



Laryngectomy: The role of the speech and language therapist

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This piece of work was commissioned by RCSLT and as such is limited to the practice of its membership. Whilst it is acknowledged that other members of the multidisciplinary team may be involved with Surgical Voice Restoration – this is outside the scope of this document. This document is intended to apply to the practice of speech and language therapists in working with people with laryngectomy, including the role of speech and language therapists within the practice of SVR.

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Operational definitions

(A)TSV – (Adjustable) Tracheostoma Valve

HME – Heat / Moisture Exchanger

PE segment – pharyngo-(o) esophageal segment (also known as neoglottis or vibratory segment)

Puncture – surgically created tract between trachea and oesophagus/pharynx

SVR - Surgical Voice Restoration

TEP – Tracheo-esophageal Puncture (USA)

TOP – Tracheo-oesophageal Puncture

Tract / Fistula - Often used to refer to tracheo-oesophageal puncture

For the purpose of this document the surgically created tracheo-oesophageal tract will be referred to as a '*puncture*' to distinguish it from a '*fistula*' which is often used to refer to a surgical breakdown/complication.

For simplicity, the abbreviation TEP will be used throughout this document.

Voice prosthesis – commercial product manufactured to shunt air between trachea and oesophagus/pharynx following surgical removal of the larynx.

Sometimes referred to as a 'valve'

When we refer to 'medical practitioner', we are assuming that this is a medical practitioner with knowledge and skills in both head and neck cancer surgery and surgical voice restoration.

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Position Paper Statement

Rehabilitation following laryngectomy in the UK, in particular voice, swallow and pulmonary rehabilitation, is led and delivered by speech and language therapists (NCAT 2013, Owen and Paleri, 2013) as part of a multidisciplinary team (MDT). Intervention from speech and language therapy is essential at each stage of the laryngectomy pathway, from diagnosis to long-term management, to support individuals in reaching and adjusting to their new optimum functional potential (Goff et al, to be published). The RCSLT Laryngectomy Competency Framework (2023) should be referred to as a guide for developing these specialist skills.

Prosthetic Surgical Voice Restoration (SVR) and management of tracheo-oesophageal puncture (TEP) prostheses is a routine part of comprehensive voice rehabilitation for those undergoing surgery for removal of the larynx (laryngectomy). Primary surgical voice restoration is the most common speech rehabilitation strategy following laryngectomy in the UK (Owen and Paleri, 2013). However, speech and language therapists (SLTs) facilitate individualised methods of post-laryngectomy voice and communication restoration including:

- surgical voice restoration
- oesophageal voice
- electrolarynx use
- use of alternative and augmentative communication and text-to-speech applications
- silent articulation

It is the position of the RCSLT that post-laryngectomy voice restoration (including SVR and management of the TEP), and stoma related issues are within the scope of practice for SLTs with expertise and specialist training in this area.

In addition, it is within the scope of SLT practice to provide specialist assessment and intervention for post-laryngectomy swallowing issues, olfactory rehabilitation, communication and pulmonary rehabilitation.

The SLT provision of pre-operative information to patients and family members regarding communication, swallowing, breathing, appearance, olfactory changes, pulmonary rehabilitation and support networks can provide reassurance and promote a more positive emotional state in the early post-operative stages (de Maddelena, 2002). Pre-laryngectomy speech and language therapy counselling reduces levels of distress, post-traumatic stress, anxious-depressive symptoms and facilitates emotional adaptation and acceptance of the new voice (Longobardi, 2023). Plans for restoring communication function should begin immediately after rendering a definitive diagnosis and establishing the need for total laryngectomy, despite the focus on survival at this point in the treatment pathway (De Lassus Gress, 2004); this should include offering to meet a person with laryngectomy pre-surgery or providing voice banking if available.

We recognise that post-laryngectomy rehabilitation is always undertaken in a multidisciplinary team (MDT) environment, and that this process is well established in a number of centres throughout the UK. All cancer centres should have a named speech and language therapist with at least 50% of time dedicated to head and neck cancer care and with specialist surgical voice restoration skills (BAHNO, 2020). Most existing services operate within an environment of mutual understanding between SLT and Ear, Nose and Throat (ENT) colleagues, and these centres will already have well-established local policies. If a specialist SLT in the MDT delegates rehabilitation work to an SLT working in another setting, the specialist SLT should be available to provide expert advice and to assist with meeting the specific needs of these patients (NICE, 2004). This Position Paper and the RCSLT Laryngectomy Competency Framework (Robertson et al, 2023) should be read within this context and should be seen as supportive and facilitating not prescriptive or prohibitive. Speech and language therapy practice is dynamic and changing. The scope of practice grows along with advances in technology enabling practitioners to provide new and improved methods of diagnosis and treatment. By identifying SVR as being within the scope of practice, it is not intended to limit any other new or emerging areas from being developed by SLTs to help improve diagnosis and treatment post laryngectomy. If practitioners choose to perform these procedures,

indicators should be developed to continuously monitor and evaluate the appropriateness, efficacy and safety of the procedure conducted (RCSLT, 2008).

There are risks to patients in the use of TEP and other procedures relating to laryngectomy management, and the SLT should be aware of these, and follow the guidelines set out in this document. In addition, if the SLT is competent to carry out other procedures for people with laryngectomy such as fiberoptic endoscopic evaluation of swallowing (FEES), videofluoroscopy (including air insufflation), modified Taub test or tracheal manometry, they should do so within the relevant RCSLT guidelines and within their competencies to minimise risk to the patient (see RCSLT Laryngectomy Competency Framework, 2023).

This position paper encompasses the following: background and evidence base, training and competencies, procedure and interpretation, health and safety, types of clinics, medico-legal aspects, patient populations and documentation.

Section 1: Context

1.1 Background

SLTs facilitate and provide rehabilitation for all methods of post-laryngectomy communication including surgical voice restoration (SVR), oesophageal voicing, use of electrolarynx, pseudo voice, gesture, text-to-speech apps and alternative and augmentative communication (AAC). This is as appropriate to each individual and to support their preferred methods of communication. UK head and neck cancer guidelines recommend offering SVR to all suitable patients and to consider incorporating oesophageal voice and electrolarynx use into communication rehabilitation (Clarke et al, 2016). SLTs may facilitate voice banking pre-laryngectomy surgery. SLTs also have particular expertise in pulmonary rehabilitation, olfactory rehabilitation and management of dysphagia post-laryngectomy within a head and neck multidisciplinary team context. SLTs carry out specific instrumental assessments (e.g. videofluoroscopy, fiberoptic endoscopic evaluation of swallowing or tracheal manometry) to holistically problem solve swallowing and voice problems post-laryngectomy.

1.2 Communication

1.2.1 Surgical Voice Restoration (SVR)

SVR is a recognised procedure for post-laryngectomy voice rehabilitation. It has been carried out by SLTs since its inception in the late 1970's (Blom et al, 1998). SVR rates approaching 90% of patients with laryngectomy are possible and laryngectomy patients using tracheoesophageal voice have a significantly better self-reported outcome and voice-related quality of life than patients using other methods of communication (Robertson et al, 2012). It involves placing a silicone (voice) prosthesis into a surgically created tract within the tracheo-oesophageal party wall, to redirect the pulmonary airstream into the oesophagus if the tracheostoma is covered. This airstream provides the energy source for the

vibratory segment in the reconstructed pharynx which produces a sound source for pulmonary powered pseudo voice.

The prosthesis is a one-way valve that allows air to travel posteriorly into the oesophagus, but prevents the return of oesophageal contents (saliva, food, drink) into the trachea, and thus prevents aspiration into the airway. It does not itself produce voice, it merely facilitates airflow and consequent vibration of the vibratory segment.

SVR procedures can be undertaken, either as a primary (at the time of laryngectomy) or secondary procedure (at some time later). The UK head and neck cancer guidelines recommend offering primary surgical voice restoration to all suitable patients (Clark et al, 2016). Some centres may create the primary TEP with voice prosthesis placement at the time of laryngectomy surgery, others may place the voice prosthesis several days later. If not suitable for primary puncture and where appropriate, an assessment for a secondary surgical voice restoration should be considered and may require air insufflation to assess the potential for this (Goff et al, to be published).

Secondary tracheoesophageal puncture should be preferred where there is a higher risk of pharyngocutaneous fistula such as following chemoradiotherapy (Chakravarty et al 2018) or more extensive reconstruction Gitomer et al (2016). It is best to decide on primary or secondary TEP on an individual basis and depending on the experience of the MDT team at the unit (Pracy et al, 2016).

Since SVR procedures were first introduced, there have been several variations on the surgical approach and the type of voice prosthesis used. SLTs with additional competencies (see RCSLT Laryngectomy Competency Framework) to size the TEP and insert and remove voice prostheses, will select the most appropriate voice prosthesis and insertion method based on voice prosthesis features and assessment of the individual's TEP including:

- sizing

- appearance of TEP and surrounding tissue
- history of voice prosthesis changes including any issues/ frequent reasons for voice prosthesis failure.

SVR practice has evolved and now includes the use of tracheostoma valves for hands free voicing and heat moisture exchangers/filters to compensate for loss of the benefits of nasal airflow (filtration, warming and humidification), laryngectomy tubes, stoma buttons etc. The use of HME systems compensate for reduced air resistance post laryngectomy and support SVR. SVR is a term referring to voice prosthesis use and part of a process of voice and pulmonary rehabilitation after laryngectomy.

