



# World Cleft Coalition International Treatment Program Standards

Serena N. Kassam, DMD<sup>1,2,3,4</sup>, Jamie L. Perry, PhD<sup>5</sup>,  
Ruben Ayala, MD, MSc<sup>6,7</sup>, Erin Stieber, JD<sup>8</sup>, Gareth Davies, BA<sup>9</sup>,  
Nan Hudson, BA<sup>10</sup>, and Usama S. Hamdan, MD, FICS<sup>11,12,13,14</sup>

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## Abstract

**Objective:** To present preliminary efforts to establish an internationally agreed set of minimum core practice and best practice guidelines, along with overarching principles to promote safe and comprehensive cleft care globally.

**Design:** Representatives from 6 national and international organizations collaborated to form a World Cleft Coalition. Representatives met monthly/bimonthly to compile standards for safe, comprehensive, and sustainable cleft care. Outcomes were circulated within each organization and to a small subset of external constituents for feedback.

**Results:** A series of overarching principles were established for those involved in International Cleft Treatment Programs, based on the experience of participating organizations. The overarching principles are followed by a structured and detailed *Recommended Practice for Ensuring Safe, Comprehensive and Sustainable Cleft Care*, which includes minimum core and best practice for the following areas: surgical safety, quality control, patient education, patient selection, patient follow-up, comprehensive care, partnership with the host nations and professionals, training and exchanges for sustainability, and local capacity building.

**Conclusions:** Outcomes aimed to provide a working document to define core principles for safe comprehensive cleft care, while balancing various levels of resources, geographic locations, appropriately trained health care professional specialists, and training limitations. The study highlights the process and benefits to a collaborative international working group not only to establish best practice but also to solicit and engage others in discussion of their experiences with building and supporting safe, high-quality, comprehensive, sustainable, worldwide cleft care.

## Keywords

international cleft care, global cleft care, global health, comprehensive cleft care, multidisciplinary cleft care

<sup>1</sup> Dental and Pre-Surgical Division, Global Smile Foundation, Norwood, MA, USA

<sup>2</sup> Department of Pediatric Dentistry, New York University College of Dentistry, New York, NY, USA

<sup>3</sup> Clinical Assistant Professor, Division of Pediatric Dentistry, Faculty of Dentistry, University of British Columbia, Vancouver, British Columbia, Canada

<sup>4</sup> Clinical Attending, Department of Pediatric Dentistry, BC Children's Hospital, Vancouver, British Columbia, Canada

<sup>5</sup> Department of Communication Sciences and Disorders, East Carolina University, CA, USA

<sup>6</sup> Operation Smile, Virginia Beach, VA, USA

<sup>7</sup> The Global Alliance for Surgical, Obstetric, Trauma and Anaesthesia Care (the G4 Alliance), Chicago, IL, USA

<sup>8</sup> Smile Train, New York, NY, USA

<sup>9</sup> European Cleft Organisation, Rijswijk ZH, the Netherlands

<sup>10</sup> Transforming Faces, Toronto, Ontario, Canada

<sup>11</sup> Global Smile Foundation, Norwood, MA, USA

<sup>12</sup> Tufts University School of Medicine, Boston, MA, USA

<sup>13</sup> Harvard Medical School, Boston, MA, USA

<sup>14</sup> Boston University School of Medicine, Boston, MA, USA

## Corresponding Author:

Serena N. Kassam, Global Smile Foundation, 21 Norwood, MA 02062, USA.

Email: serenakassam@gmail.com

## Introduction

International cleft care has been linked to numerous organizations and is delivered in various forms. There is also a gradation of care delivered in international settings. Treatment models vary and there is no standardization of cleft care that defines the involvement of international teams (Shaw et al., 2005; Lee et al., 2014; Percy et al., 2015). This can result in well-intentioned international treatment programs combining medical trips with medical tourism or teams traveling into remote resource areas without the proper safety provisions. Team may also be providing treatment without appropriate follow-up care, and/or professionals who may be practicing internationally beyond the scope of their specialty in their home country (Crump and Sugarman, 2010; Doobay-Persaud et al., 2019). Ultimately, these potential issues may place patients at high risk. At the same time, it has been proposed that health organizations and individuals addressing the burden of cleft lip and palate are well positioned to adopt a diagonal approach to care and to work collectively. With the inclusion of many disciplines, health organizations and individuals addressing cleft lip and palate have the potential to expand access to surgery, enhance quality of interventions, and to positively impact health systems (Kapetansky et al., 1992; Eipe et al., 2006; Kwari et al., 2010; Patel et al., 2012; Lalonde et al., 2014; Malherbe et al., 2014; Ng-Kamstra et al., 2016a).

