EHC Newsletter

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Editor: Amanda Bok
Editorial Committee: Brian O'Mahony, Radoslaw Kaczmarek, Jo Eerens
AISBL EHC registered office: Rue du Marché aux Herbes 105 b14, 1000 Brussels, Belgium
Tel. +32-2 521 11 50, Fax +32-2-520 68 66, Email office@ehc.eu
No. 887.106.966

President's Message

EDQM Meeting

The European Directorate for the Quality of Medicines and Healthcare (EDQM) is an official body of the Council of Europe, which issues recommendations in clinical areas including the Optimum Use of Blood and Blood Products.

The EDQM previously met in 1999 and in 2009 and issued recommendations on Optimum Use, which included recommendations on haemophilia. These recommendations are of great importance as they emanate from an official Council of Europe body and therefore carry more official "weight" than the widely known and quoted European Principles of Haemophilia Care, which have been endorsed by the European Association for Haemophilia and Allied Disorders (EAHAD), the European Haemophilia Consortium (EHC) and the World Federation of Hemophilia (WFH).

We would view the Principles of Care and the EDQM recommendations as both being of great importance and capable of judicious complementary use in advocating for improvements in treatment or care. The EDQM recommendations tend to be quite specific, which means that they can be very useful when advocating for specific targets with the government. For example, in their 2009 recommendations, the EDQM set out 2 IU per capita for FVIII as the minimum survival level of treatment that should be used nationally. This figure was of practical benefit to National Member Organisations (NMOs), which at that time were using less than 2 IU per capita of FVIII, in advocating for increased availability of factor concentrates with their government.

At the EDQM meeting in April 2013, I represented the EHC and spoke on haemophilia care in Europe based on our survey of 35 European Countries. EHC Steering Committee member Gabriele Calizzani from Italy was also in attendance as was Alain Weill, President of the WFH and ex-officio member of our Steering Committee. The co-rapporteur was Dr Paul Giangrande who is the Chair of the EHC's Medical Advisory Group (MAG) – so the EHC was well represented.

Several of the key recommendations on haemophilia were proposed by our representatives and will be, in my view, potentially invaluable at a policy level in driving forward to better care in many countries. The recommendations will be published in the near future but they include recommendations on increasing the minimum national FVIII per capita use, on improving access to prophylaxis in adults and on the certification and audit of haemophilia treatment centres. Our objective to prevent a possible monopoly supply of one new long-acting FVIII or FIX due to the market exclusivity provisions of the EU Orphan Drug legislation will be assisted by a specific recommendation in this area. Our view that National Haemophilia Committees should be formally established in each European country will also be assisted by a specific recommendation in this area. We will work to ensure that the recommendations, as soon as they are published, are brought to the attention of each NMO as well as key clinicians and health officials.

Visit to Estonia

I visited Estonia from May 24-25 at the request of the Estonian Haemophilia Society to assist them in their ongoing battle for a participative role for the organisation and for the key haemophilia treating clinicians in the selection of factor concentrates on a national level.

My views on national tenders and the procurement of factor concentrates are generally well known. I believe that national tenders have several advantages over other procurement methods. However, the key point is, whatever procurement or selection process is used, it is absolutely vital that the key clinicians who treat haemophilia in each country and who are knowledgeable about the treatment products, as well as a representative of the national haemophilia patient organisation, should be fully involved in all stages of the selection and procurement process.

This is not the case in Estonia where the products are selected without the formal participation of either the key haemophilia treaters or the patient organisation. This is unacceptable. This is wrong. This can potentially lead to the wrong people selecting the wrong products for the wrong reasons. There is an ongoing debate in Estonia regarding access to plasma-derived or recombinant products. I made the position of the EHC clear on this issue. We do not endorse one category or the other but we adamantly endorse the vital importance of the selection being made with the participation of the key doctors and the patient organisation representative.

In Estonia we met with the Social Affairs Ministry and the Health Insurance Fund, together with the key doctor and the Haemophilia Society. The level of media interest in the visit was high as the current system of selection, in addition to excluding those who understand the products, is inefficient and is also being questioned in relation to potential conflicts of interest of some of those currently involved.

We will continue to work with our colleagues in Estonia to help them with this vital issue. Health authorities must understand that the haemophilia community, which has borne so much disaster in the past, will not stand silent and allow totally inappropriate bureaucratic bungling and procedures to damage the ability of people with haemophilia to have confidence in the safety, efficacy and quality of the treatment they receive, and confidence in the probity of the procedures and people used to select these products.

ISTH Conference

The biennial conference of the International Society of Thrombosis and Haemostasis (ISTH) took place in Amsterdam in July. EHC CEO Amanda Bok and I attended and took the opportunity to hold bilateral meetings with the European Association for Haemophilia and Allied Disorders (EAHAD), with members of our Medical Advisory Group and with many of our corporate partners. I also had the opportunity to present the EHC data on the Survey of 35 European Countries and to present at the Scientific and Standardisation Committee (SSC) on the patient community view on access to new products.

At the SSC meeting, I outlined our concerns regarding the probable delays of between one and three years in access to the new longer-acting factor concentrates in Europe compared to the USA, Canada, Australia and other non-European countries. This delay is due to the provisions of the European

Medicines Agency (EMA) Clinical Trial Guidelines, which came into effect in February 2012. The first longer-acting FVIII or FIX concentrate will probably receive market authorisation in the USA and Canada in early 2014 but current indications point to a two-year delay to early 2016 before these products are available in Europe. I outlined our work with the EMA to try to change this situation and used the opportunity to alert the clinicians present about this problem. Even more serious are our concerns relating to the interpretation of the market exclusivity provisions of the Orphan Drug legislation, which could lead to a disastrous scenario whereby only the first longer-acting FVIII and FIX products to achieve marketing authorisation in Europe would be given a market exclusivity for ten years. This would lead to a monopoly situation and greatly damage all our hopes for a variety of new and exciting therapeutic options to be available in Europe on an economically viable basis.

On a clinical level, there were excellent updates on FIX Gene Therapy from Dr Anil Nathwani and from Dr Flora Peyvandi on factor concentrate developments. Both of these topics and speakers will feature on the programme for the EHC Conference in Bucharest in October. There was a significant amount of discussion on the effects of sub clinical bleeding on joints and on the ongoing work in several international collaborative studies relating to inhibitor development. Several pharmaceutical companies gave updates on their new products under development and where they currently are in the clinical trial pathway. Of course, the availability of these products in Europe will be affected by the regulatory issues I have already raised in this article.

MAG News

At its last meeting, the Steering Committee (SC) voted unanimously to invite Professor Paul Giangrande, member of the Medical Advisory Group (MAG), to become the Group's first Chairman. In the springtime the SC also invited Professor Michael Makris from the University of Sheffield to join the MAG. The EHC is delighted to welcome Prof Giangrande into his new role and Prof Michael Makris to the MAG. The MAG is currently comprised of five members: Prof Paul Giangrande, Prof Flora Peyvandi, Prof Angelica Batorova, Prof Wolfang Schramm and Prof Michael Makris.

CEO's Message

Meeting with the European Medicines Agency

A high-level meeting took place between the European Haemophilia Consortium (EHC) and the European Medicines Agency (EMA) on June 12th in London to discuss earlier access to new, longer-acting factor VIII and IX concentrates in Europe as well as to explore the applicability of orphan drug designation – and therefore the potential for market exclusivity – for those products (see "EHC Meeting with the EMA" on pg. 7).

In many ways this meeting was a landmark event for the EHC – not only the culmination of the advocacy efforts we initiated in

December 2012 (see EHC Newsletter, December 2012) but also the first such official and high-calibre meeting between our organisations. The EMA was represented by 18 individuals from six committees and the EMA secretariat.

