

## **TASK FORCE “BEYOND EUROCLEFT”**

**Gunvor Semb, Trisha Bannister, Haydn Bellardie, Kathy Chapman, Jeniffer Dutka, Ron Hathaway, Anne Marie Kuijpers-Jagtman, Gayatri Moghe-Ghadyalpatil, Terumi Okada Ozawa, Philippe Pellerin, Jorma Rautio, Nichola Rumsey, Debbie Sell, Bill Shaw, Bernard Tansipek, Elisabeth Willadsen**

### **ASSIGNED OBJECTIVES OF THE TASK FORCE**

The organizers of Cleft 2013 proposed that: the objective for this task force would be “to make recommendations for initiations of local and/or participation in multi-national cleft outcome studies”. It was suggested that: “the Task Force should consist of individuals from the European experience with cleft outcome studies (Scandcleft, Eurocleft) and those who have initiated, or intend to initiate, similar studies in other geographical areas”.

The suggestions and comments from colleagues having participated in multicentre studies showed that the objective assigned left room for different interpretations. Since this was an international congress with participants from many different disciplines and cleft interest groups it was decided that this initiative should be truly global and include all the specialties involved in cleft care as well as representatives from affected families and/or patients.

### **TASK FORCE FUNCTIONING**

#### **Membership Acquisition and Demographics**

In July 2012 contact was made with a small group of individuals with a previous interest in the topic and a great deal of support and advice was received. Over successive months an attempt was made to extend the group so that most regions of the world and a broad range of disciplines were represented. The members were asked to suggest other representatives in their regions who could contribute.

The letter of invitation included a “questionnaire” for information on the members' experience and ideas for how the Task Force work should progress. The information requested was:

- The members' involvement with collaborative cleft care and where you work
- The members' motivation for joining this specific Task Force
- The members' experience in planning and/or participating in inter-center outcome studies
- The members' ideas for the direction of this specific Task Force
- The members' suggestions for how this Task Force should be organized.

By May 1<sup>st</sup> 2013 two hundred and twenty-three individuals had been invited to participate. Thirty-one (13.9%) individuals did not reply, 9 (4%) said “no” or “not now”, the reason given as work overload. Positive replies were received from 183 (82.1%) individuals.

The members were from the following geographical areas: 12 from Sub-Saharan Africa, 5 from The Middle East, 15 from North-and 30 from South America, 23 from Asia, 3 from Australasia and 95 from Europe.

The disciplines represented so far are: 59 surgeons (44 plastic surgeons, 13 maxillofacial surgeons, 2 pediatric surgeons); 61 dental specialists (57 orthodontists, 2 pediatric dentists, 1 prosthodontist, 1 dental therapist); 28 speech pathologists and 1 pediatrician with speech interest; 12 nurses; 8 ENT surgeons/audiologists; 4 psychologists; 3 social workers; 1 geneticist; 1 basic scientist; 1 team coordinator; 1 physiologist/researcher; 1 epidemiologist; 2 representatives from cleft support groups

## **Method of Interactivity**

The communication between members was by e-mail and face-to-face meetings at conferences during the recruitment period.

During the recruitment process the organizers and the members were informed about the progress of the project, received contact details and individual members' responses to the questionnaire.

It was obvious from the start that subgroups should be formed. The members had suggested working groups to be established according to 1. discipline 2. geography 3. special interest groups to concentrate on prioritized issues. It was recommended that a lead for each working group should be chosen.

## **Survey of Members**

168 (92.8%) of the 183 completed a questionnaire survey:

### Members' Involvement with Collaborative Cleft Care

- 114 (68%) of the members replied to the questionnaire have been or are working in multidisciplinary teams that are/have been participating in multi-centre or multi-national comparative outcome studies
- Of the 54 members who have not participated in comparative outcome studies, 12 (22.3%) of members are/have been involved in other intercentre/international collaborative work. Twenty-nine of members (53.7%) have expressed a keen interest to participate in outcome studies in the future. These members are working in teams that might not be fully established yet and systematic documentation and follow-up is difficult. Thirteen members (24%) are working hard to establish a multidisciplinary cleft team.

### Members' Motivation for Joining this Specific Task Force

The vast majority answered that their main motivations are:

- a passion to improve cleft care not only in their own countries but also worldwide
- to increase their knowledge and learn from others
- to achieve agreement on global standards for documentation and outcome measures for all disciplines and cleft types
- to initiate multi-national or international collaboration as this is the only way to achieve evidence based care
- to link resources between established teams

### Members' Ideas for the Direction of this Specific Task Force

1. To make a global survey of access to care, existing outcome studies, current collaborations and lessons learned.
2. To define a strategy for areas where presently there are no multidisciplinary teams: Offer support, advice and help to establish multidisciplinary teams.
3. To define a strategy for teams who have conducted no or few outcome studies or collaborative studies:
  - Provide rules and guidelines based on earlier collaborative studies, together with support and advice.
  - Arrange hands-on workshops, lectures or whatever else needed to get started.
4. To define a strategy to go "Beyond Eurocleft":  
Reaching agreement on global standards for timing and type of documentation and consensus on outcome measures in all disciplines and for all cleft types including adults as well as younger patients.

- Focusing more on patient/family centered outcomes, on burden of care and quality of life. Develop a set of uniform quality indicators for cleft care based on sound research data that could be used as measures for quality of care.

