COUGH STRENGTH TESTING IN ACUTE DYSPHAGIA MANAGEMENT

A thesis submitted in partial fulfilment of the requirements for the Degree of Master of Science in Speech and Language Sciences at the University of Canterbury

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2019
Acknowledgments

I would like to express my gratitude towards Professor Maggie-Lee Huckabee for the opportunity to undertake my Master’s Thesis under her supervision. I am extremely grateful for all her encouragement, knowledge, and expertise in the field of dysphagia, which has enabled me to turn my clinical passion into research.

I would also like to thank Emma Wallace for her support and guidance throughout the process, and for her insight into the current literature. I feel privileged for the support I have received from both my supervisors and wider team at the Rose Centre.
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Abstract

Introduction: The primary aim of this research was to evaluate whether there was a specific decibel level of a reflexive cough epoch that was indicative of effective clearance of aspiration in patients with dysphagia. Due to unexpected limitations and findings in the proposed research, a new hypotheses arose during the process, and a second study was added to look at the relationship between reflexive cough to aspiration and its ability to clear subglottic aspirate.

Methodology: For study 1, a cross sectional, observational study design was conducted to investigate how much strength was required of a reflexive cough epoch to clear aspirated material. Audio recordings were taken during VFSS and analysed to document whether there was a relationship between reflexive cough strength, its decibel level, and clearance of aspiration. For study 2, a clinical audit was consequently conducted to determine the rate of aspiration, reflexive cough, and ability to clear aspirated material in 136 patients at a regional public hospital over the period of 12 months.

Results: In study 1, data was collected from 55 patients. Of these 55, 16 (29%) aspirated thin fluid consistency. Nine of these 16 (56%) patients elicited a cough in response to aspiration and the remaining 7 (44%) showed no outward response, hence silently aspirating. Of the 9 participants that elicited a cough response, only 4 had sufficient VFSS images to accurately interpret whether they were able to clear aspirate or not. The reflexive cough of all 4 patients was not effective in clearing aspirated material from the trachea. The results from the clinical audit (study 2) showed that of the 136 VFSS completed, 45 (33%) patients
aspirated thin fluids. Of these 45 patients, 34 (76%) of the patients who aspirated did so without a reflexive cough response. The most interesting finding from the audit is that only 11 patients (24%) elicited a reflexive cough in response to aspiration and of these 11, nine (20%) were not able to clear aspirated material following a reflexive cough.

**Conclusion:** The focus of this research was to provide unique information into the effectiveness of reflexive cough to clear aspirated material. Unfortunately, due to methodological limitations and unexpected findings, this question could not be answered. The subsequent clinical audit showed that reflexive cough very rarely clears subglottic aspirate, which highlights the importance for further research in this area. Clinicians make management plans based on, what appears to be, anecdotal evidence in regards to cough strength and ability to clear aspirate from subglottic space.
CHAPTER 1 – Introduction

Swallowing is a highly coordinated neurological, biochemical, and anatomical process, involving over 30 nerves and muscles (Matsuo & Palmer, 2008). Dysphagia is the term used to refer to disordered swallowing, and is often the result of a neurological impairment such as stroke, traumatic brain injury or a progressive neurological disease (Shaker & Geenen, 2011). Aspiration is the process of food or drink entering the laryngeal vestibule, subsequently passing through the vocal cords and into the lungs, secondary to an impaired swallowing function (Ramsey, Smithard, & Karla, 2005). The development of pneumonia becomes a high risk following an aspiration event (Addington, Stephens, Gilliland, & Rodriguez, 1999; Cabre et al., 2014; Guillen-Sola et al., 2015).

The laryngeal cough reflex is responsible for protecting the airway from aspiration of food and fluids (Widdicombe, Addington, Fontana, & Stephens, 2011). In patients with neurological impairment this reflex can be impaired (Sohn et al., 2018), resulting in compromised airway protection (Fontana, 2008), and possible silent aspiration (i.e. aspiration in the absence of a sensorimotor cough response) (Miles, Zeng, McLauchlan, & Huckabee, 2013; Pitts et al., 2013).

Currently clinicians largely determine cough strength, and the ability of an individual to clear aspirate, by subjective assessment as part of a clinical assessment. This method is known to lack reliability (Miles et al., 2013; Laciuga, Brandimore, Troche, & Hegland, 2016), and requires a videofluoroscopic swallowing study (VFSS) or other imaging technique to confirm. This thesis endeavours to research whether there is a correlation between acoustic output and clearance of aspiration on VFSS.
CHAPTER 2 - Literature Review

2.1 Cough

The Oxford Dictionary defines ‘cough’ as to “expel air from the lungs with a sudden sharp sound” (Oxford Dictionary, 2018). Although this is how the majority would define cough, it is in theory, much more complex (Fontana, 2008). Through production of large expiratory airflows (Pantaeleo, Bongianni, & Mutolo, 2002), cough is an airway defensive reflex, which acts to protect pulmonary function by expelling mucus and foreign particles situated in the upper and lower respiratory tracts (Fontana, 2008; Pantaeleo et al., 2002). Clinicians commonly know cough to consist of three phases (Magni, Chellini, Lavorini, Fonatana, & Widdicombe, 2011): an initial inspiration (the inspiratory phase), followed by a forced expiratory effort, against a closed glottis (compressive phase), and finally, opening of the glottis and rapid expiratory flow (expulsive phase) (Feinstein, Zhang, Chhetri, & Long, 2017; Fontana, 2008; Morice et al., 2007; Widdicombe & Fontana, 2006; Widdicome et al., 2011).

Coughing is a sudden protective reflex, which can be both voluntary or involuntary (Haji, Kimura, & Ohi, 2013). There are a number of mechanisms including sensory, motor, affective and cognitive, which effect the elaborate and intricate process of cough control (Ando, Farrell, & Mazzone, 2014). Although both reflexive cough (RC) and voluntary cough (VC) have similar patterns in terms of the 3-phase cough response (Fontana, 2008), the neurophysiology of cough control has been widely researched to further understand the underlying neural pathways, which result in differing motor activity between the two (Driessen et al., 2017; Magni et al., 2011; Pantaeleo et al., 2002).

The RC response can be triggered by mechanical or chemical stimulation of glottic or subglottic anatomy (i.e the vocal folds or trachea) (Fontana, 2008). When this happens,
sensory afferents are stimulated, which then carry signals to the central nervous system, specifically the nucleus tractus solitarius (NTS) situated in the brainstem (Pantaleo et al., 2002). The NTS then modulates respiratory cells in the ventral and pontine respiratory groups (Driessen et al., 2017). RC does not require input from the cerebral cortex (Hegland, Bolser, & Davenport, 2012), and is believed to be the primary defence mechanism responsible for expelling foreign material from the airway (Ando et al., 2014).

VC is elicited due to a sensation of irritation from physical or chemical irritants (Ando et al., 2014). It can be produced on command (Hegland et al., 2012; Magni et al., 2011), which suggests both cortical and subcortical control over the cough response (Ando et al., 2014). It is believed that during VC, irritants in the respiratory tract send signals through the afferent neurons to the respiratory centre in the brainstem (Lee, Cotterill-Jones, & Eccles, 2002). Here signals are carried onto the primary motor and sensory cortices, where the sensation of irritation is turned into a motor response in the form of a cough (Hegland et al., 2012). Studies with functional MRI have shown that there are multiple other brain structures involved in VC; of note, the basal ganglia and thalamus which play a role in regulation of motor functions (Hegland et al., 2012).