1.2.1.1 Suitability of SVR and contraindications

No patient should be excluded from consideration of SVR without full discussion of the options with the patient and carers. Information and support should be tailored to the individual's needs (BAHNO, 2020) including the risks, benefits and commitments of voice prosthesis insertion, and care required. Assessment and counselling regarding suitability for SVR and other communication methods is essential and it is desirable to offer patients a pre-treatment visit with a volunteer person with laryngectomy (ENT UK, to be published). Careful planning and consideration should be undertaken when considering these procedures with patients with dementia or cognitive impairment, visual impairment or reduced manual dexterity for the necessary aftercare of a prosthesis. The socioeconomic burden of the cost of and means of travel for voice prosthesis changes and sources of funding and support should be considered. Information should be provided to patients about how their unit will support them when they require urgent surgical voice restoration, in order to make an informed choice about the commitments involved (McLachlan et al 2021). Many patients can learn to change their own voice prosthesis which can lessen the burden of travel/ time commitments and this option can be discussed when considering SVR, with the option to revert to clinician-led changes if the situation for the person with laryngectomy or the TEP changes. When surgical voice restoration is offered, appropriate equipment (e.g.

valve brushes, valves, stoma products) should also be available via free prescription delivery service or supplied by the hospital or community, with long-term access to a specialist SLT and facilities for voice prosthesis changes (Owen and Paleri, 2013). It should be stressed that if a patient opts for a voice prosthesis, and subsequently cannot manage it or does not like it, alternative forms of communication can still be chosen and the TEP allowed to close. TEP's do not always close easily; planned closure may require hospital admission, insertion of cuffed tracheostomy tube into stoma, enteral feeding until the puncture has healed, staged downsizing of catheters through the TEP, cauterisation or surgical closure of the tract.

SVR is primarily an option for individuals who have had their larynx removed for oncological reasons. However, sometimes, a laryngectomy may be performed on individuals who present with a non-functional larynx due to severe trauma or other disease. Laryngectomy is generally carried out in adults, but in rare circumstances, may be performed on children.

In all cases, suitability for prosthetic SVR or other methods of communication should be assessed by the SLT as part of the MDT. Patient selection factors may include aspects such as patient's visual ability, manual dexterity, previous treatment such as chemoradiotherapy and access to appropriately trained SLTs and/or medical practitioners who can support the rehabilitation process.

1.2.1.2 Different types of voice prostheses

It is desirable that SLTs working in this area are aware of the full range of laryngectomy products including voice prostheses, available equipment and facilities to ensure the best possible outcome for each individual person with laryngectomy. A full range of techniques, products and facilities should be available for voice restoration and should be provided for those who need it (NICE, 2004, Bradley et al, 2013).

In the UK the most commonly used voice prostheses are: Blom Singer (distributed by Severn Healthcare) and Provox (distributed by Atos Medical). There are two

types of prostheses: indwelling which are clinician-placed and removed, and exdwelling which can be removed and replaced by the person with laryngectomy, carer or professional. Self-change valves do not reduce median valve lifespans (McLachlan et al, 2021). Voice prostheses are available in a range of diameters and lengths. The prosthesis lifetime can vary from a few weeks to several months: median tracheoesophageal voice prosthesis lifespan is 61 to 74 days or 3.66 prosthesis changes per year, with increased node stage or preoperative chemoradiotherapy likely to result in more frequent changes (McLachlan et al, 2021). People with laryngectomy can expect unpredictably spaced, unplanned hospital attendance for voice prosthesis changes, which will be more frequent in the first 12 months (McLachlan et al, 2021). Many patients are able to learn to change their own prosthesis, which can lessen the impact of leaking valves on day-to-day activity. Lifestyle, cleaning regime, candida and voice use can all affect prosthesis lifetime. When the prosthesis leaks (and the leak is not resolved by cleaning), consideration should be given to changing the prosthesis for a new one as soon as is practical to prevent aspiration into the airway.

1.2.1.3 Hands-free tracheostoma valves

A hands-free tracheostoma valve eliminates the need for digital occlusion for tracheoesophageal speech, freeing up hands for use of gesture and avoiding needing to digitally occlude the stoma when voicing, which can reduce the focus on difference in appearance or method of voicing post-laryngectomy. All people with laryngectomy and SVR should be assessed and offered a hands-free outer tracheostoma valve if suitable (Goff et al, to be published, Clarke et al, 2016). SLTs are able to identify people who may benefit from trialling hands-free valves, those who may need some additional measures to prepare for or enable hands-free (such as increasing duration of HME use or optimising baseplate choice) and those for whom hands free is contraindicated (e.g. inability to remove hands free valve or HME due to dexterity or cognitive issues). Using a hands-free tracheostoma valve requires wearing a baseplate with secure adhesion to the peristomal skin (or a laryngectomy tube in which the tracheostoma valve can be placed), tolerance of

HME use, ability to remove and replace valve independently and achieving sufficient expiratory effort to produce voice.

SLTs facilitate hands-free valve use by identifying the appropriate hands-free device, the most suitable baseplate shape and features and use of adhesive support devices, adhesive glues or enhanced methods of attachment or customised peristomal moulds where appropriate. SLTs explain HME airflow resistance, helping people with laryngectomy to select the most appropriate HME to use initially for hands free voicing and also for different levels of physical activity or in different settings. People with laryngectomy may choose to use a hands-free valve in certain social settings or situations to enhance their quality of life, and switch to manual occlusion of the stoma for voicing at other times. SLTs problem solve hands-free voicing, including using tracheal manometry to help identify if intratracheal pressure is an issue, providing biofeedback to help people with laryngectomy to adjust technique to the optimal pressure for hands free voicing.

1.2.3 Oesophageal voicing

Oesophageal voicing involves self-inhalation or injection of air into the oesophagus. This air in the oesophagus is then voluntarily moved up to the vibratory segment to produce alaryngeal voice. It has the advantage of not needing to use the hand or a device for voicing and may be more suitable for people with dexterity or visual issues who cannot have a voice prosthesis, or those who opt not to have one. Extensive resection of the pharynx such as pharyngolaryngectomy, makes acquisition of functional oesophageal speech more unlikely (Ward et al, 2003, Bates et al, 1990). Inability to insufflate the oesophageal reservoir or move air through the PE segment due to hypertonicity or spasm inhibits oesophageal voicing as well as tracheoesophageal voicing, therefore similar investigations to support voice rehabilitation, such as videofluoroscopy may be required to support oesophageal voicing. Techniques such as reducing muscle tension, working on articulation, loudness, pitch variation, speaking rate, digital pressure for hypotonic voice, breathing and reducing stoma blast can be used to improve oesophageal voicing -

Ward and van As-Brookes (2007), Evans (1990) and Edels (1983) give a good overview of SLT oesophageal speech training techniques.

Oesophageal voice has a slower speech rate than electrolarynx or TO speech, but with practice, as air insufflation occurs more efficiently and rapidly, the rate of speech increases and the quality of voice perceived by the listener improves (Shipp, 1967). It can take longer to acquire oesophageal voice than other methods of voicing (Xi, 2010).

Oesophageal speech has become the least utilised of the voice options post-laryngectomy in developed countries (Tang et al, 2022), but in a post-Covid era, the advantage of not requiring aerosol-generating voice prosthesis changes may mean oesophageal voice increases in popularity (Doyle and Damrose, 2022). Ultimately, the choice in voice restoration technique requires joint decision making with the MDT including surgeon, SLT and person with laryngectomy (Tang et al, 2022).

1.2.4 Use of electrolarynx

Use of electrolarynx is considered the easiest voice rehabilitation method to use (compared to oesophageal or SVR) but user satisfaction is lower than other methods of voicing due to the mechanical voice quality and noise (Xi, 2010). It may be used in addition, as a back-up or alternative to other methods of voicing. The electromechanical device produces pharyngeal or oral cavity vibrations when placed on the neck, cheek or used with an oral adaptor, and speech is produced using articulation. SLTs can help people using electrolarynxes learn to adjust pitch, tone, on-off timing, rate of speech and improve placement of the electrolarynx. Advantages of electrolarynx speech over text to speech options are utilising the natural nuances of speech such as a patients' articulatory abilities and oral cavity (Kaye et al, 2017). Electrolarynx speech production involves no pulmonary air generation and experienced electrolarynx users will decouple or decrease speech association with exhalation which improves speech acceptability (Liu et al 2004).

If the patient has had a neck dissection, the artificial larynx should be placed on the contralateral side and an electrolarynx should not be used on a sore or tender neck (Edels, 1983) such as recently irradiated skin (but could be used with an intraoral device). An electromyography controlled electrolarynx can be strapped to the neck to allow for hands free use of an electrolarynx as long as strap musculature is intact, but it can be difficult to maintain good contact for voice (Heaton et al, 2011, Kubert et al, 2009).

1.2.5 Alternative and augmentative technology (AAC)

AAC technology such as a tablet with a text-to-speech app used post-laryngectomy (when patients are aphonic), may alleviate distress by improving communication (Haring et al, 2022, Adam et al, 2022) - see RCSLT [AAC guidance](#). Voice banking and personalised speech synthesis should be offered to all patients deemed eligible pre-laryngectomy due to the possibility of using spoken word with the person's personalised voice (Repova, 2021). However, access to voice banking will vary across different SLT services within resources available as this is an emerging area. Some people may choose to mouth with silent articulation, use gesture, facial expression or writing to communicate but these methods may rely on the ability of the communicative partner to lip-read, the clarity of the articulation and the need to slow down for a conversation when full sentences are required.