Surgical procedures are intended to improve the quality of life and overall health outcomes for the patient with cleft lip and/or palate. And yet, the languishing growth of systems for surgery and anesthesia mean that conditions such as congenital anomalies carry significant risk for death and disability in low- and middle-income countries (LMICs; Meara et al., 2015) and are given limited capacity to offer treatment and follow-up care. The World Health Organization (WHO) identified this lack of growth and aimed to improve the safety of surgical care through its second Global Patient Safety Challenge: *Safe Surgery Saves Lives*. Through their patient safety challenge, the WHO was able to define a core set of safety standards to be applied by all WHO member states (World Health Organization, 2019a). The organization also formed a specialized program for Emergency and Essential Surgical Care in 2005. With the goal of strengthening health systems and optimizing health outcomes by improving access to safe, timely, and affordable surgical, obstetric, and anesthesia care, collaboration with international multidisciplinary partners served as the foundation for the specialized program (World Health Organization, 2019b). Lastly, member states of the WHO unanimously approved resolution 68.15, “Strengthening Emergency and Essential Surgical Care and Anesthesia as a Component of Universal Health Coverage,” offering hope for greater political commitment supporting surgical systems (Price et al., 2015; World Health Organization, 2015).

In addition to the WHO’s efforts, the Disease Control Priorities 3, and the Lancet Commission on Global Surgery, evidence is being used to galvanize civil society (including academia, nongovernmental organizations [NGOs], professional

associations, coalitions, and advocacy alliances) to join and expand efforts to improve global surgical and anesthesia care. Today, Harvard Medical School’s Program for Global Surgery and Social Change serves as an example of a group partnering with governments in the creation of National Surgical, Obstetric and Anesthesia Plans to provide “universal access to safe, affordable surgical and anesthesia care when needed” (Harvard Program in Global Surgery and Social Change, 2019). The Consortium for Universities in Global Health is also among those seeking to expand and disseminate new knowledge related to surgical plans. Others such as the Global Alliance for Surgery, Obstetrics, Trauma and Anesthesia Care (G4 Alliance) work on advocacy and endless entities, initiatives, and individuals focus on implementation at the national or local levels. The expansion of Global Surgery partners and the WHO to attain the “triple billion goal” to protect health emergencies and promote better health and well-being demonstrates how shared goals can be accomplished best through collaboration (Reddy et al., 2019). Methods to address safe surgical standards under limited resources have also been explored to reduce the risks associated with general anesthesia (Eberlin et al., 2013; Patel et al., 2014). The WHO-World Federation of Societies of Anesthesiologists developed the international standards for a safe anesthesia practice to present minimum agreed standards with the goal to always practice to the highest possible standards (Gelb et al., 2018). However, although standards, guidelines, and tools such as checklists serve as critical steps to safety in surgery, additional aspects must be considered to address all health needs of those affected by cleft lip and palate (Vyas et al., 2013; Ng-Kamstra et al., 2016b; Allori et al., 2017; Biccard et al., 2018; American Cleft Palate Association, 2018; International Surgeons, 2019). Although surgery may be a key intervention, it is the multidisciplinary treatment and integration of different specialties that results in comprehensive cleft care.

The true magnitude of the global epidemiology of cleft lip and palate is hard to assess, as most of the data present are from developed high-income countries that have established systems; however, these infrastructures do not always exist in many developing countries (Mossey and Modell, 2012). A study conducted by EUROCAT (Calzolari et al., 2007) examined 6 million births in 23 EUROCAT registries in 14 European countries combined with data from the IPDTC (IPDTC, 2011). Results showed birth prevalence for cleft lip and palate from 2000 to 2005 from 54 registries in 30 countries of more than 7.5 million births (Mossey and Modell, 2012). A more recent systematic review offered a pooled birth prevalence in more than 31 million total births of 1.30 per 1000 (Kadir et al., 2017).

A Global Burden of Disease Study proposed disability-adjusted life years (DALYs) as a means to measure disease burden. Disability-adjusted life years are the sum of years of life lost and years lived with disability (YLDs). From 1990 to 2010, there has been a continual shift away from communicable to noncommunicable diseases and from premature death to YLDs (in 1990 reports of 2503 billion to 2010 reports of 2490

**Table 1.** Working Group Members.

Name	Location	Clinical discipline	Affiliations
Serena Kassam, DMD	New York University, New York, New York	Pediatric Dentistry	Global Smile Foundation, Norwood, MA
Gareth Davies, BA	Hérault, France	NGO leader and patient advocate	European Cleft Organisation, Rijswijk, the Netherlands, Europe
Jamie Perry, PhD	East Carolina University, Greenville, NC	Speech-Language Pathologist	College of Allied Health Sciences, East Carolina University, NC
Erin Stieber, JD	Washington, DC	Doctor of Jurisprudence	Smile Train, New York, NY
Nan Hudson, BA/Doctorate	Kingston, Ontario, Canada	Social Worker	Transforming Faces, Toronto, Ontario, Canada
Ruben Ayala, MD, MSc	New York, NY	General Medicine and Public Health	Operation Smile, Virginia Beach, VA
Usama S. Hamdan, MD, FICS	Westwood, MA	Otolaryngology/ Facial Plastic Surgery	Global Smile Foundation, Norwood, MA