As reported in this newsletter, regrettably our discussions did not yield the immediate results that the EHC might have hoped for. However, it planted the seeds for a new and sustained relationship between the EHC and the EMA, which invited us to participate in its consultations with patients, including on the applications for marketing authorisation for new longer-acting products. The EHC is currently undertaking the necessary steps to be accredited for involvement in EMA activities.

At the same time, the EHC will not give up on its advocacy work. We will continue with our efforts to ensure earlier access to new therapies and in particular to prevent a monopoly of the first longer-acting product to hit the market. In the autumn we shall work on these issues with the European Commission, industry and other key organisations. We have already started working with industry to address market exclusivity and the dangers of a monopoly.

That dialogue began soon after our meeting with the EMA, namely during our June Round Table in Brussels on “Access to new therapies: opportunities, challenges and barriers” (see “June Round Table…” on pg. 9), continued with bi-lateral industry discussions during the Congress of the International Society on Thrombosis and Haemostasis (ISTH) in Amsterdam in early July, and will be carried forward this autumn.

Autumn forecast

The autumn promises to be a productive period for the EHC for other reasons as well, with an NMO workshop on Economics and Health Technology Assessments in September and in October our annual EHC Conference, four NMO workshops held under the auspices of the EHC Conference, our annual General Assembly and our third annual Round Table, to be held in the European Parliament (see “Announcements” on pg. 30). The EHC will also continue its dialogue and long-term relationship building with other key organisations as well as with Members of the European Parliament.

In addition, the autumn will be a time for change and for looking forward. The General Assembly will vote for a new Steering Committee in Bucharest. The first meeting of the new Steering Committee in October will also be the first joint meeting with the Medical Advisory Group (MAG) and together they will elaborate the EHC’s new Strategic Plan 2014-2016.

World Federation of Hemophilia

Across the ocean there has been an important change as well. After 11 years, the World Federation of Hemophilia (WFH) said goodbye to Catherine Hudon, who as Regional Program Manager for Europe worked closely with many of our members particularly in Eastern Europe to advance treatment and care. We wish Catherine well (see “Farewell Tribute to Catherine Hudon” for the EHC’s tribute to Catherine on pg.23) and look forward to working with her successor, Salome Mekhuzla.

EHC News

European Directorate for the Quality of Medicines and Healthcare (EDQM): a patient's view

By Daniel Arnberg

I have heard it said that most healthcare and regulatory decisions are too important to be left to doctors and authorities alone. Eager to investigate this, it was an easy decision to accept the invitation to participate in the third European Directorate for the Quality of Medicines and Healthcare (EDQM) meeting in Wildbad Kreuth outside Munich, some four years after the last meeting took place.

Besides discussing the optimal use of clotting factor concentrates, the Kreuth III meeting also focused on the use of Immunoglobulins, which makes perfect sense, as it is another blood derivative in high demand. This in turn meant that the Friday sessions were split up, using half a day to cover the current situation in each area. On the topic of clotting factors, we got an excellent snapshot of the current situation, covering everything from clinical challenges and product access, new development in clinical research or benefits, the importance of registries – and one of the most interesting points of the meeting – the current guidelines and the regulatory perspectives. This was the perfect setup for the workshop that took place on Saturday morning, with an open discussion on how best to update guidelines to reflect the last four years of clinical experiences.

To the unaware, what is said at a European meeting in Munich can be seen as quite irrelevant for a patient with haemophilia in Moldova, but not so. It is a rare event when the profession and EDQM get to meet, and any changes to the outcomes and guidelines can carry a great weight in national arenas when influencing politicians and provincial doctors with little experience.

Besides the quite positive outcomes, there were also many interesting and more informal discussions around coffee tables or dinner. One such discussion addressed the complexity that the longer-lasting factors will introduce as they become available over the coming years. Obviously these products will be of great benefit to patients over time, but there is more than one idea for optimal use. Will these products completely replace factors with normal half-life, or will they be used to complement existing products? What will their initial price point be, and how will their introduction affect the current metric of cost/IU?

I imagine the attendees of Kreuth IV in a few years will hear the answers, and will continue the process of updating the guidelines and recommendations for the benefit of patients around Europe.

EHC meeting with the European Medicines Agency

By Amanda Bok

The European Haemophilia Consortium (EHC) met with the European Medicines Agency (EMA) on June 12th in London following a letter-writing campaign that began in December 2012.

The EHC discussed with the EMA: (1) our concerns regarding timely access in Europe to new longer-acting factor VIII and factor IX concentrates in light of the EMA's 2012 clinical trial guidelines; and (2) our view that these products should not qualify for market exclusivity under orphan drug status, as the products are dissimilar in their methodology for protein modification or enhancement and therefore a monopoly of the first product introduced could be damaging to haemophilia treatment in Europe.

The EHC met with a large and high-level EMA delegation that brought together 18 Chairs, Vice Chairs and members of the Paediatric Committee (PDCO), the Committee for Medicinal Products for Human Use (CHMP), the Committee for Orphan Medicinal Products (COMP), the Blood Products Working Party (BPWP), the Scientific Advice Working Party (SAWP) and the Biologics Working Party (BWP) as well as EMA staff.

The EHC was represented by six delegates: Prof Paul Giangrande and Prof Flora Peyvandi from our Medical Advisory Group (MAG), Gabor Varga and Radoslaw Kaczmarek from our Steering Committee (SC), Mark Walker from Rohde Public Policy and myself.

On its first point, to prevent lengthy delays to access to new products in Europe as compared with North America where the first submission was made to the Food and Drug Administration (FDA) in March, the EHC proposed the introduction of a two-step market authorisation process.

The EHC suggested that the companies concerned be allowed to request a deferral for their Paediatric Investigation Plan in order to allow them to apply without delay for a European Marketing Authorisation for the adult population. We also suggested that the companies concerned be requested to develop a Risk Management Plan to minimise the risk of off-label paediatric use, as allowed for in the European pharmaceutical legislation. We further proposed that the companies concerned then be required to conduct post-marketing registry and data collection on patients with the threat of product licence removal if the metrics are not met. Finally, we underlined the economic consequences that could follow from a two-year or longer delay in access to these new therapies in Europe and the impacts that this could have on European patients.

Members of the EMA delegation listened carefully to our presentation, but concluded that they would not change their position. They felt that under a two-step authorisation process

there would remain a threat of off-label use of new products in children, which was one of the core drivers of the 2012 clinical trials guidelines. They commented that once a product is on the market, clinical trials become more difficult than before authorisation and they felt that paediatric treatment with new products was best done during clinical trials.

While the EMA agreed that an appropriate risk management plan is needed to gather information in the post-authorisation phase, for the short-term they recommended that the EHC urge the companies concerned to avoid delays by better designing their clinical trials.

On its second point, the EHC addressed the likelihood of these products qualifying for market exclusivity as orphan drugs and questioned their applicability for market exclusivity as, in the EHC's view, these products are dissimilar to each other, differing substantially in their cell lines for production, structure (e.g. B-domain deletion) and type of modification (e.g. PEGylation, Fc fusion, albumin fusion). In addition, we argued that even PEGylated products differ from each other in how they are PEGylated and should not be considered similar.

The EHC shared its concern that if, despite these differences between longer-acting products, the first approved product receives market exclusivity, it could have a ten-year monopoly, which would prevent other long-acting products that might be safer or more effective from being accessible to patients in Europe. This monopoly would also inevitably impact negatively on the affordability of these products for many countries.