1.2.6. Outcome measures for assessing post-laryngectomy communication

The Sunderland Tracheoesophageal Voice Perceptual Scale (SToPs, Hurren et al, 2019) is designed and validated for assessing tracheoesophageal voice and grading along a tonicity scale. SLTs may also use the following assessments for laryngectomy voice outcome measures: Self-Evaluation of Communication Experiences after Laryngeal Cancer (Blood et al, 1993) and the Voice Prosthesis Questionnaire (Kazi et al, 2005 and 2006). The Therapy Outcome Measures (TOM, Enderby et al, 2013) includes scales for laryngectomy, voice and dysarthria and can be used for head and neck patients (Radford et al, 2004). Voice recordings and measuring speech tasks such as: recording maximum phonation time; consistency

of achieving voice on request or on-off timing of electrolarynx; speech rate, latency time between start of oesophageal insufflation and voice; or recording number of syllables, words or phrases or social situations achieved with voice (e.g. using the telephone) may be used to monitor progress (Evans, 1990, Edels, 1983).

Communication changes post-laryngectomy include tone, pitch, rate and changes relating to social use of language and these should be considered in SLT assessment and rehabilitation; individuals may respond to changes in communication or reduced communicative competence differently (Doyle et al, 2023). The Voice Related Quality of Life (V-RQOL, Hogikyan and Sethuraman, 1999) measure may be adapted using a modified scoring procedure for use with people with laryngectomy (Bornbaum et al, 2014). Both SLT and patient-reported outcomes are important; speech outcomes impact health-related quality of life following head and neck cancer treatment (Radford et al, 2004).

1.3. Types of instrumental assessment to assess and facilitate laryngectomy voice

1.3.1. Tracheal manometry

People with laryngectomy may fail to achieve good voice restoration due to hypotonicity, hypertonicity or spasm of the vibratory segment. Tracheal manometry via stoma is an effective technique for assessing pressure in the vibratory segment and can be used to provide biofeedback for the patient.

1.3.2 Videofluoroscopy

Videofluoroscopy enables problem-solving for laryngectomy voice. It shows voice prosthesis position, leakage and areas of residue, which may explain frequent voice prosthesis failures. Videofluoroscopy can identify stricture which can impact voice as well as swallowing and may require surgical dilatation. For someone with hypotonic voice quality, there may be a lack of tone of the PE segment and greater distance between the PE segment wall: digital pressure or changing head position may be effective in improving voicing.

High PE segment pressures relating to spasm or severe hypertonicity can be reduced through selective administration of botulinum toxin to chemically denervate the pharyngoesophageal constrictor muscles (Ahluwalia et al, 2010). Dysport or botox injection is a safe and cost-effective method of improving TOP voice quality in selected patients with disturbed relaxation of the vibratory segment (Persaud et al, 2013, Khemani et al, 2009, Hoffman et al, 1997), especially when combined with speech therapy (Bartolomei et al, 2011). Lignocaine may be used to support differential diagnosis of hypertonicity or spasm and to predict the outcome of Botox injection (Deshpande et al, 2010). SLT rehabilitation techniques may include relaxation, breathing and postural techniques to encourage body and pharyngoesophageal tract muscles relaxation. Botox injection should only be carried out in accordance with local protocol, including assessment of voice quality to monitor outcome. Spector et al (2013) describe a method of using videofluoroscopy to guide botulinum toxin injections for pharyngoesophageal spasm after total laryngectomy. It is an MDT problem-solving procedure including SLT, ENT head and neck surgeon, radiologist and gastroenterologist.

1.3.3 Air insufflation testing

If patients are not suitable for primary puncture, assessment including air insufflation should be offered to assess potential for secondary SVR (Goff et al, to be published). Air insufflation testing is the insertion of air into the top of the oesophagus via a tube placed in the nose to evaluate the function of the vibratory segment for alaryngeal voicing. Air insufflation can be used to assess potential for surgical voice restoration prior to a secondary tracheoesophageal puncture or to problem-solve voicing issues with a prosthesis in place. Air is delivered via a transnasal catheter with an air hole at its tip which is passed to the top of the oesophagus. The Taub Test is air insufflation during videofluoroscopy, delivering air under positive pressure from an external air cylinder using a radio-opaque catheter (Taub, 1973). Correct airflow rates and on/off timing of airflow should be used to avoid aerophagia and severe pain for the patient.

The Modified Taub test is self-insufflation via an adaptor or air insufflation kit, which fits the other end of the catheter into a baseplate over the person's tracheostoma, allowing the person to use their expiratory air for insufflation (Blom et al, 1985). The Modified Taub test can be carried out in a clinical setting or under videofluoroscopy conditions; videofluoroscopy allows the clinician to check the correct distal position of the catheter in the oesophagus. Inserting a small amount of contrast into the distal catheter prior to insertion, and placing an opaque marker at stoma level, can ensure efficient placement of the catheter through easier visualisation of the catheter tip (Khemani et al, 2010).

The airflow rates to produce voice, tonicity of voice, analysis of the air reservoir below the PE segment and movement of the air and walls of the PE segment help are analysed. It is recommended SLTs follow a local protocol and have additional competencies (see RCSLT Laryngectomy Competency Framework) prior to carrying out air insufflation testing.

1.3.4 Flexible nasendoscopy

Flexible nasendoscopy can be used to visualise the esophageal side of a voice prosthesis to check its appearance, sizing, location and function. It can identify patients who are at potential risk of complications with voice prosthesis changes or risk of accidental closure of the tracheoesophageal fistula through identifying granulation tissue at the posterior end of the tract (Pilsworth, 2011).

1.4 Pulmonary rehabilitation

All people with laryngectomy should be considered for early post-operative pulmonary rehabilitation, including considering use of a HME within 24 hours of surgery if possible (Goff et al, to be published). Post-laryngectomy, the redirection of air via the tracheostoma (rather than upper airway) means the function of the nasal upper airway for humidification, filtration and warming of inspiratory air is lost. Pulmonary rehabilitation post-laryngectomy is essential to prevent repeated exposure to cold, dry, unfiltered air which can result in damage to the lower

respiratory epithelium, impaired mucociliary function, increased mucous production, increased chest infections, thicker secretions with increased risk of mucous plugs, and increased anxiety and depression due to effects on sleep, coughing and fatigue (Ward et al, 2023). Wearing a cover over the tracheostoma also protects the airway from foreign bodies or airborne particles entering the airway and a filter can protect against transmission of airborne viruses (Dunton et al, 2023, Hennessey et al, 2023).

Contraindications for HME use include:

- shortness of breath
- inability to insert or remove HME e.g due to dexterity or cognitive issues
- excess secretions and/ or coughing e.g. due to pulmonary infection
- patient declines wearing HME or cannot give informed consent to wearing HME
- medical deterioration e.g. active recurrent or metastatic disease or unstable pulmonary function.

Use of a 'closed-system' humidification/ filtration system (such a HME secured into an adhesive baseplate or laryngectomy tube), should be considered as soon as possible post-surgery to optimise pulmonary rehabilitation, but there is variation between services about how soon baseplates are introduced. Laryngectomy foam covers or humidification bibs provide some humidification and increase tracheal climate temperature compared to an open stoma (Quail et al, 2016), but these provide inferior humidification and filtration compared to a closed-system. SLTs should be aware of a range of laryngectomy products to support humidification, filtration and pulmonary rehabilitation, and recommend these based on their suitability for each individual at different points in their treatment pathway and in response to changing needs over time. Use of a HME is considered best practice and SLTs should support optimal HME use through knowledge and selection of the most appropriate products. 69% of people with total laryngectomy in the UK use HMEs (Dunton et al, 2022). There are different HMEs to suit daytime/ nighttime use,

and features of HMEs include different breathing resistance for different levels of physical activity, different moisture and filtration levels.

Improvement in pulmonary physiology improves alaryngeal voice quality (Onofre et al, 2013, Pawar et al, 2008); higher lung volumes are required to initiate voicing via a voice prosthesis resulting in shorter spoken phrase length, therefore breathing exercises may improve voice for people with laryngectomy (Sparks et al, 2023). Expiratory muscle strength training (EMST) is safe and feasible (using a baseplate adapter) for individuals following total laryngectomy, and can improve loudness and maximum expiratory pressure, but may not result in improvement in other clinically relevant voice outcomes, such as VHI-10 (van Sluis, 2020).

SLT's may be involved with assessing stoma size, appearance of peristomal skin and use of products to maintain stoma size. Adequate stoma size is important for maintaining the airway and ability to clean the stoma or TEP. Weekly stoma size assessment may be required during radiotherapy treatment (Goff et al, to be published). SLTs also review the appearance of peristomal skin and alongside head and neck clinical nurse specialists, make recommendations regarding suitable products (e.g. types of baseplates), suggest changes in skin care routine (e.g. promote use of barrier wipes or emollients for peristomal irritation), or refer for nursing or medical review of peristomal skin where appropriate.