Abbreviation: NGO, nongovernmental organization.

billion). The crude DALYs per 1000 reportedly decreased by 23% (472 per 1000 to 361 per 1000). Five-point 1% of the Global Burden of Disease was due to causes in the category “other,” specifically noncommunicable diseases with roughly 30% being due to congenital anomalies, skin diseases, and sense organ diseases (Murray et al., 2012). Other models have attempted to quantify the backlog of patients who are yet to receive a primary surgical intervention in LMICs (Carlson et al., 2016), highlighting the significant efforts required to address the needs of patients with cleft, given that a significant portion will require more than 1 surgical event. Additional studies support the cost-effectiveness from the human capital and value of statistical life approach (Alkire et al., 2011), while others highlight that the economic benefit and cost-effectiveness are so remarkable that the correction of cleft lip and palate should be added to a list of “Essential Pediatric Surgical Procedures” (Saxton et al., 2016).

Recognizing the need for standardized guidelines for globally safe and comprehensive cleft care, the World Cleft Coalition (WCC) was charged and formed. The WCC was initiated at the 13th International Congress of Cleft Lip and Palate and Related Craniofacial Anomalies in Chennai, India, in 2017. The objective set forth by Congress delegates at the “NGOs: Think, Treat, Teach” meeting was to encourage international collaboration in the development of an agreed set of guidelines for safe and comprehensive cleft care. The WCC is an alliance of international NGOs that work in the area of cleft lip and palate and engage in long-term local capacity-building partnerships. The overarching goal of this coalition is to encourage international collaboration in the development of an agreed set of globally recognized minimum core practice guidelines and best practice guidelines.

In this article, we present preliminary efforts to establish a set of minimum core practice guidelines and best practice guidelines, along with overarching principles that are key to safe and optimal cleft care. This working document is intended to serve as a starting point to initiate and engage external constituents and global partners in dialogue that will refine these

guidelines into a globally endorsed agreed set of standards for best practice. In addition to the guidelines, we present the process of creating the guidelines, which proved to be a notable strength to the success of the initiative. The formation of the WCC and establishment of the guidelines offer an example of diverse organizations collaborating in the improvement of cleft care. The long-term goal of this collaborative initiative is to encourage host countries and visiting organizations to collectively strive for the delivery of safe and comprehensive cleft care globally.

## Methods

### Objective

**Primary objective.** The goal was to compile standards for safe, comprehensive, and sustainable cleft care globally.

**Secondary objective.** To develop a set of globally recognized minimum core practice and best practice guidelines that will help facilitate the delivery of safe and comprehensive cleft care.

### Composition of Working Group

Team members, listed in Table 1, came together at the 13th International Congress of Cleft Lip and Palate and Related Craniofacial Anomalies in Chennai, India, in 2017. The NGO meeting entitled “NGOs: Think, Treat, Teach” was based on international NGOs that work in the area of cleft lip and palate and engage in long-term local capacity-building partnerships. The following participating organizations were represented: American Cleft Palate Craniofacial Association, European Cleft Organization, Global Smile Foundation, Operation Smile, Smile Train, and Transforming Faces. Individuals representing each of these organizations also demonstrated diversity in global experiences, professional background, and clinical area of expertise. During the process of creating the WCC “International Treatment Program Standards,” outside

consultants and constituents from organization and their different regions of service were used to provide preliminary feedback. The organizations forming the WCC have collectively provided over 1 904 000 surgical procedures and 72 000 comprehensive interventions across 125 countries and supported training of 56 000 providers through a variety of models, over 200 years of aggregated organizational service.

## Process

Between 2017 and 2019, the core team met monthly/bimonthly through teleconference meetings. The goal was to compile standards for safe, comprehensive, and sustainable cleft care. The members reviewed existing guidelines (internal and external) in order to create globally recognized international treatment program standards. Each organization shared experiences on what is of primary importance for ensuring and delivering high-quality cleft care. The discussion led to a document comprised of 3 key elements: a detailed recommendation on what should be considered minimum core practices, best practices, and a summary of the overarching principles. The primary focus was the delivery of ethical, safe, accessible, and patient-centered care, not on surgical technique or timing. While timing and details of treatment-specific approaches are ongoing areas of debate in the cleft field worldwide (eg, the use and type of presurgical infant orthopedics), the guidelines were focused holistically on the core principles and best practice for safe and comprehensive cleft care. Additionally, a decision was made to focus on using wording that is inclusive and encouraging, avoiding mandatory and prescriptive language.

Each conference was consistently attended by 90% of the working group members.