Currently, under the orphan drug legislation three types of derogations from market exclusivity are possible: (1) by consent of the original marketing authorisation holder; (2) by the inability of the original marketing authorisation holder to supply sufficient quantities; and (3) when a second medicinal product is proved to be safer, more effective or otherwise clinically superior. On this last point, the EHC commented that it is not in fact easy to show whether a product is safer or more effective (and certainly to demonstrate this would require several years post-authorisation data).

The EMA delegation expressed understanding for the EHC's position, but explained that the agency must implement the existing orphan legislation in place. However, it encouraged the EHC to continue this dialogue and to participate in the EMA's review of market authorisation applications.

Overall, the EMA acknowledged the problematic nature of some of the issues that we raised during our meeting. Although they were unable to act on these issues in the short-term, our engagement with them will continue and indeed our dialogue and advocacy on these specific issues will broaden to include the European Commission, industry and other relevant actors.

From a broader perspective, the EHC's meeting with the EMA was constructive and yielded the mutual desire to build a long-term engagement between the two organisations. As a next step, the EHC will apply to be formally involved in the activities of the EMA and consulted where relevant.

June Round Table: Opportunities, Challenges and Barriers in Access to New Therapies

By Radoslaw Kaczmarek

During the last Round Table, attendees representing a variety of stakeholders including patients, health professionals and industry representatives discussed implications of the new therapies expected to soon become a part of routine haemophilia management.

The meeting, hosted by myself, began with a clinical overview of new haemophilia products presented by Prof Paul Giangrande, Consultant Haematologist from Oxford University Hospitals NHS Trust. Prof Giangrande indicated that while the haemophilia community awaits a permanent cure, longer-acting factor concentrates are a much more realistic early goal. However, their prompt availability for European patients is uncertain due to the European Medicines Agency (EMA) regulations.

The European Haemophilia Consortium (EHC), through Brian O'Mahony and myself, discussed how longer-acting products could mean the largest break-through in the management of haemophilia since the invention of clotting factor concentrates or recombinant clotting factor products. Such technologically-advanced formulations promise improvement not only in the case of developed but also emerging countries by potentially making currently available recombinant and plasma-derived factor concentrates more affordable. But for such a scenario to be realistic, a timely approval of new products in major markets would be required, thus ensuring their prices are acceptable for governments. Cost-effectiveness will be a must if the new products are to be considered by health authorities. Mr O'Mahony also emphasised the EHC's concern over potential market exclusivity for the first longer-acting clotting factor that would reach the market. Such a scenario would mean a limited choice for patients and the new product would probably be affordable only in selected countries. Therefore Mr O'Mahony called on industry to waive their right for market exclusivity for the first product to be licensed.

The industry perspective was presented by Dr Hartmut Landgrebe (CSL Behring), Prof Armin Reininger (Baxter), Dr Karin Knobe (Novo Nordisk) and Dr Geoff McDonough (Sobi). Dr Landgrebe discussed the importance of interplay between patients, health professionals and health authorities for the successful introduction of new haemophilia products. He also suggested that longer-acting products might contribute to the elaboration of new standards of haemophilia care. Prof Reininger focused on the importance of individualised therapy and the determination of desired trough levels with respect to a patient's lifestyle. He illustrated individual haemophilia treatment success indicators and outcome measures, e.g. quality of life, annual bleed rate zero, long-term joint health, etc., as "puzzle pieces" and suggested that those pieces are not well aligned yet. Dr Knobe explained the timeline of clinical trials and pointed out that Novo Nordisk had active trials in 33 countries in 2012. This session ended with a thought-provoking speech delivered by Dr McDonough, who challenged his peers to accept the industry's responsibility to show that whatever developments are brought to the community, they be sustainable over time.

A productive and lively discussion ensued after Alain Weill, President of the World Federation of Hemophilia (WFH), started the Question and Answer session by announcing the WFH's full commitment to and support for the EHC in its call on industry to forgo applying for market exclusivity. Mr O'Mahony reiterated that the haemophilia community welcomes all options and approaches, that it needs choices and does not want them constrained by unsuitable regulatory solutions or unrealistic pricing strategies. Following up, the EHC advocacy work was acknowledged and it was agreed that, in order for the haemophilia community to fully benefit from the upcoming changes, commitment and sympathetic support would be required from all stakeholders.

All presentations and the full report are available on:
http://www.ehc.eu/round-table-of-stake-holders/last-round-table.html

NMO News

Establishing a haemophilia treatment centre in Albania

By Pranvera Neziri

When my son was born 27 years ago, "Mother Theresa's Hospital" haematology section became my second home. It was the home of life and hope, pain and sadness. Travelling abroad in Italy, I have tried to meet as many people as possible with the same diagnosis in order to understand and learn as much as possible about this condition. There, I learned that haemophilia patients were treated in a special centre in every city.

Some years later I was chosen to be president of the Association for Haemophilia in Albania and my obligations and commitments grew toward these people that were in need of help. I had the opportunity to widen my net of contacts outside Albania, and to exchange thoughts with doctors and family members of patients that were committed to their struggle. The idea to have a special centre for the treatment of haemophilia in Albania grew stronger and was supported by everyone.

I wish to recall here that not so long ago, Albania was ruled by a communist dictatorship that caused a variety of social and economic problems, and as a consequence it has been very difficult to establish a special centre for the treatment of haemophilia.

We had worked through the media to achieve public awareness, but then the time came for us as an association to establish our own journal to express the concerns of doctors, patients and parents alike.

Not to forget is the help and support of the World Federation of Hemophilia (WFH), for which special thanks goes to Ms Catherine Hudon, former Regional Program Manager for Europe.

We had continuously asked the Albanian Health Ministry to help and support us in our project to build a centre for haemophilia in Albania, and it is important to say that everyone was supportive of this project. But, the continuous political changes in Albanian politics made it difficult for us. For example, in six months three ministers changed in the Health Ministry, and just when we thought that we had made it, we had to start all over again.

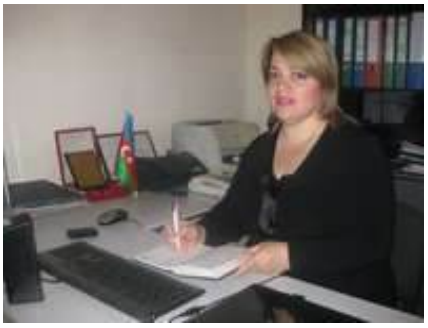
On the 23rd of May 2013 we made it.

It was an important step forward in order to help and support patients with haemophilia, but much remains to be done so that this centre can achieve the same standards as its sister centres around the world.

Opening of the Centre

Project to establish regional haemophilia treatment centres in Azerbaijan

By Gulnara Huseynova



In 2012 the Azerbaijani Ministry of Health, with the financial support of the Swiss Haemophilia Foundation, began a project to open regional treatment centres in the cities of Ganja and Shirvan. These centres will serve 13 and nine districts, respectively, with 130 people with haemophilia registered in Ganja and 114 in Shirvan.

The Azerbaijani Haemophilia Society has had three meetings with the Ministry to move the project forward. Recently a number of trainings have also taken place.

From May 16-22, regional doctors received high-level training from Professor Bulent Zulfikar from the Turkish Haemophilia Society. Four doctors, four nurses and four laboratory personnel attended his workshops; everyone is committed to working in the field of haemophilia. Also on May 16th, staff from the haemophilia centre in the Republican Hospital in Baku Mehpara Kazimova and Gunel Alizadeh trained regional staff on degrees of severity, symptoms and treatment, and prevention of bleeds.