1.5 Dysphagia

Prevalence of oropharyngeal dysphagia following total laryngectomy varies significantly in the literature (Maclean, J et al, 2009) and symptoms are mainly related to impaired bolus transport including regurgitation, food 'sticking' in the throat, globus sensation or prolonged mealtimes (Terlingen et al, 2018). Bolus propulsion is affected by changes in swallowing pressures following larynx removal, reconstruction of the vibratory segment and alteration of pharyngeal musculature, including reduced hypopharyngeal contractile pressure (Zhang et al, 2016). Post-laryngectomy pathophysiological issues include pseudodiverticulum, fistulation,

stricture, fibrosis, impaired pharyngeal propulsion, voice prosthesis leakage and reflux which may lead to impaired bolus transit, bolus obstruction or bolus regurgitation (Coffey et al, 2018). Self-reported swallowing outcomes are generally worse in the presence of free jejunal flap repair or post-chemoradiation (Lee et al, 2020). The risk of aspiration post-total laryngectomy is low, apart from fistula or voice prosthesis leakage which patients or carers should be educated to detect. Dysphagia post-laryngectomy may result in prolonged mealtimes, compromised nutrition, weight loss, decreased psychological wellbeing and distress, restricted diet and limited social interaction (Coffey et al, 2018).

1.5.1 Types of instrumental assessment to assess post-laryngectomy dysphagia

The European Head and Neck Society recommendations for Head and Neck Cancer survivorship care (Verdonck-de Leeuw et al, 2022) include to refer patients to a SLT for videofluoroscopy as the first-line test for head and neck cancer patients with suspected stricture, and to refer to a gastroenterologist or head and neck surgeon when stricture is identified. Repeat endoscopic pharyngoesophageal dilatations with close follow-up may be required to relieve dysphagia when stricture is identified (Wu et al, 2018). Other treatments for dysphagia after laryngectomy remain limited (Baijens et al, 2021).

Instrumental swallow evaluations such as videofluoroscopy, air insufflation or FEES may be required to holistically problem-solve post-laryngectomy swallowing issues (Goff et al, to be published) with results discussed with the relevant MDT members. Some evidence supports the use of instrumental dysphagia evaluation for people with laryngectomy, but alternative dysphagia rating scales and instrumental evaluation tools are required (Coffey et al, 2018). Videofluoroscopy is currently the most established tool, and there is some evidence to support FEES and manometry (Coffey and Tolley, 2015). Manometry combined with videofluoroscopy (videomanofluorography) can also be used to assess post-laryngectomy dysphagia in terms of swallowing biomechanics, pharyngeal pressure and hypopharyngeal

intrabolus pressures (Maclean et al, 2011). High resolution manometry is an emerging area.

Alongside the MDT team, a water-soluble contrast swallow should be considered for extended surgery patients (in some centres for all total laryngectomy patients) prior to commencing postoperative oral intake and there should be a documented plan for post-laryngectomy eating and drinking (Goff et al, to be published).

1.5.2 Outcome measures for assessing post-laryngectomy dysphagia

Swallowing impairment should be evaluated from the patient perspective using patient reported outcome measures as well as clinician-rated outcomes; each offers a unique perspective (Patterson and Lawton, 2023). The Swallowing Outcomes after Laryngectomy has good validity as a patient-reported outcomes tool for specifically addressing swallowing outcomes after total laryngectomy (SOAL, Govender et al, 2016, Govender et al, 2012).

The MD Anderson Dysphagia Inventory (MDADI, Chen et al, 2001) is the most commonly used patient-reported dysphagia-specific quality of life outcome measure and is designed for head and neck cancer caseloads (but with no specific validity for post-laryngectomy swallow). The patient-reported Swallowing Quality-of-Life Questionnaire (SWAL-QoL, McHorney et al, 2002) has been used as a primary outcome measure in post-laryngectomy clinical trials (Jansen et al, 2016) alongside quality of life outcome measures; the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire, Core Head and Neck Module, EORTC QLQ- C30, Aaronson et al, 1993, EORTC QLQ-H&N35, Bjorl et al, 1999).

The Sydney Swallow Questionnaire (SSQ, Dwivedi et al, 2010) is a patient-reported outcomes measure using visual analogue scales validated for use with head and neck cancer patients, but not specifically for people with total laryngectomy. The Performance Status Scale for Head and Neck cancer patients (PSS-HN, List et al, 1996) is a clinician-rated scale, as is the Functional Oral Intake Scale (FOIS, Crary et al, 2005) which includes a scale which differentiates oral feeding or enteral feeding dependence. Clinical dysphagia and patient reported dysphagia related to quality of

life are not interchangeable and should be measured separately (Pedersen et al, 2015).

1.6 Olfactory rehabilitation

SLTs should facilitate olfactory rehabilitation post-laryngectomy as part of a holistic evidence-based approach to improving quality of life (Ward et al, 2012). Intensive clinician-assisted treatment can assist patients to improve more rapidly than home-practice alone and have a positive impact on functional state (Ward et al, 2010). A systematic review by Cavalcanti Caldas et al (2012) demonstrated efficacy in the use of olfactory rehabilitation techniques for the function of smell after total laryngectomy, with likely related improvements in taste. The most commonly used technique is Nasal Airflow-Inducing Manoeuvre (NAIM) which patients with altered sense of smell should be encouraged to practise (Verdonck-de Leeuw et al, 2022)

1.7 Surgical resume

Although this is a SLT document, the therapist needs to have some understanding of the basic surgical principles involved:

- a) The techniques of voice restoration, swallow, olfactory and pulmonary rehabilitation and all subsequent discussion applies only to those patients who have undergone a total laryngectomy as part of their surgical treatment.
- b) In addition to total laryngectomy, more extensive procedures including free or pedicle flap repairs, jejunal free graft or gastric pull up re-constructions are also amenable to SVR and other voice restoration techniques. Post-surgery voice restoration can be achieved with these more extensive procedures, but in some cases may be more difficult to achieve. However, the considerations in this policy document apply equally to these more difficult cases.

- c) Various other laryngectomy techniques such as partial sub-total or near-total laryngectomy may well require SLT expertise in the re-establishment of voice but are not within the scope of this document.
- d) Timing of the creation of the puncture and insertion of the voice prosthesis will vary with local practices. Whilst most departments now practise primary puncture (at the time of surgery), there is still a need for secondary puncture in some patients. The prosthesis may be inserted at the time of creation of the puncture but may equally be inserted once the puncture tract has stabilised.
- e) Surgical technique is important for the successful development of voice. Consideration of SVR or methods of communication post-laryngectomy should start **before** the patient gets to the operating room, and in an MDT environment.

Attention to surgical details will mean significant improvement in long-term voice rehabilitation. This should include consideration of:

- preservation of as much normal tissue as possible- a 3cm (unstretched) to 8cm (stretched) posterior pharyngeal strip is sufficient to allow voice rehabilitation (Clarke et al, 2016)
- preservation of constrictor muscles and their use in reconstructing a PE segment
- horizontal closure of the reconstructed pharynx (Clarke et al, 2016)
- sternomastoid tenotomy to produce a flat neck around the tracheostoma
- a complete posterior cricopharyngeal myotomy to divide all fibres of the cricopharyngeus muscle to reduce the risk of spasm or hypertonicity in PE segment
- creation of tracheostoma and accurate placement of TE puncture.

SLTs should also be aware of potential acute and long-term complications after total laryngectomy surgery including fistula, wound breakdown, haemorrhage, infection, recurrence, dysphagia, blockage of the stoma, stomal stenosis, change in quality of life or difficulties with psychological adjustment to post-surgery changes, and respiratory changes due to loss of the warming, filtration and humidification of the upper airway. SLTs should be able to recognise abnormal presentations, liaise with other members of the MDT, recognise limits of their role and use their expertise within their role to help address issues as part of the MDT.

1.8 Aim of SLT laryngectomy rehabilitation

To assist in providing optimum voice, communication, swallowing, olfactory, pulmonary rehabilitation and quality of life after laryngectomy.

1.9 Multidisciplinary context

The SLT and the head and neck surgeon work as part of the extended Head and Neck Cancer MDT, and their joint management goals will be set initially prior to surgery. They will consider the patient's potential for SVR, for producing oesophageal voice and electrolarynx use (Clarke et al, 2016). They may also consider the structure and function of the pharyngo-oesophageal structures, as well as specific prosthesis selection and placement for secondary SVR.

Prosthetic SVR should be performed as part of a multidisciplinary team approach to laryngectomy management. The head and neck surgeon overseeing the patient's care should be involved in surgical aspects of SVR. A medical practitioner may or may not be present during some SVR procedures e.g. sizing and fitting voice prostheses. However, for complex cases, or inexperienced practitioners, a doctor with experience of SVR should be available to provide emergency medical backup for the SLT should a complication arise (see section 3.2 Health and safety). There is an urgent need for training of staff managing out of hours laryngectomy emergencies (Bradley, 2013).

The SLT, with their recognised role in communication rehabilitation, should take lead responsibility for SVR procedures involving prosthesis selection, prosthesis care, management and use for voice (Goff et al, to be published, NICE, 2004, SIGN, 2006,). Speech and language therapists with appropriate training and expertise in the management of the stoma and TEP should be part of all head and neck MDTs (Clarke et al, 2016).

Laryngectomy patients should be registered with the local ambulance service for 999 text service (Goff et al, to be published): this can be invaluable for aphonic laryngectomy patients and can ensure they are transported to the most appropriate care facility (Bradley et al, 2013). Where patients do not have access to text messaging, an individual strategy should be discussed with the patient. All patients should be provided with a neck breather bracelet or card in case of emergency.

SLTs should be aware of and promote education and understanding of the anatomical, physical and quality of life issues faced by people with laryngectomy as a result of changes in communication, swallowing, respiration and appearance. This may include participating in education of other healthcare professionals or students, reminding others of the differences in resuscitation required for neck breathers (e.g. the National Tracheostomy Safety Project, 2022), facilitating laryngectomy support groups and advocating for acceptance of different methods of communication that may be utilised by people with laryngectomy. It is the role of the SLT to be aware of the variance in information about laryngectomy and SVR and to educate and inform other services about the fundamental differences between laryngectomy and tracheostomy.

