

**Impact of new guidelines on the early care of babies born with clefts lip of the lip and palate**

**Brussels, 21 March 2016 (09:15-17:00)**

CEN-CENELEC Meeting Centre, Avenue Marnix 17, 4<sup>th</sup> floor

<https://goo.gl/maps/HeTLm4hT2Bs>

**Meeting Rooms Newton A and Newton B**



*Workshop opening slide*

In March 2015 the European Committee for Standardisation (CEN) approved a set of guidelines in the early care of babies born with clefts. The report, CEN/TR 16824 '*Early care services for babies born with cleft lip and/or palate*', spearheaded by the European Cleft Organisation (ECO) and with significant support from the ESF-funded EUROcleftNet programme, is now available as a download from ECO's website\*. The process began in 2011 and there has been input from stakeholders in Austria, Belgium, Bulgaria, Estonia, Finland, France, Germany, Lithuania, Spain, Romania and the UK. This workshop, funded by the European Science Foundation, will bring together researchers, clinicians, politicians and representatives of national and international standards bodies to discuss the way forward. In particular the workshop will consider the implementation of the CEN guidelines.

\* [www.europecleft.org](http://www.europecleft.org)

## **MINUTES**

### **09.15: Opening Remarks / Welcome**

**Professor Peter Mossey (PM), Chair of the European Science Foundation (ESF) Research Networking Programme EUROcleftNet**

PM welcomed everyone to the workshop. PM noted that it was pleasing that thirteen countries were represented. PM introduced Guido de Jongh (GdJ).

### **Guido de Jongh, NBN – Belgian Standardization Bureau**

GdJ thanked everyone for attending and for organising the event. GdJ welcomed everyone to the meeting to discuss the impact of the new guidelines on the early care of babies born with clefts of the lip and palate. GdJ explained that the elaboration of this new guideline - in the format of a CEN/Technical Report which was formally started in 2011. The creation of such a guideline was a first for the standardisation community too: traditionally CEN documents were written for industry, by industry and other "business" stakeholders. By drafting of the new guideline, CEN showed that it does not only exist for the "traditional" stakeholders; but that charities and other NGOs could take advantage from the "soft power" that stems from a CEN publication.

GdJ added that CEN/TR 16824 is one of the first publications in the field of "healthcare services" (services, and in particular "healthcare services" are becoming a niche sector within the European standards collection). However, this niche sector is getting a growing political importance - in this context it was noteworthy that the event was honoured by the presence of Dr. Vesna Knjeginjić from the Ministry of Health of the Republic of Serbia.

GdJ said that the workshop would be an opportunity to examine how the CEN guideline can impact into policy actions – and how to implement these actions. GdJ said that he looked forward to the outcome of the workshop under the chairmanship of Professor Peter Mossey. GdJ also thanked Gareth Davies and the European Cleft Organisation (ECO) for the

organisation of the workshop and to all the experts who had been engaged in the process over the years, and who were participating in the workshop.



*Networking in action*

#### **09.20: Introduction to the day**

##### **Professor Peter Mossey, EUROCleftNet**

PM explained the aims and objectives of the workshop stemming from the beginnings of EUROCleftNet in 2011. The first thing that was obvious was the difference in standards across countries and even within countries. The workshop would be an opportunity to engage with the guidelines for care and to drive towards prevention.

PM acknowledged the more recent involvement with the European Cleft Palate-Craniofacial Association (ECPA) of which Corstiann Breugem (CB) was president.

PM explained the concept of European Reference Networks (ERNs); see [http://ec.europa.eu/health/rare\\_diseases/european\\_reference\\_networks/index\\_en.htm](http://ec.europa.eu/health/rare_diseases/european_reference_networks/index_en.htm)

PM stated that the production of guidelines had been a great achievement, but they would be of no use unless it was possible to put the policy into practice. The ongoing pursuit of policy, research and funding would be touched on throughout the workshop.

PM outlined the ESF funded research networking programme EUROCleftNet's aims, objectives and achievements including:

**Network for Orofacial Clefts Research, Prevention and Treatment (EUROCleftNet) is a Research Networking Programme funded by the European Science Foundation**

- Collaborative aspects - such as improving communication and dialogue across Europe. This work was ongoing and the network was looking to continually seek out and add more relevant collaborations.
- Conferences to date had been very successful, starting with the first conference at Plovdiv, Bulgaria.
- The biobank resource had been built up.
- An innovative and productive programme of Short Visits and Exchanges (SVEs) had been successfully planned and implemented in EUROcleftNet, and this had been a real highlight of the network activities.
- The legacy of the ESF funded network included good relations with colleagues on a global scale.
- The global task force on oral clefts (“Beyond Eurocleft”) led by Gunvor Semb.
- The last year of funding was principally to hold conferences. The group had already met in Niš, Serbia with a final conference to be held in Dundee, Scotland consisting of back-to-back workshops being held on 30 June and 1 July 2016.