In the past, VC has routinely been used to guide clinicians on an individual’s ability to clear and protect their airway during clinical assessment (Smina et al., 2003). Smith Hammond and colleagues (2001), provided research to support the relationship between VC strength and aspiration risk, however they also identified reduced specificity when determining a person’s risk of aspiration. More recent research highlights that assessment of RC strength is potentially of higher importance when attempting to draw conclusions on efficiency of airway protection and clearance, as this is the cough elicited in response to aspiration (Magni et al., 2011; Widdicombe et al., 2011).
Also described in the literature is evoked coughing. This is “initiated with a tussigenic stimulus accompanied by a preceding urge-to-cough sensation” (Hegland et al., 2012, p39). Evoked cough can be suppressed to a certain degree (Magni et al., 2011), however with increasing concentration, or tussigenic potency of the stimulus it can no longer be suppressed, which in turn results in RC (Lee et al., 2002). With this information, one may suggest that the neurological control of cough may not fall simply to either volitional or reflexive, but may exist on a continuum. The literature is ever-growing in regards to the neurophysiology of cough, however the differences between cough types, and the ability to suppress cough to a certain extent, may indicate cortical involvement over cough regulation centres situated in the brainstem (Hegland et al., 2012).

The laryngeal expiration reflex (LER) and cough-on-swallow are other types of ‘cough’ described in the literature (Widdicombe et al., 2011; Fontana, 2008). When a solid, liquid, material, or chemical irritant comes in contact with the vocal folds, a LER may be elicited (Fontana, 2008). There appears to be some confusion in regards to the difference between cough and the LER, however Widdicombe & Fontana, (2006) attempt to more thoroughly distinguish between the two.

The LER is triggered in response to penetration or aspiration in the upper respiratory tract to prevent entry to the lungs (Widdicombe et al., 2011). The absence of an inspiratory phase is the defining characteristic of the LER (Widdicombe & Fontana, 2006), and suggests a different afferent pathway from VC and RC (Korpas & Jakus, 2000). LER consists of a sudden closure of the glottis, followed by strong expiratory effort as the glottis is opened, with subsequent high force airflows to expel foreign material entering the airway (Fontana, 2008). However, without this initial stage the force generated on the subsequent expulsive phase is typically not as strong, as the aim is to prevent airway entry, not to remove mucus and debris.
from deep within the respiratory tract (Fontana, 2008; Tatar, Hanacek, & Widdicombe, 2008). Addington and colleagues believe that the vital, initial component of RC is the LER (Addington et al., 2003)

Cough-on-swallow may occur in response to aspiration in patients who have suffered neurological changes (Widdicombe et al., 2011). During routine clinical assessment, clinicians will often assume if a patient coughs while eating and drinking, it may be secondary to aspiration/penetration. Further research is still needed in regards to cough-on-swallow, however Widdicombe et al. (2011) suggest that cough-on-swallow may be similar to the LER.

It is important to note that a cough response usually occurs at what is known as an epoch (Fontana, 2008; Fontana & Widdicombe, 2007). A cough epoch is “a complex sequence of motor acts resulting from a combination of true coughs and expiration reflexes” (Fontana, 2008, p. 3-4), where true coughs, being reflexive coughs. The term RC will be used herein to signify the sequence of coughing events that occurs to protect the airway.

### 2.2 Cough Impairment

The RC function can be impaired for a number of reasons, however often it is secondary to a neurological event. When the RC response is impaired, the risk aspiration increases, therefore putting them at a higher risk of developing an aspiration related pneumonia. (Addington et al., 1999).

Although aspiration is one factor that contributes towards the development of pneumonia, it is important to note that there are multiple factors that contribute to the overall diagnosis (Langmore et al., 1998). However, a correlation has been made between silent aspiration (food or fluid entering the airway without no outward sign), increased incidence of pneumonia and higher mortality rates (Miles et al., 2013). Silent aspiration is
known to be evident in 28-38% of dysphagic stroke patients (Ramsey, Smithard, & Karla, 2005), therefore the ability for clinicians to identify those patients at risk during a clinical assessment is critical for patient management.

Cough can be impaired in both sensitivity and/or strength (Laciuga et al., 2016). Being able to distinguish between cough strength and cough sensitivity is important due to a difference in neurophysiological processes (Miles & Huckabee, 2013). Cough Reflex Testing (CRT) is a validated tool used in dysphagia management to assess cough sensitivity (Mills, Jones, & Huckabee, 2017; Morice, Kastelik, & Thompson, 2001), however there is no current method of assessing RC strength. This falls to clinicians auditory perception of voluntary and RC, which has been proven to have low inter- and intra-rater reliability (Laciuga et al., 2016; Mills et al., 2017).

2.3 Assessment of coughing

CRT is an objective measure of assessing the sensory motor cough response by using a nebulised tussigenic agent (Miles et al., 2013). Due to producing consistent results over time, citric acid and capsaicin have been most frequently documented throughout the literature as preferred choices for tussigenic agents (Morice et al., 2001). CRT is increasingly used as a clinical test for stroke patients during the clinical swallow assessment to identify those patients with impaired cough sensitivity and who may be at risk of silently aspirating (Mills, 2017).

Addington et al. (1999) were the first to investigate the use of CRT in a clinical setting for the stroke population and created a platform for further research, specific to CRT and its ability to reduce incidence of pneumonia. The aim of their initial study was to determine the relationship between assessment of the laryngeal cough reflex in those patients who had
suffered an acute stroke, and their risk of developing pneumonia. Results showed that CRT reliably assessed RC, and there was a correlation between CRT outcomes and development of aspiration related pneumonia.

A further study by Addington, Stephens, Widdicombe, & Rekab, (2005) also investigated CRT and the relationship with pneumonia development, however this time they also assessed the impact of stroke location on the overall outcomes. Tartaric acid was administered via a mouth piece, and used to stimulate RC. Participants were closely monitored for chest or respiratory changes which may have be indicative of pneumonia. Results from this study showed that CRT was able to initiate RC and indicate pneumonia risk. This study was beneficial as it informed researchers of the importance in being able to differentiate between an absent or weak cough response, and the implications of this in both the development of pneumonia and clinical management.

Addington et al. (1999, 2005) provided research on an exciting new tool of RC assessment that could easily be incorporated into clinical practice, and provide clinicians with vital information on those patients at risk of silent aspiration. These studies however, did not come without limitations and had many similar shortcomings. The tussigenic agent used to stimulate RC was tartaric acid which has been found to be unreliable in clinical use (Morice et al., 2007). Furthermore, the studies did not define or give examples of what determined an adequate cough response to tartaric acid. A major flaw in the methodology of these studies was that no instrumental assessment was conducted to verify whether the identified pass/fail CRT response, was in fact consistent with silent aspiration.

A later study by Miles et al. (2013), investigated CRT in dysphagic patients post stroke, and assessed the impact CRT had on changing patient outcomes. Based on previous research (Addington et al., 1999; Wakasugi et al., 2008) it was hypothesised that, introducing CRT as a
routine tool when clinically assessing swallowing function post stroke, would enable clinicians to have critical information when creating management plans. With the aim of reducing the development of pneumonia (Miles et al., 2013). Results from this study provided clinicians with valuable information obtained from CRT which they could then use to make appropriate plans in regards to diet selection, along with early identification of the need for VFSS. However, the study failed to prove that CRT was effective, and the primary aim in reducing rates of pneumonia post stroke was not achieved (Miles et al., 2013). These studies show that we have a reliable clinical method of detecting cough sensitivity impairment, however we have no method of clinically evaluating RC strength.

2.4 Cough Strength Assessment

Cough strength is deemed important when it comes to identifying those at risk of developing aspiration pneumonia (Mills et al., 2017); however, at present there is no validated and reliable measure of RC strength for use in the clinical setting. Subjective assessment of cough strength occurs frequently during clinical swallowing assessment, however research is beginning to show that these subjective assessments are not a reliable method of assessment.