### Members Ideas for Organization of the Task Force

We need to:

1. Establish an international network of people from all countries and cleft disciplines as well as representatives from patients and/or families.
2. Establish the **main** aims and objectives. Define long-term, realistic goals (for the congress in 2017).
3. Establish working groups according to discipline and/or geography and/or special interest to concentrate on the prioritized issues. A lead for each working group should be chosen.
4. Have frequent communications via e-mail, Skype or videoconferences and hopefully an annual face-to-face meeting. Explore funding opportunities to make face-to-face meetings possible.

### **How Issues Evolved during the Process**

It was decided in the first instance to set up subgroups according to specialty. Contact was made with colleagues that had been part of international or multicentre outcome studies and were recognized and respected in their field. They were asked to provide a summary of their subgroup for the Orlando Congress.

Members also thought it important to start discussions in special fields of interest at the Orlando Congress. Ten focus groups were suggested and members were asked to choose two options for their participation in round table discussions. For practical reasons three of the planned focus groups were combined.

#### *1. Focus Group on Development of a CLP Team*

The members of this group wanted to establish a multidisciplinary cleft team in their geographical area and brainstorm with other professionals in a similar position and hopefully also with members with long-term experience in team-work. Seventeen members signed up for this group.

#### *2. Focus Group for Intercentre Comparison Studies*

The members of this group were interested to meet partners to set-up collaborative studies to compare treatment protocols and treatment outcomes. Building upon earlier studies of this kind would enable members to design and perform such projects rather quickly. Twenty members signed up for this group.

#### *3. Focus Group on Documentation and Outcome Measures*

The members of this group were keen to develop advanced documentation and outcome measures according to contemporary standards. Quality of life measures, early predictors of long-term outcome, and burden of care were also topics that needed to be addressed. The participants may want to define subgroups for different topics. Twenty-eight members signed up for this group.

#### *4. Focus Group for Studies beyond Eurocleft, creating a Website and establishing and maintaining "Beyond Eurocleft"*

The members of this group had participated in intercentre studies before. They wanted to brainstorm to define areas and research questions that still need to be investigated by a collaborative approach. Topics to discuss were prospective cohort studies, clinical trials, basic science studies, large-scale genetic and epidemiological studies, patient centered outcome studies, and development of quality indicators for cleft care. This initiative could lead to new research consortia that address particular questions.

Members also wished to discuss how to promote and sustain the project as a whole. Thirty members signed up for this group.

#### *5. Focus Group on Communication between Researchers and Clinicians*

The members of this group strongly believed in the mutual benefit of collaboration between researchers and clinicians and would like to improve their communication and develop guidelines for proper acknowledgement of the contribution of both parties. Ten members signed up for this group.

#### *6. Focus Group on the Establishment of Cleft Confederations in different Parts of the World.*

The members of this group would like to collaborate to establish suitable confederations to promote and support "Beyond Eurocleft" in different parts of the world. Philippe Pellerin has taken the initiative for this group where nine members participated.

#### *7. Focus Group for Nurses*

As nurses are not yet a member of cleft teams in many countries, the nurses in the Task Force felt it was necessary to set out the role of the nurse both in hospital and outreach in all represented countries. Seven members signed up for this group.

#### *8. Focus Group for Sub-Saharan African Countries*

There is a huge shortage of multidisciplinary cleft care services in Sub-Saharan Africa. Contacts with some clinicians in the area had been established and there was a need for participants to get acquainted and plan a strategy for future collaboration. Nine members signed up for this group.

### **TASK FORCE ACTIVITIES at the ORLANDO CONGRESSS**

The planning of the Task Force meetings started early in 2013. By April 121 members had confirmed their participation in the Task Force activities. The participants were informed of their allocated focus group and sent list of possible discussion points. The European Recommendation and Guidelines for Cleft Care was also disseminated before the meeting. The agenda consisted of presentations from members and round table discussions.

#### **Summary from Leaders of Specialty Groups**

##### ***Surgeons' group: Jorma Rautio***

There were 59 members from 28 countries in this group. All continents were represented. Many of the European respondents had a background in the 1996-2000 Eurocleft project (Standards of care for cleft lip and palate in Europe) that set guidelines for the treatment of patients with clefts, surveyed how treatment was set up in the different countries and provided a registry of cleft units. There was interest in updating this information.

Standardized data collection and outcome measures were called for to facilitate intercentre comparisons. Standardized common treatment protocols between centres would help in cooperation and assessment of outcomes and increase sample size. There was a call for integrating cleft care and research at the national level but some felt that regional and interdisciplinary rivalries made collaboration across borders easier than within one's own country.

More work was needed on assessment of nasolabial appearance. 3D image scanning may be helpful in this respect. Techniques of optimal bone grafting procedures may warrant a trial and also defining the role of cone-beam tomography in analyzing the results. Other areas of particular interest could be the best technique for primary rhinoplasty in clefts or how to best repair the lip and nose in patients born with bilateral cleft lip and palate. Closing the cleft in unilateral cleft lip and palate in a one-stage procedure should be compared in randomized trial comparing it with a suitable two-stage approach.

There was widespread interest in multicentre trials although many had no experience of such studies. Keys to success were keeping the amount of participants to a manageable level, simple protocols that do not overtax centers with more sparse resources, a good personal

relationship between the specialist involved and regular, preferably annual, meetings between the research group members involving lectures and discussions.

About 15% of the surgeons worked in areas where there was very uneven access to care for the poorest populations which is a big problem. Record keeping is difficult and long-term outcomes are hard to assess. Many have found cooperation and assistance by Smile Train to be helpful. In contrast brief cleft missions by foreign surgeons were considered to produce poor results and no continuity of care. (The challenges of these difficult working conditions are discussed later in this report).

