A Task-Shifted Speech Therapy Program for Cleft Palate Patients in Rural Nepal: Quality of life, impact, and associated healthcare barriers

by

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ABSTRACT

Background: Access to surgical care for cleft lip/palate (CL/P) has improved in low- and middle-income countries (LMICs). After surgery, however, children with cleft palate often have speech deficits such as velopharyngeal insufficiency (VPI) that significantly impact quality of life and development. Speech therapy is therefore required but often lacking in low-resource settings due to limited staff and healthcare infrastructure. Innovative programs that improve cleft care delivery in low-resource settings and tools to measure quality of life among patients with cleft palate are desperately needed.

Objectives: 1) Translate and validate the VPI Effects on Life Outcomes (VELO) instrument in Nepali; 2) Evaluate the impact of task-shifted speech therapy on a standardized speech score; 3) Describe the experiences of families and associated barriers towards achieving cleft care; 4) Explore cleft care optimization informed by the experiences of families whose children had nominal improvements after task-shifted speech therapy.

Methods: For objective 1, the VELO instrument was translated to Nepali, piloted, and modified using patient cognitive interviews. It was then administered to children aged 8-18. Internal consistency was evaluated using Cronbach's α coefficient. Concurrent validity and discriminant validity were assessed using a two-sample t-test, assuming unequal variances. For objectives 2-4, we evaluated the experience of children and families who received speech therapy from lay workers (i.e., in a task-shifted model) with a convergent parallel mixed-methods study. Standardized speech scores were compared by a blinded speech-language pathologist before and after the speech intervention. Semi-structured interviews (SSIs) and focus groups with families evaluated cleft care experiences and barriers. Qualitative and quantitative data were merged and analyzed.

Results: The VELO-Nepali demonstrated excellent internal consistency, with Cronbach's α coefficients of 0.93, 0.94, and 0.90 for VPI cases, guardians of VPI cases, and non-VPI controls, respectively. VELO-Nepali exhibited strong discriminant validity between VPI cases ($\bar{x}=45.4$, SD 22.1) and non-VPI controls ($\bar{x}=84.9$, SD 12.3), ($p<0.001$). VELO-Nepali showed strong concurrent validity with similarities in VPI case scores ($\bar{x}=45.4$, SD 22.1), and guardian scores ($\bar{x}=52.9$, $s=22.8$), ($p=0.473$). Thirty-nine children with speech deficits after palatoplasty (ages 3-18) underwent task-shifted speech therapy and demonstrated significant improvements in composite speech scores ($p<0.0001$) and weakness ($p=0.0002$), with borderline improvements in misarticulation ($p=0.07$) and glottal stop ($p=0.05$). Forty-seven SSIs demonstrated that the greatest barriers to follow-up were family responsibilities (62%), travel/distance (53%), and work (34%). In five focus groups, families expressed a desire to improve their child's speech and seek formal speech therapy. The speech intervention was found to be beneficial because of the compassionate staff, free lodging/food, and ability to socialize with other patients and families. After merging quantitative and qualitative data, we noted that younger children between 3-5 years old and families who traveled greater distances for healthcare access benefited less from the speech therapy intervention.

Conclusion: The translated VELO-Nepali demonstrates strong internal consistency, discriminant validity, and concurrent validity, and can assess quality of life for Nepali patients with VPI. This instrument represents the first VPI quality-of-life assessment validated in a low- or low-middle-income county; it supports the feasibility of its validation and implementation in other such countries, especially those in South Asia where the burden of CL/P is significant. Task-shifted speech therapy has the potential to improve cleft lip/palate speech in LMICs. Multiple biosocial issues limit access to appropriate post-operative care.

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GLOSSARY

Cleft Palate	Congenital malformation that occurs when the palatal shelves fail to fuse during development, resulting in a gap in the hard and/or soft palate
Composite Speech Score	Speech score that includes all aspects of speech targeted with therapy, including misarticulation, weakness, and glottal stop
Glottal Stop	Sound formed by stopping airflow through the vocal folds or glottis
Higher Secondary	The equivalent of grades 11-12
Hypernasality	Abnormal resonance that occurs with abnormal airflow through the nose during speech, often caused by an open nasal cavity from incomplete closure of the soft palate or velopharyngeal sphincter
Lower Secondary	The equivalent of grades 6-8
Misarticulation	An error in speech caused by a distortion, omission or substitution of a distinct unit of sound
Speech Assistant	Nurse without formalized speech therapy training who has received short-term training from a licensed speech pathologist
Speech Camp	One-week program in which children with speech deficits receive one-on-one speech therapy by a speech assistant according to their specific needs. All speech assistants supervised by a licensed speech pathologist. Participants receive one speech session per day, ranging from 30 minutes to one hour. Lodging and food provided.
Speech Therapy	Assessment of speech deficits and non-surgical treatment with sound demonstration, sound repetition and practice, and exercises targeting rate of speech, breath support, and articulation
Stigma	The process of setting apart or devaluing an individual based on a circumstance or quality, such as health status, gender, race, behavior, or socioeconomic status
Task-sharing	The sharing of healthcare responsibilities amongst team members with different competencies. There is an emphasis on direct supervision and involvement by a fully qualified health professional.
Task-shifting	The re-distribution or delegation of tasks to other members of the healthcare team, often to those with less specialized training
Upper Secondary	The equivalent of grades 9-10
VELO-Nepali	The velopharyngeal insufficiency (VPI) effects on life outcomes scale translated into Nepali
VELO-C	The velopharyngeal insufficiency (VPI) effects on life outcomes scale for the child
VELO-P	The velopharyngeal insufficiency (VPI) effects on life outcomes scale for the parent or guardian
Velopharyngeal Insufficiency	Persistent air leakage from the nasal cavity that occurs when the soft palate does not articulate against the posterior pharyngeal wall, resulting in nasal resonance during speech
Weakness	Difficulty with the production of sound during speech due to muscle weakness or lack of air flow

ABBREVIATIONS

CL/P: cleft lip with or without palate

F: female

FGs: focus groups

HRQOL: health-related quality of life

IQR: inter-quartile range

Km: kilometer

LLMIC: low- or low- middle income country

LMIC: low- and middle-income country

M: male

Min.: minutes.

N: sample size

N/A: data not available

No.: number

SD: standard deviation

SSIs: semi-structured interviews

VPI: velopharyngeal Insufficiency

VELO: velopharyngeal insufficiency (VPI) effects on life outcomes

%: percentage

Δ: difference

INTRODUCTION

Cleft Lip/Palate and Velopharyngeal Insufficiency in Low-/Middle-Income Countries

In low-and middle-income countries (LMICs), up to 85% of children have a surgically treatable condition by age 15 [1]. Of these, congenital anomalies account for 25.3–38.8 million disability-adjusted life-years worldwide [2,3]. Cleft lip and/or palate (CL/P) is the most common congenital orofacial malformation [4]. CL/P disproportionally affects LMICs, with a prevalence two to four times greater than in high income countries [5,6]. Recent evidence suggests that this disparity may be due to population-specific genetic polymorphisms and increased maternal exposures to tobacco smoke, alcohol, poor nutrition, viral infections, and teratogens [7].

A cleft palate occurs when the palatal shelves fail to fuse during development. This results in a gap in the hard and/or soft palate and causes functional problems with eating and speech [4]. Cleft palates can be surgically corrected; however, 20% of patients have persistent speech impairments most commonly due to velopharyngeal insufficiency (VPI) [8] **(See Appendices: Cleft Palate and Velopharyngeal Insufficiency)**.

VPI results from air leakage into the nasal cavity during speech production [9], and leads to diminished vocal intensity, nasal emission, and hypernasality [10]. VPI is found in up to 20% of patients who have undergo repair for cleft palate, and may occur with adenoidectomies, tonsillectomies, DiGeorge syndrome, and neuromuscular disorders [11][12]. Cleft palatoplasty or repair should occur between 9 and 18 months because an unrepaired palate during speech development increases the risk of a child developing VPI [4]. Optimal treatment of cleft palate therefore requires both surgery *and* speech therapy.

The deleterious effects of VPI on speech, swallowing, child development, and psychological well-being are well established [13]. VPI is clinically evaluated using nasal air emission, endoscopy, and resonance. However, these measures do not assess VPI's impact on quality of life. Consequently, VPI specific quality of life instruments have been developed to evaluate patient and family perspectives, and clinical improvement over time [14–19].

Cleft Lip/Palate Burden and Healthcare Delivery in Nepal and Other Low-/Middle-Income Countries

Nepal is a country of 29 million people, in which 82% of the population lives in rural areas with limited access to healthcare[20]. Only 15-20 plastic surgeons and 40 speech therapists are available to serve the estimated 5,874 cases of unrepaired CL/P [21–23]. In Nepal, 65% of patients with cleft lip and 58% of patients with cleft palate experience delays in surgical care or do not receive surgical care [21]. There is no data that defines the number of patients with cleft palate who access speech therapy. In LMICs such as Nepal, limited speech therapy, patient retention, and transportation are major barriers to comprehensive CL/P care [20,24–26]. The lack of speech therapy after cleft palate surgery can contribute to long-term disability, malnutrition, hindered speech, poor social development, and increased infant mortality [27–29]. If a patient from a rural area manages to receive surgery, post-operative speech therapy is often difficult to access. Speech therapy is standard of care and required to avoid the developmental and psychosocial consequences associated with speech deficits[28]. Therefore, innovative interventions are needed in LMICs to help improve access to speech therapy for children with cleft palate.

In LMICs, healthcare for patients with CL/P has traditionally been delivered through a combination of locally-provided surgical care, mission trips from visiting surgical teams, and humanitarian care from nonprofit organizations such as Operation Smile and Smile Train [30]. In recent years, healthcare delivery for CL/P has shifted away from short-term mission models due to questionable clinical outcomes, inadequate follow-up, and a lack of local health infrastructure development [31,32]. Recent innovations in cleft care have focused on building local capacity, broadening the scope of cleft care to include more than just surgery, and investing in health systems [33–37].

Task shifting and task sharing have broadened healthcare access across multiple areas in LMICS, including HIV/AIDS, non-communicable diseases, mental health, family planning, obstetrics, and minor surgical care, but their use has not been extensively explored in cleft care [38–40]. Task shifting is the re-distribution of tasks to other members of the healthcare team, often to those with less specialized training [41]. In task sharing, responsibilities are shared amongst team members, and there is an emphasis on direct supervision and involvement by a fully qualified health professional [42]. Although task shifting has been successfully implemented for certain surgical procedures, there have been no reported efforts to implement task shifting for CL/P surgery, as it is highly specialized. Utilizing task shifting and task sharing for other components of cleft care, such as nutrition, speech, and dental care, has the potential to improve access and clinical outcomes for patients with CL/P. Though there are limited reports that describe task shifting for speech therapy [43,44], there is a lack of evidence demonstrating its efficacy.

Purpose of Inquiry

Task shifting and task sharing may improve access to speech therapy for patients with cleft palate in Nepal. Moreover, understanding patient quality of life and the barriers for post-operative cleft care in LMICs such as Nepal is essential for bridging the healthcare delivery gap.

The present study sought to 1) Translate and validate the VPI Effects on Life Outcomes (VELO) instrument in Nepali; 2) Evaluate the impact of task-shifted speech therapy on a standardized speech score; 3) Describe the experiences of families and associated barriers towards achieving cleft care. 4) Explore cleft care optimization informed by the experiences of families whose children had nominal improvements after task-shifted speech therapy.