The meeting/teleconferences covered in sequence:

- In person meeting 1/teleconference 2: Developed the mission and the goal of the group.
- Teleconference 3/4: Examined research and discussed the existing guidelines and recommendations, in addition to each organization's operating manual (EuroCleft, 2000; WHO Meeting Craniofacial Anomalies, 2001; American Cleft Palate Association, 2010; Cleft Lip and Palate in the UK, 2011; Multidisciplinary Guidelines in the Netherlands, 2011; National Health Services England and Wales, 2013; Global Smile Foundation Safety Guidelines, 2014; European Cleft Organization, 2015; Operation Smile Global Standards of Care, 2016; Smile Train Safety & Quality Protocol, 2018; Transforming Faces).
- Teleconference 5/6/7: Created initial draft of the guidelines and overarching principles.
- Teleconference 8/9: Reviewed the drafted guidelines, editing, shortening, and experimenting with 2 different versions.
- Teleconference 10/11: Circulated draft for comments to select partner organization, then reviewed comments as a group.
- Teleconference 12: Confirmed approval from member leadership.
- Teleconference 13/14: Discussed dissemination plan.

Once the overarching principles of minimum core and best practice guidelines were discussed, developed, and agreed within the core team, they were subsequently circulated to select external constituents. The working document was shared and phone/skype and/or electronic communication was used to gather feedback from the following external consultants: Fundacion Global Smile Ecuador (monthly communication), Global Smile Foundation MENA (monthly communication), Global Smile Foundation Peru (consulted twice a year), Benjamin Bloom Children's Hospital, El Salvador (consulted twice a year), and European Cleft Organization's board members (monthly communication), including collaboration with WHO Director Collaborating Centre for Craniofacial Anomalies (consulted 3 times per year). Additional insight was obtained from Operation Smile's Executive and Medical Oversight Teams in Virginia, as well as Regional Medical Officers located in Panama, Bolivia, Sweden, China, South Africa, India, and Kenya, representing 33 countries where this organization offers patient care. Feedback from these external consultants served to provide preliminary assessment and feedback to help the WCC understand how the working document might be received by the larger community. These groups were specifically selected due to the collaborations that were already established with members of the WCC and members of the external entities. All feedback was shared during conference calls with members of the WCC and used to inform and modify the working document.

Although each member in the working group collectively came together in Chennai in 2017, affiliates of each organization also acted as representatives of their organization throughout this process. Items brought forth during the conference calls were then reflected on via email and in subsequent discussions with respective boards and parties. External partner feedback was crucial to working items and prior to final drafts circulations. Organization consulted with international partners and drew from reference documents created after extensive internal consultative processes, representing around 40 countries collectively.

The feedback received was incorporated into a final draft, which was then approved by each participant organization. Feedback included amendments to principle core and best practice guidelines and changes to word choice (eg, using "may" instead of "should") in order to avoid excluding or alienating those groups who may be actively working toward the goal of best practice. The document was intended to be inspirational and inclusive. Decisions were finalized when consensus of all members of the working group was established.

## Results

A series of overarching principles were established for those involved in International Cleft Treatment Programs based on the experiences of participating members' respective organizations. The overarching principles are followed by the *Recommended Practice for Ensuring Safe, Comprehensive and Sustainable Cleft Care*, which includes minimum core and best practice guidelines for the following areas: surgical safety, quality control, patient education, patient selection, patient follow-up, comprehensive care, partnership with the host nations and professionals, training and exchanges to ensure sustainability, and local capacity building.

### Nomenclature and Classification

During the development process, 2 categories were created: overarching principles and recommendations. Each recommendation contained minimum core standards and best practice guidelines. We defined minimum core standards as those that were needed for safe and effective delivery of care (to account for limited resources and lack of trained health care providers). In contrast, the recommendations provide more comprehensive and aspirational goals.

### Overarching Principles

1. The following overarching principles are intended to be a summary of the core treatment recommendations and guidelines for those involved with the delivery of safe and comprehensive cleft care globally.
2. Safety in all aspects of cleft care, especially surgical, is essential and cannot be compromised.
3. Comprehensive care using a multidisciplinary team approach provides the best possible cleft care. A multidisciplinary cleft team should include, at a minimum, health care professionals in the areas of anesthesiology, dentistry, nursing, orthodontics, pediatrics, psychosocial care, speech-language pathology, and surgery, with overall team coordination provided (American Cleft Palate Association, 2010; European Cleft Organization, 2015).
4. Within the range of international treatment programs, all health care professionals, visiting or practicing locally, must have recognized credentials and expertise with proven experience in their field of practice. Professionals must have active licensure in their country of residency and, if required, in the host country.
5. Cleft care should always support and strengthen local capacity for delivering comprehensive cleft care.
6. Medical care should always be delivered at the highest professional level, taking the variability of local circumstances into consideration.
7. Services must be offered to patients in a culturally appropriate manner and regardless of race, ethnicity, religion, socioeconomic background, gender, physical

and mental ability, or community resources. The aim is to always enable patients to become fully integrated in their societies and to enjoy the same opportunities as their peers.