1.10 Local arrangements

The SLT must ensure that approval has been given by their employer and manager, and that they have competencies to perform procedures such as SVR management

or instrumental assessments (see RCSLT Laryngectomy Competency Framework, 2023). Laryngectomy competencies (e.g. SVR voice prosthesis and removal) must be written into the SLT's individual job description if the SLT is to carry out such procedures. It is good practice to inform other colleagues (i.e. MDT, referrers) of changes in procedures, prostheses used or other management issues.

Services are recommended to have competency documentation for patients completing stoma care to independently manage their airway (or for carers completing this for them), voice prosthesis cleaning or self-voice prosthesis changing. A missing voice prosthesis protocol is also recommended.

1.11 Facilities and equipment

Management of post-laryngectomy communication and swallowing, including TEP procedures, tracheal manometry, videofluoroscopy, FEES and air insufflation testing are safe when performed with the appropriate equipment and resources.

A list of suggested equipment is enclosed in the appendix which is not exhaustive, but may serve as a guideline for setting up services. It is recommended that any service providing videofluoroscopy or FEES services does so within the RCSLT guidance and competency frameworks regarding these. The RCSLT Laryngectomy Competency Framework also outlines additional competencies required for services providing SVR procedures, videofluoroscopy, air insufflation testing and tracheal manometry for laryngectomy patients.

It is essential that all aspects of the procedures and equipment used, as well as rationale for choice is documented in the legal medical record (including SLT notes) as per local policy.

1.12 Different models of service delivery

Most of the equipment for management of the prosthesis is convenient to use and is portable. Prosthesis management (sizing, fitting, therapy) can be performed by SLTs in a range of settings, including ward locations, in a designated clinic room or within the patient's home, depending on local service staffing resources and service structure. Some people with laryngectomy may be trained to change their voice prosthesis at home without needing to attend a clinic or ward. The philosophy of effective team working should be applied to any location where SVR procedures are undertaken. A skilled, competent SLT may carry out the procedures single handedly, but where the SLT is working outside of a hospital setting, a minimum of two persons may be required to carry out the procedures safely and effectively. This may involve two SLTs with SVR competencies or one SLT and another individual also competent in the SVR procedures e.g. clinic nurse, medical colleague.

All laryngectomy operations are carried out in specialist centres (which see a minimum of 100 newly diagnosed head and neck cancer patients a year (NICE, 2004). Long-term SLT input is required to optimise speech after laryngectomy and all MDTs should have rehabilitation pathways covering all stages of the patient's journey with the rehabilitation of post-laryngectomy voice being the specific role of SLTs within this team (UK MDT guidelines, Clarke et al, 2016).

After a tracheo-oesophageal puncture has been created, in some services it is the SLT's responsibility to select and fit the patient with the appropriate prosthesis. SLTs involve people with laryngectomy in decision-making around prosthesis selection and to teach care and use of the prosthesis and provide vocal rehabilitation thereafter. However, some of these aspects may be delegated to appropriately trained and supervised individuals – local agreement and specific protocols should be in place when tasks are delegated to other individuals such as patients self-changing their voice prosthesis. All patients with SVR should complete self-management competencies for troubleshooting and emergency management

and be offered a self-changing competency programme if appropriate (ENT UK, to be published). If visual, cognitive and fine motor skills are intact, independence should be fostered by teaching patients to self-change their voice prosthesis (Clarke et al, 2016).

There is a significant impact of ageing on this population in terms of their independence with voice prosthesis care, ability to self-change voice prostheses, stoma care and ability to successfully use different methods of communication. Services should consider establishing protocols which ensure that rehabilitation options are regularly reviewed and revisited with individuals. This may include exploring alternative communication methods or supporting people to change the voice prosthesis independently. In the absence of clear research, services may also need to reconsider traditional service structures and delivery methods to better support individuals as they age. This may involve risk assessment and evaluation of current practice, acknowledging that where individuals are unable to access care, this may lead to greater risk than delivering care in a non-traditional way. Services may also benefit from collaboration with other charities and organisations supporting people with laryngectomy to live with the effects of cancer treatment and seek to improve their quality of life. SLT services should seek the perspective of people with laryngectomy to review service delivery and proposed improvements.

Examples of different models of laryngectomy service delivery include the following: Wilson et al (2022) outline an enhanced MDT recovery programme for patients undergoing laryngectomy. Parilla et al (2021) describe a systematic therapeutic algorithm for management of peripheral leakage around the voice prosthesis which could be a useful guide for structuring management of peripheral leak within services. McLachlan et al (2021) give a comprehensive description of how to inform patient choice and plan a SVR service based on a three year study of a UK head and neck cancer unit.

Section 2: Training and competency

It is the RCSLT's position that evaluating and treating post-laryngectomy patients using SVR procedures following laryngectomy is within the scope of practice of Speech and Language Therapists. In addition, post-laryngectomy rehabilitation of communication (by facilitating oesophageal voice, use of electrolarynx, pseudo voice, gesture, voice banking and AAC), pulmonary and swallowing rehabilitation are also within the scope of practice of SLTs.

Indicators should be developed to ensure the appropriateness, efficacy and safety of procedures (including SVR procedures).

SLTs are competent to select the most suitable voice prosthesis, to decide when to change prostheses, and when to seek help.

Speech and Language Therapists who intend to perform these procedures must ensure that in order to perform independent SVR procedures, they have undertaken appropriate training, and demonstrate that:

- they have acquired the appropriate knowledge and skills to carry out the procedure competently and safely in accordance with the additional SVR competencies in the RCSLT Laryngectomy Competency Framework (RCSLT, 2023)
- in all instances, the procedure is carried out in accordance with the policy of the employing organisation
- they have mechanisms in place to monitor the appropriateness, efficacy and safety of SVR procedures conducted
- they have a close working relationship with their other members of the MDT

- they understand and utilise the opportunity to contact RCSLT specialist advisors and their MDT colleagues for professional advice and support.

2.1 Knowledge and skills

Underpinning the knowledge and skills required to carry out SVR procedures, the SLT will have achieved relevant competencies in laryngectomy rehabilitation (see RCSLT Laryngectomy Competency Framework, 2023). Each SLT is ethically responsible for achieving the appropriate level of training to carry out SVR procedures competently.

2.1.1 Knowledge required for voice prosthesis management

The SLT will be able to:

- select appropriate patients for SVR and explain post-laryngectomy as a core member of the Head and Neck Cancer MDT
- recognise altered anatomy as it relates to voice, swallowing function, appearance, respiration, smell and taste swallowing post treatment – both surgical and non-surgical
- identify elements of a comprehensive SVR assessment including both voice quality and swallowing e.g. air insufflation test, videofluoroscopy examination
- detect and interpret abnormal findings during assessment including differentiation between central and peripheral leakage
- select appropriate prosthesis from the range available, involving the person with laryngectomy in the decision-making process
- apply appropriate treatment interventions in collaboration with people with laryngectomy e.g. SVR voice therapy techniques, voice prosthesis changes, optimising HME and baseplate use and introducing hands free if appropriate
- make appropriate recommendations to guide management
- make appropriate referral or request a second opinion e.g. ENT, other expert SLT
- request a second opinion from ENT when complications are suspected

- know when and how to re-evaluate and monitor voice prosthesis use and appropriateness
- identify elements of tracheostoma management related to SVR
- adhere to infection protection and control guidelines for SVR procedures.

2.1.2 Skills required to manage voice prostheses

The SLT will:

- appropriately use and dispose of the equipment needed for voice prosthesis selection and management – sizing, fitting, troubleshooting
- insert the voice prosthesis in a manner which minimises discomfort and risk
- be able to administer or have access to another practitioner who will administer topical anaesthetic if required (see section 3.2)
- monitor the patient's comfort and safety throughout the procedure
- interpret, document and communicate steps in prosthesis management and report any relevant findings/impressions.

2.1.3 Recognition of problems, complications and management

The SLT will know how to recognise and manage the following:

- prosthesis: position, loss, retraction, inappropriate size
- tracheostoma: position, stenosis
- puncture: position, stenosis
- partial closure of puncture
- unusual appearance of peristomal area
- split party wall
- compromised party wall
- PE segment: tonicity, stricture or spasm, including recognising there are different treatment options for these e.g. when dilation or use of botulinum toxin may be indicated
- voice prosthesis problems relating to candida, anatomical or physiological features or reflux
- dysphagia

- possibility of recurrence
- recommending appropriate referrals for further investigations e.g. endoscopy, video fluoroscopic examination
- the management of voice prosthesis and stoma during radiotherapy including maintenance of functional communication (ENT UK, to be published)
- late effects of head and neck cancer treatment
- palliative care pathways for the laryngectomy patient in their locality

2.2 Methods of acquisition of the knowledge and skills

Competence in SVR procedures may be acquired using a range of learning methods including:

- didactic/classroom/ webinar teaching (internal/external/online)
- established and accredited SVR courses
- attendance at established SVR clinics
- mentoring
- supervised clinical experience, including observation and guided practice
- peer review of clinical practice/joint practice
- attendance at relevant conferences
- journal clubs (critical appraisal of the literature)
- Clinical Excellence Network (CEN) attendance

2.3 Skills and expertise

An experienced SVR clinician or ENT surgeon will verify agreed SVR competencies, with a number of procedures to be agreed locally, carried out with supervision then with help at hand before proceeding to independent practice and off site working. These should include both simple and more complex procedures, with a range of prostheses.