A study by Laciuga et al. (2016) provided clinicians with cough samples and compared their subjective assessment of these to the objective air flow dynamic measurements. Thirty clinicians, which consisted of speech language pathologists, otolaryngologists, and neurologists, subjectively evaluated ten audio samples. The clinicians rated coughs based on strength, duration, quality, and overall effectiveness in how a particular cough may protect the airway. Results showed that the clinicians had the most agreement when determining single or multiple coughs, however identifying cough strength and its effectiveness showed
reduced consistency. The largest discrepancy between clinicians was seen in determining cough quality. The study highlighted the overall inconsistencies in clinician’s subjective assessment of cough, and the importance in a more objective measure being used.

A similar study by Miles & Huckabee (2013) endeavoured to gather information on the inter-and intra-rater reliability of clinicians subjective assessment of RC. Citric acid was used as the RC stimulus. Assessors were made up of experienced and inexperienced raters. Experienced raters consisted of eleven speech language pathologists who currently use CRT as part of their clinical practice, and inexperienced raters consisted of 34 speech language pathologists who had no experience using CRT. Participants were provided with 10 different cough response videos and were asked to rate whether the cough was strong, weak, or absent. The same video segments were then presented 15 minutes later but in a different order to determine intra-rater reliability. Results showed that speech language pathologists only showed a fair-moderate reliability in their subjective assessment of RC, and clinicians with more experience did not significantly improve inter-rater reliability. Descriptive data that was captured during the study suggests that both experienced and inexperienced speech language pathologists need to gain more confidence in determining a weak or strong cough. These studies highlight the limitations of subjective assessment of cough strength in clinical practice, and suggest that objective measures of RC strength are necessary.

### 2.5 Objective Cough Strength Measures

Risk of aspiration is routinely assessed through the measurement of VC strength. Airflow, pressure, expiratory muscle EMG’s, and acoustics are all objective ways to assess cough strength (Widdicombe et al., 2011), however there appears to be an ongoing trend in which these methods are not widely used in the assessment of cough strength following a
cerebrovascular accident. VC strength tends to be a subjective assessment administered by clinicians as part of a wider clinical assessment (Widdicombe et al., 2011; Laciuga et al., 2016). In addition to this, there is no literature that discusses RC strength and its relationship in clearing aspirated material from subglottic space.

Mills et al. (2017), investigated three different ways of measuring voluntary and suppressed RC strength, after identifying a gap in the literature for measuring RC strength. Peak and area under the curve (AUC) measurements were taken of pressure, airflow, and acoustics in 53 healthy participants 50 years or over. Their study highlighted the importance of measuring RC strength, showing that a strong volitional cough was stronger than RC in all measures. Although these data were taken in all healthy subjects, it can provide information on the relative values of measures often used to objectively measure cough strength.

2.5.1 Cough Peak Flow

Cough Peak Flow (CPF) is a reliable measure of expiratory muscle strength that is commonly seen throughout the literature. Spirometers and peak-flow meters are both tools used to assist clinicians in assessment of CPF (Kimura, Takahashi, Wada, Hachisuka, 2013).

In a study by Smina and colleagues (2003), a VC PCF cut off value of 60L/min was identified for patients who aspirated and died during their inpatient stay. The major limitation of this study however, is that aspiration was identified based on clinical assessment alone. Although aspiration can be inferred based on clinical assessment, without an instrumental assessment it is not possible for the researcher to conclude that these 9 patients were in fact aspirating.

In comparison to Mills et al. (2017), all averages for either weak or strong VC in healthy individuals were over 60L/min. RC however, was below the 60L/min figure on all trials, even
with an increasing dosage of citric acid. This therefore contradicts previous findings as this would indicate that these healthy individuals would show clinical signs of aspiration based on the measurement of their RC, further highlighting the importance of not assuming strength of RC based on VC measures.

This information is promising when trying to establish adequate cut-off levels, however it does not take into account the appropriateness of this assessment for a range of individuals who may not be able to participate in a cough peak flow assessment. The assessment requires following of specific instructions, therefore if an individual had a cognitive or communication impairment, this assessment may not be indicated.

A later study by Kimura et al. (2013) researched CPF measurements in dysphagic and non-dysphagic patients who had suffered a stroke. The study endeavoured to find a relationship between a reduction in CPF and the subsequent development of aspiration pneumonia. Results showed that the CPF measurement during VC for all stroke patients was reduced in comparison to the control group. Furthermore, it was inferred that all dysphagic patients had a weaker VC due to their inspiratory reserve volume being significantly lower than the measurements of the control group. When comparing penetration aspiration scale (PAS) scores and CPF in the dysphagia group, there was no relationship with the CPF being lower regardless of the PAS score. Therefore, attempting to identify severity of aspiration in the dysphagic patients through comparing cough strength based off CPF was not possible in this instance. The study had limitations in terms of the sample size being small and male only. This study is also limited as it assesses voluntary cough only, whereas RC would provide more relevant data when trying to assess potential for airway clearance.

A more recent study by Sohn et al. (2018), used CPF measurement during citric acid CRT to determine the appropriate cut-off values to predict aspiration pneumonia in 163
patients. A retrospective cohort analysis of patients who had been admitted to a rehabilitation ward from either the stroke or neurosurgical wards at a university hospital over a two year period were involved in this study. To meet the inclusion criteria, patients had to have a new dysphagia secondary to cerebrovascular disease, and they also must have undergone a citric acid CRT on the same day as an instrumental assessment of swallowing.

The CPF was measured during voluntary and RC tests (a fixed dosage of citric acid was used across the study), and any respiratory tract infection caused by aspiration within the first 6 months was recorded. This retrospective study identified that a CPF cut-off at 59L/min during the CRT could “predict respiratory infections with a sensitivity of 81% and specificity of 84%” (Sohn et al., 2018, p2534). The results from this study indicated that using the cut-off values identified during a CRT could, with great accuracy, help to identify those patients at risk of developing aspiration pneumonia in the first 6 months after the initial onset of dysphagia. In comparison to other studies, measuring the CPF of RC during a CRT is more manageable for the patients as the peak flow meter is connected directly to the nebuliser. Therefore, the patient is not required to produce a volitional cough or form a lip seal around the meter. It is unclear in this study the accuracy of CPF when using a meter attached to a nebuliser, however this seems to be the routine way of measuring CPF of RC as also investigated in studies by Lee, Kang, Kim, Chang, & Im, (2013) and Kulnik et al. (2016).

Although there is research to support the use of CPF in objective cough strength measurement, there are still a number of limitations when implementing the assessment into clinical practice. CPF requires a patient to have intact movement of the facial and labial muscles to create a seal around a device. This motion can be difficult for many patients following a neurological event and would therefore not be overly appropriate or effective to use in this particular population. Along with this, measuring the CPF of a VC often requires
intact cognition/receptive language. Kimura et al. (2013), had a specific inclusion criteria for their study which stated that he patient must be able to understand the examination. It is unrealistic in a hospital setting, particularly on a neurological ward, that all patients would be able to follow instructions and engage in the assessment, therefore this test is not necessarily the best option when it comes to objective cough strength measurement in a neurologically impaired population.

2.5.2 Electromyography (EMG)

EMG is another method of evaluating cough strength. The oblique (external and internal) muscles, the tranversus abdominis, and the rectus abdominis are all expiratory muscles of the abdominal wall (Strohl, Mead, Banzett, Loring, & Kosch, 1981). During the compressive and expulsive phases of coughing, these muscles are intensely activated (Strohl et al., 1981). Not only the neural mechanisms, but intensity of cough have been able to be assessed through the use of EMG (Fontana, Pantaleo, Lavorini, & Pistolesi, 1999). Recordings collected on expiratory muscle output at the time of cough can enlighten researchers into the activation of neural mechanisms during cough. As there is a relationship between EMG activity and the force expended by the contracting muscle, when there is activation of the muscles in the abdomen, this information can give insight into the strength of an induced cough (Fontana, 2008).