8. It is important for all health care professionals to understand their responsibilities when treating and managing children and young people. Health care professionals should follow all policies and practices in child protection services, which were provided at the UN Convention on the Rights of the Child (1989).

### Recommended Practice for Ensuring Safe, Comprehensive, and Sustainable Cleft Care

Eight major areas were identified by the working group, with each divided into 2 sections: *minimum core standards* and *best practice*. The 8 major areas include surgical safety, quality control, patient education, patient selection, patient follow-up, comprehensive care, partnership with the host nations and professionals, training for sustainability, and local capacity building (Table 2).

#### Surgical Safety

The working group agreed the *minimum core standards* to provide safe surgical care include careful preoperative evaluation, safe surgical and anesthesia management, optimal postoperative care with properly trained and equipped health care professionals, and following agreed protocols for emergency care and anesthetic complications. Tools such as surgical safety checklists, preparedness drills, and adding clarity in the assignment of clinical leadership roles are strategies to offer a methodic system for all settings, especially when the team members are meeting and working together for the first time. In order to ensure the safety of the patient in all aspects of their medical care, surgical safety checklists should be used and adapted when necessary for the best practice.

#### Quality Control

The working group recommended *minimum core standards* for quality control be included as part of their care offer and commitment to patients, and the ongoing improvement in services provided to them. Basic measures contain complete and accurate records available to all health professionals involved in care and follow-up (World Health Organization, 2006). Moreover, perioperative as well as mid- and long-term complications and adverse events should be documented and reviewed by the team, with additional measures established to minimize future occurrences (Jung et al., 2019). Similarly, the *best practice* should have a system in place for routine assessment of outcomes and complications, with remedial actions to improve care. Protocols should be available to maximize safety and optimize the surgical and nonsurgical treatment and outcomes, including measures to provide timely immediate and subsequent regular postoperative care and follow-up (Global Smile Foundation Safety Guidelines, 2014; Operation Smile Global

**Table 2.** Recommended Practice for Ensuring Safe, Comprehensive, and Sustainable Cleft Care.

Overarching principles	Minimum core standards	Best practice
Surgical safety	<ul style="list-style-type: none"> <li>– Careful preoperative evaluation, safe surgical and anesthesia management, and optimal postoperative care</li> <li>– Protocols for emergency care and anesthetic complications</li> <li>– Surgical safety checklists</li> </ul>	<ul style="list-style-type: none"> <li>– Every effort should be taken to ensure the safety of the patient in all aspects of their medical care</li> </ul>
Quality control	<ul style="list-style-type: none"> <li>– Outcomes reviewed and analyzed</li> <li>– Complications documented and measures put in place to minimize occurrences</li> <li>– Complete and accurate records available to the local medical team</li> </ul>	<ul style="list-style-type: none"> <li>– Routine assessment of outcomes and complications to be in place with suggestions to improve care</li> <li>– Protocols available to maximize safety and optimize outcomes</li> </ul>
Patient education	<ul style="list-style-type: none"> <li>– Patients educated and informed regarding: feeding, speech, orthodontics, dental care, psychological needs, surgery, postoperative care, long-term follow-up, and any complications</li> <li>– Fully informed and culturally appropriate consent obtained</li> </ul>	<ul style="list-style-type: none"> <li>– Patients have clear information about all health care professionals delivering care</li> </ul>
Patient selection	<ul style="list-style-type: none"> <li>– Anesthetic and surgical safety standards applied to ensure patient safety and minimize patient risk</li> </ul>	<ul style="list-style-type: none"> <li>– Screening systems to ensure safe intervention</li> </ul>
Patient follow-up	<ul style="list-style-type: none"> <li>– Provision for postoperative follow-up care and management of complications included in treatment program</li> <li>– Clear information about their follow-up and any planned or needed subsequent treatment(s) provided to all patients</li> </ul>	<ul style="list-style-type: none"> <li>– Follow-up care that includes all subspecialists is optimal</li> </ul>
Comprehensive care	<ul style="list-style-type: none"> <li>– The multidisciplinary cleft team includes health care professionals in the areas of anesthesiology, dentistry, nursing, orthodontics pediatrics, psychosocial care, speech-language pathology, and surgery, with overall coordination provided</li> </ul>	<ul style="list-style-type: none"> <li>– The multidisciplinary team includes health care professionals in the areas, including, but not limited to, audiology, pediatric and restorative dentistry, genetics, otolaryngology, psychology, and social work</li> </ul>
Partnership with host nation and professionals	<ul style="list-style-type: none"> <li>– Involvement, agreement and cooperation of host nation, local health care professionals, and applicable government agencies established</li> <li>– Commitment to building medical and other cleft treatment capacities</li> </ul>	<ul style="list-style-type: none"> <li>– International treatment programs seek ongoing exchange of knowledge with local health care providers to support the establishment of local capacities to deliver high-quality comprehensive care</li> </ul>
Training for sustainability and local capacity building	<ul style="list-style-type: none"> <li>– Training plans include engagement with host nation professionals and ensure that training is appropriate, given the local structures and resources</li> </ul>	<ul style="list-style-type: none"> <li>– A multidisciplinary approach is projected to the local hosts as the best model of care and efforts to train all specialties involved in cleft care are established</li> </ul>

