

IGEH Annual Report 2003

Vienna, Austria

Internationale Gesellschaft zur Erforschung von Hirntraumata

International Neurotrauma Organization

Mölkergasse 4/3, A-1080 Wien, Austria

Tel.:/Fax: +43 1 409 0363

e-mail: igeh@igeh.org

http://www.igeh.org/

CONTENTS

| 1 MEMBERS of IGEH. | 4 |
|---|-----------|
| 2 DONORS | 4 |
| 3 FORTSCHRITTSBERICHT IGEH AKTIVITÄTEN IN ÖSTERREICH IM JAHR 2003 | <u> 5</u> |
| 3.1 Forschungsprojekt "Behandlungsstandards bei schwerem SHT (in Andenken an Alfred von | |
| Auersperg)" Jubiläumsfonds-Projekt Nr. 8987 | 5 |
| 3.2 Anbahnung neuer Projektentwicklung | <u>5</u> |
| 3.3 Implementierung der "clinical pathways" | <u>5</u> |
| 3.4 ITCP Datenbank Aktualisierung | 5 |
| 3.5 Forschungsprojekt betreffend die Reduzierung der Sterblichkeit und Langzeit-Behinderung von | |
| Schädelhirn Trauma-Opfern durch die Erforschung von Behandlungsmethoden in Bosnien-Herzegovir | 1a, |
| Mazedonien und Kroatien. | |
| 3.6 Weitere Aktivitäten | 5 |
| 4 SUMMARY | 6 |
| 5 PROJECTS and RESEARCH ACTIVITIES. | 6 |
| 5.1 Critical Pathways or Treatment Protocols. | 6 |
| 5.2 ITCP Database. | 6 |
| 5.3 Austrian TBI (In memory of Alfred von Auersperg) 2001 – 2004. | 7 |
| 5.4 Balkan TBI: Bosnia-Herzegovina, Macedonia and Croatia, European Union, 5th FP-Copernicus | |
| 2002- 2005. | 7 |
| 6 APPLICATIONS for NEW PROJECTS | 8 |
| 6.1 Projects under evaluation. | 8 |
| 6.2 Projects rejected. | 10 |
| <u>7 TEAM</u> | . 11 |
| 7.1 Dr. Alexandra Brazinova, Ph.D., MPH. | 11 |
| 7.2 Dr. Petra Dado. | 11 |
| 7.3 Dr. Johannes Leitgeb. | . 11 |
| 7.4 Mag. Lucia Lenartova | 11 |
| 7.5 Mrs. Ingrid Wildbacher, RN. | 11 |
| 8 PUBLICATIONS. | 12 |
| 9 FUND RAISING | 12 |
| 10 PRIORITIES for the YEAR 2004. | 12 |

1 MEMBERS of IGEH

MEMBERS

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Companies and Organizations

ARROW

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Orsini-Rosenberg & Senden Vermogensverwaltung G.M.B.H PHILIPS Medizinische Systeme

Ges.m.b.H.

PFIZER CORPORATION AUSTRIA

Ges.m.b.H.

Sunny van Bullow Trust

3 FORTSCHRITTSBERICHT IGEH AKTIVITÄTEN IN ÖSTERREICH IM JAHR 2003

Folgende Aktivitäten wurden durch die Internationale Gesellschaft zur Erforschung von Hirntraumata auf den Gebieten Forschung, Entwicklung und Bildung unternommen:

3.1 Forschungsprojekt "Behandlungsstandards bei schwerem SHT (in Andenken an Alfred von Auersperg)" Jubiläumsfonds-Projekt Nr. 8987

Dieses Projektjahr wurde der Vervollständigung der Datensammlung aus den österreichischen Zentren gewidmet, welche schlussendlich mit Oktober 2003 erfolgreich abgeschlossen wurde.

Das momentane Hauptaugenmerk liegt in der Analyse der Outcome-Daten, in der Evaluierung von relevanten Einflussfaktoren auf die Traumamortalität, sowie der Analyse der Indikatoren der Lebensqualität nach schwerem Schädel Hirn Trauma nach Spitalsentlassung und bis zu einem Jahr nach Unfall. Einblicke in die Rolle der Behandlungsqualität werden ebenfalls erhoben.