The workshop would look for ways in which guidelines can be used as a tool for measuring and assessing the current level of care with the aim being to improve the quality of care cleft lip and / or palate. Themes to consider included:

- Primary prevention of birth defects in Europe - with orofacial clefts
- CEN focus
- Diagnosis pre- and post-natal
- Referrals
- Immediate post-natal care
- Feeding
- Monitoring
- Patient support

PM introduced the workshop programme and reminded those present of the planned workshop at the European Parliament on Tuesday 22 March. Round table introductions followed.

#### **09.45: The context – European Standards as a tool for improving healthcare**

##### **Maitane Olabarria, CEN-CENELEC**

Maitane Olabarria (MO) explained the various recognised European Standards Organisation bodies. The role of the European Committee for Standardization (CEN) was elaborated on. CEN provided a platform for stakeholders in a specific area to come together and reach consensus at a European level. MO explained that standards are voluntary but have added value because they represented a consensus between experts.

CEN helped to ensure that the system respected the principles such as transparency, openness, coherence and consensus.



Different types of standards were explained, e.g. test and measurement, product, management and service. Standardisation in the healthcare sector with examples of published standards was discussed, including the standard for cleft lip and/or palate. New activities included quality of care for elderly people; for example: ordinary or residential facilities, and the minimum requirements of patient involvement in person-centred care.

MO considered why there had been an increase in requests for standards. This was in part due to the mobility of patients and healthcare professionals. For increased patient safety and trust it was necessary to have quality and more effective healthcare services. MO said that there was a need for a level playing field at a European level and standards could help by help:

- Capturing and disseminating good practice at European level
- Supporting continuity of care
- Facilitate cross-border healthcare
- Improve communication and empower patients
- Increased efficiency, quality and patient safety
- Facilitate cooperation between different healthcare professionals
- Support development of new services/forms of service delivery

The conclusion was that standards are valuable tools that can contribute to improved healthcare and increased satisfaction of both healthcare service providers and patients.



*Delegates gain an insight to the work of the European Committee for Standardization (CEN)*

Questions and answers followed. Wilfried Wagner (WW) congratulated Gareth Davies (GD) for the work that he had done but felt the process had not been sufficiently evidence-based. He had been a member of the Technical Committee and had raised this on a number of occasions. He felt the final document was now acceptable – certainly from the point of view of being a service management document – but that it still encroached too far into medical practices that needed to be backed up with solid research evidence. Bill Shaw (BS) said that a way needed to be found to clearly distinguish between standards and evidence based guidelines. Emma Southby (ES) understood these arguments but stated that sometimes we felt constrained by the ‘evidence based’ philosophy with the result that people are afraid to express opinions even though they are often based on expert experience and advice. WW said he wanted the day to be useful and took it on himself to close down this particular discussion. As a final comment he suggested we might want to refer to the document as recommendations rather than guidelines.

#### **10.05: Development of the CEN Technical Report in early cleft care**

##### **Gareth Davies, European Cleft Organisation (ECO)**

Gareth Davies (GD) detailed the background to why the guideline document CEN/TR 16824 had been produced. The document was to be produced with the following aims:

- providing a blueprint for early cleft care agreed at a European level;
- developing guidelines that could be adopted by practitioners in countries where no national protocols exist;
- using the European Committee for Standardization (CEN).

The process for developing the guideline document was explained, from the CEN instruments available, to the establishment of the project committee, to input from national mirror committees up to the approval of the guidelines being made in February 2015 by CEN member bodies. 75% of countries (16) had voted positively.

Involvement in bringing about the guideline document had included representation from:

- European Craniofacial Congress;
- national cleft bodies where they existed (e.g. CSGB&I, AFFF, AFILAPA);
- national cleft palate associations (CLAPA UK and VAGA Belgium);
- all disciplines directly working in cleft care *and* ‘front line’ health professionals who are normally present at the birth of a baby or during the antenatal period ;
- plus 16 countries.

GD explained that the guidelines could be freely downloaded from the ECO website at <http://europeancleft.org/>

The guidelines addressed antenatal and postnatal diagnosis, feeding assessments, defining the care pathway for the first months of life – while covering wider recommendations such as facility requirements and organisation of the cleft service (including clinical governance and audit)

GD summarised achievements, notably that the aim of producing a document setting out recommendations on early cleft care agreed at a European level had been successful. User involvement and full multidisciplinary input had helped achieve agreement. GD added that compromise had been necessary, with some insisting the guidelines were not stringent enough, and others claiming there were over-prescriptive. The exercise had increased the profile of clefts around Europe and had helped forge links between health professionals in different countries while providing a possible model for improving quality (and equality) of care for other congenital anomalies

GD said that the next steps involved the need for implementation strategies to be understood and defined – to make sure that the guidelines made a difference. With this in mind, the forthcoming workshop at the European Parliament (Tuesday 22 March 2016) would be an invaluable opportunity to address this very point.

