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Therapy outcome measure for inducible laryngeal obstruction and chronic cough: development and testing of reliability and validity

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ABSTRACT

A Therapy Outcome Measure (TOM) is a practical tool for measuring outcomes of care, providing a quick and simple measure which can be used over time in a routine clinical setting. The TOM allows therapists to reflect on the dimensions of impairment, activity, participation, and well-being on an 11-point ordinal scale. Currently there are no therapy outcome measures for Inducible Laryngeal Obstruction (ILO) and Chronic Cough (CC). The purpose of this study was to develop two TOMs, one for ILO (TOM ILO) and one for CC (TOM CC), and to test the reliability and validity of each. Respiratory professionals working with patients with ILO and CC from eight UK locations received training in the use of TOM ILO and TOM CC. Face validity, inter-rater reliability and test-retest reliability were tested and analysed. TOM ILO and TOM CC both have strong face validity. The TOM ILO had strong intra-rater reliability and inter-rater reliability. The TOM CC had poor intra-rater but strong inter-rater reliability. TOM ILO and TOM CC have readily been adapted by those who received training. TOM ILO and TOM CC can now be used as a validated outcome measure.

KEYWORDS Chronic cough; inducible laryngeal obstruction; outcome measures; reliability; validity

Introduction

Inducible laryngeal obstruction (ILO) is an inappropriate, transient, and reversible narrowing of the laryngeal aperture in response to external triggers (Halvorsen et al., 2017). Several terms have been used to describe this including paradoxical vocal fold motion (PVFM) and vocal cord dysfunction (VCD), with ILO being a consensus term agreed by the European

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Respiratory Society, European Laryngological Society, and American College of Chest Physicians in 2017 (Christopher et al., 1983; Halvorsen et al., 2017; Kellman & Leopold, 1982). There is still a limited understanding of the pathophysiology, epidemiology, and aetiology of ILO (Haines et al., 2018). The prevalence of ILO is unknown but is more common in females with a broad age range (Haines et al., 2018; Petrov, 2019). Inducible laryngeal obstruction generally presents during inhalation and comes on suddenly with symptoms localised to the throat or upper chest (Haines et al., 2018; Halvorsen et al., 2017; Petrov, 2019). It occurs at the level of the glottis or supraglottis and leads to difficulty in breathing (Halvorsen et al., 2017). Individuals with ILO present across a variety of healthcare settings with differing levels of morbidity (Haines et al., 2018) which can lead to unnecessary medical treatment and increased healthcare utilisation (Abdelwahab et al., 2020; Tiotiu et al., 2018).

Cough is a protective reflex mechanism, which enables airway secretion clearance and prevents aspiration. Most cases of cough are acute or subacute and arise due to viral upper respiratory tract infections, usually lasting less than three weeks. However, when a cough persists for more than eight weeks it is defined as 'chronic cough' (Irwin et al., 2006). Such patients classically describe a dry irritable cough in response to environmental irritants (Hilton et al., 2013). Chronic cough represents hyperresponsiveness of the neuronal pathways involved in the cough reflex (Satia et al., 2017), and an impairment in descending inhibitory controls (Ando et al., 2016; Farrell et al., 2012), referred to as cough hypersensitivity syndrome (Morice et al., 2014). Chronic cough can remain refractory even to a systematic approach to management in approximately 20% of cases (Pratter & Abouzgheib, 2006). Persistent cough causes significant physical, psychological, and social morbidity. Many patients suffer from incontinence, vomiting and depression because of cough severity, thus negatively affecting quality of life (French et al., 1998).

The evidence base for ILO and CC is growing, but many aspects remain poorly understood (Haines et al., 2018; Patel et al., 2015). This makes it difficult for patients to explain all aspects of the disease. Progress has been made with guidelines published on laryngoscopy reporting procedures (Walsted et al., 2021), symptom-based questionnaires (Fowler et al., 2015; Pinto et al., 2016) and respiratory societies are acknowledging research priorities in this area (Halvorsen et al., 2017), but more is needed to increase clinician knowledge in this field.

The World Health Organisation (WHO) International Classification of Function, Disability, and Health (ICF) framework is a classification system for describing functioning and disability in relation to a health condition (World Health Organisation (WHO-ICF), 2001). It provides a common language and framework for describing the level of function of a person within their unique environment and has two parts 'functioning and disability' and

'contextual factors'. It reinforces the importance of looking at the client as a whole and considering the individual's lifestyle and personality. Patient questionnaires and symptom assessment scales are the two approaches used to assess and evaluate symptoms and functions.

Several symptom-based questionnaires that have been developed for respiratory or upper airway disorders are used in patients suspected with ILO and/or CC. Most focus on the impairment of body structure and function, but some include other factors, such as activity limitation, participation restriction, and contextual factors (Table 1).