CHAPTER 1:

NEPALI LINGUISTIC VALIDATION OF THE VELOPHARYNGEAL INSUFFICIENCY EFFECTS ON LIFE OUTCOMES INSTRUMENT: VELO-NEPALI

Background

The Velopharyngeal Insufficiency Effects on Life Outcomes (VELO) survey is an instrument developed by Skirko et. al to measure quality of life in six areas: speech problems, swallowing problems, emotional impact, perception by others, caregiver impact, and situational difficulty (e.g. ability to be understood by others when face-to-face, facing away, and over the phone) [45]. The VELO is available for children and adolescents as a self-reported 23-question survey, and for parents or caregivers as a 26-question survey regarding the perceived quality of life of their child (includes three additional questions on caregiver impact). The English-language VELO was abbreviated from the VPI Insufficiency Quality of Life Inventory (VPIQL) instrument [16], and was proven to be internally consistent, valid, and responsive to expected improvements after surgical or obturator treatments [13]. The instrument has the potential to inform providers about the impact of VPI on quality of life for patients and families [46]. Thus far, the English VELO instrument has been translated and validated in upper-middle- and high-income countries: Netherlands, Norway, US (Spanish speaking population), Brazil, and China, supporting its broad utility [47–51]. However, as a symptom of, and contributor to, poor access to post-surgical speech therapy in low- and low-middle income countries (LLMICs), the VELO has not yet been validated in a LLMIC.

Few studies have defined the global incidence of VPI, though many investigated the incidence of its largest contributor, cleft lip and palate. In LLMICs, the prevalence of cleft lip with or without cleft palate (CL/P) is estimated to be up to four times higher than in higher income settings [5,6,21]. Validating the VELO in a LLMIC could represent an important step towards expanding its use globally.

The official language of Nepal is Nepali, and less than 1% of the population is able to speak English [52]. Nepali is an Indo-Aryan language, and is part of a larger family of South Asian languages spoken by more than 800 million people [53]. Given the CL/P prevalence in Nepal and South Asia more broadly, there is a need for a linguistically adapted VELO instruments validated in Nepali and other local languages. Therefore, the first section of this thesis was dedicated to developing a version of the VELO instrument in Nepali and evaluating its internal consistency and validity for patients with VPI and their families.

Methods

Study Population

Patients, ages 8-18, who had undergone any type of cleft palate repair (palatoplasty) between the years 2000 and 2018 were invited to participate in the study. The catchment area of Kirtipur Hospital includes Nepal's capital Kathmandu, and four other cities where Kirtipur Hospital has satellite sites (Chitwan, Pokhara, Nepalguj, and Butwal).

Control subjects without a history of VPI, ages 14-18 years old, were recruited via convenience sampling from a public secondary school at the Butwal study site. Control participants were from the same community as the patients in Butwal, and selected to approximately match on age and gender. All enrolled subjects were evaluated by a professional speech and language pathologist using a standardized speech scale in Nepali **(See Appendices: Post-Surgical Speech Pathology Assessment)**. Cases were confirmed to have VPI, and controls were confirmed to not have VPI. Controls were excluded if they had received prior speech therapy, or if they had ever been diagnosed with VPI or a developmental disability.

This study was approved by the Nepal Health Research Council (NHRC, Reg. no 715/2018) and the Institutional Review Board of the Harvard Faculty of Medicine (IRB18-1927). Written informed assent in Nepali was performed for participants between 8-15 years of age; their guardians signed accompanying consent forms. Participants who were 16 years of age and older met the Nepal legal age of majority, and signed their own consent. All participants received verbal and written information in Nepali regarding the study before assenting or consenting.

Translation of VELO to Nepali

The VELO-Nepali was translated as previously described [49,51]. Two study staff fluent in both English and Nepali independently translated the English VELO into Nepali, and reconciled differences in wording. A third bilingual study staff member backwards-translated the Nepali version into English, and compared this version to the original English VELO. Modifications were made to the VELO-Nepali to ensure that survey question meaning was maintained.

The translated VELO-Nepali instrument was then reviewed in cognitive interviews with patients and their guardians[54]. In cognitive interviews, each item of the VELO-Nepali was reviewed with members of the target population to ensure that the translated instrument preserved the meaning and readability of the original VELO in the new cultural context. Eight cognitive interviews with children with VPI ages 8-18 and six cognitive interviews with guardians were performed. Cognitive interviews were performed by Nepali-speaking study staff. Interviews were audio recorded and securely stored in a password protected database that could only be accessed by study staff.

VELO Instrument

The VELO survey is a validated, shortened version of the VPIQL that assesses quality of life over the past month in six areas: speech problems, swallowing problems, situational difficulty, perception by others, emotional impact, and caregiver impact (answered only by guardians). There are separate questionnaires for the guardian and child. Responses are given on a Likert-scale that range from "never" to "almost always." Each item is converted to a 0-100 point scale (0 =100, 1=75, 2=50, 3=25, 4=0), with 0 representing the worst situation and a higher score corresponding to a better health-related quality of life (HRQOL). Scores within each domain are averaged to calculate a domain score, and scores across the instrument are averaged to calculate a total instrument score. The VELO instrument was administered by study staff to all participants. Study staff collected demographic data for case participants and families, as all opted-in to participate in the speech therapy intervention **(Appendices: Parent/Guardian Semi-Structured Interview Guide)**. For control participants, age and gender were collected and entered into an electronic database. Data was collected on printed forms and then entered by an independent investigator into an electronic database. Data was checked by a second independent investigator to ensure quality and accuracy.

Statistical Analysis

Microsoft Excel (version 14.6.7, Microsoft Corporation, 2010) and Stata (StataCorp. 2017. Release 15. College Station, TX: StataCorp LLC) were used for statistical analysis. Mean domain/total instrument scores and standard deviations (SDs) were calculated for the VELO administered to cases and controls, as well as for the VELO-P administered to guardians.

Internal consistency measures whether questions within a given domain produce similar outputs or scores. To evaluate internal consistency, Cronbach's α coefficient was calculated to compare each domain to the total score across the whole instrument [55]. Coefficients ≥0.70 were considered satisfactory and coefficients ≥0.60 were considered acceptable [56,57]. When domain scores demonstrated a low Cronbach's α coefficient (α≤0.70), each item within a domain was deleted and domain score was recalculated to reveal which items negatively impacted internal consistency.

Discriminant validity was defined as the ability for the VELO to detect a difference between children with VPI and control children with no VPI history [58]. Concurrent validity was defined as the ability for the VELO to detect similar HRQOL scores between patients with VPI and their guardians [58,59]. Both concurrent validity and discriminant validity were assessed using two-sample t-test, assuming unequal variances. Sample size was calculated based on past validation studies, and conservatively estimating the minimum number of participants (n≥16) per group to have 80% power to detect a difference in VELO scores between cases and controls of at least 25, with a SD of 25. Effect size was calculated using the Hedges' g measure given group size differences between cases, controls, and guardians.

Results

Translation of the Nepali VELO

Participant feedback from cognitive interviews was reviewed by a joint committee of bilingual study staff, nurses from the local community, and surgeons. Suggested modifications included changing solid food *"comes from the nose"* to *"comes out of the nose"* and "*speech is too weak*" to "*speech is very low*". Weak speech did not exist idiomatically in Nepali, and was therefore translated to best reflect the underlying meaning. According to patients and guardians, the phrase "*I get frustrated or give up when I am not understood*" did not have the intended connotations in Nepali, and was therefore adjusted in translation to "*I get frustrated or stop trying to communicate when I am not understood."*

Participant Demographics

206 participants and their families were invited to participate in the task-shifted speech camp intervention, of whom 76 were between the ages of 8-18 and eligible for the VELO study. 52 participants and families presented to the study site. Of this number, 26 participants were between 8-18 years old and invited to participate in the VELO study. However, 3 participants opted out of the study. A total of 23 children who had undergone palatoplasty for cleft palate and 19 family members who functioned as the participant's guardian (note that 4 patients between 16-18 years old were not accompanied by any family member) were enrolled in the study. For control subjects, 35 were invited, and 6 declined to participate in the study. A total of 29 control subjects without a history of VPI between 14-18 years old were also enrolled.

Characteristics of the 23 children with VPI after palatoplasty, 19 guardians, and 29 control children (ages 14-18) are presented in **Table 1**. Mean age amongst participants with VPI was 11.6 years (SD 3.9, range 8-18), and 45% were male. Patients in this cohort had undergone a mean of 2.1 previous surgeries for CL/P (includes cleft lip repair) (SD 1.1), 1.2 past palatal or pharyngeal operations (SD 0.39), and 6.2 years since their last cleft-related surgery (SD 4.1). Patients lived an average of 17.4km (SD 19.6) and 89.5 minutes (SD 110.3) away from the closest hospital, and an average of 2.8km (SD 3.8) and 41.2 minutes (SD 68.4) away from the closest health center **(Table 1)**. Amongst non-VPI controls, the mean age was 15.9 (SD 1.1, range 14-18) and 45% were male.

Amongst the 19 guardians of participants with VPI, the average age was 35.8 years (SD 7.9), and 36.8% were male. They were mothers (n=12), fathers (n=3), grandparents (n=2), and cousins or siblings (n=2). All guardians reported being literate; 42.1% had not received schooling beyond primary school, and none had gone on to university or post-graduate training **(Table 1).**

VELO Validation: Testing for Internal Consistency

The VELO-Nepali demonstrated excellent internal consistency, with Cronbach's α coefficients of 0.93, 0.90, and 0.94 among VPI cases, guardians of VPI cases, and non-VPI controls, respectively **(Table II)**. The "situational difficulty" (α=0.91) and "emotional impact" (α=0.90) domains of the VELO instrument demonstrated excellent internal consistency with the highest Cronbach α coefficient scores. Amongst cases, the "perceptions by others" domain had the lowest Cronbach's α coefficient, but still remained above the threshold for acceptable internal consistency (α≥0.60). For guardians, the Cronbach's α for the swallowing domain (α=0.61) was only slightly above the 0.60 threshold for acceptable internal consistency. Cronbach's α coefficient was recalculated after removing each item within these domains. When item #8 of the swallowing domain was removed from VELO-P ("liquids come from the nose while drinking"), the change in Cronbach's α was negligible. Cronbach's α remained unchanged or worsened with the removal of other items. Among cases, internal consistency worsened when item #8 was removed from the swallowing domain for cases (0.78 to 0.65). Removing other items in the scale either made no significant changes or worsened the VELO internal consistency for both cases and guardians.

VELO Validation: Testing for Discriminant Validity

The VELO-Nepali demonstrated excellent discriminant validity, meaning that there were statistically significant differences between scores in children with VPI ($\bar{x}$=45.4, SD 22.1) and score in controls without a history of VPI ($\bar{x}$=84.9, SD 12.3), **(**p-value<0.001, effect size=2.28), (**Table III).** Total VELO scores and scores within each domain were statistically significantly greater in cases than in controls, indicating strong discriminant validity. VELO-Nepali scores of guardians ($\bar{x}$=52.9, SD 22.8) also showed satisfactory discriminant validity from controls **(**p-value<0.001, effect size=1.40), being statistically significantly greater in total score and most domains when compared to control scores (**Table III**). This indicated that the VELO instrument was able to distinguish between VPI guardian scores and control scores.

VELO Validation: Testing for Concurrent Validity

Concurrent testing was performed to evaluate whether there were significant differences between the experiences of patients with VPI and their guardians **(Table IV).** Given similar perceptions regarding how VPI is affecting the child's life, concurrent validity should demonstrate similar scores between children with VPI ($\bar{x}$=45.4, SD 22.1) and their guardians ($\bar{x}$=52.9, SD 22.8). Testing showed that there were no statistically significant differences in total scores (p-value=0.473, effect size=0.33) nor within each of the VELO domains, supporting the VELO-Nepali's concurrent validity.