3.2 Anbahnung neuer Projektentwicklung

Das Bundesministerium für Bildung, Wissenschaft und Kultur gewährt Unterstützung zur Entwicklung eines Projektantrags für das EU 6th Framework Program: "Provision of Instant Scientific Evidence for Professionals Treating Patients with Neurotrauma ISE-NEURO". Das Projekt wurde in Kooperation mit der Universitat Wien, Institut für Softwarewissenschaft, entwickelt.

3.3 Implementierung der "clinical pathways"

Unter der Leitung von Prof. Dr. Walter Mauritz begann das IGEH Team mit der Entwicklung des "Kritischen Leitfaden zur Behandlung von Patienten mit schwerem Schädelhirn Trauma". Dieser Leitfaden basiert zur Gänze auf wissenschaftlichen Grundlagen und entspricht strikt den TBI Guidelines der New York Brain Trauma Foundation von 1995. Es werden darin verschiedene Komponenten der Behandlung von Schädelhirn Trauma Patienten enthalten sein, wie: Präklinische Versorgung und Transport, akute Intensivbehandlung, diagnostische und chirurgische Verfahren, Pflege, Langzeitbehandlung und Rehabilitation.

3.4 ITCP Datenbank Aktualisierung

Die Datenbank wurde einer Zusammenführung und technischen Verbesserung unterzogen und in neuer Version (1.3.1) in allen teilnehmenden Zentren, die mit der IGEH an dem Projekt zusammenarbeiten, installiert.

3.5 Forschungsprojekt betreffend die Reduzierung der Sterblichkeit und Langzeit-Behinderung von Schädelhirn Trauma-Opfern durch die Erforschung von Behandlungsmethoden in Bosnien-Herzegovina, Mazedonien und Kroatien.

Projektbeginn dieser Arbeit war Jänner 2003. Mit einem Seminar in Wien wurde die Forschungstätigkeit eingeleitet, im ersten Jahr wurden etwa 200 Patientendaten erfasst.

3.6 Weitere Aktivitäten

Sieben neue Projektkonzepte wurden entwickelt und bei österreichischen und internationalen Förderorganisationen beantragt. Einige davon sind noch in der Begutachtungsphase, betreffende Entscheidungen daher noch ausständig.

4 SUMMARY

IGEH team in its fourth year of existence focused on enhancing activities within Austria with a vision to improve the understanding of national TBI situation. During series of seminars they have discussed the situation, analyzed collected evidence and started to prepare a series of papers for Austrian audience. The team worked hard to secure more funding from national as well as international sources, too. Number of project proposals was developed in close cooperation with cooperating organizations in Austria, Netherlands, Croatia, and Italy. This will hopefully result in more activities next year, securing thus the position of IGEH in the world of TBI research and development. ITCP was continued in number of centers and number of collected patients was significantly increased. Activities were centered on increasing quality of data and in increasing the compliance with TBI guidelines. Iterim analysis was performed for data from Austria and Balkan.

5 PROJECTS and RESEARCH ACTIVITIES

5.1 Critical Pathways or Treatment Protocols

Under the leadership of prof. Dr. Walter Mauritz IGEH team started to develop critical pathways for the treatment of patients with severe TBI. The pathways are fully based on Scientific Evidence and are strictly complement with the TBI Guidelines. There will be several components addressed by the pathways: prehospital care and transport, acute intensive hospital care, surgical part, X-rays, nursing and long term care and rehabilitation. Currently, after a year we have the first part ready to be discussed with colleagues before to be implemented for clinical testing.

Comment: Essentially, critical pathways can be viewed as interdisciplinary practice guidelines with predetermined standards of care. Since the Scientific Evidence Based Guidelines does not provide concrete instructions on individual procedures, clinical practice even based on the guidelines remain variant. Critical pathways provide opportunities for collaborative practice and team approaches that can maximize standards of care as well as the expertise of multiple disciplines. These pathways prospectively and directly link clinical care activities and their costs with predetermined time points and outcomes. When benchmarks are incorporated into the pathways, they could facilitate clinical evaluation, especially evaluation of the effectiveness and efficiency of treatments and intervention strategies.