Standards of Care, 2015; Smile Train Safety and Quality Protocol, 2018). It is important to consult with any supporting or funding agency-specific timelines of reporting they may require, in addition to the general overview listed. Lastly, and very importantly, a concerted effort toward understanding the patient's perspective of the care received should remain a priority (Wong et al., 2018).

### Patient Education

The working group recommended under *minimum core standards* that patients and their families or caregivers should be provided with appropriate education and information about their diagnosis and treatment, including information on feeding, speech, orthodontics, dental care, psychological needs, surgery, postoperative care, and long-term follow-up. Families should be provided with

information on their ability to access care and additional treatment for management of any complications that may arise. A fully informed and culturally appropriate consent should be obtained prior to the delivery of any care. Patient privacy should be respected and in line with internationally accepted ethical codes. The *best practice* for patient education should ensure all patients to have clear information about all the health care professionals delivering their care.

### Patient Selection

The working group agreed the *minimum core standards* for patient selection should be centered on rigorous surgical and anesthetic safety standards, which should be applied preoperatively by qualified persons to ensure patient safety and minimize patient risk while maximizing benefits. This screening

should be carried out before any type of health care intervention. The *best practice* should include screening systems established to ensure safe intervention. In the event that a medical condition precludes treatment, counseling should be available, which will include options for treatment at another time or location.

### Patient Follow-Up

The *minimum core standards* for patient follow-up must include provisions for timely postoperative follow-up care and management of complications in the treatment program. Patients should have clear information about the health care professionals responsible for their follow-up and any planned or needed subsequent treatment(s). The *best practice* acknowledges that follow-up care that includes all subspecialists are optimal.

### Comprehensive Care

This area was focused on quite extensively within the working group. Acknowledging that many cleft teams/groups may not have all the needed cleft specialists due to resources or lack of trained health care providers, we felt it was important for all involved in cleft care to know the importance of comprehensive versus fragmented cleft care. The *minimum core standards* for treatment programs should be multidisciplinary, addressing all aspects of the patient's care. The aim is to enable patients to become fully integrated into their societies and to enjoy the same opportunities as their peers. Treatment programs should also address the family's needs and provide community education regarding cleft care from infancy through adulthood. A multidisciplinary cleft team should include, at a minimum, health care professionals in the areas of anesthesiology, dentistry, nursing, orthodontics, pediatrics, psychosocial care, speech-language pathology, and surgery, with overall coordination provided. The *best practice*, in addition to the minimum core team members (above), should demonstrate access to health care professionals, including, but not limited to, audiology, pediatric and restorative dentistry, genetics, otolaryngology, psychology, social work, and psychosocial services. As with other sections of the document, our goal was to provide an aspirational goal map for care providers at all stages.

### Partnership With Host Nation and Professionals

The working team identified that for visiting groups, partnership with the host nation and professionals is an integral and focal part of the establishment of any international treatment program. For this reason, there are only *minimum core standards* in this area. This focuses on involvement, agreement, and cooperation of the host nation, local health care professionals, and applicable government agencies in order to ensure the sustainability of the health care services. There should be a commitment toward ensuring that any visiting treatment program include local collaboration as a critical pillar in the

building of any care delivery, training, and infrastructure platform. The goal of addressing gaps in care in austere areas and enhancing medical and other cleft treatment capacities rather than displacing or replacing existing resources shall remain in the forefront of interventions.

### Training for Sustainability and Local Capacity Building

Following the previous point on partnership, the working group felt it was important to identify how to ensure sustainability, namely, through training and local capacity building. The *minimum core standards* for training plans should include engagement with host nation professionals and must ensure that training is appropriate, given the local structures and resources. Any training opportunities should be provided under the senior health care professional's strict and continuous supervision. For *best practice*, visiting treatment programs should seek ongoing exchange of knowledge with local health care providers to support the establishment of local capacities that can deliver high-quality comprehensive care. A multidisciplinary approach should be projected to the local hosts as the best model of care and efforts to train all specialties involved in cleft care should be established. Innovative evidence-based treatment and technology approaches for training, provision of comprehensive care, and/or ongoing treatment should be considered as opportunities arise. The next steps for the working group are to engage in discussion on what constitutes tangible outcomes to quantify local capacity building and what evaluations should be in place to examine the outcomes of such services. This is a complex discussion and should involve partnership with researchers who are already examining outcomes measures and sustainability. These partnerships may strengthen the directions for the working group in identifying key outcome measures for evaluating the success of teams in training for sustaining local capacity building.