Discussion

In this study, the VELO was translated into Nepali, adapted to fit the local cultural context through cognitive interviews, and tested for adequate internal consistency, discriminant validity, and concurrent validity. Past studies have evaluated quality of life amongst Nepali-speaking populations. However, these studies relied on the World Health Organization Quality of Life-BREF Nepali instrument, which does not explicitly address the impact that altered speech and communication has on quality of life [60,61]. The VELO has many advantages compared to other quality of life tools for assessing VPI. Namely, it allows for patient and guardian-reported outcomes; it is integrated into the HRQOL model for patients with VPI; and it is more succinct than other surveys [14–19]. To the author's knowledge, this study represents the first instrument validation specific to language-related quality of life in a LLMIC, which is where the majority of the VPI global disease burden exists [21].

The VELO-Nepali demonstrated excellent internal consistency. Compared to other VELO validation studies, the VELO-Nepali had similar internal consistency. Of note, domains with the lowest internal consistency had fewer items (e.g. caregiver impact α=0.67, three items; Swallowing Problems α=0.78 for cases and controls, α=0.67 for guardians, three items; Perception by others α=0.66 cases, α=0.12 controls, four items). This is expected as fewer items would statistically increase variability. This was also observed in other VELO-validation studies, such as those in English, Chinese, and Spanish [62]. Modifying the VELO led to minor changes in internal consistency, none of which significantly improved the domain in question's α above the established satisfactory level ($\alpha \geq 0.70$) [57].

There was strong discriminant and concurrent validity demonstrated by the VELO-Nepali, supporting the integrity of the VELO-Nepali tool. Our study was able to demonstrate excellent discriminant validity in all domains; this is distinct from what was found in the Dutch study (non-significant differences in the swallowing, situational difficulties, emotional impact, and perception by others domains) [47]. Adequate discriminant validity in each subdomain was similar to what was found in the Chinese VELO study, which to date included the largest sample size [51]. These findings corroborate the validity of the VELO-Nepali.

In contrast to the other VELO validation studies in Chinese, Dutch, and English, our study found that the mean score of VPI cases were consistently lower than their guardians, meaning that the children had a lower quality of life than what their guardians perceived. This difference may be explained by cultural differences specific to the Nepali population, or lack of family awareness regarding the impact of VPI on quality of life. Past studies in LLMICs have found that parents may have limited knowledge of their child's disability or underestimate associated burden [63]. It is also possible that parents struggling with basic needs such as food, housing, childcare, and safety face greater challenges that make it more difficult to be as attuned to their children's needs [64,65]. These are important findings to consider when clinicians counsel family members regarding the impact of VPI on quality of life, and the ways in which they can best support their developing child.

The VELO-Nepali showed lower quality of life scores among patients with VPI compared to parallel studies in higher income countries such as the United States, China, and Denmark. This was also the case across the majority of subject domains in the VELO. Differences in VPI etiology across the study populations is unlikely to be a major contributor. The English and Chinese studies included patients with VPI due to developmental disorders and hearing loss, in addition to those with cleft lip/palate [45,51]. However, the Dutch and U.S.-based Spanish versions limited enrollment to patients with cleft palate, and still reported scores higher than in the present study population [47]. Income inequality is known to affect health and quality of life, especially amongst families of children with disabilities, and may be contributing to score differences [66,67]. A higher percentage of people in Nepal live in poverty, therefore poor living conditions, inadequate health care access, and limited access to education may further exacerbate quality of life for those with VPI [68]. On the other hand, control scores had quality of life scores that were comparable or only slightly lower to control scores in other VELO studies. This suggests that local socioeconomic factors specific to Nepal may not significantly impact scores of children without VPI. It is possible that poverty and other socioeconomic barriers are amplifying the quality of life challenges faced by children with VPI in low-resource settings. Further investigation is needed to better understand why quality of life appears to be lower in Nepal compared to other contexts where the VELO has been validated, and specifically explore how socioeconomic barriers impact quality of life scores in both case and control populations.

This study supports the feasibility of validating HRQOL instruments in LLMICs, where low resources often constrain the ability to provide comprehensive post-operative care. Recently, there has been an expansion of research investigating quality of life in LLMICs [60,69,70]. However, measuring the impact of surgical care in low resource settings and associated impact on quality of life is often limited by poor follow-up and limited healthcare access [1,47]. This holds true for surgical needs of the head and neck, such as cleft lip and palate. In Nepal, post palatoplasty follow-up care (e.g. speech therapy) is delivered on a short term basis, and is often limited due to an overall lack of trained speech pathologists [71]. In fact, only 41% of lower-middle income countries and 5.5% of low-income countries are reported to have at least one speech therapist per million people [72]. A VELO validated in Nepali broadens the potential for measuring patient centered impact and outcomes for speech in LLMICs. Finally, this study establishes a jumping off point for South Asia and other LLMICs for using quality of life instruments to measure disease burden before and after CL/P surgery and incorporating quality of life outcome measures into quality improvement for VPI programs.

This study is limited by its study population, as only 26 of the 76 individuals eligible for the VELO study were able to travel to the study site. It is unclear how the distribution of quality of life scores would have changed with a higher recruitment yield, as the reasons for not participating were not explicitly explored. However, there was an even distribution of participants from Kirtipur Hospital's satellite sites. Of note, controls were not perfectly age matched, and may have not captured the range of quality of life scores for children without VPI between 8-13 years of age. Differences in the age distribution between cases and controls may introduce bias for discriminant validity, as older children may have more developed speech. However, past studies have not explicitly reported age as a confounder, and our analysis showed a poor correlation between age and VELO score [47,51]. As stated in past VELO validation studies, there is no standardized method for determining sufficient sample size [13]. Our sample size, which was based on past validation studies and a power calculation, was large enough to detect statistically significant differences for discriminant validity. This instrument was validated amongst children with VPI due to cleft palate from different regions of Nepal. Future studies can broaden the study population to children with other causes of VPI and increase the sample size to optimize overall validity and ensure wider applicability.

CHAPTER 2:

MIXED METHODS ANALYSIS OF A TASK-SHIFTED SPEECH THERAPY PROGRAM FOR PATIENTS WITH CLEFT PALATE IN RURAL NEPAL: IMPACT AND ASSOCIATED HEALTHCARE BARRIERS

Background

Nepal is a low-income country with a population of nearly 30 million people, and an estimated 5,874 unrepaired CL/P cases [21]. Most children with CL/P in Nepal, particularly those who live in rural areas, experience delays in speech therapy because of a lack of qualified speech language pathologists. In Nepal, there are only about 40 speech pathologists, most of whom work in the capital city of Kathmandu [22,23]. In 2000, the Public Health Concern Trust (Phect) Nepal and Resurge International partnered with Kirtipur Hospital to establish Nepal's first cleft program in Kathmandu. Recognizing that a large proportion of cleft cases existed outside of Kathmandu, Kirtipur Hospital worked to decentralize the delivery of cleft care by sending multidisciplinary medical teams to various hospital satellite sites around the country. More than 1,000 cases of untreated CL/P were identified during the program's initial outreach efforts in the year 2000. Since then, the number of untreated CL/P within Kirtipur Hospital's catchment area has steadily declined **(Table 5)**. However, the high number of patients with cleft palate and speech deficits both pre- and post-operatively demanded improved access to speech therapy.

A task-shifted speech therapy program was soon started that utilized professional Nepali speech pathologists to train nurses as speech assistants to perform targeted speech therapy. Trained speech assistants regularly travel to six different areas of Nepal to provide speech therapy. The program also included elements of task sharing given that speech assistants are supervised by speech and language pathologists (SLPs) who rotates between speech therapy sessions. Since the program's inception in the 2000, the number of speech therapy participants has more than tripled, with as many as 620 participants receiving task-shifted speech therapy in a single year **(Table 5)**. Despite these widespread efforts in Nepal, the impact of task-shifted speech therapy on speech outcomes is still largely unknown [73]. Furthermore, there is a dearth of evidence investigating the healthcare barriers facing children with CL/P in low-income countries.

The subsequent section of this thesis, therefore, sought to: 1) Evaluate the speech outcomes of this decentralized, task-shifted speech therapy program in Nepal; 2) Describe family experiences with post-operative cleft care and associated healthcare barriers; and 3) Explore cleft care optimization informed by the experiences of families whose children had nominal improvements after task-shifted speech therapy.

Methods

This study used a convergent parallel mixed-methods design. Quantitative and qualitative data were collected, analyzed separately, and then merged.

Study Population

The study population included individuals aged 3-18 years who had previously undergone cleft palate repair (palatoplasty) at Kirtipur Hospital, Kathmandu, Nepal, who exhibited speech deficits confirmed by a SLP, and who resided in the intervention catchment area (Butwal, Pokhara, Nepalguj, Kathmandu).

Task-Shifted Speech Therapy Intervention

A one-week speech camp was hosted in Butwal, Nepal that provided task-shifted speech therapy [41]. 2 licensed Nepali SLPs oversaw 13 “speech assistants” who administered daily, one-on-one speech therapy sessions for 30-60 minutes to each participant. “Speech assistants” were auxiliary nursing midwives trained to perform specific speech exercises that targeted weakness, misarticulation, and glottal stop. SLPs rotated between therapy sessions to supervise and aid in speech exercises. Guardians were encouraged to attend speech therapy sessions and model targeted speech exercises at home with their child. While not participating in speech therapy sessions, children were able to participate in interactive activities and games that promoted social interaction. Lodging and food were free for participants and their caregivers; however, transportation was not. The present study was designed to evaluate the impact of this task-shifted speech therapy intervention.

Pre-/Post-Intervention Cohort Study, Quantitative Data Collection and Analysis

Demographic data was collected by study staff before participants began the study intervention. For assessing speech, each participant was filmed before and after the task-shifted speech intervention following a script from a standardized speech scale. The scale was developed by 4 Nepali speaking SLPs. Participants were tested on 30 unique mono-syllabic sounds. Each sound was tested at the beginning, middle, or ending of different Nepali words, for a total of 90 words tested.

A Nepali SLP, blinded to whether videos were pre- and post-intervention, scored the videos based on the presence of misarticulation, weakness, glottal stop, and hypernasality. Normal distribution of score differences was confirmed by quantile-quantile plot and histogram analysis. Sample size was estimated for a paired t-test. Our study required a sample of 34 to achieve 80% power, with a p-value of 0.05 (two-tailed), for detecting a mean difference of 5 (SD 10) between pairs.

All participants who had worse speech scores after the task-shifted speech intervention were included and analyzed to identify patterns in demographic data (age, gender, guardian age, education level, family income, and literacy), healthcare access data (distance and time from healthcare center, hospital, and speech intervention),

Quantitative data was collected on printed forms and then entered by an independent investigator into a secure electronic database. Data was checked by a second independent investigator to ensure quality and accuracy. Microsoft Excel (version 14.6.7, Microsoft Corporation, 2010) and Stata (StataCorp. 2017. Release 15. College Station, TX: StataCorp LLC) were used for statistical analysis.

Qualitative Data Collection and Analysis

Semi-structured interviews (SSIs) were conducted with guardians of all consented participants, and participants who were not accompanied by parents. SSIs included close-ended questions (strengths, weaknesses, opportunities, threats of speech camp intervention), and open-ended questions related to perceived healthcare barriers and optimal cleft care **(See Appendices: Parent/Guardian Semi-Structured Interview Guide)**. Focus Groups (FGs) had 5-9 participants per group, and focused on perceived speech intervention effectiveness, healthcare access barriers, and ways to develop optimal cleft care **(See Appendices: Focus Group Interview Guide for Parents/Guardians)**. FG discussions continued until thematic saturation was achieved. Qualitative data collection was conducted by Nepali-speaking study staff. SSIs and FGs were transcribed, translated, and then coded by two independent investigators to identify emerging themes [74]. Codes were organized into a narrative using inductive logic and grounded theory [75].