EMG has been used in a study by Vovk et al. (2007) to research LER and cough reflex in all healthy subjects. For the purpose of this study, cough was induced by the tussigenic agent, capsaicin. Results showed that as the stimulus became stronger, so did the cough in which was produced. During the sequence of coughs elicited, EMG data showed that the pressure measurements decreased the longer the cough sequence continued. This implies
that the cough is at its strongest point in the initial response elicited, and becomes weaker secondary to a reduction in lung volume. Although one may hypothesise that a stronger stimulus is going to result in a stronger cough, it does not enlighten us on whether the cough would effectively expel aspirate from subglottic space.

Cough strength assessment through the use of EMG does not come without further limitations. For example, variability in the placement of electrodes may create variable results across, and within patient measurements (Cox et al., 1984). EMG data can also be effected by the composition of an individual’s body. This includes aspects such as, percentage of abdominal fat, muscle size, skin resistance, and surface area in regards to electrode placement (Pitts & Bolser, 2011). It is also important to mention that EMG focuses on the abdominal region, however does not provide information on laryngeal function and airway protection at this level.

2.5.3 Cough Pressures

Another alternative measure of cough strength that has been described in the literature is measurement of cough pressure. Catheterising of the urethra and rectum is a tool that has been used to calculate intra-abdominal pressures (IAP) as a way to then measure cough strength (Addington, Stephens, Phelipa, Widdicombe, & Ockey, 2008).

Stephens, Addington, & Widdicombe, (2003) completed a study which assessed volitional and reflexive cough strength by evaluating diaphragm movement under VFSS. Results showed that the diaphragm had a larger upward movement after a RC was elicited than when compared to a VC. The external abdominal obliques, intercostals and associated expiratory muscles contract during a cough. When these muscles contract, both diaphragm movement, and an increase in IAP is seen (Addington et al., 2008).
Addington et al. (2008) used cough pressure measurements to further investigate IAP in both volitional and RC. Results showed that the area-under-the-curve (AUC) was greater for RC than VC. This could be due to the nature of a RC in response to inhalation of tartaric acid, where multiple coughs are elicited compared to fewer coughs when prompted to volitionally cough. One finding that was of interest to the researchers was that the time length of IAP was much greater with RC than with VC. When the glottis was adducted and there was no expiratory flow, the IAP duration was greater. As soon as the glottis was abducted, a noticeable drop of IAP was observed. Due to glottal closure being an important mechanism of airway protection (Widdicombe et al., 2011), one can infer that adduction of the glottis and therefore a longer IAP duration, may play an important role in airway protection and the RC response.

The study by Mills et al. (2017), which looked at objective cough strength measures in healthy individuals, found that whether a VC was strong or weak, it was still stronger than reflexive coughs across majority of measures, with pressure and flow being the most useful objective measure. This re-enforces the importance of objective measurement of RC and not basing management on how a voluntary cough may appear at bedside in a dysphagic high risk population.

A major limitation for using cough pressure as a measurement of cough strength is the invasive nature of the assessment. It may not be well tolerated by patients, and is also not clinically practical.

### 2.5.4 Acoustics

Through the use of a free-air microphone and a cassette recorder, recording of cough sounds have been documented as early as the 1960s (Subburaj, Parvez, & Rajagopalan, 1996).
With modern recording technology, integrating measurement of cough sounds into an objective measurement of cough strength is simple (Fontana & Widdicombe, What is cough and what should be measured?, 2007). Acoustic measurement is advantageous as it is easily accessible and portable (Subburaj et al., 1996).

Smith Hammond and colleagues (2001), were the first to objectively assess aeromechanical and acoustic characteristics of cough strength in stroke patients. They hypothesised that patients who had suffered a stroke, and were aspirating, would have reduced cough airflow measures and cough sound when compared to both healthy subjects and stroke patients who were not aspirating. VFSS or fiberoptic endoscopic evaluation of swallowing (FEES) assessments were completed on all stroke patients and then measurement of sound pressure level (SPL) of VC was conducted blinded to these. An airtight mask placed over the oral-nasal region, and a calibrated microphone attached to a pneumotachograph, recorded SPL during the cough. Results showed that all SPL measures of cough were reduced in the stroke patients when compared to those patients in the control group. Although those patients who aspirated had a reduced SPL than those who did not, the study concluded that the SLP did not differ whether the patient’s had mild or severe amounts of aspiration. Smith Hammond and colleagues (2001) highlighted that the loudness and intensity of cough can be affected by secretions in the airway. Although this method may not help distinguish severity of aspiration in patients, there is potential for it to be a useful means to help identify patients who are at an aspiration risk of some degree.

A later study by Smith Hammond et al. (2009), assessed a wider range of objective cough strength methods, however once again used an airtight mask and a calibrated microphone attached to a pneumotachograph to assess SPL. Results were also assessed in conjunction with VFSS or FEES. The finding of most relevance was that a relationship was
identified between SPL and aspiration risk, suggesting potential in measuring acoustics as an objective measure of cough strength in patients susceptible to aspiration. The most significant limitation in both studies however, is that RC has not been assessed. This once again identifies a gap in the literature in terms of objective RC strength measures.

Subburaj et al. (1996) identified the need for a more objective measure of assessing cough strength, so endeavored to create a thorough and rounded analysis of cough acoustics through the use of a computerised system. This was achieved by locating a small microphone lateral to the left nostril, in conjunction with a simultaneous recording using a digital tape recorder. This study did not assess the relationship between aspiration and cough strength, however highlighted the importance of microphone placement. Results showed that intensity of the cough was reduced with an increase in distance between the source and the microphone. It also showed that horizontal distance had a greater impact on cough intensity compared to vertical distance. In comparison, a study by Paul, Wai, Jewell, Shaffer, & Varadan (2006) discusses the advantages of attaching the recording device at the suprasternal notch as this is below the level of the larynx and avoids interference from speech or swallowing. Both studies concluded that their methods were valid and reproducible for an objective method of cough strength.

Although all studies show possible advantages in assessing cough strength through sound, they do however require further research to incorporate the assessment of RC strength. There does not appear to be any research which compares an acoustic measure of RC strength and the ability of the patient to clear aspirated material from subglottic space.
2.6 Conclusion

CRT is a sensitivity test of RC that is merging into clinical practice; however the objective measurement of RC strength continues to have no routinely used assessment. Objective measurement of cough strength is assessed a number of ways throughout the literature, however there continues to be a gap in the literature that specifically looks at an individual’s ability to clear aspirate from the airway through the RC mechanism.

Mills et al. 2017 discuss that given RC and VC are controlled differently neurologically, the impact on RC and VC following a neurological impairment will be different. RC is the first response post aspiration event, and although VC may help clear aspirated material, it cannot prevent it. Therefore, due to the differences both neurologically and physiologically in control of RC and VC, assessment of a person’s ability to protect their airway should be assessed by RC. Establishing an objective measurement of RC strength will provide clinicians with further tools when assessing patients with dysphagia, with the overall goal being reduced rates of aspiration pneumonia.
CHAPTER 3 - Research Question and Hypotheses (Study 1)

3.1 Research Question

Is there a specific acoustic output (i.e. decibel level) of a reflexive cough epoch that is consistent in effective clearance of aspiration in patients who present with dysphagia?

3.2 Objective

The aim of this study was to determine a more reliable method of identifying effective clearance of aspiration. An audio microphone and a decibel meter on an iPhone/iPad were attached to participants during VFSS to measure the root mean squared of decibel levels during a reflexive cough response elicited to aspiration. Instrumental assessment in the form of VFSS was used to assess airway clearance during an aspiration event.

3.3 Hypotheses

The relationship between the acoustic output measurement obtained during a reflexive cough response, and the effectiveness of aspirated material being cleared from the airway, will be significant. It is hypothesised that patients who have a louder cough, will be more likely to expel aspirate, compared to those with a softer cough who are less likely to expel material from subglottic space.
CHAPTER 4 - Research Design and Methodology

4.1 Study Design

A cross sectional, observational study design was conducted to determine the required strength (as measured in decibels) of a reflexive cough epoch and its ability to clear aspirate from the airway.