Comments were invited from the floor. WW said that they would have to look at the future from 'both sides'. CB said that people didn't always understand the standards in different countries. PM said that the guideline documents would evolve over time.

## **10.25: Break**

### **10.45: Transforming health guidelines into policy and action**

#### **Nicola Bedlington, Director of European Patient Forum (EPF)**

Nicola Bedlington (NB) provided the background to EPF including their vision for all patients to have equitable access to high quality, patient-centred health and social care. EPF's mission is to ensure that the patient community drives health policies and programmes that affect them – i.e. patients were seen as part of the solution. EU policy context was outlined as was the need for a coherent strategy while working with patients.

Patient engagement with policy was critical and used the 'full circle' approach. Patient organisations had to be respected as transparent organisations. Examples of the EPF's approach were described including:

- the Cross Border Healthcare directive;
- the European Patients Academy on Therapeutic Innovation (EUPATI);
- Driver Diagram on Patient Centred Care in Radiology;
- And the European Multiple Sclerosis Platform (EMSP) Code of Good Practice.

EPF is an independent and non-governmental advocacy organisation representing 65 members:- non-disease specific patients' coalitions at a national level, and disease-specific

patients' organisations at the EU level; and provided a resource for cross-cutting issues relevant to all patients in Europe.

Strategic goals included health literacy, healthcare access and quality, patient involvement, patient empowerment, sustainable patients' organisation and non-discrimination. On the theme of patients being part of the solution it was necessary to have a strong evidence base (patient-centred care models which were cost effective, with better outcomes and patient satisfaction). The idea of 'patients as experts' was explained – where patients could identify unmet service and therapeutic needs and point out inefficiencies and waste in the system. Patient involvement in co-designing healthcare and patient empowerment (self-management and self-care) were also key features of inclusion of patients as part of the solution.

In the EU policy context patient-centredness was recognised as a key dimension of quality, and there was a case for further work at an EU level to define and measure this.

With respect to patients' engagement in public policy NB provided an overview of the Patient Empowerment Campaign (<http://www.eu-patient.eu/campaign/PatientsprescribE/> ; #PatientprescribE). Leading patient organisations had influenced legislation on:

- Orphan Medicinal Products Regulation
- Paediatric Use Regulation
- Advanced Therapy Regulation,
- Pharmacovigilance Directive
- Revised Clinical Trials Regulation.
- Upcoming Data Protection (etc.)

Moreover, patient engagement is also crucial in effective implementation through the European Medicines Agency (EMA) and at a national level.

NB concluded that the critical success factors were

- Evidence base for change
- Full circle approach
- Capacity and knowledge building for patient leaders to drive change
- Sustained buy-in from health professional community
- Utilising political opportunities and political capital wisely
- Leadership and Partnership.

### **11.15: How to ensure medical schools bring cleft guidelines into their curricula – a perspective from Spain (1)**

**Dr Pedro del Caño, General Practitioner, Madrid, Spain**

Pedro del Caño (PdC) said that while he had been working on his presentation he had referred back to his medical training which had reminded him that there was extremely limited information around cleft care. This created a challenge: cleft had a low incidence - which is good – and lower was what everyone wanted. However, cleft did not get sufficient attention.



PdC said that it was currently an amazing time to live in for healthcare with the rapid development of new technologies raising new possibilities - and there could be great opportunities for cleft care. The patient empowerment process was growing fast, and cleft should not be the centre of the life of the patient. PdC added that protocols should be for the whole treatment. Medical specialist committees determined which specific procedure to be used.

PdC stated that cleft was a typical case of personalised medicine - each patient should need a specific pathway. In Spain there existed a common informatics for primary health care and they had to be sure that information was accessible for healthcare professionals. Technology had given great opportunities to share knowledge and data. PdC stressed that children with cleft should not grow up thinking they are sick. In the future the call of the cleft team will be to share knowledge with team member CLPs wherever and whenever doctors and other professionals need it and can use it.

Discussion followed. PdC agreed with Emma Southby (ES) that cleft should be a huge priority for every doctor in training. It was very important to tackle the essentials of information so that lack of knowledge does not impact on children. Wilfried Wagner (WW) outlined goals for treatment. NB was concerned about being unable to make any changes and the scenario that cleft patients could become like an experiment. KK said that in Greece the gynaecologist is the only person who deals with the birth and therefore it is they who should have the specialised knowledge about clefts, rather than general doctors.

#### **11.45: How can health ministries ensure health guidelines are applied? (2)**

**Dr Vesna Knjeginjić, Assistant to Minister, Public Health Sector, Ministry of Health, Republic of Serbia**

Vesna Knjeginjić (VK) explained the organisation of the healthcare system in the Republic of Serbia. Guideline development was discussed with the associated aim being better treatment outcomes. The rationale for evidence based decision making was clarified with the goal being to reduce variation in practice. CB said that there was no way of checking that people followed the guidelines. Emma Southby (ES) said that in the UK they had developed a national service specification.