At the Task Force meeting a group of colleagues found they had a common interest in collaboration on Pierre Robin Sequence and planned an international consensus meeting on October 31st to November 1st 2014. "Diagnosing, analyzing and treating Robin sequence" Utrecht, The Netherlands.

### ***Speech pathologists' group Elisabeth Willadsen and Kathy Chapman***

This group consisted of 29 members from 19 countries. All continents except Australia were represented.

The majority of participants expressed a keen interest in taking part in multidisciplinary, inter-center, and inter-language outcome studies. In addition, they expressed a need for the development of rigorous methodology regarding speech outcome measures and analyses to be used in inter-center studies. The prevailing view of the group was to establish sub-groups in topics of interest. This would control group size, but at the same time keep an interdisciplinary focus.

Suggestions for future work:

1. to organize a practical seminar that would include information about: how to collect outcomes, the records needed, the specific speech outcome parameters that should be measured and the common terminology that could be used and understood by all cleft professionals.
2. to support colleagues in developing countries and in countries with few economical resources. Individuals from these areas expressed the need for "local support", so they could begin to develop collaborations with centers that have comparable working conditions and that are within reasonable travel distances. Another suggestion was pairing experienced and inexperienced members of the Task Force as a means to help "jump-start" outcome studies.
3. to collaborate in studies of early intervention for speech and language, and consideration of ICF perspective (International Classification of Functioning, Disability and Health).
4. to create a website for discussions and development of ideas within the different subgroups and identify a webmaster to maintain the site. This proposal will need funding.

It was mentioned that the existing CLISPI website (Leader Anette Lohmander) might host such a resource. These webpages ([www.clispi.org](http://www.clispi.org)) were originally created within the Eurocran project in order to disseminate the recommendations by the Eurocleft network and for sharing information from the Scandcleft project on how to collect, record and analyze cleft speech across different languages.

The webpages are now internationally extended (Cleft palate International SPeech Issues - CLISPI) and further developed. The aim is to encourage good practice among clinicians aiming to collect, record and analyze speech to a high standard and in similar ways, wherever they work. There are also suggestions for equipment, setting, and ages for documentation as well as general information on devising speech material, the speech material to be collected at different ages, and language specific single word assessment and restricted speech assessment (cross-linguistic). There are also suggestions on elicitation techniques and the listening exercises.

Some members of this group have continued collaboration of clinical and research outcome data and will present a symposium: "Study guidelines on cleft palate speech" at the International Clinical Phonetics and Linguistics Association conference (ICPLA) in Stockholm, June 2014.

### **Orthodontists' and Dental Specialist's group: Ron Hathaway**

The group consisted of 61 dental specialties, 57 of them were orthodontists, 2 pediatric dentist and one dental therapist from 34 countries. All continents were represented.

The majority of responding orthodontists had some experience of intercentre comparisons, including a smaller group who had been involved in at least one randomised trial. On the other hand, a significant proportion was enthusiastic about participation in such studies but felt they lacked the knowledge, opportunity, or resources to embark upon this.

There was a strong expression of the importance of multicentre studies to improve the evidence base for cleft care, both by those who had already participated in such research, and those who were yet to do so.

The commonest proposal for the direction of the Task Force was for the creation of a website that would provide a resource for teams and individuals wishing to start standardized record collection and embark upon outcome studies, whether local or multicentre. Several respondents with experience of rating outcomes also expressed a willingness to provide help and support for newcomers to this activity.

Several of the orthodontists considered naso-alveolar molding to be a subject of urgent multicentre research.

Attention was also drawn to the need for groups in different countries to work in a collective manner in defining outcome measures, to avoid the production of reports that could not be compared.

A range of parallel approaches would be required depending on the experience, resources, and challenges of regions, teams, and individuals. The need for creation of a register of teams and research interests, such as that developed in the Eurocleft Project, "Standards of care for cleft lip and palate in Europe" carried out in 1996-2000 (but now needing revision).

### ***Nurses' Group: Trisha Bannister***

This group had 11 members, 10 from Europe and one from USA.

The first job would be to set out the role of the nurse both in hospital and outreach in all represented countries and look at models of care around antenatal diagnosis, birth and hospital admissions. It is important to gather information of cultural approaches to feeding an infant born with cleft lip and/or palate

Suggestions for collaborative projects were:

- Investigate the support needs of parents at diagnosis.
- Study factors that empower parents in different cultures in order to make suggestions for care.
- Study parents' perspective of the antenatal face at diagnosis and then after birth
- Investigate different models of care and outcomes for infants born with Pierre Robin Sequence.
- Make an overview of pain-assessment, length and level of hospital stay and feeding after surgery in different countries, looking at factors which influence any given model.
- Study the information and education needs of parents and children throughout the treatment period.

- Design a training package/passport for nurses delivering care.
- Study the needs of adopted children and their careers/adoptive parents.
- Agree on minimum standards of care.

The nurses had a separate focus group at the Orlando meeting consisting of nurses from the UK, Denmark, Finland, USA, and Norway. After discussions the group decided to look into the development of a possible feeding program for infants born in areas of the world where there is no hands on support and advice on maximizing nutrition for these infants. A decision was made to gather the available literature around general nutrition programs already in existence.