Mixed Methods

Convergent parallel mixed-methods data collection was followed by explanatory sequential analysis to explore the experiences of children who had nominal improvements in speech scores after the task-shifted speech therapy intervention. Additionally, some themes from the SSIs and FGs were transformed to quantitative data; we report percentage of participants manifesting themes. In the sub-group of patients identified to have worse speech scores after the task-shifted speech intervention, we specifically explored experiences and identified health barriers in the qualitative data (SSIs and FGs). Purposive sampling was then used to select participants with unique experiences (greatest delay in surgery, other family members with cleft palate, and families with the greatest time or distance to a healthcare center, a hospital, or the speech intervention). Among this group, the experiences and speech outcomes were analyzed and related.

IRB Approval and Informed Consent/Assent

This study was approved by the Nepal Health Research Council (NHRC, Reg. no 715/2018) and the Harvard Faculty of Medicine IRB (IRB18-1927). Patients <8 years old were consented by their guardian. Patients 8-16 years old assented to participation per Nepal IRB guidelines, and their guardians signed accompanying consent forms. Patients 16 years and older met the Nepal legal age of majority, and signed their own consent. All participants received verbal and written study information in Nepali before assenting/consenting.

Results

Patient Demographics

206 patients and families were invited to participate in the study, 52 arrived and were consented; 47 completed semi-structured interviews; and 39 completed the study intervention (5 left early, 3 were discharged for normal speech development, and 2 were too young to evaluate).

Among the 39 participants who completed the task-shifted speech therapy evaluation, the average age was 7.7 (SD 4.6), 46.2% were male, and 35.9% had prior speech therapy **(Table 6)**. Patients had undergone 2.03 past surgeries (SD 1.01) for CL/P repairs, and 3.39 years since their last surgery (SD 3.34). Patients lived 17.4 km (SD 19.6) and 89.5 minutes (SD 110.3) away from the closest hospital, and 2.8 km (SD 3.8) and 41.2 minutes (SD 68.4) away from the closest health center. Patients traveled 309.7 minutes (SD 241.2) to the speech intervention **(Table 6)**.

Task Shifted Speech Therapy Intervention

Participants experienced significant improvements in composite speech scores ($p<0.0001$) aggregated across all measures of speech: weakness, misarticulation, and glottal stop scores. Reductions in weakness ($p=0.0002$) were most dramatic, while improvements in misarticulation ($p=0.07$) and glottal stop ($p=0.05$) were more modest **(Table 7)**.

Families rated their experience on a Likert scale from 0 to 5 with higher numbers indicating higher satisfaction. Families reported a mean score of 4.5 (SD 0.8) for "the speech camp was useful for my child"; a mean score of 4.5 (SD 0.8) for "I found speech assistants helpful and competent"; a mean score of 4.5 (SD 0.7) for "I would voluntarily return"; a mean score of 4.8 (SD 0.5) for "I would recommend the camp to a close friend"; and a mean score of 4.8 (SD 0.6) for "I feel confident that I understand my child's speech therapy needs".

Family Perceptions of Post-Operative Cleft Care and Associated Barriers

Family Demographics for Semi-Structured Interviews and Focus Groups

Forty-seven SSIs were completed by 40 family members and 7 participants (age≥16) not accompanied by a guardian. 34 family members participated in five FGs. The average age was 31.9 years (SD 7.93), and 25.0% were male. The majority were mothers (75%), followed by fathers (10%), grandparents (7.5%), and cousins or siblings (7.5%). All families were literate; nearly 40% had not received schooling beyond lower-secondary school. **(Table 8).**

Parent Investment in Child's Speech and Professional Speech Therapy

Families in FGs expanded on themes related to the importance of speech therapy and aspirations for their child's future **(Table 9)**. Families recognized the burden that underdeveloped speech had on their child's development. In particular, families viewed speech as an important skill for developing social networks, excelling in school, and integrating into their community. Although guardians expressed interest in learning speech exercises to practice with their children, they also recognized that their ability to be involved was often limited by time, finances, and childcare. Therefore, many desired to enroll their children in speech therapy provided by a healthcare professional.

"Whatever we do, wherever we go, speech always seems to be so important. A child can do anything if they have good speech. If the child's speaking is not clear, the task will not be completed." –Grandfather of female patient with cleft palate (age 6)

Additionally, families experienced stigma related to their child's cleft palate, and discussed how this made it difficult to pursue proper cleft care **(Table 9)**. In some cases, stigma originated not only from the surrounding community, but also from other family members. This often made it difficult for the child to continue in school or seek out speech therapy. Families that accompanied children to surgical treatment often learned about the importance of speech therapy and other follow-up services.

"My family doesn't support this. My family says: why do you have to go to the speech camp if the child is speaking? We will not go." –Mother of male patient with cleft palate (age 5)

"My child doesn't feel inferior when she improves her speech and is surrounded by children who are similar to her. When at home, she doesn't feel confident." –Grandmother of female patient with cleft palate (age 5)

Major barriers to follow-up cleft care

In SSIs, the greatest barriers to follow-up cleft care were family responsibilities (62%), travel/distance (53%), and work (34%). These barriers were echoed in FGs, though families also noted other barriers, including school conflicts (32%), lack of follow-up communication and care coordination (23%), and financial resources (23%). (**Table 10)**. Of note, guardians wanted their child to participate in speech therapy, but were often unable to do so because of other responsibilities. Multiple guardians discussed how their surgeon did not provide instructions about proper follow-up care such as speech therapy or nutrition. Additionally, families were unsure whether they could afford surgical treatment or follow-up care for their child, and had not received information about non-profit organizations that would cover the cost of care.

"We can't come because there is no family support, nobody to take care of the other kids." –Mother of female patient with cleft palate (age 4)

"It is not because I do not give importance [to speech therapy] but because of the housework, I cannot come." –Mother of male patient with cleft palate (age 3)

Optimal Post-Operative Cleft Care per Families

FGs highlighted that optimal post-operative cleft care includes compassion from providers and treatment that supports their child's self-esteem. Families also discussed how travel was a barrier to care, and home visits or local care would help improve access to post-operative care. Guardians highlighted the importance of continuity of care, and thorough teaching on follow-up care needs. Finally, families thought that care should include a multidisciplinary team of medical, dental, nutritional, and speech specialists that was free of charge to patients and families **(Figure 1)**.

"Because of all the training and manpower, you give care to our child according to their needs, nature, and psychology, which I think is a really good thing." –Mother of female patient with cleft palate (age 6)

"We are very poor and needy. You providing this speech therapy with lodging, food, and facilities has been really great for us." –Mother of female patient with cleft palate (age 3)

When asked about their vision for ideal post-operative speech therapy, families cited the importance of outreach through phone-calls, radio, or television. They also highlighted the value of frequent and continuous therapy, as well as diverse speech activities that included individual therapy, games, and social interactions with other families. Families felt it was important to interact with other cleft families for emotional and logistical support. Additionally, parents had interest in learning how to perform speech exercises during therapy sessions, so that they could encourage their child to practice these exercises at home **(Figure 1)**.

"Nobody in my village was born with cleft lip and palate. My brother was so worried about his nephew, so he brought the pamphlet about where my son could get an operation. The pictures on the pamphlet looked like my child, so I knew I could go to this place for care."
–Mother of male patient with cleft palate (age 9)

"When my child is in a group, if one child is speaking a lot, my child will get jealous and speak more. The child who is speaking will also get positive reinforcement. This way, my child can get better. They learn to copy each other." –Mother of female patient with cleft palate (age 5)

Mixed-Methods: Optimizing Speech Score Improvement and Speech Therapy Access

Quantitative and qualitative data were merged to investigate cohort outliers' responses to speech therapy and their healthcare barriers. Among six patients with poorer speech scores after the intervention, all were ages 3-5 with one exception (age 8). There were no differences in guardian education level, family income, or healthcare access compared to the overall study population. Within this sub-group, themes that emerged from FGs and SSIs included increased value placed on socializing with other children and improving community outreach for speech therapy opportunities. Despite only marginal score improvements after the speech interventions, guardians were committed to continuing speech therapy at home (**Table 11)**.

"Sometimes your child learns by watching another child also to see how they do it. I think that's a valuable aspect of the camp" -Mother of female patient (age 3)

"If it is their very first time getting therapy, it might be good to start them in a group rather than an individual session. Here at the camp, my child is able to mix with other kids" -Mother of female patient (age 5)

"What happened to the other children who had surgery who need speech therapy. Access to information at his village is very limited. How can we register their name and number so that we can invite them as well?"-Father of female patient (age 3)

Among families who reported greatest distances traveled for healthcare access, speech score improvements were less than the cohort mean **(Table 11)**. Of note, the patient living farthest from a health center had the worst speech outcomes and was between the ages of 3-5. This patient's mother was concerned that the speech intervention was not continued over time and was enthusiastic about learning how to perform speech therapy exercises at home. Similar to others in this sub-group analysis, she wanted to spread awareness about the speech therapy camp to others in her village.

"We should also train them in their home. We should teach games to them"- Mother of male patient with cleft palate (age 4) living farthest from a health center

“There are other kids who are operated on in my village, but they have never been able to speak. When I return, I will inform them so that other kids may come and get care.” –Mother of male patient with cleft palate (age 4) living farthest from a health center

One mother reported that her daughter received surgery as a baby, but did not access speech therapy until age 16. This family was from a remote community without nearby access to a health center or hospital. The mother was not previously aware that speech therapy existed, and was concerned that this held true for others in her community (**Table 11)**. Her daughter’s speech improvements were slightly below the mean speech improvement.

“After a few days, one of my child’s teeth came out and the lip didn’t look good, and a re-operation was needed. I didn’t know if it could be done. Later, one of the staff called me and invited me to have the re-operation and speech therapy for free. It was the first time it happened. We didn’t know about the surgery or the speech therapy camp before. I am from the village, and I didn’t know where to go.” - Mother of female patient with cleft palate (age 16) who experienced significant delay in speech therapy access

A different parent born with cleft palate noted that she faced limited family and financial support for her child’s speech therapy despite her own experiences. Despite these barriers, this mother was committed to overcoming the stigma facing her child by improving his speech and education (**Table 11)**.

"I want my child to speak well and to speak clearly. Some of his friends tease him, saying ‘Why is he speaking like that?’ Aren’t they his friends? I have a problem with money, but I still came

here for my child's speech. If our children say they want to study, we will want to teach them."

–Mother with cleft palate of male patient with cleft palate (age 5)

Discussion

In this chapter, a convergent parallel mixed methods approach was used to: 1) evaluate the impact of task-shifted speech therapy on speech outcomes; 2) describe family experiences and barriers to post-operative cleft care; and 3) explore cleft care optimization informed by the experiences of families whose children had nominal improvements after task-shifted speech therapy.

Task-shifted speech therapy demonstrated significantly improved speech in children who had undergone palatoplasty for cleft palate in Nepal. Greatest improvements were noted in weakness, then in misarticulation and glottal stop. As expected, there were no significant differences in hypernasality. Hypernasality is caused by underlying anatomy and cannot be improved through speech therapy alone [76].

Past research has investigated developing SLP capacity for short-term cleft speech therapy in low-resource settings such as Uganda or Mexico [77,78]. However, outside of a study published in Thailand [73], our study represents one of the first models for task-shifted speech therapy in a LMIC. Task-shifting broadens access to speech therapy, and makes it available in regions where finances, lack of specialty services, and geography pose major barriers. One of the key components of the present task-shifted speech therapy model was the supervision and support by a trained SLP. This is a fundamental concept also present in many task sharing models that minimizes the risk of unqualified health professionals overstepping their competencies [79]. Overall, this model may prove useful in other LMICs with similar barriers.

To support task shifting/sharing and other innovative efforts that expand speech therapy access, universal speech tests have been created that use nonsensical syllables for countries without standardized speech scales [80]. Innovative methods for providing speech therapy for cleft palate in LMICs and research to validate their utility are needed.