From May 17-18, Prof Zulfikar gave a presentation on living with haemophilia, inhibitors and the complications of haemophilia with reconstructive surgery. Sister Hanife Ozcan gave a presentation on infusing factor concentrate. There was also practical training in the haemophilia centre on how to infuse

factor and how to care for patients with haemophilia. Finally, four laboratories in Ganja and Shirvan participated in theoretical and practical training, given under the leadership of Sakina Zeynalova from the Centre's Haemophilia Clinical Laboratory.

On May 19th, the Azerbaijani Haemophilia Society hosted a meeting that brought together 35 members including doctors, patients and family members. Prof Zulfikar presented the role and activities of the Turkish Haemophilia Society and provided advice to patients with mobility problems. Ms Ozcan provided practical training on infusing factor concentrates.

Prof. Bülent Zülfikar

On May 20th, participants engaged in discussions, questions and answers during the seminar. On May 21st, Ms Ozcan visited the regions to review the work of the Society at a regional level. Further training sessions were conducted on June 7th, involving 18 participants with haemophilia.

The Society has visited Shirvan twice to inspect the renovations and to supply necessary laboratory and other equipment. Repairs of the premises were finished and there was a meeting with the staff and medical personnel, who received workshop certificates for their training with Prof Zulfikar and Ms Ozcan from Turkey.

We express our gratitude to Prof Zülfikar for his availability and support with the workshops.

WFH 50th Anniversary in Copenhagen

By Maria Christensen

Brian O'Mahony, Alain Weill, Terkel Andersen, Mark Skinner

On June 25, 2013 it was exactly 50 years since the World Federation of Hemophilia (WFH) was established. Back then representatives from 12 countries gathered in Moltkes Palæ in the middle of Copenhagen, Denmark, with Frank Schnabel as their visionary leader to establish the WFH.

The Danish Haemophilia Society was established seven years later in 1970, and since the establishment of the WFH took place in Copenhagen, The Danish Society marked the day with a symposium titled "Where do we go from here?"

Current WFH President Alain Weill and the two former Presidents Mark Skinner and Brian O'Mahony opened the symposium by looking back in time, celebrating the many milestones achieved during the years. They presented a video made by the WFH, which illustrated the establishment of the WFH and its developments with Frank Schnabel in the lead. Mr Weill presented the WFH's three new programs and

declared that even though we have come a long way, there is still a lot to be done. The journey continues. (Learn more at www.wfh.org/50).

The results from the Danish quality of life survey

Danish Professor Jakob Bue Bjørner presented the results from the third Danish quality of life survey carried out in 2012. The survey shows that the life expectancy of people with haemophilia (PWH) has increased and therefore we have a new generation of elderly haemophiliacs. In addition to this, the survey shows that more Danish PWH are able to participate in the labour market. For the youngest generations the participation rate is equivalent to the general population. Prof Bjørner commented that even though there has been great progress, challenges still remain. For example, the survey shows that mobility limitations and joint injuries are still a problem for young PWH. Joint injuries are delayed but are still an issue in the life of the younger PWH.

After the presentation, a panel consisting of Prof Bjørner, Vice Chairman of the Danish Society Jacob Bech Andersen, Chairman of the Swedish Haemophilia Society Anders Molander, Mr Weill and member of the Danish Society's Board Theis Bacher disussed the survey results.

The Comprehensive Care Centers

Finnish Professor in Coagulation Medicine Riitta Lassila presented how the Finnish system is organised and talked about the Comprehensive Care Centre-model and its benefits, both financially and in terms of increased health and life expectancy.

After the presentation, a panel debate consisting of members of the Danish Society's Board Naja Skouw-Rasmussen and Mr Bacher, Marianne Jespersen from the Danish Health and Medicines Authority, Prof Lassila and EHC President Mr O'Mahony took place. The panel and the audience discussed the perspectives of the specialised centres and the overall conclusion was that there is a great need for comprehensive care, and that patients, doctors and governments must collaborate in order to develop and institutionalise the concept.

Mr O'Mahony recommended national haemophilia committees as a relevant collaboration forum and Prof Lassila directed the attention to the upcoming standards on Comprehensive Care Centres developed by EUHANET, which should be published very soon. (Learn more at www.euhanet.org.)

Participants at the symposium listening to the presentations

Together to advance research

By Marion Berthon-Elber

For the French Association of Haemophilia (AFH), World Haemophilia Day 2013 was the opportunity to launch its new research campaign in the field of rare bleeding disorders. Like every year, the AFH relied on the support of partners[1] *and volunteers from across France to make this event a success.*

Research, an exemplary challenge

Over the past 20 years, the AFH has been committed to developments in patient treatment and care, both with the development of patient education about treatments and prophylaxis as well as with the onset of recombinant products. Today, the organisation has taken on a new challenge: to commit patients together with treaters and researchers to the fascinating albeit long research path.

To make the AFH a key organisational player in research for haemophilia and von Willebrand Disease is a major challenge. Yet it is a challenge that **sets an example** and once again demonstrates that we stand ready and that we will act to change our lives. It is a challenge that **mobilises** our volunteers and people affected by rare bleeding disorders. This challenge provides a **unique opportunity** to unite researchers and patients around a single cause: to cure a disorder. This challenge is also **deeply human** because it is human to envisage reaching new frontiers and to say that nothing is impossible for us. And finally, this challenge **ensures a future** to build attractive treatment centres that integrate researchers, clinicians, nurses, physiotherapists, psychologists and patient resources[2] to offer the best possible care to all patients and their families.

Research, an encounter with the general public

On April 13-17, on the threshold of the Montparnasse Train Station in Paris and with the high patronage of the Ministry of Social Affairs and Health, the AFH unveiled its research ambitions. "Together to advance research"[3] was the theme that brought together and mobilised more than 1,000 people from amongst the general public, patients, families, healthcare professionals and organisations to highlight innovation and hope on World Haemophilia Day.

For this occasion, the AFH built an exhibition village of more than 400 m², composed of four tents, each dedicated to medical and related fields and offering fun activities for children and adolescents. Visitors and passers-by also enjoyed a number of activities. During those five days, they had the opportunity to see a

Thomas Sannié, president of the AFH giving a visiting tour of the exhibition.

[1] With Gold support from: Baxter and CSL Behring
With Silver support from: LFB Biomédicaments, Novo Nordisk, Pfizer and Sobi

[2] Patients or parents participating in treatment education workshops together with health professionals. See the journal *Hémophilie et maladie de Willebrand* n° 201 page 4.

[3] « Tous ensemble pour que la recherche avance »

performance by stilt-walkers and to participate in daily Tai Chi and Qi Gong classes and exhibitions from the French Federation of Chinese Energy and Martial Arts.

Patients, families, people active in the haemophilia community, curious passers-by and onlookers attended, and more than 5,000 leaflets and balloons with the colours of World Haemophilia Day were distributed on the footsteps of the Montparnasse Train Station.

Research, between scientific conference and exhibits

On Saturday, April 13th, many people – both affected and unaffected by rare bleeding disorders – gathered in the main tent to attend the scientific conference organised by the AFH, which introduced this week's focus on research. Catherine Costa opened the conference with a presentation of genetics applied to haemophilia and Jean-Marc Costa shared his work on diagnosing unborn children through mothers' blood. Professor Claude Négrier then presented the history of treatment and care opportunities for people with haemophilia. Finally, Genevieve Piétu, chair of the AFH's Research Working Group, gave an overview of the organisation's efforts in the field of research.[4]

Physicians, geneticists, nurses, physiotherapists, patients and parents also worked together on the production of 24 posters, which were presented from April 13-17 during a scientific exhibit. These posters outlined different bleeding disorders, the organisation and its committees and working groups, the history of treatment and patient care, adverse events, patient education, physical therapy and physical activity, the World Federation of Hemophilia and other topics.[5] In this way, the public was able to learn about the efforts that have taken place in the field of rare bleeding disorders, ranging from the origins of care to current research.