As the next International conference is in India it was decided to concentrate on an area within this country, especially as Dr Jyotsna Murthy, the president of Cleft2017, had appealed for help at the Orlando conference. Articles were circulated, discussions were had with American colleagues involved in overseas care and possible avenues of funding was explored. An attempt was made to gather the contacts of the international regional representatives involved in existing programs and look at the success of various rural programs. Information was sought about the "Nifty cup", as it is not yet clear whether this is an acceptable method of feeding.

It would appear from the available literature that there are some very successful regional programs addressing nutrition in parts of India where a combination of professional and locally trained support workers are making improvements. In a later telephone conference members of the group discussed with the Assistant Director of International Programs and a member of Operation Smile, the possibility to bring those people already involved in International Programs together. This idea needs further discussion and a formal business plan to be developed.

#### ***Psychologists group: Nichola Rumsey***

This group has 4 members, 3 from Europe and 1 from South-Africa.

As cleft/craniofacial professionals around the world are at very different stages of development, we see a key task as being to facilitate their development – and in doing so to try to make it collaborative and avoid domination in this process by the more advanced countries. To generate a better consensus can be a challenging process, and has to be done with some degree of compromise from all parts and a strong focus on dialogue. Individuals involved in helping others in developing networks and larger projects should have a certain experience of the importance of such dialogues, and their importance for further motivation and commitment to a study.

The hardest task will probably be to develop simple documentation/measurement protocols, which are acceptable to all. Maybe one of the early tasks should be to undertake a simple survey of patients/parents views of what the key outcomes should be in cleft care. This could then be used to drive the shared protocols in multi-national outcome studies.

In the light of recent research findings, and from a recent exercise in the UK to establish research priorities from a patient/family perspective it is strongly felt that long term (adult) outcomes should be high up on our agenda.

A key priority is to identify the 'next generation' of enthusiasts for collaborative work and both national and disciplinary representatives are needed to drive these initiatives forward. An over-reliance on only disciplinary groups has considerable drawbacks, as the numbers of people belonging to the various groups (and the resources available to members of different professions to attend meetings) varies considerably between groups. I also believe that a multi-disciplinary perspective on assessing outcomes is an important one to retain. For those ready to engage in research, existing European networks could perhaps be extended beyond Europe - or international delegates could join the European ones if funding can be found for travel. The psychologists are of course keen to encourage providers to collect patient-centered measures. This could be facilitated in a similar way via a new research network that will be established this year, which will focus on psychosocial issues associated

with differences in appearance (but could be extended to other psychosocial issues too). The network will have 5 working groups, with one focusing on sharing good practice in research and on developing research networks relating to psychosocial issues in cleft/craniofacial care. The network will have funding for training workshops (for delegates from Europe) and short-term exchanges, and maybe some of this activity could be harnessed/extended to international delegates should funding be forthcoming.

***Cleft Interest Group: Information on European Initiatives. Gareth Davies***

This task force group has so far only 2 members from Europe. None of the members participated at the Congress.

The European Cleft Organization (ECO) is currently embarking on a project under the auspices of the European Standards Agency in Brussels (CEN) to produce a set of guidelines on early cleft care. The importance of evidenced based recommendations based on reliable outcome studies is crucial and these guidelines, when published, will provide a useful template for cleft care services.

Another initiative is the EUROcleftNet establishing a European network of health professionals and scientists which will make recommendations on future research in treatment and prevention of clefts. As part of this programme, ECO is building a web-based resource called the European Cleft Gateway, which will provide a directory of cleft services in Europe and a list of past and present research studies. In time the resource plans to host an online research library for the benefit of health professionals and users alike - worldwide.

***Sub-Saharan Africa group: Haydn Bellardie, Ranti Da Costa, Merley Newman-Nartey, Aisha Sekalala-Bataringaya, Emad Ghabriel***

The Focus group on Sub-Saharan Africa was very well received with a great deal of interest and enthusiasm from the Sub Saharan Delegates. Great interest was shown in establishing connections between countries and units.

There was a very good response and interest shown in establishing a Task Force for Sub Saharan Africa with replies from the 27 Orlando delegates from Sudan, Ethiopia, Ghana, Nigeria, Senegal, Gambia, Uganda, South Africa and the Congo. The respondents include a speech pathologist, orthodontists, maxillo-facial surgeons and a plastic surgeon.

There are many gaps in our knowledge of incidence and provision of cleft care in Sub Saharan Africa and one of the main areas of concern is the shortage of multidisciplinary cleft care services and the shortage of cleft specialists. The challenge being to improve the quality of the current services. In many countries surgical care is provided but other cleft related specialties are poorly represented in the care pathway.

It was suggested that due to the great cultural and language diversity in Sub Saharan Africa, language and geographical sub-groups should be formed. These groups will provide mutual support and an opportunity to collaborate in development and research.

It has also been suggested that those who are involved in cleft care should, with the help of the Task Force, be encouraged to engage with local Health Departments, Professional bodies and Universities and promote the provision of all aspects of care thereby creating multidisciplinary services.

Ultimately it would be ideal if the Task Force could encourage intercentre collaboration to measure outcomes and in time establish Africacleft. The hope is that this collaboration will be under the umbrella of an advisory body which has most experience and that in time the group, which should be multinational, will develop into regional units and groups.