### Discussion

Initial recommendations by the WCC working group to establish a working document for cleft care were developed based on discussions from the following questions: What are standards for safe, comprehensive, and sustainable cleft care globally? Can we encourage cleft organizations (local and visiting) with different models in providing care to collectively work together, through international collaboration, in the development of an agreed set of globally recognized minimum core practice and best practice guidelines to strive for the delivery of safe and comprehensive cleft care? The formation of the WCC and the internally agreed set of minimum core and best practice guidelines, along with the overarching principles, is a result of thoughtful discussion, rebuttal, and collaboration. Each organization's long-term experience throughout different parts of the world and the unique multidisciplinary team of health care professionals, academicians, and administrators added holistic perspectives to creating and agreeing on the guidelines.

This initiative could serve as an example of collaborative efforts among diverse organizations working synergistically to enhance cleft care. Creating, agreeing, and establishing the guidelines was a rich process, from which all in the working group learned. A set of foundational beliefs first defined by the group guided the discussions of the working document. Focus was placed on principles considered essential for holistic cleft care globally. It was noted that in addition to basic, overarching areas of care, equal space should be given to quality of life, respect, and value. Additionally, the guidelines place the patient first, requiring care to be delivered with equal value, regardless of race, ethnicity, religion, socioeconomic background, gender, physical and mental ability, or community resources. For visiting teams, it was deemed essential that health care participants uphold the highest standards of practice and conduct treatment, as they would in their own country. The group agreed that it is not ethical to use a population of patients with cleft lip and palate (considered vulnerable) to train health care providers without a supervised and structured program that guarantees patient safety and offers quality medical treatment. The responsibility of care provision should always fall on fully trained and licensed professionals.

We also agreed and recognized that comprehensive cleft care is what serves patients with cleft best. Recognizing that international teams may not include all health care specialties for full comprehensive care during international visits, we aimed to provide a description of what comprehensive cleft care should aspire to involve. This was a means to encourage and provide an aspirational model for cleft care to those who may currently have limited resources to expand health care professionals within their team. Lastly, the working group maintained that safety, in high- or low-resource settings, is the utmost importance when delivering cleft care, particularly for surgical treatment.

Challenges and debates during the creation process stemmed around being aspirational and inclusive, while providing standards and guidelines. This is why the minimum core versus best practice division came to fruition. This division allows a “work plan” for teams currently servicing patients, who may not have all the resources, health care providers, or training. Safety (surgical and anesthesia) was one area that was nonnegotiable despite differences in resources or limitations. Cleft care is not normally associated with mortality but lack of preoperative screening, lack of postoperative follow-up, complications, and unsafe surgical settings can lead to sentinel events. Therefore, we agreed this was an area where the guidelines would be more prescriptive. The remaining guidelines were intended to be holistic and aspirational. The working group debated extensively on the types of specialists who should be on the team (eg, pediatric anesthesiologists, general anesthesiologists, nurse anesthesiologists, general practitioners, cardiologists, pediatricians, pediatric nurse practitioners). In an effort to not be exclusionary, we determined that the medical care team should be constructed in a manner that is specific to the age and specific health needs of patients they would be treating. The agreed outcome was to provide a

list of what was considered a comprehensive cleft team. This was done as a means of detailing which professions a team should strive to include in order to ensure safe, effective, high-quality comprehensive cleft care. The working group also elected to list specialties in alphabetical order, as opposed to listing by perceived differential importance of specialty in care.

One specific change included the use of the term “active” licensure and credentials and “active” caseload in cleft lip and/or palate as a criterion to determine that the health care provider has the professional skills to be providing service within cleft care. We also came to realize that each country and government had their own laws and process for allowance of temporary credentialing process for international visiting professionals, and any guidelines of the host country must be followed and consulted prior to visits.

A pilot “test” of the guidelines was presented at a panel discussion at the European Cleft and Craniofacial Equality Initiative in Nis, Serbia, on September 14 to 16, 2018, with participants from 28 countries. Suggestions given were to include gender and disability in the breakdown of overarching principles for inclusion and to include perspectives from a patient group in the review and input of the guidelines. The suggestions were incorporated into the working document. The discussion also centered on the use of the word *disability* and was decided to be more inclusive by placing it as physical and mental *ability*. The overarching principles for inclusion were therefore altered. It was recommended that the guideline document be subject to periodic reviews at which time additional feedback will be considered. Additionally, it was suggested that the WCC solicit feedback via a patient working group to create a culturally and geographically diverse patient perspective group to review the guidelines going forward. These are currently being explored.