We are grateful to all of our volunteers and partners for making this event possible and for helping to commemorate World Haemophilia Day with a week filled with hope as the AFH officially launched its commitment to research: more than ever, we stand "together to advance research."

The team of volunteers at the exposition area.

[4] All presentations can be found on the AFH website : www.afh.asso.fr
[5] All posters can be found on the AFH website : www.afh.asso.fr

Latvia Haemophilia Society celebrates its 20th anniversary

By Baiba Ziemele

Baiba Ziemele, the current president, and Aija Pebo, the previous president

This year, when the World Federation of Hemophilia (WFH) celebrates its 50th anniversary, people with bleeding disorders in Latvia join to celebrate 20 years since the Latvia Haemophilia Society was established in July 16, 1993. Ever since then, we have been a national member organisation of the European Haemophilia Consortium (EHC) and the WFH, learning from other countries, sharing our stories and strengthening our community. Now, we are in the middle of a rocky road, striving to achieve the same exemplary haemophilia care as in other European countries.

Just over twenty years ago we started in the desert; people with bleeding disorders were either not treated at all or treated only in hospitals with fresh frozen plasma and cryoprecipitate. In severe cases, patients were sent to Moscow, capital of the then-Soviet Union, because we had no resources to provide adequate treatment in our country. Regaining independence from the Soviet Union did not change anything overnight; there were more difficult problems to solve. Yet people with bleeding disorders saw a possibility to improve the situation by joining forces.

We joined the EHC and the WFH, we twinned with Germany and we started to participate in various international events to get access to the latest state of the art knowledge, which should be implemented in our country of more than 2 million people. We did much to raise awareness. We published books and booklets for our patients, their families and doctors, and teachers in schools and kindergartens. We have been in the press and on TV through various interviews, articles and other coverage. Thanks to a WFH grant, we were able to improve our website and to be present on all major social networks. We regularly participate in various ministry councils and work groups not only to explain what a bleeding disorder is, but also to make sure they do not forget us when planning budgets and policies.

The provision of factor concentrates has always been an issue. In the beginning, we received factor donations, mostly for use in summer camps for people with bleeding disorders. Then, from 2002 on, thanks to doctors and government officials we could finally use factor concentrates at home: doctors prescribed the necessary factor amounts for each case and people learned how to use it at home. The amount of factor concentrates that were fully reimbursed by the government kept growing – until the economic crisis in 2008.

The last five years have been a struggle to ensure the availability of factor concentrates for people with bleeding disorders. The government now pays only for the cheapest products and cannot guarantee that they are always available in drugstores.

We are very proud that since the autumn of 2012 all children receive an adequate amount of recombinant factor products. Yet, when they turn 18, they will face the same problems that adults face; they will receive only the cheapest available factor products, they will not receive government-paid products for planned surgeries, etc.

There are 120 people with haemophilia A, 25 with haemophilia B, five people with FVII deficiency and 102 people with von Willebrand Disease (VWD) in Latvia. VWD is treated only with DDVAP (in some cases they receive FVIII concentrates in hospitals) and only in early 2013 did it become possible to diagnose the VWD type (the project will be finished in the autumn).

Due to the geography of our little country, all major cities are located not further than 250 km from the capital, Riga. Therefore both haemophilia treatment centres (HTCs) – for children and adults – are located in the capital. Due to this, people with bleeding disorders can receive prescribed factor concentrates in their nearest home drugstore, and HTCs are implementing a project to teach local medical staff about bleeding disorders and what to do in extreme cases.

Every summer we send our kids to summer camps – this year the Lithuanian Haemophilia Society and the Estonian Haemophilia Society have kindly invited children from Latvia to participate in their summer camps. We also participated several times in the EHC youth summer camps and in camps organised by the German Haemophilia Society. We had organised several summer camps ourselves during the past 20 years. Recently they have been replaced by overnight excursions for people with bleeding disorders to various beautiful places in Latvia, financed by them.

In the last years we have supported all those students who have written their theses on subjects of interest to our community: dental care, emergency care, physiotherapy, business, sociology and other topics. We also closely cooperate with other rare disorders communities in Latvia.

We are very grateful to our sponsors and well-wishers who help not only with financing, but also patiently help us understand the difficult environment of healthcare and guide us to be aware of and protect our rights.

Our next goal is to ensure a sufficient supply of factor concentrates for all people with bleeding disorders, to improve special physiotherapy care and to help women bleeders in Latvia.

Members of the Latvian Haemophilia Society celebrating its 20th Anniversary on July 27th

World Haemophilia Day in Poland

By Radoslaw Kaczmarek

On April 16th the Polish Haemophilia Society (PHS) held a press conference in Warsaw to promote World Haemophilia Day and to take the opportunity to discuss the quality of haemophilia care in Poland.

Speakers included leading Polish haematologists, the Director of the National Blood Centre (subordinate to the Ministry of Health and responsible for the distribution of clotting factor concentrates) and patient representatives.

Bogdan Gajewski, the President of the PHS, gratefully pointed out that the National Program of Haemophilia Care for the period of 2005-2011 brought remarkable improvements, including the provision of primary prophylaxis.

Having said that, further changes foreseen in the new program covering the years 2012-2018 are lagging. As yet unmet provisions include the extension of prophylaxis to cover young adults and the development of comprehensive care centres. Children have been covered with prophylaxis for five years now, however every patient becomes ineligible at the age of 18 and has to return to treatment on demand, said Mr Gajewski.

This is a turning point in an individual's life as patients that age face final exams, apply to colleges or jobs. Depriving them of the best possible treatment makes these transitions far more difficult and limits patients' chances for success, he added. Dr Ewa Stefanska-Windyga further explained that lack of prophylaxis leads to more frequent bleeding episodes, which in turn result in a permanent joint damage. She emphasized that prevention of bleeding episodes is the only chance for normal activity.

Patients in the audience were given an opportunity to share their experiences. Twenty-year old Alan spoke about his dramatic fall into a decline once he turned 18 and stopped prophylaxis, and his lost struggle to successfully finish the first year of study as a result of an overwhelming number of bleeding episodes. Another patient spoke about how he was in awe of the quality of comprehensive care in Ireland, where he worked for a few months and sought help in a local centre.

Dr Jolanta Antoniewicz-Papis, Director of the National Blood Centre, admitted that the implementation of the new National Program of Haemophilia Care proved difficult but was already pending, and said that the patients should see clear results in the following year, mainly in improved access to secondary prophylaxis. How much of those promises will become a reality remains to be seen.

Haemophilia and economic crisis in Portugal – a civilisational set back

By Miguel Crato

The Portuguese Haemophilia Society, Associação Portuguesa de Hemofilia e Outras Coagulopatias Congénitas (APH), was founded in 1976. It has been a beacon for the rights of people with haemophilia from the early years when treatments were scarce, through a difficult phase of viral infections, until a recent phase of treatment stabilisation – as was common in most European countries. Currently, there are 700 people with haemophilia and other inherited bleeding disorders registered in our association, though we estimate about 1,000 people all over the country.

These days, the haemophilia community in Portugal and particularly the new Board (April 2013) should be concerned with recent therapeutics; with setting up Comprehensive Care Centres, which still do not exist; and with establishing haemophilia clusters around the country as well as communication platforms for the community as a whole.

Nevertheless, since 2011 Portugal has been in a severe economic crisis, which led the country to a financial bailout by the Troika (the International Monetary Fund, the European Central Bank and the European Commission) and this in turn led to budget cuts for health. Therefore our main concern and central battle in the last months has been to guarantee treatment for all. On the one hand we need to ensure that treatment is available in hospitals and on the other that the amount of treatment is not reduced.