One of the main comments from the delegates was the gross shortage of cleft care specialists in the Sub Saharan Region. In the whole of East and Southern Africa (Kenya, Uganda, Tanzania, Malawi, Zambia, Zimbabwe, Botswana, Angola, Mozambique, South Africa, Swaziland, Lesotho and Madagascar, with a population of about 270 million) there are only about: 130 plastic surgeons, 120 maxillo-facial surgeons, 120 orthodontists, 4000 + psychologists, 2100 speech therapists, 0 clinical nurse specialists, 4000+ dentists

Of these the vast majority are in South Africa, and only a handful have experience in or provide cleft care. Most countries do not have any cleft specialists from any discipline and cleft care is often provided by general or pediatric surgeons and other non-specialist practitioners.

For many of the patients there are extra problems beyond the cleft. These can be associated with travel, social and work conditions. Access to care particularly from distant rural areas can involve a three-day journey to the nearest health facility. The cost of transport even for urban people can be a big challenge. In many countries the burden of paying for care and transport lays with the family not the state or health department.

A significant and often mentioned area of concern amongst the delegates was the subject of aid, how and who provides it and the way certain images are used to portray Africa. It is not uncommon for the worst aspects of Africa to be used for fund raising, e.g. that of a malnourished child with flies around the mouth and a tear in the eye. Is this an image which is more likely to generate donations, one wonders? The consensus was that 'aid' be more closely monitored and that all health aid organizations work with established medical, nursing and dental schools, professional bodies and societies.

Bearing in mind that for many of these countries there are priorities about education, health and economics the main concerns of the Sub Saharan group were;

- the staggering shortage of personnel
- the challenges in improving the availability and access to care
- the training and support for local care providers
- the establishment of multidisciplinary care
- and linking up with established units.

***Focus Group on developing Cleft Teams. Debbie Sell, Gayatri Moghe-Ghadyalpatil, Bernard Tansipek***

About 25 % of task force members work in areas with few or no comprehensive cleft teams, few resources and very difficult working conditions. The focus group dealing with development of cleft teams has submitted a comprehensive report. The group at the Congress consisted of 17 members from 13 countries (9 surgeons, 5 speech pathologists, 2 orthodontists and one pedodontist). The report also includes information from the individual members' replies to the Task Force survey. It is hoped that the complete report will be disseminated to a much wider audience.

**A brief summary:**

One of the overwhelming characteristics of this focus group's membership was one of passion, enthusiasm, willingness and commitment to cleft care, wishing to improve knowledge and services to patients, realizing the need to evaluate outcome and having a desire to learn from others' experience.

Their main motivation to join the Task Force was to support any global cleft initiative on research, treatment protocols and evidence based care in the Developing World. Indeed, in developing countries and areas, this particular craniofacial anomaly has been frequently abandoned and needs urgent attention. The expectation was that this Task Force would be able to improve cleft care by helping to stimulate record collection and initiate outcome studies, which would have a big contribution in improving the quality of care for patients with clefts. Another motivation developed from the desire to be able to use the group for political leverage to improve awareness, funding and resources, and to act as quality control of cleft care.

## Challenges

The many challenges for undertaking outcome studies were reported in detail. These included:

- Women and newborn health considered a low priority.
- Poor patient recall leading to lack of adequate follow up, no database registries.
- Difficulties in access to care and in affording treatment.
- Poor patient/family understanding of the typical pathway of cleft intervention.
- Lack of appropriately trained team personnel, equipment and resources.
- Untrained personnel providing dubious treatment increasing burden of care.
- Lack of financial help from NGOs for recordkeeping and outcome studies.
- No funding for professionals to attend meetings and get involved in intercentre studies.
- Understanding the impact of socio-economic conditions on outcomes.

## Missions

Another area of much comment was the impact of missions. These continue to be undertaken by both local and foreign groups, even though when there are already local teams available to see patients. Missions do not provide holistic care; often leaving patients with poor or inadequate follow-up. There is frequently no mention of continuity of ancillary care that is a must for rehabilitation. There is also a major untoward effect on the population. They often view clefts a problem which should be reserved for missions only and therefore will not seek treatment for a newborn child with a cleft. Furthermore with regard to outcome studies the incidence and prevalence of individuals with cleft lip and/or palate is disturbed by these patients being managed by missions, thereby potentially limiting the number of patients in outcome studies. Indeed an interesting view was expressed: “the mission method of providing cleft care is an old model” and must be reserved for areas that do not have ANY capability of providing cleft care. There should be national and international coordination and cooperation in their delivery where these are undertaken.

The end goal of the mission approach (if it must be done) must be the following:

- to provide the needed cleft treatment for patients
- to coordinate with the local staff and begin forming a local team to provide care
- to begin information dissemination regarding cleft care to the local population.

## Experience of Research

Many of the respondents had not been able to undertake any research, had little experience in planning and or participating in inter-center outcome studies, but were very enthusiastic to do so. Some had visited teams overseas, but not all the models observed overseas were directly transferrable. There were also some excellent examples of well-established centers active in research with many collaborations. Many viewed Eurocleft and Scandcleft as a model for intercenter outcome study. One quote: “Intercenter collaboration can function as a benchmarking process which can lead to good practice sharing among cleft centers and breakthrough innovation in cleft care”.

## Twinning with Established Centers

There were examples of teams in less developed parts of the world working in partnership with a well-developed team, with much pride in benefits. After the Orlando meeting information of two “twinning” of teams have been reported.

## Recommendations for the Task Force

- Cleft Lip and Palate should be listed as a NOTIFIABLE defect worldwide. If such a law is enacted it would automatically facilitate formation of cleft registries and generate a realistic picture of the burden of care.
- This task force should function as the "Heartbeat" and/or support center for outcome studies globally. The task force would come up with a 'model' or 'pathway' for how national outcome studies should be undertaken given the proviso that resources and government/health department bureaucracy in countries might dictate slight or significant “detours”.