The RCSLT Laryngectomy Competency Framework (RCSLT, 2023) outlines a range of skills useful for the SLT to acquire when working with people with laryngectomy including core and additional competencies (SVR TEP sizing, voice prosthesis insertion and removal, teaching patients to self-change the prosthesis, tracheostoma (hands free) valve, tracheal manometry, videofluoroscopy for laryngectomy and air insufflation testing).

2.4 Maintenance of competencies

SVR practitioners are expected to maintain their skills and seek opportunities to update and maintain them. SLTs intending to perform SVR procedures must ensure that they have a demonstrable interest in this area and acquire the specific specialised knowledge and skills to become proficient. It is essential that the SLT has undertaken experiential and theoretical training under the supervision of colleagues with specialist experience in this area.

SLTs are responsible for maintaining their competency to be involved in SVR and to ensure the prerequisites for practice are in place including completing RCSLT core competencies prior to progressing to SVR competencies. It is anticipated that maintaining laryngectomy competencies, including SVR, would involve regular practice. SLTs have a professional responsibility to review their competencies for working with laryngectomy regularly with access to clinical supervision. SLTs should be working at expert level 3 or 4 as per Cancer Rehabilitation Measures in England (DoH, 2008).

Practitioners must maintain and enhance their knowledge and skills on a regular basis, by attendance at appropriate meetings e.g. Clinical Excellence Networks and conferences. On-going education must be recorded and available for review in line with the HCPC guidelines.

There are postgraduate training courses in SVR and instrumental procedures for Speech and Language Therapists. Information sessions, webinars and educational

courses are run by manufacturers of prostheses, RCSLT Head and Neck Clinical Excellence Networks, higher education institutions, NHS Trusts and independent organisations.

Section 3: Procedural issues

3.1 The SVR procedure

Initial management of the prosthesis may require access to medical and nursing personnel, sterilisation and emergency equipment. It should be completed with the agreement of the medical practitioner responsible for the patient.

It is essential that the following facilities are available when a prosthesis is being sized, fitted, changed or manipulated in the airway:

- appropriate equipment
- good lighting
- equipment and suitable room in accordance with infection control procedures for aerosol-generating procedures
- suitable chair for patient and practitioner
- suitable working surface
- protective clothing for SLT e.g. apron, gloves, mask, eye protection/ visor in accordance with latest local/ national guidance on personal protective equipment for aerosol generating procedures
- suction.

The following may be required for some early or more complex changes where appropriate and necessary:

- suction
- access to a medical practitioner
- nursing staff support
- bed or reclining chair
- oxygen
- resuscitation facilities.

3.1.1 Voice prosthesis changes

SLTs undergoing voice prosthesis management should be aware of, and adjust, their practice according to the type of prosthesis being used, following manufacturer's guidance, and adjust practice according to the type of procedure e.g. first prosthesis change, routine change, re-sizing, introduction of HME, stoma filters or other laryngectomy equipment such as fitting and using tracheostoma hands free valves. See the RCSLT laryngectomy competency framework (RCSLT, 2023) for additional competencies in 'SVR: TEP sizing, voice prosthesis insertion and removal'.

3.1.2 Sizing and troubleshooting

SLTs should be aware of how to recognise and manage difficulties or problems as detailed in section 2.1. See the RCSLT laryngectomy competency framework (RCSLT, 2023) for additional competencies in 'SVR: TEP sizing, voice prosthesis insertion and removal'.

3.1.3 Teaching the person with laryngectomy to self-change their voice prosthesis

Where a patient is encouraged to self-change the voice prosthesis, this should be undertaken with locally approved guidelines, with robust protocols and support for the individual whilst learning these skills, and access to problem solving and clinician-led changes if required. This may involve visiting the patient at home to support them in acquiring self-changing skills. See the RCSLT laryngectomy competency framework (RCSLT, 2023) for additional competencies in 'SVR: teaching the patient to self-change the voice prosthesis'.

3.1.4 More extensive procedures

We also acknowledge that due to progress in cancer management, and access to chemo-radiotherapy and surgery for progressively more extensive tumours, practice in the UK is changing and surgeons are required to operate as salvage surgery on irradiated tissue with associated management difficulties such as

wound breakdown and salivary fistulas. These may then lead to subsequent difficulties and complications in prosthesis management, with potentially more compromised tissue. Hutcherson et al (2012) reported patients with nodal metastases or more extensive surgery had significantly increased risk of an enlarged TEP.

3.1.5 Out of hours provision

The MDT should ensure that there are locally agreed procedures for managing out of hours prosthesis problems (prosthesis extrusion, aspiration etc), including access to recent clinical history prior to undertaking SVR procedures, and completion of appropriate documentation.

NB. Managing emergency out of hours procedures for patients with SVR problems by people not experienced in the technique should be strongly discouraged. Temporary management of prosthesis extrusion should be limited to inserting a nasogastric tube, stent or Foley catheter into the TEP while awaiting specialist advice.

3.2 Health and safety

The SLT must ensure that approval has been given by their employer and manager with recognition of competence to perform the procedure. SLTs are required to work within the scope of their knowledge and skills as per HCPC standards (HCPC, 2015). Use of SVR procedures must be written into the SLT's individual job description (RCSLT, 2008, RCSLT, 2006, RCSLT, 2005, RCSLT, 1999).

The SLT managing the clinic is responsible for adherence by any staff within his/her department to local policies. They should therefore be aware of policies on:

- use and care of substances hazardous to health (COSHH, 2013) with appropriate training to be undertaken if such substances are to be stored, used or disposed of within the department.

- control of infection - healthcare associated infection is possible via contact with equipment contaminated by saliva, blood and other body fluids. Reducing the risk of transmission of infection during SVR procedures requires following the most recent infection control and procedural guidance, including using risk assessment frameworks and wearing personal protective equipment (PPE) as determined by the latest national (RCSLT, ENT UK, BAHNO, Public Health/ Department of Health, NHS) guidelines, and local policies. Sterilisation and storage of equipment should adhere to current infection control procedures to avoid cross infection of both patients and staff involved in the clinic. This includes local, institutional and national policies regarding the use of single patient use items, cleaning, decontamination, sterilisation, disposal and storage of equipment (COSHH, 2013). Speech and Language Therapists, therefore, should be familiar with and adhere to national code of practice on control of infections, Care Quality Commission regulations regarding safe care and treatment (CQC, 2022) and universal precautions (WHO, 2022).
- use of topical anaesthesia for successful prosthetic change.

Usually, voice prosthesis management can be performed safely without any anaesthesia, but topical anaesthesia or nasal decongestant may be required in some cases and may be applied to the dilator and then placed in the TEP to avoid triggering coughing. Speech and Language Therapists should be aware of the protocols which need to be followed to administer anaesthesia, their indications and contraindications and possible drug interactions with their use. SLTs are entitled to administer topical anaesthesia under patient group directions (NICE, 2017, RCSLT, 2008). Patient Group Directions (PGD) for administering topical anaesthesia should be developed with the MDT at the organisation employing the SLT. Each PGD must be signed by a doctor or dentist, as appropriate, and a pharmacist, and be approved by the organisation in which it is to be used, typically an integrated care system or NHS trust (NICE, 2017, Carding et al., 2008).

3.2.1 First aid and resuscitation

Due to the invasive nature of the procedure, SLTs involved in managing voice prostheses must undergo regular training in first aid and cardiopulmonary resuscitation (including training which makes reference to resuscitation via the laryngectomy stoma) with and without a voice prosthesis in situ. The National Tracheostomy Safety Project (2022) website is a useful resource for laryngectomy emergency resuscitation algorithms, videos and e-learning regarding ventilation via the stoma. The NALC website and manufacturers and suppliers of laryngectomy products can provide cards/ car stickers explaining emergency laryngectomy resuscitation procedures and wristbands identifying the wearer as a neck breather requiring resuscitation via the stoma.

3.2.2 Environments

SLT voice prosthesis procedures and management may be carried out on a hospital ward, or in a designated clinical area. If SVR procedures are to be performed outside a formal clinical environment, such as nursing homes or domiciliary settings, or if patients are self-changing valves, local policies to minimise risk should be in place. Environmental, TEP-related and individual risk factors such as patient comorbidities, general health, health of TEP and surrounding tissue and previous ease of voice prosthesis change and infection control should be considered, alongside competency levels of personnel present e.g. for suctioning or TEP sizing, voice prosthesis insertion and removal (see RCSLT Laryngectomy Competency Framework, 2023).

During the COVID-19 pandemic, many SLT services proactively adapted to provide rehabilitation via telephone and video conferencing or telehealth (Patterson et al, 2020); some aspects of SVR rehabilitation may be offered via these innovative methods of service delivery where this is deemed clinically safe, delivered within local information governance guidelines and patients are both suitable and receptive to these methods with access to suitable devices.

3.2.3 Disposal of materials

Any used items of consumable equipment should be disposed of as clinical waste or as advised by local infection control policy.

3.2.4 Decontamination and infection control

Disease transmission is possible via contact of equipment contaminated by saliva, blood and other bodily fluids e.g. during voice prosthesis changes. Sterilisation, use of single patient-use items and storage of equipment should adhere to universal, local and institutional infection control and decontamination policies to avoid cross infection. The practitioner should adhere to universal, local and institutional hand hygiene policies, wearing of correct personal protective equipment, barrier nursing precautions and working in a suitable environment to avoid cross infection.