Portuguese hospitals, which function as treatment centres for people with haemophilia, report delays and irregularities in the delivery of factor. Children and adults under prophylactic treatment have been seriously affected by this situation since the factor quantities attributed to each person were diminished. In the past, hospital boards bought factor, particularly recombinant products, on an annual basis and purchasing was centralised by the government. Today this practice has been replaced by short-term purchases, which has led to a predictable brand replacement without hearing patients' views and, as a result, has caused uncertainty and insecurity amongst users.

The criterion to select products for treatment is now a criterion of cost/price. In this scenario, medical views concerning the efficacy of treatments are often undervalued.

Moreover, the government typically does not respect legal payment deadlines to pharmaceuticals that provide treatment; there are cases of two-year delays in payment. This causes great instability for companies and erodes the ability of hospitals to make fair choices regarding treatment products. Both the haemophilia community and treating doctors find themselves caught in the middle.

In the past few months, the core action of the APH has been to present and denounce this situation both to hospitals as well as to the media. Radio, TV and newspaper interviews and testimonies on World

Haemophilia Day led hospitals to ensure that the diversity and supply of treatment products would go back to normal. However, we still face the same problems and are working on a new advocacy and awareness-raising strategy for the government and the media.

The APH is aware of the economic difficulties across Portugal and of the budgetary constraints that will be needed to achieve the financial balance that we all desire. However, the APH will never accept that this financial balance seeks to be achieved at the expense of the health of people with haemophilia through the rationing of treatment that is critical to their quality of life.

We appeal to the haemophilia community around the world and especially in Europe to help pressure European Union organisations and to spread the message about what is happening in Portugal and may spread to other countries already facing or approaching financial difficulties.

The English Bridge

By Andrei Egorenkov

"The English Bridge" winners together with Dan Farthing near the office of the Haemophilia Society Scotland

In the winter of 2012-2013, young people with haemophilia from across Russia took part in a national English competition called "The English Bridge."

Organised by Haemophilia Scotland and the Russian Haemophilia Society, and financially supported by Baxter, the competition was designed to increase the social activity of people with bleeding disorders and their involvement with their haemophilia society.

Participants represented a vast geographic range, including different parts of Siberia, the Volga region, south-western Russia, the Moscow region and the city of Moscow. The leader of the group came from the far east of Russia, near China.

Contestants were required to submit an essay in English and then pass an interview with a jury. Eight winners received the opportunity to visit the United Kingdom (UK). On April 15th they arrived in Edinburgh via London.

"The English Bridge" winners first visited the office of Haemophilia Scotland. Later, Susan Hook and Irma Shea, Haemophilia Clinical Nurse Specialists, gave them a tour of the Edinburgh Haemophilia Centre. It was very exciting to learn about the differences and similarities in the treatment of bleeding disorders in each country. Later, the group had a sightseeing tour along the Royal Mile – a charming street where every building has its own fascinating story.

In Edinburgh, the group participated in activities dedicated to World Haemophilia Day and in the evening took part in the Scottish Parliament. The next day they had the honour of meeting with the First Minister of Scotland Alex Salmond. Then the group visited the admirable and fantastic Edinburgh Castle, full of Scottish history.

On Saturday, April 20th the group took part in the meeting of Haemophilia Scotland, where participants learned many things about the organisation and its activities. The leader of the group also reported on the situation of haemophilia in Russia.

Next the group stayed in the capital of the Highlands of Scotland: Inverness. The city is not very big, but very beautiful. On the Sunday, they attended a traditional Scottish party called “Ceilidh.” The most energetic and vigorous members of the group were able to dance together with Scottish people. The group was hosted by Susan Warren’s family and the families of her friends. One day there was a cruise on the famous Loch Ness.

London was the final destination of the group’s visit. There, they visited the British Museum and attended the West End Show “We will rock you” based on the famous songs of the “Queen” rock band. They met the staff of the UK Haemophilia Society, and they took bus and river sightseeing tours.

The winning group of “The English Bridge” competition expresses its deep gratitude to Susan Warren, who organised the tour. During the whole stay in the UK, she sensitively took care of each group member. She ensured that everyone felt comfortable and carefree. Her huge efforts and time dedicated to the group are priceless.

The group also thanks the Haemophilia Scotland committee, which hosted and welcomed them with all their hearts, and thanks the families who showed their hospitality.

“The English Bridge” winners at the office of the First Minister of Scotland Alex Salmond

Extensive donation to haemophilia patients in Nepal

By Örjan Bjermert

The Swedish Haemophilia Society has donated 1.4 million units of factor concentrate to the Nepalese Haemophilia Society for the treatment of bleeds in patients with haemophilia A. The donation, made possible by Baxter Medical, is six times the volume of what is normally available during one year in Nepal. Nepal is one of the world's poorest countries and does not have public funding or provision of public healthcare for haemophilia patients.

A donation of this size will save many lives as access to medicine is practically non-existent. Haemophilia is often treated in Nepal with ice and compression bandages, which results in people living lives characterised by indescribable pain, long periods in bed and dependence on strong painkillers. Even very young children have permanent joint damage and many die before the age of 30.

The delivery was made during a visit to the capital city of Kathmandu in late May and was very well received. The medicine is now free to distribute by the factor committee of the Nepalese Haemophilia Society with the supervision of haematologists. The donated products will be used to treat severe bleeds and life-threatening traumas in hospitals in Kathmandu and in other treatment centres around the country.

Repacking and registration of donation at NHS office in Kathmandu

The donation is part of an ongoing project between the Swedish Haemophilia Society and the Nepalese Haemophilia Society, which started in 1999. The project aims to support both awareness and health-care activities, to change public views of disabled people in general and to lobby for appropriate healthcare for haemophilia patients in Nepal.

Swiss Haemophilia Society revises its mission and structure

By Hans Meier

I was first elected President of the Swiss Haemophilia Society (SHG) in the 1980s. This spring, I was re-elected for this task on a limited two-year term. I have been mandated by the Board to lead a two-year project that seeks to take stock of the SHG's current situation and to set its future course. It seems that for the moment I appear to be a good fit for this role, being an early retiree who has broad experience with organisational management and multiple years of experience as President of the SHG.

Purpose of this project

Like in most other countries, the funding of the SHG relies greatly on external sources. Membership fees cover only about 25% of the expenses. The remaining funding is provided by the Swiss Disability Insurance (IV) and by sponsorship from the pharmaceutical industry (product manufacturers).

However, IV funding is dependant on the services we provide (i.e. days participated in the courses, summer camps, etc., that we organise). As the demand for these activities has recently begun to decrease, it is to be expected that the IV funding will decrease as well.

As for product manufacturers, they have clearly signalled that the current form of pooled funding (fixed annual contribution) cannot continue. They dispose of generally diminishing sponsorship funds and prefer to directly support individual events in the future.

In addition to this we have noted that, as haemophilia treatment centres evolve towards a comprehensive care model, they increasingly overlap with the offers and services that the SHG can provide.

It is for these reasons that the Board decided to conduct the above-mentioned project, which sets out the following objectives:

1. Conduct a comprehensive analysis to determine the needs of our stakeholders, particularly of those affected;
2. Evaluate the resulting needs and priorities;
3. Define future services and activities in light of these priorities;
4. Determine an organisational structure that can provide these services and activities in a user-friendly and efficient manner; and
5. Establish a financial structure that secures the long-term provision of these services and activities.