4.2 Ethical Considerations

Approval from the national Health and Disability Ethics Committee (HDEC) was granted for this study. A local authorisation of the regional health board was completed before data collection commenced. Written consent was gathered confirming that all participants had been given both verbal and written explanations of the study and procedure before individual data collection commenced. An additional, communication friendly, information form was provided to participants with visually supported written information.

4.3 Participants

Patients who were referred for VFSS as part of their ongoing clinical dysphagia management were invited to participate in the study. Participants were recruited by the researcher across both inpatient and outpatient settings. Participants who were referred by someone other than a speech and language therapist underwent a phone screen prior to their VFSS appointment. Participants were not recruited for the study if they had cognitive and/or receptive communication impairments and were not deemed competent to consent. In cases where the patients Enduring Power of Attorney (EPOA) was present, they were able to consent on behalf of the participant. Participants were excluded from the study if they did
not aspirate, or did so silently, during VFSS. Post-hoc, data was excluded if the quality of the VFSS images were not adequate or if there were technical issues with the saving of VFSS images.

4.4 Location

Data collection took place at a regional public hospital. This included a medium size city, a provincial city, and a wider rural surrounding region.

4.5 Sample Size

A pilot study which used the same research question and methodology as the current study, based sample size off the limited published research around testing reflexive cough strength. Sample sizes of 10-23 can be seen throughout the published literature. Data collection took place over a 10 month period, with the aim of gathering data from as many participants as possible over this time.

4.6 Resources

A small lapel microphone (RODE smartLAV+) connected to an iPad/iPhone was used to collect the audio recordings. An application that measures acoustic output (Decibel 10th) was downloaded to the iPad/iPhone and stored the acoustic information during the procedure. A standard, clinical VFSS recording form was used to document oral trials throughout the procedure.
4.7 Preparation

Throughout the data collection process, all New Zealand and VFSS radiation guidelines were adhered to. The small lapel microphone used to collect decibel levels was attached to the tragus of each participant’s ear and firmly secured with adhesive medical tape to ensure it did not move throughout the study. The cable of the microphone was placed over the patient’s ear, where it did not interfere with imaging. The microphone was connected to the iPhone/iPad ready to record and save acoustic output.

4.8 Procedure

The VFSS was completed by radiology staff, alongside two speech language therapists (the researcher and one other) as per hospital protocol. For each participant, the bolus type and consistency trialled was recorded on the clinical VFSS recording form. If a participant elicited a reflexive cough response to aspiration during the procedure, the data collector took note of this and recorded the number of coughs.

Audio recordings were taken in conjunction with the clinical VFSS. Care was taken to ensure that screening time enabled visualisation of airway clearance during the study. This was done by consulting with the radiographer or radiologist and ensuring optimal positioning of the patient. When the procedure was completed, the researcher stopped the audio recordings. The microphone was removed from the patient and cleaned with a sterile wipe.

If the patient aspirated during the study and elicited a RC epoch due to this, the acoustic data collected during the VFSS was saved and emailed to the researcher via the iPhone/iPad. All VFSS images were saved onto the local electronic medical record portal for later analysis and an additional hard copy (DVD) was also be kept by the researcher. If the patient did not aspirate during the study, any data collected during the procedure was deleted.
4.9 Data Extraction

Once the data was collected, the audio files were downloaded to Audacity (Audacity Team (2018). Audacity® Version 2.2.2), a computer software programme which enables audio editing. Data collected from thin fluid consistency was the main point of analysis. A cough was identified by the first explosive phase and a throat clear was not considered as a “cough” response; therefore the data collected from a throat clear was not included in the final analysis. For each identified epoch in response to aspiration, the root mean square of the decibel level was extracted.

Audio was recorded in Decibels relative to full scale (dBFS) where 0 dBFS is assigned to the maximum level. This is a unit used for amplitude levels in digital systems with a maximum available peak level, and explains why results will be a negative integer. VFSS images were recorded at 30 frames per second (CASPLO, 2007) and saved to a picture archiving and communication system (PACS) used by the radiology department at the location where data collection took place.

All VFSS reports and findings were peer reviewed by another speech language therapist before being finalised. Airway entry and reaction was determined by Rosenbek’s 8-point penetration aspiration scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996).

4.10 Results

A limited number of participants met the inclusion criteria for the primary aim of this study. Data was collected over a 10 month period from the 22nd of May 2018 until the 1st of March 2019. During this time, data were collected on 55 patients. Of these 55 patients, 16 (29%) aspirated thin fluid consistency. Nine of these 16 (56%) patients elicited a cough in response to aspiration, and the remaining 7 (44%) showed no outward response, hence
silently aspirating. Of the 9 participants that elicited a cough response, only 4 had sufficient VFSS images to accurately interpret whether they were able to clear aspirate or not.

The 4 patients whose data were able to be analysed all elicited a RC in response to aspiration. Audacity was used to extract the root mean square and the peak level, both measured dBFS (see table 1 for a breakdown of figures). The RC of all 4 patients was not effective in clearing aspirated material from the trachea. It is also worthy to note that there were 5 participants where VFSS images were not saved so could not be included. There were an additional 12 participants where positioning was a problem, and accurate assessment of airway clearance could not be determined.

Table 1: Summary of reflexive cough RMS and Peak values measures in dBFS and the relationship between clearing aspirate

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>RMS (dBFS)</th>
<th>Peak (dBFS)</th>
<th>Bolus Consistency</th>
<th>Clear aspirate (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>-30</td>
<td>-14</td>
<td>Thin</td>
<td>No</td>
</tr>
<tr>
<td>17</td>
<td>-31.8</td>
<td>-14.9</td>
<td>Thin</td>
<td>No</td>
</tr>
<tr>
<td>26</td>
<td>-34.6</td>
<td>-17</td>
<td>Thin</td>
<td>No</td>
</tr>
<tr>
<td>32</td>
<td>-30.7</td>
<td>-23.4</td>
<td>Thin</td>
<td>No</td>
</tr>
</tbody>
</table>
CHAPTER 5 – Research Question and Hypotheses (Study 2)

The primary aim of this research was to establish a relationship between reflexive cough strength, acoustic output, and the ability to effectively clear subglottic aspirate. Due to a limited number of participants that met the inclusion criteria for the study, an additional retrospective clinical audit was conducted to further evaluate RC and its effectiveness in clearing aspiration.

5.1 Research Question

How many people elicit a RC to aspiration, and what is the incidence of clearing aspirated material from the trachea following this?

5.2 Objective

The aim of this study was to conduct a clinical audit to answer the clinical questions that arose from study 1. These questions included:

1. What is the incidence of aspiration of thin fluids in patients with dysphagia?
2. What proportion of these patients elicit a RC in response to aspiration of thin fluids?
3. Subsequently, what proportion of those who elicit a RC are able to clear thin fluid aspirate from subglottic space?

5.3 Hypotheses

Based on data presented in Chapter 4 and previous studies by Garon, Sierzant, & Ormiston, (2009) and Smith Hammond, Goldstein, Zajac, Davenport, & D.C., (2001), approximately 50% of patients who aspirate will do so without a cough response. It is
difficult to hypothesise the incidence of patients who will clear aspirated material following a RC response due to there being no prior published literature on this. However, the researcher would predict that the patients who have a subjectively “strong” RC response will be effective in clearing aspirate.
CHAPTER 6 - Research Design and Methodology

6.1 Study Design

A retrospective clinical audit was conducted over a one year period to determine; incidence of thin fluid aspiration on VFSS, RC response to aspiration, and the patient’s ability to effectively clear aspirated material from subglottic space.

6.2 Participants

A clinical audit was conducted of all patients who had a VFSS from the 1st of January 2018 to the 1st of January 2019 across both inpatient and outpatient settings at a regional public hospital.