- One group believed the priority was for the task force to be directed towards firstly setting up teams in the developing world, initiating interdisciplinary care rather than multidisciplinary treatment, setting up protocols of care, and developing the standards for evaluating the simpler outcomes initially.
- To set mind maps for clinical situations unique to the developing world where the patient does not report on ideal time, encouraging cleft care with minimum burden in terms of finances, encouraging collaborative research and finally looking at setting up a remote unit where tele-medicine and web medicine can have a reach out to the needy.
- To identify centers with a lack of all specialties and try to improve upon the prevailing situation.
- To start community outreach programs for continued care after surgery.
- To help provide education for the medical and/or dental professionals who take care of the patients with clefts.
- A holistic approach is required as there are a lot of social issues that need to be dealt with not just the medical, dental and speech problems alone. These socio-economic issues if they are ignored will lead to failure or poor outcomes.
- Small steps and simple targets are recommended at the beginning for outcome studies. Epidemiology and holistic care should be our initial areas. Surgical technique, speech outcomes and growth outcomes are much more difficult due to the wide range in ability, quality and willingness to participate. These can follow once we hit the low-lying fruit.
- Even at present there are NGOs who closely work and support their cleft teams. Probably WHO should take the initiative of this task force. It needs to identify its Vision and Mission.

Drawing on the last two reports the following recommendations for the Task Force are common to both:

- Encourage and implement multidisciplinary care
- Link with established research teams
- Link and twin with advisory units for specialist training
- Create regional groups to liaise with an umbrella group
- Start collecting records as soon as possible
- Develop a template for basic collaboration amongst teams
- Develop a roadmap/template for undertaking single center or multicentre studies
- Use standards for cleft care to act as political leverage for funding, resources and the management of missions
- Aim to make the Task Force to function as the “Heartbeat”/Support/Center for outcome studies/sharing/problem solving/lessons learned
- Recognize the huge commitment and enthusiasm towards improving services in the Developing World

**Brasileleft by Terumi Okada Ozawa and Jeniffer Dutka:  
An example of building up a multicentre collaborative initiative**

Brazil is the world’s fifth largest country with about 200 million inhabitants. By the end of 2011 there were 26 cleft centers registered with the Ministry of Health to treat patients born with cleft lip and palate. A large multidisciplinary cleft and craniofacial center in Bauru, São Paulo, started standardized record taking some time ago and intercentre outcome comparisons of dental arch relationship in UCLP and BCLP have been completed. The Team has also completed a randomized control trial of primary surgery (Florida Project) and initiated a cleft prevention project was initiated the 1990s, both funded by National Institutes of Health, USA.

Learning from the international collaborative projects and observing the progress reported by Europeans (Scandicleft, Eurocleft) and North American (Americleft) 17 Brazilian centers engaged in a task force with the goal of establishing parameters for outcome documentation: the Brasilcleft initiative.

Since 2011 the professionals involved with the Brasilcleft Initiative have met regularly:

2011: first official meeting with invitations for all Brazilian teams to join to the Initiative

2012: surgeons, SLPs and orthodontists met twice during the year to discuss protocol and outcome measures, sharing lectures, workshops, panel discussions and training sessions

2013: two national multidisciplinary meetings for development of tools for outcome documentation and training of professionals.

Further plans:

- SLPs have meet with experts from Europe and North America and have improved the documentation protocol and started a reference data bank of speech samples
- All 17 teams involved in the task force will use the same protocol for speech recording and editing starting in 2014
- Workshops for training SLPs from all teams to engage in multiple judges' ratings of speech are planned and should address the possibility of online ratings to avoid mobility problems
- Issues regarding confidentiality and security of patients' and centers' data are to regulated before online ratings are established
- Following discussions during the International meeting at Orlando, May 2013 the Brasilcleft task force plan to address measures of quality of life and burden of care in 2014
- Data collection, storage, scanning and rating work-shops are on-going. Some inter-center comparison studies have been done.
- A protocol for capturing, editing and rating facial appearance will be completed in 2014
- A protocol for describing the routine surgical procedure as well as modifications implemented during surgery
- A protocol for documenting post-surgical complications (Fistula, dehiscence, hemorrhage etc.) is being written

A Brasilcleft blog is under development to allow team members to share the task activities and to communicate more effectively.

Colleagues from other countries in South America have also participated in these meetings. The final goal is to establish a South-American Cleft.

## **CONCLUSIONS OF CLEFT2013 TASK FORCE**

There is an overwhelming sense of passion, enthusiasm, collaboration and willingness to improve cleft care in this group. It is also very clear that the great majority in the Task Force members want this to be a global initiative, recognizing the huge commitment for improving cleft care both in the Developing World and in countries with established multidisciplinary centers. It was suggested to change the title of the group to Global Cleft (Initiative/Network?). The vision for this group is to build a dynamic, well-functioning Task Force that will work globally and multidisciplinary with inclusive and respectful behavior to improve care for all individuals born with cleft lip and/or palate.

At the Congress members confirmed their motivation and ideas for the direction and organization of the Task Force expressed in their answers to the Survey of Members (listed in the beginning of the paper). As there is a large diversity in needs and interest in the group a range of parallel approaches would be required depending on the experience, resources, and challenges of regions, teams, and individuals. Many recommendations for future work have also been listed in reports from the different specialty groups and focus groups.