*How can health ministries ensure health guidelines are applied? Dr Vesna Knjeginjić presents her experiences at the Ministry of Health, Republic of Serbia.*

### **12.15: How can hospital service directors and medical directors ensure that guidelines are followed? (3)**

Dr Radu Spataru, Medical Director, Children's Hospital, Bucharest

Radu Spataru (RD) began by outlining the background of the hospital that he worked in and more broadly introduced the management of cleft lip and palate in Romania with a detailed description of his cleft team. The 500-bed Clinical Emergency Hospital for Children "Maria Sklodowska Curie" had a good tradition in primary cleft surgery and was the main centre dealing with clefts in Romania. 120-150 surgical procedures relating to cleft were carried out each year.

RD explained how the management of cleft lip and palate in Romania was

- still inappropriate, the treatment stages being many times chaotic
- there was a lack of coordinated general measures at national level – prenatal diagnosis, genetic advice, national registry, equal access to treatment, clear rules for cleft treatment
- there was a lack in multidisciplinary – team, coordinated protocols
- deficiency in information, both for professionals and for parents
- there were deficiencies in long term management

The consequences of this were that afflicted patients developed severe disabilities, both functional and aesthetic, such as speech impairment. Social isolation was another consequence, especially among poor families (including the Roma community); and there were a number of institutionalized children.

Strategies for improving cleft care required coordinating efforts of hospital service directors and medical directors and included:

- strengthening the cleft team structure
- training of specialist nurses;
- promoting contacts (e.g. with maternity units, antenatal diagnostic units and geneticists);
- clear leadership;
- access to information for parents.

The means for achieving this included establishing protocols of collaboration, encouraging common conferences, producing informative leaflets for the parents (with links to specialized sites) and harmonizing the guidelines

Feedback from patients allied with specialised training was very important, as was making common efforts in the same direction. Different interests / egos could get in the way. However, it was vitally important to establish a national programme for cleft care. ES said that because of low incidence it would be mostly patients and parents who pushed for change and also some health professionals from their own countries.

Katerina Koleventi (KK) explained her experience of cleft care in Greece. GD summarised the afternoon session

#### **12.45: Break**

#### **14.00: Working groups (1), (2) and (3) as above; i.e.**

- **Medical education**
- **Ministries**
- **Service providers**

Parallel discussion sessions followed with delegates split into three evenly sized groups to discuss and provide feedback on the themes introduced by earlier speakers.

#### **15.00: Break**

### **15.20: Feedback to plenary**

GD summarised the discussion and the differences between countries. Various important questions were considered, for example: how is it possible that cleft care became a part of the curriculum? Each working group reported back in full about their discussions. Common questions had been reflected on:

#### **A) Impact: Medical education**

The group spent some time discussing the great differences between the health and education systems in each of their countries (Belgium, Germany, Ukraine, Serbia, and Spain). The number of medical schools ranged between 6 and 40 which were 'managed' by either health or education ministries. This meant strategies to make an impact on curricula would be different in each country. However, everyone felt that the role of professional associations (craniofacial/cleft) was key and that their knowledge and experience, gained through research and expert opinion were probably key to having an impact at the right level. To retain their authority these bodies needed to promote evidenced based impartial research.

The message itself was also complex with a divergence of views between the need for basic cleft education (aetiology, types, typical treatment pathways etc.) obligatory for ALL medical undergraduates (with exam questions) to targeting only those groups who really needed the knowledge – i.e. post specialization (especially obstetrics, gynaecology, paediatric). The point was made that a general doctor may not come across a cleft child in their entire career so why should it be part of the undergraduate curricula.

In practice medical undergraduate resources across Europe were being squeezed so realistically it might be better to not place too much hope on changes at medical school level. Should cleft teams themselves take more responsibility for educating relevant people – e.g. midwives, pediatricians, sonographers etc.? Should they seek opportunities at relevant conferences to present at conferences of the above disciplines (this happens in Bulgaria and the UK – maybe elsewhere too?). What role could voluntary associations and pressure groups play in facilitating training at local and regional levels, beyond the medical schools.

#### ***Distilling the conversations to answer the pre-set questions:***

- **What do we want to happen? What is our desired result?**

The desired result is that when a child is diagnosed with a cleft, the person making the diagnosis, and those around them, need to have some basic knowledge of cleft care so they say the right things and refer on to the right people. The point was made that a lot of damage can be done in the hours and days after diagnosis.