This work also described family perceptions of optimal cleft care in Nepal. Parents recognized speech improvements after their child interacted with other patients with cleft palate. Children with speech delays often minimize interactions with peers [81], and studies have stressed the importance of group interactions for optimizing speech improvement [82]. Importantly, family members also expressed how their participation encouraged them to perform speech exercises at home. Previous research has demonstrated that parent involvement during speech therapy directly improves child's speech development [83]. Parental involvement in speech development is critical and efforts to encourage this are paramount to improved speech outcomes [84–87]. In our study, parents demonstrated enthusiasm for learning and performing the targeted speech exercises with their children at home. Future research should explore parent involvement as its own form of task shifted speech therapy because of its potential to supplement existing care and extend the practice of speech exercises over time. Overall, these results emphasize the value of having parent and group engagement during speech therapy, and should be explored further in both low- and high-resource settings.

Multiple barriers to follow-up care were identified, including lack of outreach communication, care coordination, and financial support. This is supported by other LMIC cleft care surveys, finding that travel cost is the most common barrier in sub-Saharan Africa, the Middle East, North Africa, South Asia, and Southeast Asia; while cost of care to patients and families is the most common barrier in the Americas, Eastern Europe, and East Asia [86]. Lack of coordinated care and outreach for patients is often addressed by a multidisciplinary effort with case management, and may prove useful in coordinating post-operative cleft care access [87]. Compared to SSIs, FGs enabled families to expand on sensitive themes related to stigma and shame [87]. Past studies highlight the importance of FGs in establishing a safe environment and represent an important component of healthcare barrier evaluations.

Applying a mixed methods approach offered further insight into optimal post-operative cleft care, especially for those most marginalized. Amongst the study cohort, speech score improvements were limited amongst 3-5 years old participants. Younger patients are in the earliest phases of acquiring language skills, and may experience slower improvements in speech [88–90]. Alternatively, a different speech scale may be needed to detect differences in this population. Further research is needed to investigate how speech evaluations vary with age [88]. Patients who live in lower income countries or belong to families with limited education are at increased risk for delays in CL/P surgery and care [80,91]. In this work, patients did not have worse speech outcomes if their family income or education level was below the mean, though the study sample size may not have been large enough to detect a difference. Though these patients may be at higher risk for worse outcomes, this study demonstrates that speech therapy has the potential to benefit patients of all backgrounds. Additionally, patients from more remote regions of Nepal continued to emphasize the need for improved community outreach. Future speech therapy interventions should focus on improving awareness about the importance of speech therapy, and the resources that are available to families for comprehensive cleft care.

CONCLUSION AND FUTURE DIRECTIONS

The translated VELO-Nepali demonstrates strong internal consistency, discriminant validity, and concurrent validity, and can be a useful tool for assessing the impact of VPI, and its treatment, in Nepal. This represents the first VPI quality of life instrument validated in a LLMIC setting, and provides a model for further validation studies in other LLMICs. Future studies should explore other types of validity such as construct validity, which examines the VELO-Nepali's ability to capture changes over time, changes with corrective surgery, or changes with speech therapy. The VELO is now available to be applied to Nepali-speaking populations, and can be harnessed to monitor the impact of speech therapy or surgical programs on quality of life for patients with cleft palate and their families. With the ability to investigate quality of life, the VELO can be applied broadly to better estimate the resources and systems needed to appropriately treat VPI. This could include modifying the disability weight attributed to VPI when calculating the DALY for policy, and also include expanding access to non-surgical cleft care services where stand-alone surgical centers are already in place. Additionally, given that this present study proved the ability to validate the VELO in a low-income country, efforts should be made to expand its validation in other regions. For example, validating the VELO in Hindi (VELO-Hindi), a related Indo-Aryan language, would allow quality of life to be monitored in Nepal's neighboring country, India, where nearly 130,000 cases of unrepaired CL/P are estimated to exist [21].

Task shifted speech therapy demonstrated significant speech improvements in patients with cleft palate. In LMICs, task shifting and task sharing have proven to be essential in improving healthcare access. Although originally developed to overcome the global workforce shortage for HIV/AIDS care, task shifting and task sharing has expanded the pool of human resources available for medical and surgical care [92]. It has been shown to increase cost savings and efficiency in scaling up health interventions[93]. Despite its advantages, there have also been reported cases in which task shifting has led to medical and surgical errors, inappropriate medicine prescriptions, and inadequate supervision [94].

Optimized models of task shifting and sharing have focused on assigning discrete tasks that do not extend beyond the competencies of any given team member. Additionally, there has been increased emphasis on moving towards task sharing models, as task sharing removes the hierarchy associated with task shifting and maintains supervision from qualified health professionals [42]. By learning from experiences in HIV care, models for task shifting and task sharing can be more ethically introduced for surgical conditions. For cleft care, it would mean defining what constitutes comprehensive care and establishing guidelines for tasks that can be shifted or shared to less qualified workers. There would need to be sustained training and supervision for healthcare workers, and referral systems in place so that more complex cases can be addressed by a qualified health professional. Outcomes would need to be closely monitored and regulated to ensure that care is provided ethically [95]. At the moment, there has been little standardization of what can be shifted/shared for cleft care. However, there is significant potential for exploring cleft prevention programs that focus on smoking cessation and folic acid supplementation in expecting mothers, as well as efforts that broaden access to speech, nutrition, and dental care [7].

The speech intervention was valuable for families, not only for providing individualized speech therapy, but also for promoting socialization and establishing a community network. Families identified poverty, lack of outreach, and lack of care coordination as the major barriers to post-operative cleft care and speech therapy. Future studies can improve the robustness of speech evaluations by developing a scale that is validated in the local context. Future research should also investigate the long-term outcomes of task-shifted speech interventions, opportunities for sustainable speech therapy care models, and ways to minimize the long-term sequelae associated with CL/P.

Overall, there is significant potential to replace the traditional mission model for cleft palate, incorporate the perspectives of families and patients when measuring outcomes, and develop the local health system to provide comprehensive and longitudinal cleft care. Where short-term humanitarian missions once existed for cleft care, long-term care centers, multidisciplinary teams, and programs for capacity building and workforce expansion are becoming more standard [96,97]. These efforts, and others that invest in sustainable programs for surgical care, should be supported. With growing efforts to expand access to comprehensive cleft care around the world, patients with CL/P may one day be able to fully realize the comprehensive care they deserve.

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TABLES AND FIGURES

Table 1: Participant Demographics for VELO Validation

TABLE 1
Participant Demographics for VELO Validation

Variable, Mean (SD)	**VPI Cases (n=23)**	**Controls (n=29)**
Age		
Mean (SD)	11.6 (3.9)	15.9 (1.1)
Male, no. (%)	10 (43.5)	13 (44.8)
Number of Prior CL/P Surgeries	2.1 (1.1)	
Years Since Last CL/P Surgery	6.2 (4.1)	
Hospital Distance (km)	17.4 (19.6)	
Hospital Travel Time (min.)	89.5 (110.3)	
Health Center Distance (km)	2.8 (3.8)	
Health Center Travel Time (min.)	41.2 (68.4)	

Variable	**Guardians of VPI Cases (n=19)**
Age	
Mean (SD)	35.8 (7.9)
Male, no. (%)	7 (36.8)
Relation (%)	
Mother	12
Father	3
Grandparent	2
Cousin/Sibling	2
No parent	4
Education Level, no. (%)	
No school	0 (0)
1-5 (Primary)	8 (42.1)
6-8 (Lower Secondary)	4 (21.1)
9-10 (Upper Secondary)	5 (26.3)
11-12 (Higher Secondary)	2 (10.5)
University	0 (0)
Postgraduate	0 (0)
Unknown	0 (0)

Abbreviations: SD, standard deviation; VPI, Velopharyngeal Insufficiency; IQR, inter-quartile range; no., number; CL/P, cleft lip and/or palate; km, kilometer; min., minutes.

Table 2: Cronbach's α Result for Internal Consistency: VELO Validation

TABLE 2
Cronbach's α Result for Internal Consistency: VELO Validation

	Speech	Swallowing	Situational Difficulty	Emotional Impact	Perception by others	Caregiver Impact
Cases	0.78	0.78	0.91	0.9	0.66	N/A
Guardians	0.72	0.61	0.89	0.87	0.85	0.67

Internal consistency measures whether questions within a given domain produce similar outputs or scores. Abbreviations: VELO, VPI Effects on Life Outcome; N/A, not applicable.

Table 3: Discriminant Validity by Question Category: VELO Validation

TABLE 3
Discriminant Validity by Question Category: VELO Validation

	VPI Cases vs. Controls					VPI Guardians vs. Controls		
	VPI		Control					
Domain	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	*p-value*	Median (IQR)	Mean (SD)	*p-value*
Total VELO Score	44.6 (38.0)	45.4(22.1)	89.1 (7.3)	84.9 (12.3)	<0.001	48.1 (38.9)	52.9 (22.8)	<0.001
Speech Limitation	46.4 (35.7)	44.1 (21.9)	85.7 (17.0)	81.8 (16.3)	<0.001	53.6 (33.9)	52.6 (21.3)	<0.001
Swallowing Problems	75.0 (41.7)	66.3 (29.9)	100 (8.3)	89.1 (18.5)	0.002	91.7 (33.3)	79.4 (24.9)	0.156
Situational Difficulty	35.0 (55.0)	40.0 (28.9)	100 (10.0)	89.1 (19.6)	<0.001	45 (52.5)	49.2 (30.7)	<0.001
Emotional Impact	25.0 (43.8)	32.3 (33.6)	100 (17.0)	91.2 (13.8)	<0.001	56.3 (56.3)	47.7 (33.2)	<0.001
Perception by Others	50.0 (50.0)	52 (23.9)	75.0 (0)	75.6 (7.7)	<0.001	62.5 (50)	61.5 (30.1)	0.059
Caregiver Impact	—	—	—	—	—	25 (37.5)	28.9 (21.8)	—

Discriminant Validity: Participant (Cases) or Guardian Scores vs. Control Scores. Abbreviations: SD, standard deviation; VPI, Velopharyngeal Insufficiency; IQR, inter-quartile range.

Table 4: Concurrent Validity by Question Category: VELO Validation

TABLE 4
Concurrent Validity by Question Category: VELO Validation

	VPI Cases		VPI Guardians		
Domain	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	*p-value*
Total VELO Score	44.6 (38.0)	45.4(22.1)	48.1 (38.9)	52.9 (22.8)	0.473
Speech Limitation	46.4 (35.7)	44.1 (21.9)	53.6 (33.9)	52.6 (21.3)	0.203
Swallowing Problems	75.0 (41.7)	66.3 (29.9)	91.7 (33.3)	79.4 (24.9)	0.122
Situational Difficulty	35.0 (55.0)	40.0 (28.9)	45 (52.5)	49.2 (30.7)	0.318
Emotional Impact	25.0 (43.8)	32.3 (33.6)	56.3 (56.3)	47.7 (33.2)	0.136
Perception by Others	50.0 (50.0)	52 (23.9)	62.5 (50)	61.5 (30.1)	0.265
Caregiver Impact	—	—	25 (37.5)	28.9 (21.8)	—

Concurrent Validity: Participant (Cases) vs. Guardian Scores. Abbreviations: SD, standard deviation; VPI, Velopharyngeal Insufficiency; IQR, inter-quartile range

Table 5: Number of Surgical and Speech Therapy Participants in Kirtipur Hospital's Cleft Lip/Palate Outreach Program. 2000-2018

TABLE 5
Number of Surgical and Speech Therapy Participants in Kirtipur Hospital's Cleft Lip/Palate Outreach Program. 2000-2018

Year	Total Patients	Cleft Lip Patients	Cleft Palate (+/- Cleft Lip) Patients	Speech Therapy Participants
2000-2001	1252	1058	194	83
2001-2002	1031	842	189	119
2002-2003	658	513	145	212
2003-2004	642	495	147	284
2004-2005	597	471	126	182
2005-2006	577	480	97	172
2006-2007	723	667	56	297
2007-2008	940	813	127	366
2008-2009	925	782	143	376
2009-2010	851	714	137	620
2010-1011	794	474	320	587
2011-2012	819	452	367	566
2012-2013	846	478	368	424
2013-2014	757	444	313	409
2014-2015	671	375	296	407
2015-2016	600	339	261	413
2016-2017	548	306	242	302
2017-2018	646	355	291	258

*De-identified data of program trajectory presented with permission from Kirtipur Hospital.