Defining what comprises safe and comprehensive cleft care proved to be a task of great magnitude, and it is perhaps inevitable that there are some limitations both in scope and detail of the guideline document. First, the balance between being exhaustive and comprehensive versus providing more of a fundamental principles approach was an area of early debate among the group members. The resulting document is intentionally designed to be comprehensive and focuses on minimum core principles and best practice guidelines for those involved in global cleft care. It is possible that a more exhaustive “how to” document may be warranted as an extension to the current development. Second, although our organizations are drawing on their experiences throughout many parts of the world, it is not complete, and there is space for more diverse inputs. There are issues that are unique to many countries and cultures that have not yet been represented within the WCC. The document is intended to be seen similar to that of a standard operating procedures document, which is constantly evolving and adapted based on changes to the socioeconomic climate, culture, patient needs, and/or resources. The decision was made to agree to a minimum core of principles and to build on this as feedback and additional information is incorporated. The intent of this article is to present preliminary guidelines to



engage the broader scientific community in discussion as part of the dissemination and feedback process. The goal is to encourage input and feedback from external constituents and partners around the world that can further support directions of the WCC and establish potential research partnerships to enhance the progress of the working group. Lastly, although the goal of the working group was to place the patient at the nucleus of the guidelines from all parameters, we would like to expand this document to include involvement and feedback from the patient groups and families served through global cleft care initiatives. This will be a primary focus for the working group in 2020.

### Clinical Translation

Phase II of the document consists of incorporating a patient working group to provide feedback to the guidelines and opening it up to other organizations for feedback and potential alignment to build consensus on this working document. The WCC is not a legal entity but an informal think tank established at the International Cleft Congress in Chennai in 2017 to address concerns about inconsistent standards of care provided by organizations and individuals undertaking international cleft treatment programs, largely but not exclusively, in LMICs. The goals were to establish standard guidelines focusing primarily on safety, ethics, and user experience, which would then be widely disseminated and put on the table for discussion and approval. This article explains the process of developing the guidelines and is part of that dissemination process. Currently, there is no global authority that is responsible for regulating cleft care. In the absence of such a body, it is the intent that these guidelines can become part of a larger movement ensuring safe, ethical, and high-quality cleft care is delivered globally. The implementation of such guidelines is a much bigger step that requires a global roadmap, which the WCC is inviting others to participate in to develop.

An agreed initial set of globally recognized minimum core practice guidelines, based on the experience of participating organizations, is offered for all those involved in the delivery of cleft care globally. We aimed to provide a working document to define core principles (ethics and clinical practice) for safe, comprehensive cleft care, while simultaneously balancing various levels of resources, geographic location, appropriately trained health care providers, and training limitations. In addition to the creation of the guidelines, the purpose and strength of this article is to present results of this collaborative effort not only to establish best practice guidelines but also to solicit and engage others in discussion of their experiences with building and supporting safe, high-quality, comprehensive, sustainable, worldwide cleft care. We offer an example of diverse organizations collaborating in the enhancement of cleft care, which we feel models a multi- and transdisciplinary team approach to addressing a complex global issue in cleft care.

Consensus and input from broader organizations will further enhance this process and facilitate standardization of outcomes and data. Further engagement with the holistic outcomes task

force, International Consortium for Health Outcomes Measurement (ICHOM), and Cleft Q are examples of entities making strides to unite and ultimately standardize data collection and enhance patient outcomes in the cleft field. Assessment of outcomes and standardization of data are important areas for the WCC to consider as part of successful comprehensive cleft care in future activities.

### Conclusion

Through collaboration among participating organizations (American Cleft Palate Craniofacial Association, European Cleft Organization, Global Smile Foundation, Operation Smile, Smile Train, and Transforming Faces) and consultations with outside constituents and partnerships, the WCC created an “International Treatment Program Standards” core document. Overarching principles are followed by the *Recommended Practice for Ensuring Safe, Comprehensive and Sustainable Cleft Care*, which includes minimum core and best practice for the following areas: surgical safety, quality control, patient education, patient selection, patient follow-up, comprehensive care, partnership with the host nations and professionals, and training for sustainability and local capacity building.

This process was built on each organization sharing experiences of what is of primary importance for ensuring and delivering high-quality cleft care. This collaborative process has generated agreed guidelines, aimed at improving safe comprehensive cleft care globally. It is an example of diverse organizations collaborating in the enhancement of cleft care. The goal is to encourage host and visiting organizations to collectively strive for the delivery of safe and comprehensive cleft care globally. Organizations and centers interested in learning more about the guidelines can find information at <http://www.worldcleftcoalition.org/>.

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### ORCID iDs

Serena N. Kassam, DMD  <https://orcid.org/0000-0001-5418-3568>  
Jamie L. Perry, PhD  <https://orcid.org/0000-0001-7866-9159>

### Supplemental Material

Supplemental material for this article is available online.

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