5.2 ITCP Database

The database underwent comprehensive evaluation and current version (1.3.1) is being used in all the centers of IGEH collaboration (see Tab.1).

| | Center | # of cases |
|---|---|------------|
| | AUSTRIA | |
| 1 | AKH Trauma Department, Vienna | 5 |
| 2 | LB Unfallkrankenhaus, Vienna | 121 |
| 3 | Universitätsklinik für Neurochirurgie, Graz | 56 |
| 4 | LNK Wagner Jauregg, Linz | 14 |
| 5 | Universitätsklinik für Neurochirurgie Innsbruck | 3 |
| 6 | LKH Salzburg | 70 |
| 7 | LKH Klagenfurt | 10 |
| | TOTAL AUSTRIA | 279 |

| | BALKAN | |
|---|---|----------|
| 1 | Rebro Hospital Zagreb, Croatia | 6^1 |
| 2 | Hospital in Osijek, Croatia | 15^{1} |
| 3 | Hospital in Rijeka, Croatia | 7^1 |
| 4 | Clinical Centar at Medical faculty Skopje, FYROM Macedonia | 133 |
| 5 | Clinical Center University of Sarajevo, Bosnia and Herczegovina | 110 |
| | TOTAL BALKAN | 271 |

¹ The center has additional cases in TBI_trac

| | OTHER CENTERS | |
|---|-----------------------------|-----------|
| 1 | University of Ancona, Italy | installed |
| 2 | Bosnia and Herczegovina | installed |
| 3 | Banska Bystrica, Slovakia | installed |
| 4 | Michalovce, Slovakia | installed |
| | | |

Table 1 ITCP installations and patients registered

GRAND TOTAL

Some centers have the ITCP installed, but for different reasons they did not start with registering the cases, yet. Recently added features to the ITCP database:

- → One year follow up with a letter requesting information on patients;
- → Enhanced help with web links;
- → English and German versions;
- → Debugged.

Issues for further development: Once the collected data will be analyzed, some variables will be removed or replaced with others, depending on results. The ITCP database will be made simpler and data input faster.

5.3 Austrian TBI (In memory of Alfred von Auersperg) 2001 – 2004

This year of the project was devoted to complete the collection of data from Austrian sources, which has been successfully achieved by October 2003. Now on the focus is on analysis of outcomes in terms of exploration into factors influencing mortality, as well as indicators of early and late quality of life after TBI. Insights into the role of health care facility structures are being evaluated, as well. Some of the results with comments are to be found in annex I.

5.4 Balkan TBI: Bosnia-Herzegovina, Macedonia and Croatia, European Union, 5th FP-Copernicus 2002-2005

The project started effectively in January 2003, however December was devoted to prepare the first workshop and other related conditions for the kicking off. The activities started with a kick-off meeting, held in Vienna in January. Representatives from IGEH, AU Vienna Epidemiology, CZ Brno, SK Nove Zamky, HR Osijek and Zagreb, FYROM Skopje and BH Sarajevo were in attendance. The principle goal of the meeting was to share and discuss information on the current situation in participating centers, to discuss the communication policy of the project and to demonstrate the software for the ITCP database system. All issues raised related to project implementation were addressed accordingly. All participants familiarized with the project methodology. All centers will start collecting data immediately upon returning home. The coordinator will secure purchases of computers and will visit Balkan centers personally to asses the situation

The coordinator visited all centers. He has had presentations to introduce and discuss the project concept to staff of the centers. In Skopje and in Sarajevo he had dedicated presentations on evidence based approaches to TBI at local conferences.

Collected data were statistically processed and patterns described. During the workshop details of the analysis were discussed and conclusions derived. The concept of Evidence Based Medicine in TBI treatment was introduced. The centers will start collecting data on patients prospectively.

6 APPLICATIONS for NEW PROJECTS

IGEH stronger work force has been reflected by the number of new project requests for funding. Each of them represents an attempt to enhance our activities and to broaden our impact in the community of brain trauma research and development within EU (current and enlarged), Balkan region and Asia.

6.1 Projects under evaluation

6.1.1 EU INTAS – Russia, Georgia, and Armenia

Treatment Variation and Health Outcome in Traumatic Brain Injuries (TREATVAR)

The general objective for the project TREATVAR is to assess and reduce the human and social burden of severe head injuries and to identify risks for avoidable death or life long disability following Traumatic Brain Injury (TBI).