3.2.5 Adverse effects of SVR procedures

SVR is a safe procedure but there are possible medical risks and complications associated with voice prostheses procedures or presence of voice prosthesis, including:

- stimulation of vagal response during voice prosthesis insertion/ removal, particularly if the patient is anxious, causing, for example hypotension, bradycardia, vasovagal syncope
- adverse reactions to local anaesthesia
- tissue trauma, bleeding and discomfort
- aspiration of foods, fluids and gastric contents via the TEP, into the airway
- accidental aspiration of the brush, equipment, tissue, prosthesis, tissues into the airway or loss of prosthesis, instruments, etc. into the oesophagus
- infection of the TEP or mediastinum
- tracheo-oesophageal wall separation or trauma to TEP
- adverse reactions to adhesive preparations used in conjunction with the tracheoesophageal puncture
- creation of false tracheo-oesophageal tract

3.2.6 Indications and contraindications

When considering performing any SVR procedure, the SLT must always consider possible contraindications. These are outlined in section 1.4. The rationale for performing SVR procedures on an at-risk patient must be clearly outlined in patient records. Failure to demonstrate and record careful consideration of the risks and benefits to the patient in these circumstances prior to proceeding with the procedures may constitute a breach of acceptable professional conduct (see Section 4, Medico-legal Issues).

3.2.7 Incident reporting

If an adverse reaction occurs during any SVR procedure, appropriate medical assistance should be sought and local incident reporting procedures followed.

3.3 Information for people with laryngectomy, family and carers

Pre-operatively, SLTs should share information about proposed methods of communication and changes in breathing, olfaction, taste and appearance to be expected post-laryngectomy. SLTs should be aware of local support available e.g. offering to arrange to meet a person with laryngectomy pre-operatively, giving information on cancer support centres where financial and counselling support is offered, support groups and online resources. People who are awaiting laryngectomy surgery, should be fully informed about the benefits and any potential complications of SVR (if appropriate for them) or other post-laryngectomy voice restoration options. This includes informing them of any options to self-change voice prostheses, and the commitment to voice prosthesis management and changes that SVR requires. Information should be given in verbal and written form and include management and care of the prosthesis and any other equipment provided.

Post-surgery, people with laryngectomy should complete voice prosthesis training competencies if a prosthesis is in place (ENT UK, to be published). During the

postoperative acute ward admission, SLTs may also be involved in ensuring that district nurses, family members or carers learn about stoma, voice prosthesis (if in situ) and pulmonary care before discharge home. This can include learning how to insert and remove laryngectomy tubes or stoma studs, HME use or use of other filtration/ humidification methods, how and when to clean the voice prosthesis and stoma and recognising signs of voice prosthesis failure/ need for change or review. Improving patient stoma training needs to be prioritised (Wilson et al, 2022).

Laryngectomy voice prosthesis education for people with laryngectomy and carers/ family may also include how to use the correct sized/ brand voice prosthesis plug to occlude the leaking prosthesis temporarily in cases of central (rather than peripheral) leakage. They should be advised regarding temporary use of thickened fluids to minimise aspiration until voice prosthesis change and to avoid being placed nil by mouth. They should also be provided with advice regarding local procedures for a leaking, displaced or missing voice prosthesis.

Publications and resources from national support organisations e.g. Macmillan Cancer Support, The Swallows Charity or National Association of Laryngectomee Clubs (NALC) may be useful for some people with laryngectomy. See RCSLT Head and Neck Cancer Members Guidance for lists of organisations and resources for people with head and neck cancer. Details of available peer-support services (such as NALC support groups, or buddy systems) should be made available to patients – this may be in variable formats (including online videos) or languages (BAHNO, 2020).

3.4 Consent

Laryngectomy rehabilitation including SVR or instrumental assessment such as FEES, videofluoroscopy or air insufflation testing, may include invasive procedures that carry some risks and hence a full explanation must be given and consent obtained prior to any procedures (Health and Social Care Act, 2008). Information about the proposed care and treatment must be provided in a way that patients

can understand and should include information about the risks, complications and any alternatives. The SLT must explain the procedure, answer questions and provide written information, diagrams or videos where appropriate to the patient and/or their carer. Where a person lacks mental capacity to make an informed decision, or give consent, staff must act in accordance with the requirements of the Mental Capacity Act (2005) and associated code of practice (CQC, regulation 11, 2014).

It is recommended that the SLT reviews their departmental consent policy regularly and that it is adapted in light of local and national changes. SLT's should also review their local ENT consent document as appropriate. Policies and procedures for obtaining consent to care and treatment must reflect current national legislation and guidance (CQC, 2014).

3.5 Documentation

Procedures relating to voice, communication or swallowing rehabilitation for people with laryngectomy, including SVR and voice prosthesis management procedures should always be recorded as part of the patient's record as per local policy. Documentation should be kept according to the RCSLT professional guidelines and national policies (e.g. NHS England, 2021). Individual organisation policies will vary, but we would recommend the following as a minimum.

Departmental records should include:

- all the patient's referral details along with any assessments, letters and reports.
- details of the procedures carried out, including any untoward incidents, complications or emergencies and the management thereof, must be entered into the patient's health record. Untoward incidents must be further reported in accordance with local policy.

There may be differences between local policies about recording of information in Speech and Language Therapy notes, within the medical record and within the patient held record. Recording should be done in accordance with local departmental policy. There should be a suitable records management system including policies on organising, storing, retaining and deleting records (NHS England 2021) in accordance with UK GDPR and Data Protection Act 2018.

Recorded material is part of the patient's record, and therefore should be kept in accordance with local policy. The clinician should employ a system to facilitate retrieval and identification of recorded data, whilst maintaining patient confidentiality.

Procedures should be developed according to each service's requirements for out of hours access and documentation. Patients and their carers should be made aware of, and given written information, regarding procedures to be followed if emergency aid is required out of SLT working hours.

3.6 Audit

SVR services should be audited on a regular basis within a local clinical governance framework. As mandatory national audit systems emerge, clinicians may be required to contribute laryngectomy data including of SVR e.g. DAHNO in England and Wales (2005-2017) or HANA (Head and Neck Cancer National Audit in England and Wales 2015 onwards). It is recommended that SLT services providing voice prosthesis changes, management of SVR complications and treatment for problem-solving collect data on these for audit and service planning.

Section 4: Developing and maintaining a SLT laryngectomy service

4.1 Long term rehabilitation issues

Following initial intensive input with the people with laryngectomy and their carers, the SLT involved in laryngectomy rehabilitation should be aware of, and be able to address, issues involved in long term rehabilitation post-laryngectomy.

These might include:

- non-SVR voice rehabilitation: use of communication aids, electronic larynx, teaching oesophageal voice, use of gesture and pseudo voice
- informing discussions regarding suitability for secondary puncture
- ability to carry out and interpret air insufflation testing to assess the viability of the PE segment for voicing such as the Taub (Taub and Spiro, 1972) and Modified Taub (Khemani et al 2010, Blom et al, 1985) tests
- stoma care – including stoma covers, humidification and nebuliser use, Heat Moisture Exchangers, stoma filters, laryngectomy tubes, stoma buttons or studs.
- hands-free/tracheostoma valves
- troubleshooting long term stoma care e.g. narrowing of the stoma.
- party wall problems e.g. thinning party wall
- extruding prostheses
- tissue health of TEP
- granulation tissue formation/ change in the appearance of the tissue surrounding the tract or stoma may be a warning sign and the patient should be referred back to the MDT

- supporting people with laryngectomy as they age or if they develop health issues impacting on laryngectomy care.

4.2 Troubleshooting and complications

At each prosthesis change there should be an analysis of the reason for the change and prosthesis type, size, site of leakage, prosthesis deterioration, tissue change. Indications for changing the prosthesis should be recorded at each change, with opportunities taken for reflective practice and discussion with other MDT members or clinicians more experienced in SVR for more complex changes.

SLTs should be aware of, and be able to identify rationale for a range of troubleshooting procedures and management options:

- videofluoroscopic, FEES and manometry examination for voice and swallowing difficulties
- stricture management e.g. dilatation
- severe hypertonicity and spasm e.g. Botox/ Dysport injections
- radiotherapy – management of TEP, stoma, peristomal skin, swallowing and communication during and following treatment
- reflux management
- deteriorating physical and cognitive status of the patient e.g. discussing ability to self-change if needs or abilities of patient change.

SVR management including:

- central or peripheral leakage
- candida management
- range and choice of prosthesis types including customised
- embedded prostheses
- false tract/ partially-closed tract/ split party wall/ puncture closure
- granulation tissue/tissue breakdown/fistula formation

- abandoning SVR
- holiday planning and out of district patients e.g. consideration of provision of spare voice prosthesis and emergency presentation whilst on holiday
- recognising when discussing training in self-changing voice prosthesis may be introduced

A full range of techniques, products and facilities should be available for swallowing and voice rehabilitation and electronic larynx equipment should be provided for those who need it (Clarke et al, 2016, NICE, 2004, SIGN, 2006). All patients should be provided with a neck breather emergency card/ bracelet. Patients should be registered with a prescription delivery service for laryngectomy supplies (Goff et al, to be published).