*Group discussion*

- **Who are we trying to reach?**

This was complex given the different medical systems and educational environments in our countries. There is not a single solution. We need to reach those who have control over medical school curricula and medical deans. This will be either through working with Health Ministries or Education Ministries. However one area that seemed to be common for all countries is the power of specialist professional groups/associations (Craniofacial societies, surgical societies, interdisciplinary societies). Governments listen to these bodies. In the wider sense it was felt we needed to be looking at voluntary parent/patient led groups to facilitate training as well as we could not solely rely on medical schools. In this context we felt that there was an onus on the cleft teams themselves to promote education of appropriate people in their geographical area (e.g. midwives, sonographers etc.).

- **What is our message and why should it be heard?**

The message is that if a basic knowledge of cleft information is imparted to all those who are likely to be around at diagnosis of a baby with a cleft, then referrals to the right people will happen quicker, parents will be more reassured and supported meaning that there will not be 'bonding' issues and if timely care is provided there will be less burden on healthcare services and the family in the longer term.

- **Who should be giving the message?**

- cleft team specialists
- families/parents groups

- professional specialist associations (e.g. craniofacial)
- media articles /TV with com
- **How should the message be delivered?**
  - Scientific papers highlighting the importance of timely and correct information on clefts at the time of diagnosis
  - Letters from / lobbying by scientific professional associations to Ministries/Medical schools
  - Parents' stories collated for media articles
- **How do we know if we have been heard?**
  - When the issues expressed in 'desired outcome' are addressed

## **B) Impact: Governments and Ministries**

### • **What do we want to happen? What is our desired result?**

Optimal healthcare for all those born with a cleft. As well as improving the lives of the patient, this makes good long term economic sense with a cost/benefit advantage. This health economics 'business approach' should not be lost in the arguments for better care, and is important in the health ministries in both the high income countries who are concerned about the spiraling costs of health care, and in the developing world as well. The argument for the investment and focus on early care would be that this could potentially reduce the dependence of the individual on healthcare services. In the longer term we are potentially preventing a disability and ensuring that these individuals play their full part in society which particularly in the developing world does not currently happen.

- **Who are we trying to reach in each sector i.e. who will be able to action our demands?**
  - Health Ministers / Ministries
  - Parliamentary groups and other interest groups at government level
  - Health insurance companies
  - Local / regional government
  - Patient / parent organisations
  - Hospital Directors
  - Health professionals and especially sonographers and gynaecologists
  - Media – local, national, international
  - Social Media
  - Health Professional organisations
- **What is our message and why should it be heard?**
  - Cleft care is a basic human right. The principle of access to expert timely affordable health care is promoted by the WHO.

- Reducing inequalities is core to the EU health agenda. Reducing inequalities is more difficult than improving healthcare.
- We feel that there should be no problem with introducing minimum standards of care and our objectives are guidelines as opposed to directives.
- **Who should be giving the message and how should the message be delivered?**
  - Health professional specialist groups together with patient / parent / user groups
  - European Patients Forum (EPF - who presented earlier at the CEN workshop)
  - International bodies such as WHO, IADR (GOHIRN) and EUROcleftNet.
  - Use of real stories, patient case histories, anecdotes as well as compelling evidence based research studies (such as CSAG UK).
  - The message should be carefully put together – not ‘pitying’ but factual, honest and frank.
  - Taking a leaf out of the “Smile Train” and “Operation Smile” message. The message is designed to elicit both sympathy and empathy.
  - The message in Europe could mention abandonment, and its negative consequences, as well as the positive messages of transforming lives, rehabilitation and allowing people to reach their full potential.
  - Mass media AND social media.
  - Use evidence base and statistics where possible and appropriate.
- **How do we know if we have been heard?**
  - Before v after studies/statistics demonstrated percentage
  - improvement (e.g. Bulgaria study – abandonment issues)
  - Adoption of cleft guidelines/standards by official bodies
  - Whether concerns expressed in ‘desired outcomes’ have been addressed
  - Success with integration into healthcare policies
  - Become part of the European Reference Network
  - Appear in the narrative in H2020, and become fundable

### **C) Impact: Service Delivery**

- **What do we want to happen? What is our desired result?**

The implementation of guidelines across Europe. The impact of the guidelines varies across Europe, they are not as high as the service level in the UK but they are ambitious for Romania. They are oriented towards countries where this is a lack of service.

Romania – is looking for support from the Ministry of Health to create a structure. They need proper centres with minimal standards e.g. which specialties are involved. The service currently depends on people’s willingness to do things not a planned / standardized service. They want the Government to agree to help by setting up 6 or 7 centres with specified staffing by an agreed deadline. If the centres were established funding would follow. The service is paid for by National (rather than private) health insurance and in theory it’s free - but it isn’t in

reality because it doesn't exist. The guidelines help because they provide an argument for improved cleft care. This is good timing because the Paediatric Surgery leads are aiming to have a national programme for all congenital malformations, therefore this is a good opportunity to speak to them about cleft care. Investment in programmes such as child cancer care have seen a reduction in mortality and these help to show the benefits of investing in improved care. The barrier is that this is a new situation but the timing is good.