Table 6: Demographics of Speech Intervention Population

TABLE 6
Demographics of Speech Intervention Population

Demographics

n=39	% (n)
Sex	
Male	46.2% (18)
Female	53.8% (21)
Age	
3-6 years	51.3% (20)
7-10 years	25.6% (10)
11-14 years	10.3% (4)
15-18 years	12.8% (5)
Prior Speech Therapy	
Yes	35.9% (14)
No	64.1% (25)

Surgical History

n=37	Mean (SD)
Number of Prior Surgeries	2.0 (1.0)
Years Since Last Surgery	3.4 (3.3)
0-4 years, % (n)	69.2% (27)
5-9 years, % (n)	15.4% (6)
10-14 years, % (n)	7.69% (3)
Unknown, % (n)	7.69% (3)

Healthcare Access

n=37	Mean (SD)
Hospital Distance (km)	17.1 (17.2)
Hospital Travel Time (min.)	87.8 (98.5)
Health Center Distance (km)	4.39 (6.0)
Health Center Travel Time (min.)	37.4 (52.0)
Speech Intervention Travel Time (min.)	309.7 (241.2)

Table 7: Impact of Task-Shifted Speech Therapy Intervention

TABLE 7

Impact of Task-Shifted Speech Therapy Intervention

n=39	Pre-Camp Score mean (SD)	Post-Camp Score mean (SD)	Δ mean (SD)	p-value
Speech Aspects Expected to Improve with Therapy				
Composite Speech Score	42.2 (19.8)	35.6 (18.0)	6.6 (9.6)	0.0001***
Weakness	25.8 (17.3)	21.3 (15.0)	4.6 (7.5)	0.0005***
Misarticulation	11.3 (10.4)	10.2 (10.4)	1.1 (3.8)	0.077
Glottal Stop	5.1 (8.3)	4.0 (7.6)	1.0 (3.0)	0.051
Speech Aspects Not Expected to Improve with Therapy				
Hypernasality	42.1 (43.0)	40.4 (41.4)	1.7 (9.0)	0.231

Table 8: Family Member Demographics of Speech Intervention Participants

TABLE 8
Family Member Demographics of Speech Intervention Participants

n=40*	% (n)
Sex	
Male	25.0% (10)
Female	75.0% (30)
Age [Mean (SD)]	31.9 (7.93)
Relation	
Mother	75.0% (30)
Father	10.0% (4)
Grandparent	7.5% (3)
Cousin/Sibling	7.5% (3)
Literacy	100% (40)
Education Level	
No school	0% (0)
1-5 (Primary)	25.0% (10)
6-8 (Lower Secondary)	12.5% (5)
9-10 (Upper Secondary)	20.0% (8)
11-12 (Higher Secondary)	35.0% (14)
University	5.0% (2)
Postgraduate	2.5% (1)
Monthly Income (n=24) [Mean (SD)]	15,622 NPR (10,407)

*Note that 7 speech camp participants (age≥16) were not accompanied by a family member and completed semi-structured interview surveys.

Table 9: Family Investment in Post-Operative Care and Concerns for Child’s Future

TABLE 9
Family Investment in Post-Operative Care and Concerns for Child's Future

Family investment in speech	
Sub-themes	
Families value speech	"You are giving the gift of speech to my child "
Desire for increased healthcare access	*"If she gets medical evaluation and keeps up with the speech therapy, she will be able to do better in her studies. We cannot teach them well."*
Desire formal speech therapy	*"We don't have time to teach them speech therapy at home. My child comes all the way here and works very hard at speech therapy. When we go home, I know my child will say “can we try and speak this way?”. That is why we came here so that my child will learn how to speak well."* *"I came here so my child’s speech would get better. There are other kids who are operated on in my village, but they have never been able to speak."*
Concern for child's future	
Sub-themes	
Community stigma	*"My family and relatives say that you have given birth to a cleft child, a defected child! Now you have to give birth to another child who does not have this defect! I’m also the sufferer from my cleft."* *"You have given birth to a bull? People would say that about my child. I felt really bad to hear that."* *"In my village, it was a curse to have a child with a cleft palate. One of my fellow villagers had a cleft as well, and they weren’t concerned about him and didn’t feed him well, so the child died at 6 years old. Parents of this child use to come to their home and discouraged him, told me that my child wasn’t go to live that long either. After, when my child was operated on, the friend’s family came to the home to see the child, and the friends mother started crying thinking that she wishes her family had access to this surgery for the child."*
Future education and career	*"My sister was studying in two classes, but she wasn’t advancing and not doing well in the school, so my family discontinued school for her."* *"I’m worried that my child will not study or will not get better education. My child is good at studying, but I worry that he will not be heard by the teacher."*
Developmental milestones	*"Most of them have problems with speaking…and have not reached their speaking milestones."* *"To improve her speech as a child, it takes lots of hard work, even harder than if she were to come as a little child. If it were done before, it would have been easier for her."*

Table 10: Major Barriers to Comprehensive Post-Operative Cleft Care

TABLE 10
Major Barriers to Comprehensive Post-Operative Cleft Care

Theme	SSI (n=47) n (%)	Quote ● Focus Groups ○ SSIs
Family Responsibilities (Childcare, Family Health, Housework)	29 (62%)	● "Nobody is at home, and I have another child there, so it is hard. Dad is not at home often because he works...I was all alone, I couldn't come for three years." ○ *"I have other family members but they tell me that I am the mother, and it's my child so I need to bring her. I have other baby so it's very difficult to travel."*
Travel/Distance	25 (53%)	● *"We are coming from a very long distance, so it's difficult to come. If it were organized near our home, it would have been better for us…It is a 6-hour drive from here. "* ○ *"We are unable to get to doctor's appointment all of the time because of transportation and time."*
Work	16 (34%)	● *"I have a small child who I left at home who somebody else is taking care of me, and I had to temporarily close the shop that I own. Today is an important market day, and I had to come here for my child...so it's hard."* ○ *"Both parents work and there is nobody to take our child"*
School	15 (32%)	● *"Other child will be promoted to class 2 or 3, but our child might not and remains in class 1 because they are coming to the speech camp and not attending school."* ○ "Child needs education and needs to go to school but it sometimes happens at the same time as therapy. It is work to bring the child in."
Lack of Follow-Up Communication and Care Coordination	11 (23%)	● *"Some doctors come and do surgeries. People get their surgeries and then they don't know they should go for speech therapy. Totally unknown."* ● *"Doctor surgeon said that after your operation, your speech will be better but my speech was not better! I was told to come after three months, but I didn't know who to see, where to go. I had no phone number."* ● *"I was unsure whether my child would have an operation. Would he remain the same after the operation? We never knew about the surgical camp or the speech camp. I didn't know and was worried about where to take my child."*
Financial	11 (23%)	● *"If we had to pay, I would find it very difficult to afford this care for my child. if we had gone to the private clinics for speech therapy, we would have had to pay money."* ● *"I have a problem with money but I still came here for my child's speech."*

Figure 1: Optimal Post-Operative Cleft Care from the Family Perspective

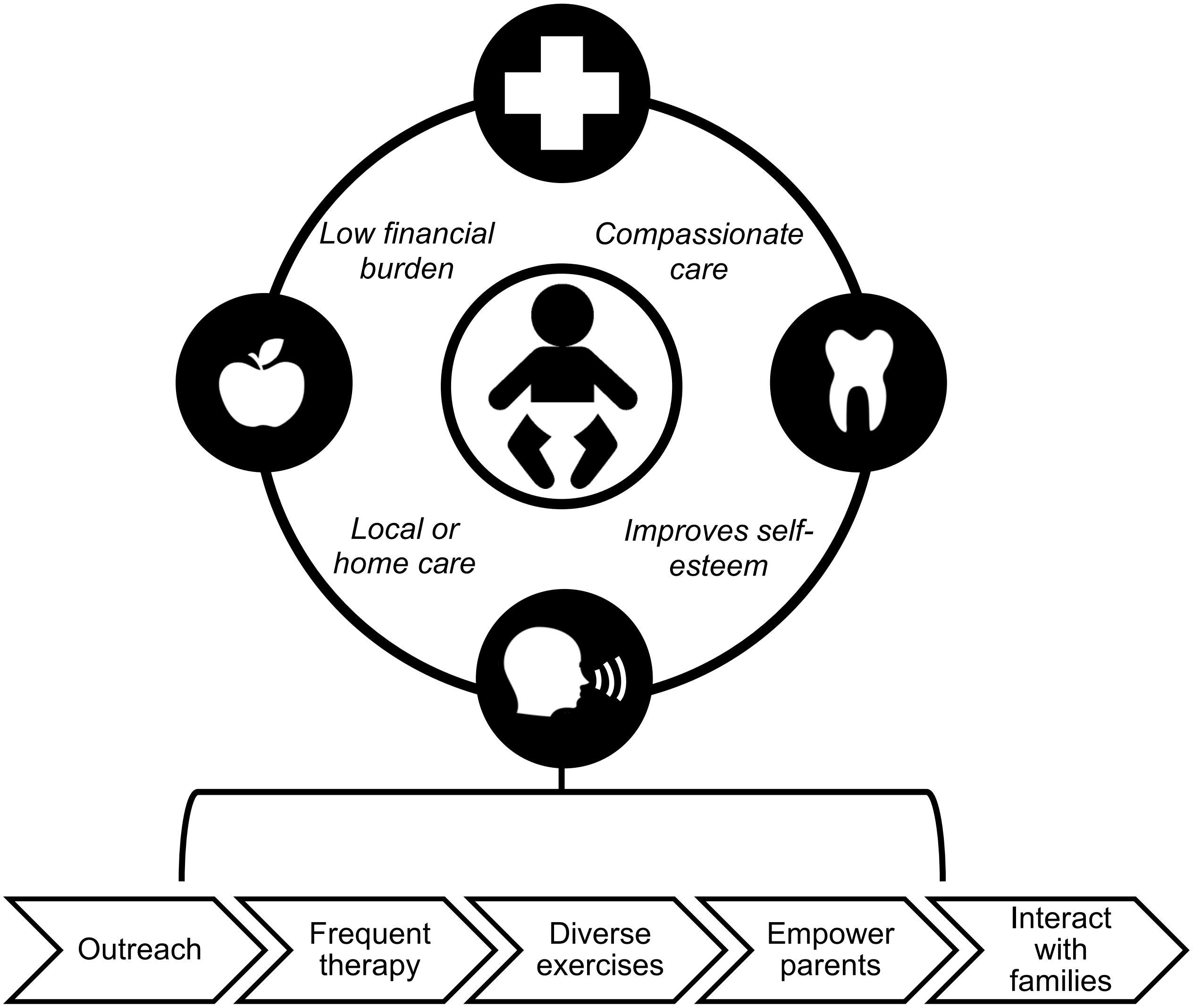


Figure 1: Optimal Post-Operative Cleft Care from the Family Perspective. Per families, optimal cleft care includes multidisciplinary attention from medical, dental, nutritional, and speech specialists (indicated by symbols in the outer ring). Families agreed on four values of care (included in the circle). For speech therapy, families valued: outreach via radio/television/telephone, diversity in speech exercises, education for parents to continue exercises at home, and opportunities to interact with other families undergoing cleft care.