6.3 Sample size

One hundred and thirty six VFSS were completed in the one year period in which the audit was conducted.

6.4 Procedure

All VFSS were completed by radiology staff, alongside two speech language therapists as per hospital protocol.

6.5 Data Extraction

VFSS images were recorded at 30 frames per second (CASPLO, 2007) and saved to a picture archiving and communication system (PACS) used by the radiology department at the location were data collection took place. All VFSS reports and findings were peer reviewed by
another speech language therapist before being finalised. Airway entry and reaction was determined by Rosenbek’s 8-point penetration aspiration scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996)

6.6 Results

There were a total of 136 VFSS completed across both the inpatient and outpatient settings during the review period. Ages ranged from 21 to 94 with the mean age of patients who underwent VFSS during this time being 68 years old. Of the 136 VFSS completed, there were 83 males and 53 females with a broad range of aetiologies as outlined in Figure 1.

The inpatient clinical audit showed that, in the mentioned time frame, there were 406 patients referred to the speech language therapy department for dysphagia assessments. Of these 406 patients, 65 were then referred on for a VFSS to further assess their swallowing function. The outpatient clinical audit showed that from the 1st of January 2018 to the 1st of January 2019, there were 71 patients who underwent a VFSS in the outpatient clinic. Outpatients were referred to the service either by speech language therapists who worked either within or outside of the local health board, general practitioners, the Ear Nose and Throat department, or the Neurology department. Patients who had been referred directly from a speech language therapist had undergone a clinical swallowing assessment prior to VFSS, however those referred by another medical professional participated in a phone screen prior to their VFSS procedure.
Figure 1: Aetiologies of Patients Referred for VFSS. Patients who fell in the ‘other’ category had aetiologies that consisted of: recurrent pneumonia, muscular dystrophy, cerebral palsy, cerebellar disorders, tetraplegia, thyroidectomy, oesophageal dysmotility, post extubation and retropharyngeal abscess.

Combined findings

Of the 136 VFSS completed, 45 (33%) patients aspirated thin fluids. Of these 45 patients, 34 (76%) of the patients who aspirated did so without a RC response. Of these 34 patients who silently aspirated, 22 (65%) were the result of a stroke, with 17 (50%) having a cortical CVA, and the remaining five (15%) having a brainstem infarct. Three (8%) instances
of silent aspiration came from patients who had a head-neck cancer, and two cases in both neurodegenerative disease (6%) and brain cancer (6%). There were five (15%) cases of silent aspiration where the cause of dysphagia was unknown. The most interesting finding from the audit is that only 11 (24%) elicited a RC in response to aspiration and of these 11, nine (20%) were not able to clear aspirated material following a RC. This therefore meant that only two (4%) of patients were able to clear the aspirated material from subglottic space.

Patient's Responses to Thin Fluid Bolus

- Aspiration (n=45)
- No Aspiration (n=91)

- Aspiration - No cough response (n=34)
- Aspiration - Cough response - not cleared (n=9)
- Aspiration - Cough response - cleared (n=2)
CHAPTER 7 – Discussion

The primary aim of study 1 was to determine a more reliable method of identifying effective clearance of aspiration by attempting to establish a relationship between RC strength, its acoustic output (measured in dBFS), and the ability to effectively clear aspirate from subglottic space. This was the first study to specifically evaluate a proxy measure of cough strength and the ability to clear subglottic aspirated material under VFSS. Conclusions cannot be determined due to the limited number of patients whose data could be included in the study.

Although no conclusions could be drawn, there were a number of interesting observations. The most important, but unanticipated, question that arose from data collection was “Does reflexive coughing effectively expel aspirated subglottic material?”. To the researchers knowledge, there is no current literature that investigates this question. Studies by Garon, Sierzant, & Ormiston (2009) and Smith, Logemann, Colangelo, Rademaker, & Pauloski, (1999), have looked into silent aspiration and VFSS, but no studies have evaluated clearance of aspiration on VFSS. Therefore, study 2 is unique in this respect.

This is an important question to be answered, as clinical management is often based on the presence or absence of a cough to aspiration. These findings prompted a clinical audit to be conducted (study 2). This showed that in the patients who elicited a RC response to aspiration, very few were able to clear the aspirate from subglottic space. Data collected from the audit supported the limited findings that were identified in study 1 where none of the patients were able to clear aspirated material with a RC. This suggests that reflexive coughing in response to aspiration may not effectively or consistently clear aspirated material from subglottic space.
The focus of this research was to provide unique information into the effectiveness of RC and the ability to clear aspirated material. Unfortunately, we could not answer this question, and could find no evidence in the literature or prior research on the topic. A significant amount of research suggests that cough is thought to clear the airway (Addington et al., 2005; Fontana, 2008; Langmore et al., 1998; Mills et al., 2017; Wakasugi et al., 2008; Widdicombe et al., 2011), it was therefore assumed we would be able to produce data to support this. It is remarkable that in the world of dysphagia management this question has never been answered. One can hypothesise that this could be due to the assumption that RC works in the same was as expelling material as VC, however without research to support this, these assumptions are just anecdotal evidence.

Study 1 was based on previous research as part of a PhD thesis. There were similar findings in terms of only a small number of patients meeting the inclusion criteria (i.e. aspirating and eliciting a RC on VFSS). Of these patients, none were effective in clearing aspirated material with a RC. It was predicted that as the current researcher was working clinically within the field, there would be greater access to VFSS and therefore a larger cohort of patients would be included in the current study (study 1). This would provide a bigger range of results and perhaps some patients who cleared aspirated material. However, the results were consistent with previous findings.

It has been routinely accepted by clinicians that a ‘strong’ cough is more likely to expel subglottic material than a ‘weak’ cough, which may not have sufficient strength to remove aspirate. Based on this, it was hypothesised that in this present study, those patients who had a stronger cough and therefore a higher acoustic output, were more likely to clear aspirate than those who had a weak cough. Data collection however proved otherwise, showing that in all patients who aspirated and elicited a cough response,
coughing was ineffective to clear aspirate. Decibel readings ranged from -30.6 to -34.6; however, with only four participants being included in the original study, it is difficult to determine whether these numbers are an accurate representation of cough strength range. These numbers may just represent a “weak” cough strength and therefore do not provide information on whether a “stronger” cough would be more effective in clearing aspirated material. This study needed a much larger cohort of patients so that a larger range of decibel measurements could be interpreted, as with the current data is it is difficult to infer anything at all. This further highlighted the gap in the literature in the field of RC strength and clearance of aspiration.

A number of unpredicted methodological limitations were identified during the course of data collection which may explain the findings of study 1. Access to VFSS was not always timely. Bookings for a VFSS were dependent on radiology availability and then the clinician being available during these proposed times. A limitation that appeared prominent during inpatient data collection was that often patients would be identified as being a high risk of aspiration clinically, however by the time a VFSS appointment was available, their clinical presentation had changed. One assumption is that this could be due to spontaneous recovery, therefore it meant that what was initially seen during bedside assessment, did not match what was seen on VFSS. This reduced the number of patients that met the inclusion criteria.

Another limitation to the study was the quality and accuracy of the VFSS images. With the researcher not having control over the VFSS machine, there were times where recording stopped before being able to confirm whether aspiration had ejected, and also where images were not saved so there was no ability to re watch and confirm the presence of aspiration and the patients ability to clear. Another issue in regards to overall quality of
the VFSS images was that there were often times where the patients positioning did not allow direct visualisation of the laryngeal vestibule and trachea, therefore analysis of whether the patient cleared aspirate or not was not reliable.

Although widely known as the gold standard for objective swallowing assessments (Burns et al., 2015), VFSS only allows the clinician to see a snap shot of the swallowing function. Once screening is completed there is no way of knowing whether the delayed cough that is elicited is in response to airway entry, and whether this cough clears aspirate. Often trials of different textures are recorded, however this is not necessarily a reflection of what a person’s swallow function may look like over the course of a meal. This is therefore a limitation to data collection as we cannot capture potentially valuable information outside of screening time.