The commonest proposal from members was to make a global survey of access, existing outcome studies, current collaborations and lessons learned. The Task Force should also work towards the creation of a lasting, living resource for newcomers to intercentre collaboration that is kept fresh with new reports, copies of relevant publications, model grant applications, and a list of volunteers with the right experience to provide support and guidance for new initiatives.

Another key collaborative task would be to develop simple online training modules to provide information about the benefits and principles of multidisciplinary care, collaborative data collection and auditing short and longer-term outcomes. These could also be used to promote an ethos of collaboration amongst trainee and established professionals.

**To assure Global Multidisciplinary Collaboration the Task Force should:**

- Raise awareness for comprehensive team care not just surgical repair
- Recruit task force participants in all countries and identify contact persons for the regions and/or countries to drive the different initiatives forward
- Boost representations in specialty groups with few participants (e.g. develop an otolaryngology/audiology group)
- Encourage the participation of the next generation of cleft enthusiast
- Improve communication between colleagues, and clinicians and researchers

**Establish Subgroups that will:**

1. Work within regions such as Africa, Asia, Australia/New Zealand, North America, Latin America, The Middle East and Europe. Within these regions other sub-groups could be established. National and regional leaders must be identified. An evaluation of current standards of care should be undertaken and country/region specific remedies to optimize treatment outcome suggested.
2. Reach agreement on minimum standards of care, minimum record collection and reach consensus on simple outcome measures in all disciplines. This should include all cleft types and all ages. The basis for this would be scaled down versions of standards already in existence – these could be shared and pared down by a working group with representatives from developed and less developed nations. Once different points for discussion has been listed separate e-mail threads for each of them could be set up. These standards could be used to encourage governments to fund multidisciplinary care.
3. Encourage teams to start and continue record keeping using simple and agreed protocols, according to agreed standards of minimum records.
4. Encourage teams to share their data with other teams (one or two to start with to reduce the threat; then bigger groups).
5. Embark on outcome studies.

**Teams already active in research should:**

Create a register for cleft professionals and teams to reach agreement of contemporary and comprehensive multidisciplinary outcome measures, explore the possibilities using modern technology and plan large multi-national studies. A patient/parent centered data collection should always be included. These studies need a lot of funding. One task could also be exploring whether health care at a distance could be initiated using new technology.

**Continuity**

Unfortunately the Confederation of countries that organize the four yearly conferences is not yet active between meetings, and some continuity is essential for a new initiative to take root. However, the commitment of any surplus funds arising from the four yearly conferences could provide some income.

Subject to the availability of funds, which also requires exploration, a possible home needs to be explored. This might be an existing organization, a university, a World Health Organization center or some other permanent entity. Dissemination could possibly be assisted by the Cleft

Palate-Craniofacial Journal or another similar publication.

### **Critique (positive and negative) of the Task Force Process**

From the beginning there was a lot of positive feed-back during the process of building up the Task Force. There were many e-mails of appreciation of the inclusion of members from all parts of the world. Many showed great willingness to help find interested colleagues in their geographical or specialist area, a support that was essential in the process. There were many reports from colleagues getting in contact with each other as e-mail addresses were disseminated. The document including the individual summaries was reported to be very helpful: this was an opportunity to hear the voice of individuals.

The group was large, and there was a large diversity between geographical areas and diversity in needs and interests and what they wanted out of the Task Force. A few members felt that the motivation to join the workforce sometimes was rather distanced from the original aim of "making recommendations for initiation of local and/or participation in multi-national cleft outcome studies". This was not unexpected at the start of a global initiative. The main goal for the first meeting was for colleagues from all parts of the world to meet face-to-face, and together start discussions on goals, expectations, visions and brainstorm on the different ways to take this initiative forward. Many members would have liked to have more time allocated for these discussions and connections.

Time will tell how easy the road ahead will be for this global initiative. It has been decided that the project will continue at least to Cleft17 Congress in India. The great majority of the members think the initiative has large potentials, as one respondent writes: "I appreciate very much the goals set for this task force and it will be an exciting and wonderful pathway for recommendation of multicentre cleft outcome studies"