There are no recommendations on whether the surgery is carried out by Paediatric or Plastic surgeons and no control over who does surgery. The protocols state that they must have "appropriate level of expertise" but there is no definition of appropriate level, therefore they need support from the Government to control who does the surgery. They also need to review the "tariff" for cleft care since the fee for a cleft lip is lower than for an appendectomy.

It's too early to involve parents; there are Facebook groups but they tend to get less involved when their children are not receiving treatment.

Bulgaria – there have been increased communications with the Ministry of Health and things are moving but slowly. They need a dialogue with the right ministers.

Norway – There are two teams who meet twice a year and they can discuss the guidelines at the next meeting. It is against Government policy for any other teams to treat cleft patients, the Government can control the service because they pay the bill and the parent's society also got involved. Norway doesn't currently follow all the steps e.g. the role of the cleft nurse – they exist but are not specialist trained. They can use the guidelines to know what's going on in Europe, currently only Denmark and England have cleft nurse specialists as specified in the guidelines.

Ukraine - poorer than Bulgaria and Romania and parents have to pay for all the materials that used during treatment.

## Databases

Can be used for quality control but no money attached and records don't necessarily show what is good treatment. A prospective randomized control trial is the best way to look at techniques, however, the outlooks in cleft care are complex. It would be helpful to share knowledge of what databases work. Audit data could include: photos and impressions but these don't exist in the Ukraine.

UK - The CRANE database in the UK was set up during the review of services and is paid for by the National Health Service and there is a paid role to administer it.

Norway – the Government set up a Registry with a paid leader to run it. They have to make time to enter data but need to get parental consent (and child consent at 16). The service is based at a university hospital so they have permission to use the data for research.

## Training



Ukraine – opportunities for young doctors to have residency in another country but there isn't much money.

UK – The maxillofacial and plastic surgeons were competing over who did the surgery but the results showed they were equally bad so new rules were introduced and new surgeons had to do 6/9 months training in a recognized cleft unit.

Romania - Radu has operated in Norway and has had visitors in Romania who can observe surgery. Romania has had a partnership with Gothenburg involving 9 visits in 4 years. It didn't necessarily change the protocol but the whole team came which showed the importance of team working.

- **Who are we trying to reach in each sector i.e. who will be able to action our demands?**

All disciplines in each sector: health leaders, clinicians, parents and the ones with the money?

- **What is our message and why should it be heard?**

Cleft care is not good enough now and we are letting down our children. There are guidelines on how to provide cleft care and it's not too expensive to do it right.

- **Who should be giving the message?**

Parents using the media and promoting the guidelines. There are two arguments for their adoption:

- Evidence from research into the effects of centralization
- Costs can be reduced if the guidelines are followed because they will reduce the number of repeat surgeries required.

There needs to be clarity about how the guidelines can be used, what are the rules about their distribution. They could be a double edged sword: they are evidence of how a service should be provided but they could have a negative impact on parents who see that they are not getting this service.

- **How should the message be delivered?**

Use the media.

- **How do we know if we have been heard?**

Something will change and we will be able to measure the impact through looking at outcomes.

#### **15.45: Research perspectives – using CEN/TR 16824 as a tool for measuring, assessing and improving levels of cleft care**

*Professor Bill Shaw, University of Manchester, UK, EUROCLEFT lead*

Bill Shaw (BS) discussed levels of evidence from expert opinion to systematic reviews, and explained events from the 10<sup>th</sup> European Craniofacial Congress in Gothenburg, Sweden

during June 2015 (see <http://ecc2015.se/>) where a key theme was meeting the challenges of intercentre and international collaboration.

#### Article 2 – Objectives

2.1 To promote and facilitate the management of cleft lip and palate deformities, and related craniofacial anomalies, in Europe by

(A.) Organizing a multi-disciplinary European Congress held once every four years for dissemination of experience and knowledge in the field.

**(B.) Assisting and encouraging the establishment of European agreed standards and methods of assessment and documentation that would permit comparison of results of different methods of treatment worldwide.**

**(C.) Facilitating the establishment of multi-centre trials and research projects**

(D.) Promoting and encouraging multidisciplinary education and surgical support in the areas of the world where cleft care is not yet comprehensive or universal.

Since the government had made recommendation in 1998 date in 2015 data had shown that things had improved after centralising services.

BS described the contributions which projects and initiatives such as the Scandcleft group, UK national studies, Eurocleft / WHO consensus recommendations, TOPS (Timing Of Primary Surgery for Cleft Palate) had made. BS described barriers to progress such as:

- personal egotism of some clinicians
- competition between surgical specialities
- surgical training pathways
- lack of clinical leadership
- lack of responsiveness in health authorities - locally and / or nationally
- no tradition of record keeping

PM said that not all 'big' countries (in terms of population) were around the table.