A study by Corrigan & Williams-Jones, (2003), discusses the extreme vulnerability of incompetent patients. When collecting data, patient consent appeared to be a limitation that resulted in multiple participants not being appropriate. When working with patients who are neurologically impaired as a result of a stroke, TBI, brain tumour, or other form of brain damage, communication and cognitive impairments are common. There were a number of patients who were not competent to consent to the study, did not have family close by to consent on behalf of them, or cognitively were unable to participate in the procedure. This resulted in patients, in a specific population of interest, not being able to be involved in the research. This may have been a contributing factor in the limited amount of useable data obtained.

With inconclusive results from study 1, it was identified that there appeared to be a limited amount of patients who elicited a cough response to aspiration. Unexpectedly, this resulted in being one of the largest limitations of the proposed aim of this study. This meant
that a large proportion of patients who were initially included in data collection could not be included in the final analysis. It was this limitation that resulted in a clinical audit being conducted to further investigate aspiration and the effectiveness of a RC clearing aspirate.

The clinical audit (study 2) offered information on 136 VFSS over the course of one year. The most interesting findings from this audit were; that only 4% of patients who elicited a RC response to aspiration, cleared aspirated material from subglottic space, and of the patients that did aspirate, 76% did so with no RC response. This re-enforced the importance of not relying on a clinical bedside assessment alone in those patients at risk of aspiration, as a large number may not show any RC response at all.

A major learning point from the audit was the finding that of 406 in patients who were referred to the speech language therapy department for dysphagia over one year, only 65 patients (16%) were then referred for VFSS. With the results of the overall audit showing a large amount of patients eliciting no RC response to aspiration, this raises concern over the amount of patients who may have been assessed clinically, with vital information being overlooked. Specifically, dysphagia severity and an individual’s ability to protect their airway. This audit has been useful to prompt a review of dysphagia and VFSS practice, and encourages more frequent auditing for all speech language therapists to ensure they are providing best practice.

Another learning point was identified by the unexpected finding that when patient’s elicit a RC response to aspiration, it rarely is effective in clearing aspirate. This questions clinician’s thought processes during VFSS assessment. Clinicians routinely identify whether there is a RC response or not to aspiration, but do they routinely assess whether that cough is effective in clearing aspirated material? This is a question that warrants further research.
to ensure clinicians are identifying all aspects of airway protection, and understanding the implications of their findings to help guide overall dysphagia management.

Interestingly, subjective rating of cough strength continues to guide clinical decision making in clinical practice. This involves clinicians judging airway clearance ability after listening to the acoustic signal of the sensorimotor cough response. The current study aimed to offer insight into the validity of acoustic intensity and cough strength, however due to a number of limitations, we were unable to achieve this aim. There is a need for further research on the validity of acoustic cough strength measurement for predicting ability to clear aspiration on VFSS, if this is the measurement that clinician’s will use to guide clinical decision making. Although not specific to RC strength, perhaps measuring the decibel level of VC in those patients who have already had a VFSS and have been given a PAS score of 6 (aspiration ejected), and 7 (aspiration not ejected despite effort) (Rosenbek et al., 1996), may be a better initial experiment design as it minimises the risk of missing the RC response on VFSS. For a more comprehensive study, data could also be collected on those patients who penetrate, their response, and whether they eject/not eject. With the identification that only 16% of in patients who were referred for dysphagia received a VFSS, it could be worth repeating the current study with a much larger cohort of patients at a centre where VFSS is done more routinely and regularly. This would enable more data and provide a much more thorough study.

We still do not fully understand how to rate cough strength. We attempted to provide information on this, but there were a lot of limitations in the study that need to be addressed before the question of “how strong is strong enough to clear aspiration?” can be answered.
CHAPTER 8 – Conclusion

Although the literature related to cough and aspiration continues to expand, there is still limited research in regards to RC to aspiration and effectiveness of RC in clearing subglottic aspirate. The findings of this study highlight the need for further research in both areas, but in particular to answer the question; “Is RC effective in clearing aspirated material from subglottic space?”

Clinically, decisions on the management of patients are made daily based on, what appears to be, anecdotal evidence. The suggestion that a RC may not clear aspirated material, and identifying a weak or strong cough could be irrelevant, is a foreign concept to clinicians. Further research is most definitely required in this field as the implications these findings could have clinically have the potential to change every day management and patient outcomes.

Although conclusions from the study could not be drawn, the study provides a platform for future research on a larger scale.


on Swallowing and Swallowing Disorders (Dysphagia), 20(1), 3-8.


APPENDIX 1
Participant Information Sheet

You are invited to participate in a research project on Cough Strength Testing

What is the project about?
A strong cough is important to protect our lungs if food/drink goes down the wrong way. Results from the study will give us more information on how we can measure cough strength to identify patients with a strong or weak cough.

Why should I participate in the study?
- Whether or not you take part is your choice
- If you do not want to take part, you don’t have to give a reason. It will not affect your care in any way.
- If you want to take part now, but change your mind later, you can pull out of the study at any time.

What will I need to do?
- You will need to sign a consent form. We can help you with this.
- We will need to know some information about you.
- You will be asked to wear a small microphone on your ear during a cough reflex test.
- The Cough Reflex test involves wearing a face mask that is connected to a nebuliser. The air omitted form the face mask contains citric acid (the acid in oranges and lemons). This air may/may not make you cough.
- The test will be repeated three times.
- No additional time is required after this.
- If you cough during your x-ray swallow study, the researcher will keep a copy of the audio file and the x-ray of your swallow study for further analysis.
- If you do not cough, your audio recording will be deleted and your information will not be included in the final analysis.

What happens after this?
● We will keep your information at Dunedin Public Hospital.
● Your name will be removed from all paperwork and you will be assigned a code number.
● All information will be kept safely on a password protected computer.
● The data will be stored for 10 years; after that it will be deleted.
● The results of the study will be included in the researcher’s MSc thesis and may be submitted for publication in a peer reviewed journal. If you would like a copy of the study when it’s complete, please indicate this on the consent form.

Are there any risks?
● There are no risks in taking part in the study. Your participation will not effect your care in any way.
● You will have the opportunity to ask questions and to find out more information from the researcher.

What if I decide I do not want to be involved in the study?
● You can withdraw from the study at any time by contacting the primary investigator.
● If you do not wish to contact the primary investigator, you can contact your speech and language therapist who can inform the primary investigator on your behalf.

You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.
If you would like to participate in the study, please sign the consent form the accompanies this information leaflet, and bring it to your x-ray swallow study.

What if I have more Questions?
Principal Investigator: Leah Hay
Email: leah.hay@southerndhb.govt.nz
Phone: 027-318-7577

Supervisor: Prof Maggie-Lee Huckabee.
The University of Canterbury Rose Centre for Stroke Recovery and Research.
Email: maggie-lee.huckabee@canterbury.ac.nz
Phone: +64 3364 2014
# Appendix 2

## Participant Information Sheet

You are invited to take part in research on cough strength measurement

<table>
<thead>
<tr>
<th><strong>What is this project about?</strong></th>
<th>![Cough Image]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A strong cough is important to protect our lungs when food/drink goes down the wrong way. More research is needed into cough strength.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Why should I participate in the study?</strong></th>
<th>![Checkmark and X Images]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your help will help others. Whether or not you take part is <a href="#">your choice</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>What will happen during the study?</strong></th>
<th>![Consent Form Image]</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will need to sign a consent form. We can help you with this.</td>
<td></td>
</tr>
<tr>
<td>We may look in your medical file to find out more information about you.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>![Microphone and X-Ray Image]</th>
<th>![Audio and X-Ray Images]</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will be asked to wear a small microphone during your x-ray of your swallow.</td>
<td></td>
</tr>
<tr>
<td>If you cough, we will keep a copy of your audio and x-ray swallow recording. If you do not cough we will not keep any of your information.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>What happens after this?</strong></th>
<th>![Lock Image]</th>
</tr>
</thead>
<tbody>
<tr>
<td>We will keep your information at Dunedin Public Hospital. All information will be kept safely on a password protected computer. The data will be stored for 10 years.</td>
<td></td>
</tr>
</tbody>
</table>
The information will be used in the researcher’s thesis. If you would like a copy of the study when it’s complete, please indicate this on the consent form.