Epidemiological survey will be implemented to identify incidence and risk factors of different types of severe brain injuries as well as to describe treatment modalities used. This will flash light on the extent of TBI treatment variation. The variation itself is indicative on how closely the scientific based treatment procedures are being followed in different TBI treatment facilities in the region. Once the data are collected from representative sample of trauma centers the analysis will be performed to reveal the extent of treatment variation. That would also allow for identification of trauma centers which treat most of the traumatic brain injuries in the area. Their procedures will be evaluated focusing on a degree of compliance with existing TBI guidelines. Then the traumatic brain injury protocols will be developed and physicians instructed in their use. Effects of the protocol implementation on reduced treatment variation and health, economic and social outcomes will be measured using International Traumatic Coma Program database. Hypothesis tested are that the Scientific Evidence Based Treatment decreases poor treatment outcome, reduces costs for treatment, and increases professional skills of the personnel in charge. The project will contribute to increased quality of research, too. Partners from EU countries will help in implementing the project and share their experiences in the field of Evidence Based treatment of traumatic brain injuries. Results of the project will be disseminated in all countries of the project.

The project was proposed by a consortium of organizations led by IGEH (Table 2)

| INSTITUTION | ROLE | COUNTRY |
|--|---------------|---------|
| Internationale Gesellschaft zur Erforschung von Hirntraumata | Lead, project | Austria |
| | management | |
| Universita' Degli Studi Di Ancona | Resource | Italy |
| National Health Management Center | Beneficiary | Georgia |
| National Center for Disease Control and Medical Statistics | Beneficiary | Georgia |
| State Medical Academy, Sarajishvili Institute of Neurology and | Beneficiary | Georgia |
| State Medical University | | |
| Georgian Society of Child Neurologist and Neurosurgeons | Beneficiary | Georgia |
| Healthy Child in the World | Beneficiary | Georgia |
| Yerevan State Medical University | Beneficiary | Armenia |

Table 2 Members of the consortium

The total budget requested from EU is 300.000 EUR for 3 years of the project. The budget includes 4 licenses for ITCP database 7.000 EUR per center and a year.

6.1.2 Österreichische National Bank – Jubiläum Projekt

Next Generation Information Technology to Support Evidence Based Approaches in the Management of Patients with Severe TBI

For health care professionals it is very hard if not impossible to keep a pace with ever increasing number of medical information, even in relatively narrow field of TBI. Therefore, the general objective of this project is to provide health professionals involved in the treatment of TBI patients with advanced Information technology tools, which

enable them to discover and manage relevant knowledge and information from different sources, including hospital databases, medical libraries, and documents on the Web. The tools developed will be integrated within a novel infrastructure, called TBI Semantic Grid (TBI-SG), which will be based on the existing Web, Grid, intelligent agents, and distributed database technologies, and research and development experience of the institutes participating in the project. TBI-SG will allow accesses for data generation (production), querying, and analysis from different platforms (desktop, local wireless, and hand-held devices) used at the accident scene, ambulance, hospital bed, strategic specialist consultations, etc. The project will be led by the Institut für Softwarewissenschaft, Universität Wien. The total requested grant is 109.000 EUR for 4 years of the project. The IGEH will receive 1 PC, 2 PDA and several man-month for the medical coordinator and medical specialist.

6.1.3 EU 6th Framework Program

Open Source System Ensuring Complex Data Transformations and Preprocessing for Data Mining and Grid Applications SumatraGrid

SumatraSuite will be developed as a modular, computational Grid based open source enabling its users to design, efficiently implement/re-use and deploy specialized Grid services, which will carry out general transformations of geographically distributed data. Applications from the area of Traumatic Brain Injuries are considered for verification and utilization of the system implementation, mainly in linking the database ITCP with other databases, and with internet literature sources. The consortium of research institutions is led by Prague University and the University of Vienna. IGEH will mostly utilize the software tools developed within the project. The total grant requested for IHEG is 44 426.75 EUR for the 3 years of the project. Beside the financial benefit for IGEH, the project when finished will provide brain trauma community with strong tool to keep up with the most up to date information from the field with minimal investment.

6.1.4 EU SANCO

SANCO 2003/S 166-151874 Surveying, assessing and analyzing the health challenges in the candidate countries

This project proposes a study in order to improve understanding of the health challenges facing the 13 applicant countries and how to address them in the context of the EU enlargement process.

