countries for all the data. The data analysis should be directed in those areas: epidemiologic and social aspects, pre-hospital care, hospital care, treatment, surgery and outcome.
- Influence of the changes in the law for the use of seatbelts and helmets in Croatia on the frequency of injury
- 6th month outcome and the 1 year outcome, and comparison between them
- Pre-hospital Care, comparing Balkan countries and Austria in variables as direct transportation, fluids, monitoring and special focus on intubation vs. outcome. These results could provide the background for the improvement of physicians' education in pre-hospital management of TBI
- Influence of the mechanism of trauma on GCS and outcome
- Correlation between CT and outcome
- Correlation between CPP and Outcome
- Difference of CPP <50mmHg and <70mmHg correlate to outcome
- Are there tendencies of CPP? When does it go <50, when >50 and on whom?
- Type of surgery vs. ICP and vs. the outcome (i.e. decompressive surgery vs. ICP and vs. outcome)
- Does the type of lesion (especially mass lesion) affect GCS and outcome?
- Differences in outcome between patients with the same clinical aspects but with different types of lesions (diffuse axonal injury vs. mass lesions), and between patients with the same lesions where ICP was monitored vs. patients without ICP monitoring
- Differences in outcome between patients with a mass lesion in the first CT and without mass lesion in the first CT
- Isolated versus multiple trauma correlated to TRISS and Outcome
- Comparison of all centres on GCS, type of trauma and outcome
- Do ICP level and PCO₂ level correlate?
- Fluid management and level of electrolytes (sodium) vs. ICP and vs. outcome (with a range of normal sodium value from 130 mEq/l to 147 mEq/l)

- Relation between crystalloids and colloids, saline against balanced (NaCl/Ringer) vs. outcome
- Who uses hypertonic solutions, who colloids?
- Time for decompressive surgery vs. outcome
- Level of first lactate (shock indicator) related to outcome
- Level of glucose and insulin treatment related to outcome
- Influence of FiO₂ level in first 24 hours related to outcome
- Hypothermia on first six hours correlated to outcome
- Hypotension and hypoxia during the first 24 hours correlated to CPP and to outcome

Afternoon.

EURO TARN: European Trauma Audit and Research Network presented by Dr. Fiona Lecky, Manchester Univ., UK

Dr. Lecky presented, in quality of Research Director, the work of the Trauma Audit Research Network (TARN), a network of UK hospitals coordinated by the University Hospital of Manchester. TARN activity consists in registering data concerning trauma patients and performing epidemiological and clinical data analysis to provide a statistical base to support clinical audit, and aid the development of trauma services. In particular Data Analysis for the Quality of Trauma Care of every participating hospital is performed, based on the comparison between the TRISS model of Probability of Survival and the observed outcome, using the so called Ws score. All the hospitals included in the network receive data about their quality of care compared to the other hospitals.

Since 2002 a European trauma register was created by the same group of researchers from the University of Manchester, the EURO-Tarn, with the aim of extending trauma research and audit, based on the UK experience, also to other European countries. The website of EURO-Tarn can be visited: eurotarn.infonet.co.uk (user: eurotarn, password: eurotarn)

After Dr. Lecky's presentation the possibility of joining the EURO- Tarn network, providing our data of TBI patients, was discussed and was accepted by all the members of our group.

Hospital and Prehospital Trauma Services in Rijeka Region presented by Dr. Fred Zeidler

Dr. Zeidler presented the situation and the problems of the hospital and pre-hospital trauma care in the region of Rijeka.

**Presentation of Schwandner Klinikprodukte OEG TBI on ICP
Monitoring Mr. Fritz Hochwimmer**

Mr. Hochwimmer presented the ICP Monitoring devices produced by the Schwander Klinikprodukte.

The second day of the meeting was devoted to discussing issues bilaterally.

6. DATA SHEET FOR FINAL REPORT

Contract number : ICA2-CT-

Year : 2002

Data sheet for final report

(to be completed by the co-ordinator for the whole project)

1. Dissemination activities

Number of communications in conferences

Published Submitted

--	--

Number of communications in other media (internet, video, ...)

--	--

Number of publications in refereed journals

--	--

Number of articles/books

--	--

Number of other publications

--	--

2. Training

Number of PhDs

--

Number of MScs

--

Number of visiting scientists

--

Number of exchanges of scientists (stay longer than 3 months)

--

3. Achieved results

Number of patent applications

--

Number of patents granted

--

Number of companies created

--

Number of new prototypes/products developed

--

Number of new tests/methods developed

--

Number of new norms/standards developed

--

Number of new softwares/codes developed

--

Number of production processes

--

Number of new services

Number of licenses issued

4. Industrial aspects

Industrial contacts

yes no

Financial contribution by industry

yes no

Industrial partners : - Large

yes no

- SME¹

yes no

5. Comments

Other achievements (use separate page if necessary)

Less than 500 employees.