#### **16.00: Global perspectives – opportunities for adoption by international bodies** **Peter Mossey, World Health Organisation collaborating centre for craniofacial anomalies**

PM described the network's previous workshop at the European Parliament in October 2012 which had highlighted some of the key discrepancies in treatment, care and prevention of birth defects throughout Europe – and which had made a case for a coherent European health strategy dedicated to congenital anomalies.

Since the last delegation to the European Parliament there was still a clear need for an EU-wide approach – from expert collaboration to formulating social and economic strategies. The workshop at the European Parliament the following day (Tuesday 22 March 2016) would be the group's next invaluable opportunity to raise awareness about the inequalities in healthcare, and in access to appropriate care across Europe. Cleft lip and palate would be used to illustrate what can be done in an effort to quantify and address such problems.

While guidelines are regarded as an excellent first step, the translation of guidelines into policy and practice is a much greater challenge, and a multi-dimensional approach would be required.

The European Parliament workshop was designed to deal with various components of the 'problem', i.e.

- public health and EU priorities
- clinical outcomes and standards
- patient perspective
- research

The workshop wasn't intended to only outline challenges, but was designed to provide potential solutions and conclude with an action plan that will have immediate, medium term and long term objectives for improving standards of care across Europe.

#### **16.15: Next steps – group discussion and recommendations**

Open group discussion forum led by Peter Mossey, Gareth Davies and Bill Shaw. Consensus around the need for (sustained) engagement with stakeholders.

For engagement and dialogue at a European level, a set of legal instruments (EU Regulations, Directives and other acts) at the disposal of the institutions is available at: [http://europa.eu/eu-law/decision-making/legal-acts/index\\_en.htm](http://europa.eu/eu-law/decision-making/legal-acts/index_en.htm)

See also [https://en.wikipedia.org/wiki/Policy\\_measures\\_of\\_the\\_European\\_Union](https://en.wikipedia.org/wiki/Policy_measures_of_the_European_Union) for information on policy measure of the European Union, including a description of how to get a "recommendation". Additionally, there are also the European Parliamentary questions, where a MEP can ask a question to the Commission and then the Commission provides an answer (see <http://www.europarl.europa.eu/plenary/en/parliamentary-questions.html>).

GD noted that there were many members of the original CEN Technical Committee around the table and that it would make sense to remain in touch on a regular basis and organise future meetings – even if only small – to drive implementation. Martin Persson (MP) said this would be most effective if the group members were given specific tasks to do, either collectively or individually. Task driven always achieves better results than meeting for the sake of meeting. Gareth said he would work on task-setting, focusing on themes that had come out of the discussion during the meeting.

[Please copy and paste links to your browser if they do not open automatically]

**17.00: Close**

## **Impact of new guidelines on the early care of babies born with clefts lip of the lip and palate**

**Brussels, 22 March 2016 (08:00-12:00)**

Hotel ibis Centre St Catherine (rue Joseph Plateau N°2)

<https://goo.gl/maps/JXkYX43S1Mx>

**Europe and Schuman meeting rooms**

**NB** This meeting was held in the hotel where most delegates were staying ahead of a planned workshop at the European Parliament (13:00-15:00). The proposed agenda for which is included at the end of this document.

Owing to the terrorist attacks in Brussels the European Parliament workshop was cancelled. To make best use of the network's time together, the workshop at the Hotel ibis Brussels Centre St. Catherine was extended.

The network continued to brainstorm and hold open discussions. Presentations intended for the European Parliament session were delivered and feedback provided. The meeting eventually broke up around 18:00 in the evening.

### **08.00 – 09.00: SESSION 1: GUIDELINES / DISCUSSION**

**Chair: Gareth Davies**

#### **Cleft guidelines coming out of translational research**

- The Cleft Collective, UK (15 mins)  
*Professor Nichola Rumsey, Centre for Appearance Research, Bristol, UK*
- Development of evidence based guidelines in the Netherlands (15 mins)  
*Dr Aebele Mink van der Molen, Utrecht, Netherlands*

#### **Historical Europe research context**

- Lessons for the future from last generation of collaborative research – the legacy of Eurocleft (15 mins)  
*Professor William Shaw, University of Manchester and Royal Manchester Children's Hospital, UK*

### **9.00 – 10.00: SESSION 2: FUTURE PERSPECTIVES/ DISCUSSION**

**Chair: Prof William Shaw**

#### **The future - the case for future collaboration and Europe on the world stage**

Network for Orofacial Clefts Research, Prevention and Treatment (EUROcleftNet) is a Research Networking Programme funded by the European Science Foundation



- The ScandCleft Project (15 mins)  
*Professor Gunvor Semb, Oslo*
- The Global Task Force (15 mins)  
*Dr Debbie Sell, North Thames Regional Cleft Service, Great Ormond Street, London, UK*
- Psychology research – European level research projects (15 mins)  
*Dr Martin Persson, UWE, Bristol, UK*