The proposal is supported by Interaction in Health/Public Health Consultants in the Netherlands (the lead organization), Internationale Gesellschaft zur Erforschung von Hirntraumata and Central European Expert Network GmbH, both in Austria as well as Zdrowie i Zarządzanie in Poland and a group of 14 consultants from candidate countries. The consortium possesses broad experience in both EU as well as in EU candidate countries with experiences in the field both locally and internationally. IGEH will have a stake in this endeavor in the field of trauma care. This project if received will allow us to broaden our activities in the new EU countries and candidate countries. It will also provide us with personal contacts within the EU administration. Dr. Rusnak will be in a position of deputy project leader, enabling him to visit Brussels on regular basis. The total budget is 361.085 EUR for 2 years of the project. IGEH will have proportional share of the overhead and also 3 experts will be reimbursed for their activities.

Österreichische Austauschdienst (ÖAD) – Croatia 2004 – 2005 Wissenschaftlich-technische Zusammenarbeit Österreich – Croatien: Research on Quality of Care in Traumatic Brain Injuries

The principal goal of the project is to cooperate with colleagues in Rijeka and Zagreb on implementation of scientific evidence medicine practice in the field of Traumatic Brain Injury and specifically to reduce death and disability in victims of head injury. The project's objectives are to work together on implementing the scientific, evidence-based Guidelines for the Management of Severe Head Injury in identified hospital centers of excellence in traumatic brain injury in Rijeka, and Zagreb. The second major objective is to establish education centers in Rijeka and Zagreb. Hospital centers will be the educators for dissemination of TBI Guidelines throughout the country and can become centers for future clinical research. The grant will fund visits from both sides only. This will enhance our presence in the region and will facilitate creation of new centers.

6.1.6 Österreichische Austauschdienst (ÖAD) – Italy 2004 - 2005 Wissenschaftlich-technische Zusammenarbeit Österreich – Italien: Evidence Based Approach to Traumatic Brain Injuries Management

The overall goal of the project suggested is to evaluate impact of Scientific Evidence Based approach based on guidelines and clinical pathways to the management of patients with severe Traumatic Brain Injury. Hypothesis to be verified during the project is that managing a TBI patient along the lines of Scientific Evidence Based Guidelines

(SEBG) based Critical Pathways (good medical practice) increases the probability of a good outcome for patients with severe Traumatic Brain Injury. The funding will cover 2 visits of each team.

6.1.7 Injury prevention

EU Health and Consumer Protection Directorate-General: Maintenance, Development and Promotion of the ISS Hospital Survey in the current and enlarged EU

The general objective of this project is the Maintenance and Quality Assurance of the ISS/EUPHIN Data Collection. Specifically this includes an expansion of ISS hospital survey to Candidate Countries, extension of ISS survey to all injuries, including intentional injuries, provision of EHLASS/ISS data and promotion of EHLASS/ISS data collection through the European Network of Injury Registries (ENIR; Module: ISS data collection), maintenance of the "total" ISS Quality Management and QM Training of NDAs - for de-central Upload and Quality Assurance, eventually (Module: QM Manual and Training), maintenance and further development of central Data Transformation (incl. MDS-I), Quality Control Programs, Upload and Auto-Reporting Tools (QM Module - Common Tools), development of standardized procedures for statistical analysis: population based injury rates (QM Module - Statistics), and development of guidelines of Ownership of data, rules of dissemination (QM Module - Copyrights). Participation in this project beside about 20.000 EUR for two years will add opportunities for expanding our network in Europe.

6.2 Projects rejected

6.2.1 Bill Gates – Global Challenges

Traumatic injuries (and traumatic brain injury (TBI) in particular) represent one of the most significant causes of death and disability throughout the world. TBI, the most devastating of all traumas, is the leading cause of death for people between the ages of 15 and 44. In developing countries, the incidence of TBI has lagged behind the developed world, but with the recent increase of motor vehicles (especially motor-scoters and motor cycles) the incidence of devastating traumas and TBI are increasing rapidly there as well. Trauma has enormous economic consequences for countries and societies. This initiative proposes to develop and implement a practical methodology of implementing standardized, evidence-based procedures, utilizing an interactive database, to improve care and outcome. Furthermore, this approach to trauma care provides on-going clinical education, assures that the "best practice" is being followed in each case, and the data can be used for clinical research to further improve evidence-based treatment. And last but not least, it is very important to point out that the implementation of scientific, evidence-based protocols is not costly, and in nearly all instances does not require new equipment, but directs and guides health care professionals to use their available resources to implement "best practices." Remarkable results follow when this happens: mortality drops dramatically and the number of patients with good to moderate outcomes can triple.