Table 11: Mixed Methods: Exploring Experiences of Outlier Speech Intervention Participants

TABLE 11
Mixed Methods: Exploring Experiences of Outlier Speech Intervention Participants

Subject	Age	Sex	Speech Score Δ	Parent Education	HC Distance (km)	Hospital Distance (km)	Barriers Faced
Cohort, Mean (SD)	8.47 (5.58)		6.64 (9.6)	Upper Secondary***	4.03 (5.45)	17.2 (17.3)	
Speech Composite Score Worse after Intervention							
A	4	M	-14	Higher Secondary	25**	12	*"I came here so that my child's speech would get better. There are other ki who are operated on in my village, but they have never been able to speak When I return to my village, I will inform them so that other kids may come and get care."*-Subject A *"We are not well spoken, we wish that you would bring other children to make them better speaking. We are weak but we want other children to develop their child's speech. If he will not be as normal as a normal child, I want my child to at least be better than now."*-Subject C
B	8	F	-5	Lower Secondary	2	16	
C	5	F	-5	Higher Secondary	3	25	
D	3	M	-5	Higher Secondary	2	25	
E	4	F	-2	Higher Secondary	18	16	
F	3	M	-1	Upper Secondary	3	3	
Mother with history of cleft palate							
G	5	M	7	Upper Secondary	5	40	*"I'm also the sufferer from my cleft. My operation was done in India...I didn know that the surgery could be done here, so I went to Kathmandu when m child was 6 months old, and they told me that the cleft surgery could be do in the peripheral center"* -Subject G *"My family doesn't support this. My family says: why do you have to go to t speech camp if the child is speaking?... If this is your child, you should go. There are several problems for me. The child's father is dumb and deaf, ar there are no working people in my home."* -Subject G
Patients with over 10 years since surgery and no speech therapy							
H	17	F	10	Higher Secondary	3	15	

I	16	M	4	Upper Secondary	Unk	Unk	*"I didn’t know what follow-up care was available, that speech therapy was important."*-Subject I
J	16	F	N/A	Lower Secondary	6	1	"*My daughter was operated at a young age and now she is 16 years old ar I didn’t know about the speech therapy!! Many people don’t know that the surgery or speech therapy exists."* -Subject J
Greatest Distance to Healthcare							
A	4	M	-14	Higher Secondary	25**	12	*"If the next camp is after a long time my child will forget his therapy and wil have to re-learn it again."* -Subject A
K	8	F	2	Upper Secondary	0.2	60	
Greatest Time to Healthcare							
L*	18	M	17	Upper Secondary	Distance Unknown; Travel Time: 5 hours	Distance Unknown; Travel Time: 8 hours	*"Child only started to speak well after 2.5 years. No one said that this is my child after the operation—there was that much of a difference. My child wa malnourished before, and nobody believed that this was the same child aft the operation!"* -Subject L

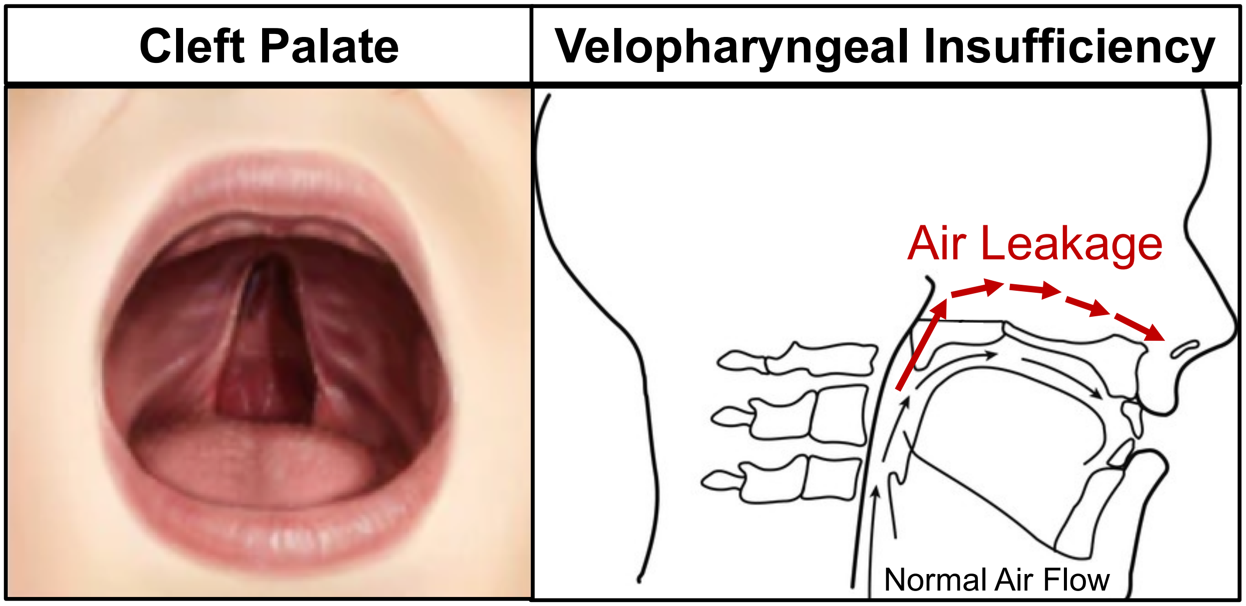
*Patient had greatest time to both health center and hospital

**Patient with the worst speech outcomes had the greatest reported distance to health center in the study population

***Median education of study population

APPENDICES

Cleft Palate and Velopharyngeal Insufficiency



Adapted from Mayo Clinic and Leduc et al., 2008

भिलो

VELO (VPI Effects on Life Outcome)
बोलीको कारणले जिवन स्तरमा पार्ने असर
बालबालिकाका लागि अभिभावकको रिपोर्ट

निर्देशिका :

तल लेखिएका प्रश्नहरु तपाईको बालबालिकाको बोलीको समस्यासँग मिल्न सक्छ । कृपया गएको चार हप्तामा तपाईले **कत्तिको समस्या** महसुस गर्नु भएको छ । गोलो चिन्ह लगाउनुहोस् ।

० समस्या छैन ।
१ बिरलै समस्या हुन्छ ।
२ कहिलेकाँहि समस्या हुन्छ ।
३ प्रायजसो समस्या हुन्छ ।
४ धेरैजसो समस्या हुन्छ ।

यसमा कुनै सहि गलत उत्तर हुदैन । तपाईले कुनै प्रश्न बुझ्नु भएन भने रिसर्च सहायकलाई सोध्न सक्नुहुन्छ । कृपया सबै प्रश्नहरुको उत्तर दिनुहोला ।
प्रत्येक अभिभावक वा सेवा प्रदायकले यो भिलो प्रश्नहरु भर्नुहोला ।

हेरविचार गर्नेको विवरण:

१) अभिभावक वा सेवा प्रदायक: महिला / पुरुष
२) तपाई अभिभावक वा सेवा प्रदायक हो कि होईन चिन्ह लगाउनुहोस् । हो / होइन

गएको चार हप्तामा तपाईको बालबालिकाको बोलीमा कत्तिको समस्या महसुस गर्नु भएको छ। (एउटा मिल्ने उत्तरमा गोलो लगाउनुस्)

बोलिमा सिमितता	**समस्या छैन**	**बिरलै समस्या हुन्छ**	**कहिलेकाँहि समस्या हुन्छ**	**प्रायजसो समस्या हुन्छ**	**धेरैजस समस्या हुन्छ**
१. कुरा गर्दा नाकबाट हावा बाहिर आँउछ।	०	१	२	३	४
२. कुरा गर्दागर्दै स्वाँस रोकिने हुन्छ।	०	१	२	३	४
३. लामो कुरा गर्न गाह्रो हुन्छ।	०	१	२	३	४
४. धेरै सानो स्वर छ।	०	१	२	३	४
५. हत्तारिएर बोल्दा कुरा बुझ्न गाह्रो हुन्छ।	०	१	२	३	४
६. दिनको अन्त्यमा बोली नबुझ्ने हुँदै जान्छ।	०	१	२	३	४
७. अरु बालबालिकाको भन्दा फरक बोली छ।	०	१	२	३	४
निल्नको लागि समस्या					४
८. झोल पर्दाथ पिउदाँ नाकबाट बाहिर आँउछ।	०	१	२	३	४
९. खाना वा ठोस पदार्थ खादाँ नाकबाट आँउछ।	०	१	२	३	४
१०. झोल वा खाना खादाँ नाकबाट बाहिर निस्केको देखेर अरुले जिस्काउँछन्	०	१	२	३	४
परिस्थितिको समस्या					
११. अपरिचित व्यक्तिलाई बोली बुझ्न गाह्रो हुन्छ।	०	१	२	३	४
१२. साथीहरुलाई बोली बुझ्न गाह्रो हुन्छ।	०	१	२	३	४
१३.परिवारका सदस्यहरुलाई बोली बुझ्न गाह्रो हुन्छ।	०	१	२	३	४
१४.आमुन्ने सामुन्ने नबसी बोल्दा बुझ्न गाह्रो हुन्छ।	०	१	२	३	४
१५. फोनमा कुरा बुझ्न गाह्रो हुन्छ।	०	१	२	३	४

भावनात्मक असर					
१६. बोलेको सुनेर अरुले जिस्काउँछन् ।	०	१	२	३	४
१७. बोलीको कारणले बच्चा निरास हुन्छ ।	०	१	२	३	४
१८. बोलेको अरुले नबुझ्दा बच्चाले दिक्क मान्छ ।	०	१	२	३	४
१९. बोलीले गर्दा बच्चा पछाडि बस्छ वा लजाउछँ ।	०	१	२	३	४
अरुले कसरी लिन्छन्					
२०. बोलीको कारणले गर्दा अरु बच्चा जस्तो चलाख छैन भन्ने सोच्छन् ।	०	१	२	३	४
२१. बोलीको कारणले गर्दा मेरो बच्चालाई अरुले वास्ता गर्दैनन् ।	०	१	२	३	४
२२. बोलीको कारणले गर्दा अरु मेरो बच्चासगँ फोनमा कुरा गर्न रुचाउदैनन् ।	०	१	२	३	४
२३. परिवार वा साथीहरु मेरो बच्चाको सत्तामा बोल्ने गर्छन् ।	०	१	२	३	४
अभिभावकको नजरमा					
२४. मेरो बच्चाको बोलीको लागी म चिन्तित छु ।	०	१	२	३	४
२५. मलाई मेरो बच्चाको बोली बुझ्न गाह्रे हुन्छ ।	०	१	२	३	४
२६. मेरो बच्चाको बोलीले गर्दा म दुःखी हुन्छु ।	०	१	२	३	४

भिलो

VELO (VPI Effects on Life Outcome)

बोलीको कारणले जिवन स्तरमा पार्ने असर
युवावर्गको रिपोर्ट

निर्देशिका :

कृपया तलका प्रश्नहरुको उत्तर भर्न बालबालिकालाई सहयोग गर्नुहोला ।

तल लेखिएका प्रश्नहरु तपाईको बोलीको समस्यासँग मिल्न सक्छ । कृपया गएको चार हप्तामा तपाईले आफ्नो बोलीमा **कत्तिको समस्या** महसुस गर्नु भएको छ । गोलो चिन्ह लगाउनुहोस् ।

० समस्या छैन ।
१ बिरलै समस्या हुन्छ ।
२ कहिलेकाँहि समस्या हुन्छ ।
३ प्रायजसो समस्या हुन्छ ।
४ धेरैजसो समस्या हुन्छ ।

यसमा कुनै सहि वा गलत उत्तर हुदैन । तपाईले कुनै प्रश्न बुझ्नु भएन भने अभिभावक वा रिसर्च सहायकलाई सोध्न सक्नुहुन्छ ।

कृपया सबै प्रश्नहरुको उत्तर दिनुहोला ।

गएको चार हप्तामा तपाईले आफ्नो बोलीमा कत्तिको समस्या महसुस गर्नु भएको छ । (एउटा मिल्ने उत्तरमा गोलो लगाउनुस्)