Farewell Tribute to Catherine Hudon

Ukraine bids farewell to Catherine Hudon

By Oleksandr Shmilo and Sergiy Shemet

We met Catherine Hudon in Kiev at the First Constitutive Conference where the Ukrainian Haemophilia Association (UHA) was created in 2006. Catherine directly helped create our organisation and later helped us with all the challenges that we faced. We can remember very well how she tried to understand our needs and problems – Yuri Zhulyov provided a simultaneous interpretation for her since we could not afford an interpreter. From the first words it became obvious that she is a very communicative person and easy to talk to. We can also recollect how she was amused in the Conference Hotel when she discovered that in order to go to the ground floor she had to press the button #8 (even though the

hotel had only five floors). We think that for the World Federation of Hemophilia (WFH) the entire work with Ukraine and all other ex-USSR countries is similar to that elevator – you never know exactly which button you must push to achieve a desired result. Catherine understood these features of our country very well and always took them into account throughout our collaboration. We think that thanks to how well she understood our internal problems she forgave us many times for delayed replies or long preparations of reports, etc. As far as Catherine's way of work is concerned, we could ask her for a letter of support on the eve of a meeting in the Ministry of Health and Catherine would prepare it even outside of her working hours, in just 30 minutes! While working with Catherine (which in certain 'hot' periods meant very extensive work for many days or even weeks), we also tried to raise our own level of responsibility and reliance.

Many activities of the UHA were prepared in collaboration with the WFH. Catherine helped us tackle the main problems of haemophilia care in Ukraine: low factor supply, diagnostics and absence of proper pre- and post-operative physiotherapy that dramatically decreased the success of surgery. All these areas have already improved significantly. The factor supply in Ukraine in 2012 rose to over 1 IU per capita for the first time ever. Diagnostics in every region of Ukraine is now a reality while it used to be a pipe dream. And just before Catherine left the WFH in May she organised an exceptionally successful physiotherapy workshop in Kiev. Attended by key orthopaedic surgeons, haematologists and physiotherapists, it inspired them to totally revise the way they work and facilitated their successful professional collaboration within the 'Comprehensive Healthcare Team.' Yet another victory, Catherine!

Working with Catherine, we always knew that we had a true friend in the WFH. Hopefully this collaboration and friendship will continue in the future.

Other farewell tributes

"Catherine was dedicated to our cause and had a very clear understanding of a patient association role. She has always underlined that European patients can make the difference to achieve the WFH and EHC goals: treatment for all, education for everyone and improvement of comprehensive care. She travelled all across Europe to defend our community. Many thanks Catherine and the best for you in your new life." *Thomas Sannié, French Haemophilia Society*

"Catherine was a professional. On behalf of the Azerbaijani colleagues, we wish her the best of luck in her future career." *Gulnara Huseynova, Azerbaijan Republic Association of Haemophilia*

"Catherine was always ready to help and she had the knowledge and experience how to do it best. She has helped us a lot with her good advice. And she had personal charm so that meeting her at conferences or workshops was always a pleasure." *Adam Sumera, Polish Haemophilia Society*

Articles

How might hepatitis C spread?

By Dr. med. Uwe Schlenkrich

Background

In the 70's and early 80's thousands of people with haemophilia (PWH) were infected by high concentrated clotting factors that had been newly introduced and produced commercially. As these products were not virus inactivated, almost every vial was contaminated with hepatitis C viruses (and often also hepatitis B and HIV).

With the introduction of virus inactivation steps and through the exclusion of infected donors, the risk of transmission of hepatitis B and C and HIV was eliminated. Therefore, in the developed world almost all hepatitis C infections in PWH occurred before the mid-80's.

However, over 75% of all haemophilia patients worldwide receive no or inadequate treatment. Usually blood or plasma is used for therapy. In developing countries, these products are often not tested for infectious viruses or are not virus inactivated. Unfortunately, hepatitis C infections still occur in developing countries. For example, in Pakistan 90% of all PWH are HCV positive.

Testing

Every PWH should know whether he is infected with hepatitis C. So he should be tested. These are the possible test results:

IgG anti-HCV: Negative

Interpretation: You have never had contact with the hepatitis C virus.

IgG anti-HCV: positive / HCV-NAT (PCR): positive

Interpretation: You have had contact with the hepatitis C virus. It is not possible to tell when that happened. The virus is replicating in your body.

Conclusions: Your blood is infectious. The disease has become chronic. Consult a hepatologist about your treatment options.

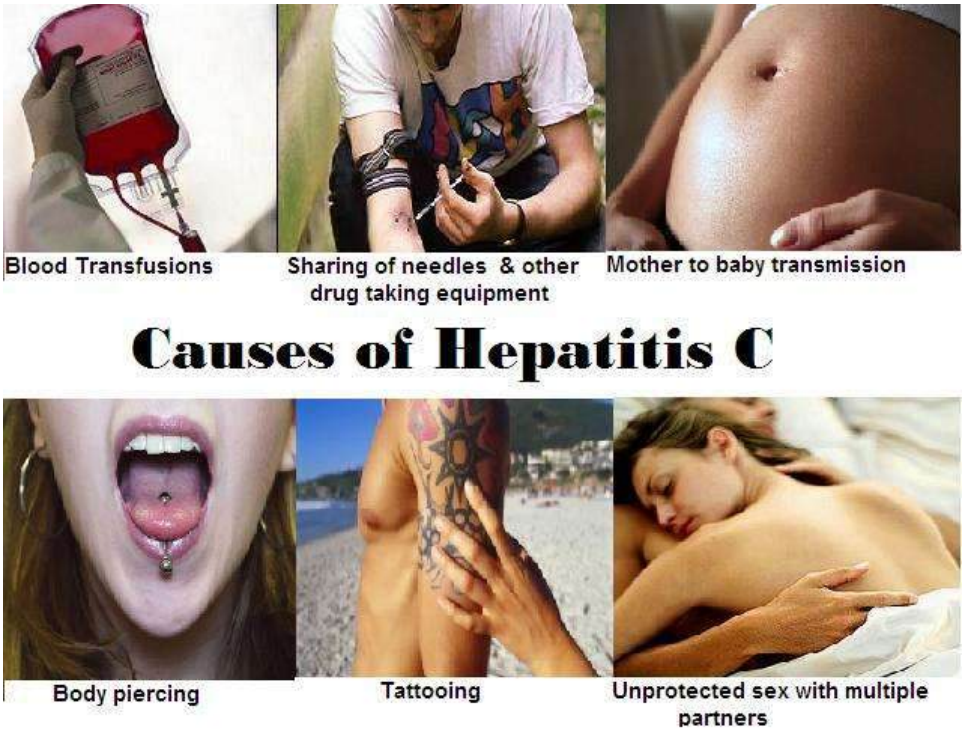
IgG anti-HCV: positive / HCV-NAT (PCR): negative

Interpretation: You have had contact with the hepatitis C virus. It is not possible to tell when that happened. Your immune system or a therapy has fought the virus successfully.

Conclusions: Your blood is not infectious. The antibodies against the hepatitis C virus are not protective.

I am HCV-NAT positive, what do I have to consider?

- HCV-positive people should be advised to avoid alcohol because it can accelerate cirrhosis and end-stage liver disease.
- Viral hepatitis patients should also check with a health professional before taking any new prescription pills, over-the counter drugs (such as non-aspirin pain relievers) or supplements, as these can potentially damage the liver.



Transmission

As transmission by blood is the most effective way to spread HCV you should keep the following in mind:

- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others.
- Used needles and syringes must be disposed in special containers.
- Cuts and sores on the skin should be covered to keep from spreading infectious blood or secretions.
- Donating blood, organs, tissue or semen can spread HCV to others.
- HCV is not spread by sneezing, hugging, holding hands, coughing, sharing eating utensils or drinking glasses, or through food or water.