"Where there is love there is life" Mahatma Gandhi

### **Task Force members**

Abbas Shaza (Sudan), Adam Saleigh (South-Africa), Adeyemi Abigail Toluwani (Nigeria), Akota Ilze (Latvia), Al-Khaja Anwar (Dubai), Aljohar Aziza (Saudi-Arabia), Alonso Nivaldo (Brazil), **Anastassov Youri** (Bulgaria), Andersen Bjørn Terje (Norway), 1 Andersen Mikael (Denmark), Antonelli Melissa (Brazil), Aukner Ragnhild (Norway), Bakri Sherif (Egypt), Bannister Patricia (UK), Basnayake Sriyani (Sri Lanka), Bataringaya-Sekalala Aisha (Uganda), Batra Puneet (India), Becker Magnus (Sweden), Bellardie Haydn (UK/South-Africa), Berenguer Beatriz (Spain), Bermudez Luis (Colombia), Billaud Feragen Kristin (Norway), Boboc Lidia (Romania), Bogh Nielsen Joan (Denmark), Bojikova Kostadinka (Bulgaria), Bonanthaya Kristnamurthy (India), Brandao Giovana Rinalde (Brazil), Breeeugem Corstiaan (Belgium), Brusati Roberto (Italy), Chapman Kathy (USA), Chorbachi Raouf (UK), Chowchuen Bowornsilp (Thailand), Clarke Noreen (USA), Clayton-Smith Jill (UK), Coelho Micheline (Brazil), Cohen Marilyn (USA), Cooper Daphne (South Africa), Costa de Melo Edna (Brazil), Courtemanche Douglas (Canada), daCosta Ranti (Nigeria), Dahl Jørgensen Line (Denmark), Daskalogianniakis John (Canada), **Davies Gareth** (France), deMey Albert (Belgium), del Pilar Echeverri Maria (Colombia), Derakhshandeh Fatemeh (Iran), DoVale Dione (Brazil), Dogan Ege (Turkey), Dogan Servet (Turkey), Dominguez-Gonzalez Susana (UK), Donkor Peter (Ghana), Dutka Jeniffer (Brazil), Elfving-Little Ulla (UK), Escobedo Margot (Peru), Fayyaz Ghulam Qadir (Pakistan), Filip Carles (Norway), Fisher David (Canada), Fowler Peter (New Zealand), Friede Hans (Sweden), Fudalej Piotr (Poland), Fujiwara Yuri (Japan), Fukushima Ana Paula (Brazil), Garattini Giovanna (Italy), Garcia Regina Celia (Brazil), Ghabrial Emad (South Africa), Gillett David (Australia), Gonzalez-Landa Gonzalo (Spain), Gozalez-Meli Beatriz (Spain), Gundlach Karsten (Germany), Gundsekera Romesh (Sri Lanka), Habte Mesay Gebrehanna (Ethiopia), Hakelius Malin (Sweden), Handayani Siti (Indonesia), Hariharan Savitha (India), Hashova Nedlalka (Bulgaria), Hathaway Ron (USA), Heliövaara Arja (Finland), Herzog Georges (Switzerland), Hjertman Helene (Sweden), Huang Daniel C.Shing (Taiwan), Hudson Nichola (UK), Jagomägi Triin (Estonia), Jonsson Anette (Sweden), Jost-Brinkmann

Paul-Georg (Germany), Jury Silvia (Argentina), Karsten Agneta L-A (Sweden), Karunathilleke Tharushie (Sri Lanka), Katsaros Christos (Switzerland), Kasakova Maria (Bulgaria), Kerameddin Sharareh (Iran), Kharbanda Omprakash (India), Khondoker Sazzad (Bangladesh), Kilpatrick Nicky (Australia), Kirschner Richard (USA), Klimova Irena (Slovakia), Koenig Caroline (Austria), Kogo Mikihiro (Japan), Koselj Vesna (Slovenia), Kresante Prasetyanugraheni (Indonesia), Kuijpers Mette (The Netherlands), Kuijpers-Jagtman Anne-Marie (The Netherlands), Kulak Kayikci Mavis (Turkey), K seler Annelise (Denmark), Latter Katrine (UK), Lenz Jan-Hendrick (Germany), Lilja Jan (Sweden), Lindberg Nina (Norway), **Lohmander Anette** (Sweden), Long Ross (USA), Loven Jens- yvind (Norway), Ma Lian (China), Marchino Margarita (Peru), Marcusson Agneta (Sweden), Mark Hans (Sweden), Martinelli Roberta (Brazil), Matic Damir (Canada), Maulina Inese (Latvia), Mazioero Custodio Sivana Aparecida (Brazil), Mehendale Felicity (UK), Mercado Ana (USA), Mesuita Sonia Tebet (Brazil), Moghe-Ghadyalpatil Gayatri (India), M lsted Kirsten (Denmark), Mooney Jeanette (UK), Morovic Carmen Gloria (Chile), **Mossey Peter** (UK), Murthy Jyotsna (India), Neuman Sandra (Germany), Newman-Nartey Merlyn (Ghana), Ngom Papa Ibrahima (Senegal), Nyberg Jill (Sweden), Oberoi Sneha (USA), Ogut Fatih (Turkey), Okada Ozawa Terumi (Brazil), Ongkusuwito Edwin (The Netherlands), Oravkinova Zuzana (Slovakia), Paganini Anna (Sweden), Painter Gill (UK), Pedersen Nina-Helen (Norway), Pellerin Philippe (France), Pereira Rui (Brazil), Pereira Valerie (China), Pergoraro-Krook Maria Ines (Brazil), Persson Christina (Sweden), **Persson Martin** (UK), Piazzentin Penna Silvia (Brazil), Pinto Joao (Brazil), Prada Rolando (Columbia), Rautio Jorma (Finland), Rizell Sara (Sweden), Rocha Diogenes (Brazil), Rumsey Nichola (UK), Russel Kathy (Canada), Sader Robert (Germany), Paul S ele (Norway), Samson Thomas (USA), Sandy Jonathan (UK), Schachner Peter (Austria), Scherer Nancy (USA), Sell Debbie (UK), **Semb Gunvor** (Norway/UK), **Shaw Bill** (UK), Sierwald Ira (Germany), Siqueira Niede (Brazil), Smedegaard Lisa (Denmark), Souza Telma (Brazil), Spataru Radu (Romania), Susami Takafumi (Japan), Sweeney Triona (Ireland), Tansipek Bernard (The Philippines), Thompson John (New Zealand), Tosun Zekeriya (Turkey), Trindade Inge (Brazil), Uvemark Annika (Sweden), Uzel Aslihan (Turkey), Velez Juanita (Colombia), Vindenes Hallvard (Norway), Vrtiskova Jitka (Czech Republic), Wahyuni Luh K. (Indonesia), Willadsen Elisabeth (Denmark), Yamashita Renata (Brazil), Yeow Vincent (Singapore), Zaleckas Linas (Lithuania)