बोलिमा सिमितता	**समस्या छैन**	**बिरलै समस्या हुन्छ**	**कहिलेकाँहि समस्या हुन्छ**	**प्रायजसो समस्या हुन्छ**	**धेरैजस समस्या हुन्छ**
१. मैले कुरा गर्दा नाकबाट हावा बाहिर आँउछ ।	०	१	२	३	४
२. मैले कुरा गर्दागर्दै स्वाँस रोकिने हुन्छ ।	०	१	२	३	४
३. मलाई लामो कुरा गर्न गाह्रे हुन्छ ।	०	१	२	३	४
४. मैले बोल्दा स्वर धेरै सानो सुनिन्छ ।	०	१	२	३	४
५. मैले हत्तारेर बोल्दा अरुलाई कुरा बुझ्न गाह्रे हुन्छ ।	०	१	२	३	४
६. मेरो बोली दिनको अन्त्यमा नबुझ्ने हुँदै जान्छ ।	०	१	२	३	४
७. मेरो बोली अरु बच्चाहरुको भन्दा फरक सुनिन्छ ।	०	१	२	३	४
निल्नको लागि समस्या					४
८. झोल पर्दाथ पिउदाँ मेरो नाकबाट बाहिर आउँछ ।	०	१	२	३	४
९. खाना खादाँ मेरो नाकबाट बाहिर आउँछ ।	०	१	२	३	४
१०. झोल वा खाना खादाँ नाकबाट बाहिर निस्केको देखेर अरुले जिस्काउँछन् ।	०	१	२	३	४
परिस्थितिको समस्या					
११. मेरो बोली अपरिचित व्यत्तिलाई बुझ्न गाह्रे हुन्छ ।	०	१	२	३	४
१२. मेरो बोली साथीहरुलाई पनि बुझ्न गाह्रे हुन्छ ।	०	१	२	३	४
१३.मेरो बोली परिवारका सदस्यहरुलाई पनि बुझ्न गाह्रे हुन्छ ।	०	१	२	३	४

१४. आमुन्ने सामुन्ने नबसी बोल्दा मैले बोलेको अरुले बुझ्दैनन् ।	०	१	२	३	४
१५. मेरो कुरा फोनमा बुझ्न गाह्रो हुन्छ ।	०	१	२	३	४
मलाई कस्तो महसुस हुन्छ					
१६. मेरो बोली सुनेर अरुले जिस्काउँछन् ।	०	१	२	३	४
१७. मेरो बोलीको कारणले गर्दा म दुःखी हुन्छ ।	०	१	२	३	४
१८. मैले बोलेको अरुले नबुझ्दा मलाई दिक्क लाग्छ वा बोल्न मन लाग्दैन ।	०	१	२	३	४
१९. मेरो बोलीले गर्दा मलाई बोल्न लाज लाग्छ ।	०	१	२	३	४
मेरो बारेमा अरुले कस्तो महसुस गर्छन्					
२०. मेरो बोलीको कारणले गर्दा म अरु बच्चा जस्तो चलाख छैन भन्ने सोच्छन् ।	०	१	२	३	४
२१. मेरो बोलीको कारणले गर्दा मलाई अरुले वास्ता गर्दैनन् ।	०	१	२	३	४
२२. मेरो बोलीको कारणले गर्दा अरु म सँग फोनमा कुरा गर्न रुचाउदैनन् ।	०	१	२	३	४
२३. मेरो परिवार वा साथीहरुले मेरो सट्टामा बोल्छन् ।	०	१	२	३	४

Post-Surgical Speech Pathology Assessment

Name: ____________________________ Age: ________ Sex: M/F Reg'd: Y/N
Examiner's Name: _________________ Date: ______________________

Surgical History:				
Name	Type of surgery	Surgeon	Date	Complication
First Surgery				
Secondary Surgery				

Has the surgery helped with:	Yes	No
- Speech - Language - Feeding/Nasal Regurgitation		

Oro-musculature Assessment and Cleft Information:

1. Lip: WNL / Impaired/ Other: _________________________
2. Hard Palate: WNL / Impaired / Other: _________________
3. Soft Palate: WNL / Impaired / Other: __________________
4. Tongue: WNL / Impaired / Other: ____________________
5. Cleft type and position: _________________________________
6. Other: ____

Articulation Measurement #1 (Pre-Camp)

Bilabial	**Dental/Alveolar**	**Retroflex**	**Alveolar**
म घ फ भ प झ	च त थ छ ज ध	झ ञ ढ ठ त्र	ण र ट स ह ल
Palatal	**Velar**	**Glottal**	WNL/Compensatory # of Errors: ___ Type: Glottal Stop ___ Backing ___ Fronting ___ Other: _____
य	क ग ख य ड	ङ	

Articulation Measurement #2 (Post-Camp)

Bilabial	**Dental/Alveolar**	**Retroflex**	**Alveolar**
म घ फ भ प झ	च त थ छ ज ध	झ ञ ढ ठ त्र	ण र ट स ह ल
Palatal	**Velar**	**Glottal**	WNL/Compensatory # of Errors: ___ Type: Glottal Stop ___ Backing ___ Fronting ___ Other: _____
य	क ग ख य ड	ङ	

Parent/Guardian Semi-Structured Interview Guide

Participant ID# (e.g. 01 if parent, match with child ID + P: 01P)	Date of interview	Interviewer’s Initials
☐☐☐☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐☐☐
	Day Month	Year

PARENT/GUARDIAN SEMI-STRUCTURED INTERVIEW GUIDE
SWOT + Satisfaction Survey

This is a semi-structured interview for parents of children participating in the Nepal Speech Camp. It includes both closed- and open-ended questions. Thank you for your participation.

Demographic Characteristics

1. Record participant’s gender

○ Male ○ Female

2. a. What is your age? ☐☐

b. What is your date of birth?

☐☐/☐ ☐☐/☐☐☐☐ If unknown, check box: ☐

Day Month Year

3. What is your relationship to the child participating in the camp?

○ Mother ○ Father ○ Sibling ○ Grandparent

○ Cousin ○ Other: ○ Not answered

Specify other: ☐☐☐☐☐☐☐☐☐☐☐☐

4. What is the highest level of school you completed?

○ Grade 1-5 (Primary) ○ Grade 6-8 (Lower Secondary) ○ Grade 9-10 (Upper Secondary) ○ Grade 11-12 (Higher Secondary)

○ University ○ Postgraduate ○ No school ○ Not answered

5. Are you able to read and write?

○ Yes ○ No ○ Not answered

6. Have you completed any other type of “job training school”?

○ Yes ○ No ○ Not answered

7. What is the main activity or job you do to provide your family/household – either jobs you are paid for or for which you are given other good or services?

Mark one selection

○ None/Unemployed	○ Local brew seller/ bar or restaurant attendant
○ Student	○ Selling goods (direct interaction with customers)
○ Technician/artisan (plumber, electrician, welder)	○ Business person (other than selling goods)
○ Military/police/security	○ Government/clerical/secretarial
○ Trucker/driver/conductor	○ Mechanic
○ Construction worker	○ Health care worker
○ Housekeeper	○ Homemaker/primary childcare provider
○ Farmer (agro, animal husbandry, etc)	○ Hairdresser/barber
○ Teacher	
○ Other	

Specify other: ☐☐☐☐☐☐☐☐☐☐☐☐

○ Not answered

8. Optional question: Considering all sources of income from your household, what is your average household income per month over the past 3 months?

Prompt subject with a short range of categories and then average for the chosen category for entry

☐,☐☐☐,☐☐☐ Nepali Rupees

○ Not answered

9. Where do you live? Start with the broadest unit like county or district. Start by listing the broadest unit (e.g. county or district) and then move down to list the name of the smallest geographic unit typically known in the area. Check unknown for any geographic unit that is not known.

Street Address

If unknown, check box: ☐

____

Village

If unknown, check box: ☐

District

If unknown, check box: ☐

Province

If unknown, check box: ☐

○ Not answered

Healthcare Access	
1.	How far is the nearest health center from your house? ☐☐☐☐KILOMETERS ☐UNKNOWN. ○ Not answered
2.	How long does it take to travel to the nearest health center from your house? ☐☐☐☐Days ☐☐☐☐Hours ☐☐☐☐Minutes ☐UNKNOWN. ○ Not answered
3.	How far is the nearest hospital from your house? ☐☐☐☐KILOMETERS ☐UNKNOWN ○ Not answered
4.	How long does it take to travel to the nearest hospital from your house? ☐☐☐☐Days ☐☐☐☐Hours ☐☐☐☐Minutes ☐UNKNOWN. ○ Not answered

Child's Surgery and Parent Experience	*If more than one child per parent, fill out separate form
1.	What is the age of your child participating in the camp? ☐☐ ○ Not answered
2.	What is the date of your child's birth? Leave day or month blank if unknown ☐☐/☐ ☐☐/☐☐☐☐ Day Month Year ○ Not answered
3.	How many surgeries has your child undergone to correct the cleft lip/palate? ☐☐ ○ Not answered
4.	Before the camp and after surgery, had you received any training to perform speech exercises with your child? ○ Yes ○ No ○ Not answered
5.	How often do you carry out these speech exercises with your child? ○ Daily ○ 3-5 times/week ○ 1-2 times/week ○ 1-3 times/month ○ 2-5 times/year ○ Never ○ Not answered
6.	During the camp, have you learned any exercises that you plan to perform with your child? ○ Yes ○ No ○ Not answered
7.	If so, how often do you plan to carry out these speech exercises with your child? ○ Daily ○ 3-5 times/week ○ 1-2 times/week ○ 1-3 times/month ○ 2-5 times/year ○ Never ○ Not answered

8.	What are the three biggest barriers to your children accessing follow-up cleft lip/palate care? (e.g. Anything that might have made it difficult for your child to get care. Follow up prompt: what makes it hard for your child to get this care?) 1. 2. 3. ○ Not answered
9.	What barriers exist to providing high quality speech therapy to children who have undergone cleft lip/palate repair? Select all that apply. ○ Lack of trained professionals ○ Lack of equipment ○ Lack of available staff ○ Lack of financial support ○ Lack of patient awareness ○ Patient travel costs ○ Childcare/Nobody to accompany child ○ Other (please specify):___________________________ ○ Not answered

Satisfaction Survey ○ Not answered					
Statement (Likert Survey Questions)	**Agree**	**Somewhat Agree**	**Neither agree or disagree**	**Somewhat Disagree**	**Disagree**
I found the speech therapy camp useful for my child	5	4	3	2	1
I would voluntarily return with my child to a speech camp if it were available again	5	4	3	2	1
I would recommend this speech camp to a close friend who also had a child requiring speech therapy	5	4	3	2	1
I feel confident about understanding my child's speech therapy needs	5	4	3	2	1

Focus Group Interview Guide for Parents/Guardians

Focus Group Number	Date of Focus Group	Interviewer's Initials
☐☐☐☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐☐☐
	Day	Month Year

FOCUS GROUP INTERVIEW GUIDE FOR PARENTS/GUARDIANS

This is a focus group interview for parents of children participating in the Nepal Speech Camp. It includes open-ended questions. Groups should last at least 20-30 minutes. Remind all participants that their participation is entirely voluntary and that they can remove themselves from the group at any time. They are not obligated to share anything; however encourage them to share their experiences to the best of their ability so that we can improve upon speech camps in the future. Thank all participants for their participation.

Number of Parents Participating	Number of Children Participating
☐☐☐	☐☐☐

1. **Tell me about your experience at the camp so far**
2. **What at the camp works well? What are the strengths?**
3. **What at the camp doesn't work so well? What are the weaknesses?**
4. **What are ways that we can improve the speech camp?**
5. **What are the three biggest barriers to your children accessing follow-up cleft lip/palate care? (e.g. Anything that might have made it difficult for your child to get care. Follow up prompt: what makes it hard for your child to get this care?)**
6. **In your mind, what does the best type of care for your child look like?**