Sexual transmission

Sexual transmission of HCV had been considered to occur rarely. An Italian study published in 2004 concludes: “Our data indicate that the risk of sexual transmission of HCV within heterosexual monogamous couples is extremely low or even null. No general recommendations for condom use seem required for individuals in monogamous partnerships with HCV-infected partners.”

This was proved also by a recently published study. A total of 500 anti-HCV-positive, human immunodeficiency virus-negative persons and their long-term heterosexual partners were observed. The maximum incidence rate of HCV transmission by sex was 0.07% per year or approximately one per 190,000 sexual contacts. No specific sexual practices were related to HCV positivity among couples. A French study from 2005 found a risk of HCV acquisition from 0 to 0.6% per year.

This risk of HCV transmission by sex seems to increases among persons with multiple sexual partners, but this association may be confounded by an increased likelihood of injection drug use with an increased number of partners.

Men who have sex with men (MSM) without a history of injection drug use are also not at increased risk for infection.

Should HCV-infected persons be restricted from working in certain occupations or settings?

The United States Centers for Disease Control and Prevention (CDC) recommend that persons should not be excluded from work, school, play, child care or other settings on the basis of their HCV infection status. There is no evidence of HCV transmission from food handlers, teachers or other service providers in the absence of blood-to-blood contact.

There are no restrictions to healthcare workers who are infected with HCV. The risk of transmission from an infected healthcare worker to a patient appears to be very low. All healthcare personnel, including those who are HCV positive, should follow strict aseptic techniques and Standard Precautions, including appropriate hand hygiene, use of protective barriers and safe injection practices.

Is there a risk that I infect healthcare personnel or my dentist?

After a needle stick or sharps exposure to HCV positive blood, the risk of HCV infection is approximately 1.8% (range: 0%–10%).

Although a few cases of HCV transmission via blood splash to the eye have been reported, the risk for such transmission is expected to be very low.

No transmission has been documented from intact or non-intact skin exposures to blood and it seems to occur rarely from mucous membrane exposures to blood.

The risk for a dentist to be infected by an HCV positive patient seems also to be very low. A study found HCV antibodies in 2.0% of oral surgeons and 0.7% of general dentists.

The same figures are shown by an Israeli study, where the prevalence of HCV antibodies among Israeli dentists of 1/301 (0.33%) was similar to the prevalence range (0.1-0.5%) among the general Israeli population.

Avoiding occupational exposure to blood is the primary way to prevent transmission of blood borne illnesses among healthcare personnel. All healthcare personnel should adhere to Standard Precautions.

Depending on the medical procedure involved, Standard Precautions may include the appropriate use of personal protective equipment (e.g., gloves, masks, and protective eye wear).

You would like to get a tattoo or a piercing

This should be performed only under sterile conditions. Never should it be done under potentially non-sterile settings as in prisons, homes or by friends to avoid HCV infection by contaminated instruments.

Maternal-infant transmission

The rate of mother-to-infant transmission is 4-7% per pregnancy in women with HCV viremia. The transmission occurs at the time of birth and no prophylaxis is available to prevent it. The risk is increased by the presence of maternal HCV viremia at delivery and is also 2–3 times greater if the woman is co-infected with HIV.

All statement made in this article concern only people that are infected by HCV. Additional infections by hepatitis B and HIV need further protective measures.

Sources upon request.

EU Policy

Update on Health Technology Assessment within the Cross-Border Healthcare Directive

By Mark Walker

Following on from the news regarding the European Commissioner for Health and Consumer Policy, Dr Tonio Borg, visiting the European Parliament's Committee on Internal Market and Consumer Protection (IMCO), there was a further update on the Cross-Border Healthcare Directive with regards to the issue of Health Technology Assessment (HTA).

As previously discussed in reports from the European Haemophilia Consortium (EHC), HTA is a Member State responsibility, being strongly attached to national competences in the healthcare systems such as funding and reimbursement. HTA has developed differently in various Member States with different levels of sophistication.

With this in mind, on June 26th the EU Institutions adopted the "Commission Implementing Decision providing the rules for the functioning of the Network of National Authorities or bodies responsible for Health Technology Assessment." This decision is now in force.

As discussed in previous Round Tables, HTA provides policy-makers with information on the benefits and comparative value of health technologies and procedures. The Network of National authorities or bodies responsible for HTA, foreseen in the Directive on Patients' Rights in Cross-Border Healthcare, will help facilitate efficient use of HTA resources in Europe, create a sustainable system of HTA knowledge-sharing, and promote good practice in HTA methods and processes.

Privatisation Announcement Of Plasma Resources UK

By Mark Walker

On July 19th the privatisation of Plasma Resources UK was announced. This privatisation of the supply and sourcing of blood plasma made front-page news.

Since it came into power in 2010, the UK Coalition Government had earmarked the sale of Plasma Resources UK to the private sector with the rationale that the organisation needs modernisation and that an outside company should carry this out.

The deal was made with Bain Capital of the United States, best known for being run by Mitt Romney, former US Presidential Candidate. Bain will have an 80% stake in Plasma Resources UK and the UK Government will retain the remaining 20%.

Plans for the sale had been announced in January, but the Department of Health only now announced the winning bid. Bain stated that it planned to invest more than £50 million in the business to increase production capacity, refurbish facilities, develop new products and expand the company’s international reach.

According to news reports, Bain fought off competition from a number of buyers, including South Korean Green Cross Corp and German blood plasma specialist Biotest.

The deal bolsters Bain's presence in the healthcare sector. Bain also owns Quintiles, a biopharmaceutical services provider, as well as pharmaceutical company Warner Chilcott. It is also part of a consortium that bought hospital operator HCA – a big buyer of plasma-derived products – in a $21bn deal in 2006.

Announcements

EHC

EHC conference Bucharest

The EHC will hold its annual EHC Conference in Bucharest, Romania, from October 4-6, 2013. To register visit the website at www.ehc2013.eu.

Round Table of Stakeholders

The next Round Table will be held on October 17, 2013 at the European Parliament in Brussels on the topic of Haemophilia Centres of Expertise in Europe. For further information visit our website at http://www.ehc.eu/round-table-of-stake-holders/upcoming-round-table.html.

WFH

The WFH Congress will be held from May 11-15, 2014. For further information please visit the website of the WFH Congress: www.wfh.org/congress/en/WFH-2014-World-Congress. Registration is open.

EURORDIS

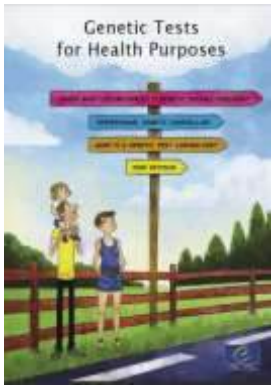
EUROPLAN National Conferences 2012-2015

EURORDIS published a map on its website featuring the locations, dates, organisers and details of all EUROPLAN National Conferences. The final report of each EUROPLAN Conference is posted when available. The report describes the outcomes of the discussion during the conference, focused on the different pillars of forthcoming or existing National Plans for Rare Diseases.

http://www.eurordis.org/content/europlan-national-conferences-2012-2015

Council of Europe

Leaflets on genetic tests for health purposes



The Council of Europe, in collaboration with Eurogentest and the European Society of Human Genetics, has released a leaflet series in 17 European languages that provides information on different types of genetic tests available to patients. The leaflet also discusses the significance and limitations of each test. http://www.coe.int/t/dg3/healthbioethic/Activities/07_Human_genetics_en/Brochure/default_en.asp

EAHAD

The European Association for Haemophilia and Allied Disorders (EAHAD) will hold its next Conference in Brussels from February 26-28, 2014. For further information visit the website at http://eahad2014.com/.