#### **The future - the case for future collaboration and Europe on the world stage (contd.)**

- Speech/Surgery research – the TOPS trial (15 mins)  
*Associate Prof Elisabeth Willadsen, University of Copenhagen, Denmark*

#### **10:00: Break**

#### 10.20 – 11.45: PAN-EUROPEAN PARTICIPATION/ DISCUSSION

#### **Encouraging participation from member states who have not engaged in the past – Horizon 2020 and European Reference Networks (ERNs)**

#### **Facilitator and introduction: Professor Peter Mossey**

Round table discussion following **brief** presentations on research ideas and past challenges from:

- **Bulgaria** – *Prof Youri Anastassov, Cleft Surgeon, St George's Medical University Hospital, Plovdiv*
- **France** – *Dr Cecilia Neiva, cleft surgeon, Necker Hospital, Paris*
- **Germany** – *Prof Dr Wilfried Wagner, Cleft Surgeon, University Hospital of Mainz*
- **Italy** – *Dr Maria Costanza Meazzini, Research Coordinator, Cleft Lip and Palate Regional Center, S.Paolo Hospital, Milano; Consultant for Craniofacial Anomalies, Dept. of Maxillo-Facial Surgery, S.Gerardo Hospital, Monza*
- **Spain** – *Dr Pedro del Caño, General Practitioner, Madrid*
- **Romania** – *Dr Radu Spataru, Cleft Surgeon and Medical Director, Maria Skłodowska Curie (MSC) Children's Hospital, Bucharest*
- **Serbia** - *Dr Julija Radojičić, Orthodontist, Cleft Centre, Medical University of Niš, Niš*
- **Ukraine** – *Dr Natalia Borchenko, Orthodontist, National Medical University, Odessa*

#### 11.45 Summary and way forward

#### 12.00 Close of formal meeting (note: room is available until 13.00)

Departure of delegates visiting European Parliament (workshop at Parliament from 13.00-15.00)

Action points arising from both days	Owner	Due by
Re-organise European Parliament workshop / alternative meeting with MEP/s	Peter Mossey	On-going
Using outputs from CEN workshop sessions define an ongoing strategy to implement the CEN guidelines	Gareth Davies	<ul style="list-style-type: none"> <li>Gareth to remain in touch with all participants with a view to setting tasks relating to workshop outputs: Ministries, Medical Schools, Service providers.</li> <li>Meetings by arrangement (Skype?). On-going</li> </ul>
European Reference Network applications	All	<ul style="list-style-type: none"> <li>Check own Member State deadline for national endorsement.</li> <li>ERN applicants wishing to apply to become an ERN and for grant (funding) must apply during the first period of the call (from the <b>16th of March 2016</b> to the <b>21st of June 2016</b>).</li> <li>ERN applicants wishing to apply only to become an ERN and not for funding must apply during the second period of the call (from the <b>23rd of June 2016</b> to the <b>22nd of July 2016</b>).</li> </ul>



## Impact of new guidelines on the early care of babies born with cleft lip and/or palate

**Objective:** This Workshop aims to raise awareness about the inequalities in healthcare, and in access to appropriate care across Europe, and will use cleft lip and palate to illustrate what can be done in an effort to quantify and address such problems. While guidelines are regarded as an excellent first step the translation of guidelines into policy and practice is a much greater challenge, and a multi-dimensional approach will be required.

The proposed workshop schedule will deal with various components of the problem, which are a) Public Health and EU priorities b) Clinical outcomes and standards c) Patient perspective d) Research e) Summary and Discussion.

The workshop will not only outline the challenges, but will be designed to provide potential solutions and conclude with an action plan that will have immediate, medium term and long term objectives for improving standards of care across Europe.

Venue: European Parliament, Brussels, Belgium (room A5F385)		
Tuesday 22 <sup>nd</sup> of March, 2016		
5 min	Welcome / Opening remarks	Seán Kelly, MEP
5 min	Introduction to workshop	Peter Mossey
Public Health		
7 min	Public Health and European priorities in relation to Orofacial cleft	Martin Persson
7 min	Policy & Public health in relation to Eastern Europe perspective	Vesna Knjeginjić, Ministry of Health, Republic of Serbia
Inequality in provision of care		
7 min	Surgical	Radu Spataru / Youri Anastassov
7 min	Orthodontist	Julija Radojičić
7 min	Nursing	Kostadinka Bojikova / Nina Lindberg / Emma Southby
7 min	Psychological aspects	Nichola Rumsey
Patient perspective		
7 min	European Cleft Organisation	Gareth Davies
7 min	Patient perspective from Spain	Pedro del Caño
Research		
7 min	The way forward towards clinical improvements	Bill Shaw
Summary and discussion		
25 min	How can EU assist with solutions in order to ensure equality of care	Peter Mossey
<b>Total time</b>	<b>98 min</b>	(10 min extra time available for change of speakers)

### *European Parliament workshop agenda*