SVR should be available for all patients who undergo laryngectomy, normally at the time of primary surgery. This service should be supported, with specialist SLT input on wards and for long-term follow-up, appropriate rehabilitation services and equipment. The specialist SLT should be involved in the training of nurses and medical staff to carry out basic troubleshooting for these patients so that they are able to deal with common problems such as leaking or blocked voice prostheses and breathing and swallowing problems that may occur out of hours (NICE, 2004, SIGN, 2006). Issues regarding tissue management should be referred to the head and neck surgeon.

Manipulation of the tract e.g. management of granulation tissue, forceful insertion of non-standard dilators, should be avoided by the SLT. Issues regarding unusual appearance of the tissues, TEP, trachea, stoma, peristomal area or neck should be noted and referred for a medical opinion at an appropriate level, as should issues regarding pain and/or bleeding.

4.2.1 Fungal infection

The need for frequent voice prosthesis changes due to obstruction or leaking may indicate a candida fungal infection. Attention may need to be given to appropriate

treatment of this infection by the SLT and MDT, such as topical candida treatment or use of a candida-resistant voice prosthesis.

4.2.2 Laryngopharyngeal / extraoesophageal reflux

It may well be the speech and language therapist, because of their regular contact with the patient, and involvement in prosthesis management and communication who first identifies reflux as a possible problem, and therefore refers back to the Head and Neck Surgeon for discussion and appropriate management.

Laryngopharyngeal reflux may be a factor in the development of (long-term) complications. A significant proportion of patients with Head and Neck Cancer also suffer with reflux – this can lead to problems both in the immediate post operative situation and in the longer term (Koufman, 2002, Vaezi et al., 2006). Effective management of reflux with proton pump inhibitors may reduce the incidence of pharyngocutaneous fistula (Manelli et al, 2018, Stephenson et al, 2015).

Problems may include:

- failure to achieve voice
- persistent sore throat
- dysphagia or stricture formation
- poor voice prosthesis survival
- risks to TEP tissue health

Such problems should raise the suspicion of reflux. There should be careful investigation (it is often difficult to diagnose) and treatment should be aggressive (it often requires very high doses of medication etc to control). Patients who develop reflux related post Laryngectomy problems may have/need life-long treatment.

4.2.3 Prosthesis modification

Prosthesis modifications are documented as a recognised procedure (Lewin et al, 2012, Hutcheson et al, 2011, Blom et al., 1998, Hilgers et al., 2008). This entails using a commercial product modified for a specific patient. Clinicians will need to seek

clarification from their employers about the regulation of use of modified products in their patient population. Some services may be able to offer in-house modifications of voice prostheses following risk assessment, clinical governance mechanisms and adhering to national regulations. Alternatively, there are a wide range of commercially modified voice prostheses available. Examples of modified products include prostheses with enlarged flanges, disc modification, washers, hinged / weighted flaps.

4.3 Service configuration

Patients undergoing laryngectomy have multiple complex needs necessitating a MDT service (Wilson et al, 2022). All units should have a named SLT with at least 50% of time dedicated to head and neck cancer care and with specialist voice restoration skills (BAHNO, 2020). The NICE guidelines for head and neck cancer management (NICE, 2004) give the following recommendation: SVR should be available for patients who undergo laryngectomy, normally at the time of primary surgery. This service should be adequately supported, with specialist SLT support on wards, appropriate rehabilitation services & equipment". SLT service resourcing should not be a barrier to tracheoesophageal speakers receiving the support they require to maximise their function in the face of a significant challenge to their communication (Sparks et al, 2023).

RCSLT recognises head and neck SLT as both a highly specialised and costly service, requiring multiple clinical competencies (RCSLT, 2021), and actively supports members' need for staffing, training and equipment budgets for the provision of this expert service which is vital for post- laryngectomy rehabilitation.

Tracheoesophageal speech and post-laryngectomy communication and swallow rehabilitation are specialised areas of practice for SLTs due to the complex nature of presentation and the invasive components of the SLT role; postgraduate training and experience are required to work competently and safely, including hands-on

learning, learning with and from others and access to formal training programmes (Hancock et al, 2020).

4.4 Costs and budgets

Laryngectomy services and provision of a comprehensive service including SVR to this population involves the SLT using a range of specialist and often expensive equipment and consumables. The service should be funded at an appropriate level to ensure the patient receives the most effective service possible, respecting their choice of communication method within the options available to them. This includes a range and variety of equipment for communication rehabilitation are available including voice prostheses and accessories, electrolarynxes and oral adaptors, access to voice banking recording equipment and alternative and augmentative communication equipment. All head and neck cancer units should have appropriate equipment including video screens for nasendoscopy, and appropriate personal protective equipment available as recommended by national guidelines (BAHNO, 2022). Services should have access videofluoroscopy as an evaluation tool for laryngectomy patients, as this may be needed to contribute to surgical considerations such as use of botulinum toxin or dilatation to treat dysphagia (BAHNO, 2020, Clarke et al, 2016). They should also have access to kit for performing and interpreting Taub (Taub and Spiro, 1972) and Modified Taub (Khemani et al 2010, Blom et al, 1985) air insufflation testing. Services should also have access to FEES including sound and video recording equipment, or use of nasendoscopy to check voice prosthesis placement and for problem solving voice prosthesis, voice or swallowing issues.

Systems should be in place to ensure that 'value for money' and economic concerns do not compromise optimal care for the individual. Models of service delivery should allow for urgent, irregular and elective voice prosthesis changes with a budget for modifications, choice of valves, patient transport, extra capacity in staffing to allow for variation in demand and systems to allow for safe aerosol-generating procedures (McLachlan et al, 2021).

Laryngectomy rehabilitation has become increasingly complex with a greater proportion of people in the UK requiring laryngectomy following chemoradiotherapy treatment, and rehabilitation service requirements have increased (Owen and Paleri, 2013); this should be reflected in SLT service commissioning and funding arrangements, including budget to address training needs to achieve the competencies required to manage this highly complex caseload.

Section 5: Medico-legal issues

This document is the RCSLT's official statement of professional practice for SLTs participating in laryngectomy rehabilitation including SVR procedures. Adherence to its content and recommendations are the professional responsibility of the individual therapist and will ensure professional indemnity through the individual's employer. Failure to comply with the details of this policy statement, without a clearly documented and acceptable rationale for any change, and given individual circumstances, may amount to a breach of acceptable professional conduct. The RCSLT acknowledges that professional practice continues to grow and develop as outlined in the 'emerging roles' section of the RCSLT website. Members should contact the RCSLT for advice about any areas of practice development relevant to this policy.

The SLT must ensure that approval has been given by the employing authority or directorate, with recognition of competence to perform the procedure, adherence to local health and safety policies and adequate professional liability insurance cover, either through the employer, the professional body or professional union.

The SLT must have knowledge and understanding of:

- potential risks to patients
- the appropriate environments in which procedures may be undertaken
- appropriate emergency medical procedures and back-up
- procedures/precautions which protect both client and clinicians from accidental exposure to disease
- department/institution policies with respect to required approval/qualifications for performance of the procedures
- professional liability/indemnity issues
- legal requirements regarding client confidentiality
- avenues of continuing professional development in the area.

Section 6: Appendix

6.1 Equipment and consumables

This list of suggested equipment is not exhaustive but may serve as a guide for setting up services.

6.1.1 Equipment

- focussed lighting or headlight
- dressings trolley
- good quality suction cylinder
- locking haemostats
- tilley forceps
- scissors
- sharps box
- mirrors
- manometer
- electrolarynxes
- voice recording equipment
- access to good quality flexible nasendoscope with light source, camera, and monitor with audio and capacity for live recording (if undertaking FEES as recommended by RCSLT FEES Position Paper, Wallace et al, 2020).

6.1.2 Consumables

- gloves, apron, visor, eye protection, masks (as per local infection control policy)
- instrument dishes e.g. receivers/ kidney dishes
- sterile water
- clinical wipes
- microporous surgical tape
- central sterile services department bags (for equipment to be sterilised)

- tissues
- skin preparation cleaning and barrier wipes
- cotton tip buds
- paper cups
- milk
- drinking water
- patient held record book with emergency contacts
- clinical waste disposal bags and access to clinical waste disposal (as per local policy)
- dressing packs/towels
- gauze swabs
- silicone adhesive
- adhesive removal wipes
- topical anaesthesia – as per local policy
- sharps (blades/scissors etc.) and sharps disposal box – as per local policy
- range of catheters for downsizing or puncture ‘retrieval’
- written/ digital material for patient and/or carer
- selection of tracheostoma covers/filters
- pen torches and mirrors for patients
- neck breather bracelets and cards
- micropore tape or similar
- lubricating water soluble gel
- selection of suction ends e.g. plastic Yankauer, Zoellner ear
- suction tubing and catheters
- foley catheters
- spigots
- blades
- prosthesis cleaning brushes
- prosthesis plugs
- tracheo-oesophageal dilators
- tracheo-oesophageal sizers
- selection of voice prostheses in range of sizes, diameters and types

- suture material
- gel cap kits
- air insufflation test kits
- selection of laryngectomy tubes and stoma studs
- selection of baseplates and filters/HME's
- tracheostoma valves and attachments
- tube tapes and holders
- shower guards
- food colouring dye
- Jobson-Horne probes
- tracheostoma adaptors for manometer.

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The Royal College of Speech and Language Therapists (RCSLT) is the professional body for speech and language therapists in the UK. As well as providing leadership and setting professional standards, the RCSLT facilitates and promotes research into the field of speech and language therapy, promotes better education and training of speech and language therapists, and provides its members and the public with information about speech and language therapy.

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