Result: The proposed area was not included.

6.2.2 EU Marie-Curie Fellowship: Factors of patients' management determining long term outcome of victims of Traumatic Brain Injury

This project proposed a fellowship to be awarded to Dr. A. Brazinova to pursue a research in public health aspects of TBI. Specifically to combine different approaches to assess the extent of TBI problem on the European level, combining information from different sources, and different levels of the system exploiting the methodology of Evidence Based Medicine. This approach would allow for developing conclusions about the extent of the problem, the policies needed to solve it and also to educate the fellow in various methodologies in use.

Result: The fellowship was not allocated.

7 TEAM

Prof. Dr.Med. Walter Mauritz, Univ.Doz. Dr. Martin Rusnak and Dipl.Ing. Ivan Janciak was in 2003 joined with a group of young researchers from Austria and Slovakia. This significantly enhanced "power" of IGEH allowing for more activities to be planned and undertaken. Neither of them is employed by IGEH, although if funding is received from individual projects, they will be financially compensated for their efforts. Condensed characteristics of the new team members follow:

7.1 Dr. Alexandra Brazinova, Ph.D., MPH

Medical doctor graduated 1996 from Charles University, Prague. Specialized in Public Health (Masters and PhD levels) with specific orientation to epidemiology of chronic diseases, quality of care and ethics. She has been involved in several international projects in the field of quality of care and patients' rights. Her field of interest with IGEH is primarily epidemiology and ethics involved in brain trauma R&D activities. She visits Loren Bohler Unfall Krankenhaus regularly to enhance her skills in trauma intensive care.

7.2 Dr. Petra Dado

Medical doctor graduated 1998 from Vienna University. She went through extensive training in general surgery and 26 months of neurosurgery. She was admitted for PhD program in Public Health this year and will take 6 month course in Hospital Management in London. Her interests are quality of care for trauma and managerial aspects.

7.3 Dr. Johannes Leitgeb

Medical doctor graduated 1999 from Vienna University, employed as assistant professor in the University of Vienna in the Department of Traumatology, AKH. He has spent a year in South Africa as trauma surgeon. His major research interests are in quality of care and clinical outcome.

7.4 Mag. Lucia Lenartova

Public health graduate from Trnava University, Slovakia in 2003. Continues PhD study at the same university. Her research aspect is trauma systems.

7.5 Mrs. Ingrid Wildbacher, RN

Registered nurse, studies social sciences in Vienna University, will graduate next year. Her research interests are in nursing aspects of care for TBI victims and their relation to outcome.

8 PUBLICATIONS

- a) Urbansky, M, Rusnak, M, Janciak, I.: Improving Quality of Care for Severely Head Injured Patients in Nove Zamky Hospital. J. of Hlth Sciences Management and Public Health, 4(1), 2003, 51-56.
- b) 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

2) **OFFICE**

Office rooms (75 m²) were rented in the vicinity of Vienna city center. The office is fully equipped with furniture, computers, and standard office appliances thank to generous support from the Erste Bank, which provided most of them. Fast internet connectivity allows for running the ITCP database as well as the web site. The office is used for business meetings, seminars and small conferences. It proved to be very useful.

9 FUND RAISING

New flyer was developed based on two grants: pharmaceutical company EBEWE and Orsini-Rosenberg&Senden Vermogensverwaltung G.M.B.H. Outline of accompanying letter was developed by professional marketing office in kind. Addresses for possible donors were provided by members of the Board of Directors.

10 PRIORITIES for the YEAR 2004

Next year activities will be oriented to:

- Continue the Balkan project and other projects as grants will be allocated;
- o Finalize Critical Pathways and start implementing them into clinical practice;
- o Publish series of papers in European journal(s), participate at international conferences and meetings;
- Develop new version of ITCP database;
- o Apply for new Austrian grant to keep on the Austrian activities;
- Strengthen IGEH team and collaboration with Neurotrauma Foundation.