Are there any risks?
There are no risks in taking part in the study. Your participation will not effect your care in any way. If you are worried or concerned about the study, you can ask questions and find out more information.

What if I decide I do not want to be involved in the study?
- You are free to withdraw from the study at any time.
- You can do this by contacting the primary investigator, Emma Wallace (e-mail: eswallac@tcd.ie or phone: 027-456-21-69)
- If you do not wish to contact the primary investigator, you can contact your speech and language therapist who can inform the primary investigator on your behalf.

What if I have more Questions?

Principal Investigator: **Leah Hay**
Email: leah.hay@southerndhb.govt.nz  
Phone: 027-318-7577

Supervisor: **Prof Maggie-Lee Huckabee**.  
The University of Canterbury Rose Centre for Stroke Recovery and Research.  
Email: maggie-lee.huckabee@canterbury.ac.nz  
Phone: +64 3364 2014
APPENDIX 3

Consent Form

Project Title: Cough Strength Testing in Acute Dysphagia Management

● I have been given a full explanation of this project and have had the opportunity to ask questions.
● I understand what is required of me if I agree to take part in the research.
● I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided, if this is still possible.
● I understand that any information or opinions I provide will be kept confidential to the researcher and supervisors, and that any published or reported results will not identify the participants.
● I understand that a thesis is a public document and will be available through the UC Library.
● I understand that all data collected for the study will be kept in locked and secure facilities and/or in password-protected electronic form and will be destroyed after ten years.
● I understand that I can contact the researcher Leah Hay, (leah.hay@pg.canterbury.ac.nz) or her supervisor Maggie-Lee Huckabee (maggie-lee.huckabee@canterbury.ac.nz) for further information.

Optional: I would like to receive a summary of the findings. If so, please provide email address:
_________________________________________________________________________________

By signing below, I agree with the statements above, and to participate in this research project.

Print name of participant: _______________________________________

Signature of participant: _______________________________________

Date: _______________________

______________________________
Title of Project: “Cough Strength Testing in Acute Dysphagia Management”

Principal Investigator: Leah Hay, MSLT Student.
Dunedin Public Hospital
The University of Canterbury Rose Centre for Stroke Recovery and Research.
Email: leah.hay@southerndhb.govt.nz
Phone: 027-318-7577

Supervisor: Prof. Maggie-Lee Huckabee.
The University of Canterbury Rose Centre for Stroke Recovery and Research.
Email: maggie-lee.huckabee@canterbury.ac.nz
Phone: +64 3364 2042

Dear: Speech and Language Therapists,

I am conducting a research project on cough strength testing in acute dysphagia management as part of my MSc. I am seeking help from speech and language therapists to identify potential participants for the study.

Potential Participants
Any patient who has been referred for a video-fluoroscopic swallowing Study (VFSS).

What is the purpose of the study?
The study aims to objectively measure the cough strength using acoustic intensity (decibels) during VFSS.

What will the study involve?
- All data will be collected during the patients’ routine VFSS.
- A small lapel microphone will be attached to the patient’s ear prior to their VFSS.
- The microphone will be inserted into the headphone connection of the iPad device.
- The audio recording application (“Rode Rec”) will be opened on the iPad and started when oral trials commence.
- After the VFSS, the audio recording will be stopped and the microphone will be removed from the patient.
The audio and VFSS files will be sent to the researcher for analysis.

**What are the potential risks of the study?**
Participation in the study does not pose any serious risks. It is possible that the participant may feel anxious or concerned regarding their participation in the study. The researcher will minimise this by giving all participants time to ask questions about the study and discuss and concerns they may have.

**Who pays for the study?**
The study is paid for by the University of Canterbury Rose Centre for Stroke Recovery and Research. The hospital, Speech and Language Therapist or participants will not incur any costs.

**Who can I contact for further information?**
The contact details of the principal investigator, Emma Wallace and the project supervisor, Prof. Maggie-Lee Huckabee are above.

Please give the participant information sheet and consent form to any patients you consider suitable for the study, or if the patient prefers, please send me their email address and/or phone number and I will contact them directly.

If you have any further questions, please do not hesitate to contact me.

Nga Mihi,

Leah Hay

Leah Hay, BSLT (Hons), MSLT Student.
The University of Canterbury Rose Centre for Stroke Recovery and Research.
Dunedin Public Hospital
Email: leah.hay@southerndhb.govt.nz
Phone: 027-4318-7577
## APPENDIX 5

# Procedure for Data Collection

## Patient Information

<table>
<thead>
<tr>
<th>Consent form Signed?</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID (Hospital Initials_Participant Initials) e.g. (Ch_EW)</td>
<td></td>
</tr>
<tr>
<td>DOB</td>
<td></td>
</tr>
<tr>
<td>Medical Diagnosis?</td>
<td></td>
</tr>
<tr>
<td>Reason for VFSS Referral?</td>
<td></td>
</tr>
<tr>
<td>Inpatient / Out-patient</td>
<td>(please circle)</td>
</tr>
<tr>
<td>Ethnicity: (please circle): New Zealand European Maori Samoan Cook Island Maori Tongan Niuean Chinese Indian Other: _________________________</td>
<td></td>
</tr>
<tr>
<td>Results of Patient’s Cough Reflex Test</td>
<td>Pass / Fail (no cough response / weak cough response)</td>
</tr>
</tbody>
</table>

## Procedure for Data Collection

- VFSS should be set up according to typical procedure.
- Place the microphone on the tragus of the participant’s ear (See supplemental photo).
- Set iPad so that it doesn’t “fall asleep” during the VFSS, to do this, go to: settings > general > auto lock > never.
• Open the RODE Rec application on the iPad.
• **Reduce the “gain” on the recording app to zero.** This is really important. (See IMAGE)
• The “sampling rate” should always be at 44100 Hz (this should be the default setting).
• Start the audio recording before the liquid/food trials begin by pressing “record”.
• When the VFSS is finished, stop the audio recording by pressing “stop”.

**After the VFSS**

• **Naming the Audio and VFSS Files:** Files should be named by Hospital initials _ participant initials (e.g. Ch_EW – Christchurch Hospital and Emma Wallace)
• **Exporting the audio files:** The audio files can be exported directly to the dropbox account that is set up. Press the export symbol (square with an arrow facing ↑). Click dropbox and wait for the export to complete. This requires a wifi connection.
• If there is no wifi connection, **name the file correctly** (Hospital initials _ participant initials), it will be saved automatically on the application and it can be exported when there is wifi available.
• **Exporting the VFSS Recording:** VFSS request form to be sent to Radiology for copy of images.

<table>
<thead>
<tr>
<th>After Recording Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the patient cough during their VFSS Study?</td>
</tr>
<tr>
<td>Are audio and VFSS files named correctly?</td>
</tr>
<tr>
<td>Has the audio recording been sent to the researcher?</td>
</tr>
<tr>
<td>Has a copy of the VFSS Recording been sent/copied to the researcher?</td>
</tr>
</tbody>
</table>

**Bolus Type & Consistency**

<table>
<thead>
<tr>
<th></th>
<th>Cough / No Cough</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thin Liquids</td>
<td></td>
</tr>
<tr>
<td>Thickened Liquids</td>
<td></td>
</tr>
<tr>
<td>Solids</td>
<td></td>
</tr>
</tbody>
</table>