A health outcome can be defined as 'a change in the health status of an individual group or population which is attributable to the planned intervention or series of interventions (World Health Organisation (WHO-ICF), 1998). Currently there are no therapy outcome measures for ILO and CC to allow us to evaluate changes over time and identify meaningful changes for the patient and the effect of interventions on the individual. Outcome measures are required to demonstrate the impact and value of therapy and services, identify areas of improvement and benchmark against other organisations, services, and standards.

The RCSLT has adopted Therapy Outcome Measures (TOMS) (Enderby et al., 2013) as its preferred outcome measurement tool. This is an outcome measure used by many rehabilitation professionals to measure and record the impact of their interventions, and based on the WHO-ICF (2001). The TOM was initially developed by Professor Pamela Enderby in the 1980s and has been adapted over the years. Therapy Outcome Measures are administered following assessment/intervention of an individual by a healthcare professional. People are rated in relation to four domains: Impairment, Activity, Participation and Well-being. Well-being is not included within the WHO-ICF framework but is included within the TOM tool after reviewing goals of therapy. The therapist rates individuals using an 11-point ordinal scale with 6 defined points.

In this study we therefore aimed to develop TOMs for ILO and CC (TOM ILO and TOM CC). We have tested these for face validity, inter-rater reliability and test-retest reliability in a group of SLTs specialising in laryngeal dysfunction.

Materials and methods

Development of TOM ILO and TOM CC

The TOM ILO and TOM CC scales were adapted to reflect varying degrees of impairment, activity, participation and well-being of the ILO and CC population (Appendixes A and B). The 'core' TOM was initially formed by Pamela Enderby in the 1980s, but the wording has been altered for specific client

Table 1. Respiratory and upper airway disorder questionnaires.

Respiratory/upper airway questionnaire	Disorder group targeted	WHO-ICF framework checklist – areas considered					Personal factors
		Impairments of body functions	Impairments of body structures	Activity limitations and participation restriction	Environmental factors	Personal factors	
Dyspnoea-12 (D-12) (Yorke et al., 2010)	Multi-dimensional breathlessness	●					
Multi-dimensional Dyspnoea Profile (MDP) (Williams et al., 2021)	Multi-dimensional breathlessness	●	●				
Medical Research Council (MRC) dyspnoea scale (Bestall et al., 1999)	breathlessness	●		●			
Paradoxical Vocal Fold Motion dysfunction symptom questionnaire (PVFMD-SQ) (Ye et al., 2017)	Inducible laryngeal obstruction	●	●		●		
Pittsburgh VCD index (Traister et al., 2013)	Inducible laryngeal obstruction	●	●		●		
Leicester Cough Questionnaire (LCQ) (Birring et al., 2003)	cough	●	●	●	●	●	
Cough-Specific Quality-of-Life Questionnaire (CQLQ) (French et al., 2002)	cough	●	●	●	●	●	●
Hull Airway Reflux Questionnaire (Wen et al., 2020)	cough	●	●				
Newcastle Laryngeal Hypersensitivity	Laryngeal hypersensitivity	●	●				

(continued)

Table 1. Continued.

	WHO-ICF framework checklist – areas considered					
	Disorder group targeted	Impairments of body functions	Impairments of body structures	Activity limitations and participation restriction	Environmental factors	Personal factors
Respiratory/upper airway questionnaire						
Questionnaire (Vertigan et al., 2014)		●				
Voice Handicap Index (VHI) (Rosen et al., 2004)	voice	●	●	●	●	●
Voice Symptom Scale (VOISS) (Deary et al., 2003)	voice	●	●	●	●	●
Vocal Cord Dysfunction Questionnaire (VCDOQ) (Fowler et al., 2015)	Inducible laryngeal obstruction	●	●			
Nijmegen (Grammatopoulou et al., 2014)	Hyperventilation	●	●		●	
Breathing Pattern Assessment Tool (BPAT) (Sedeh et al., 2018)	Breathing pattern disorder	●	●			
Reflux Symptom Index (RSI) (Belafsky et al., 2002)	Reflux	●	●			
Total Nasal Symptom Score (TNSS) (Schatz et al., 2010)	Nasal disease	●	●			
Exercise Induced Laryngeal Obstruction Dyspnea Index (EILODI) (Olin et al., 2022)	Exercise induced laryngeal obstruction	●	●	●		

● signifies that this area of the WHO-ICF framework checklist is considered within this outcome measure.

groups. There are currently over 70 different TOMs that have been developed and published. These contain descriptors that have been developed by experts working in those areas and aim to improve inter-rater reliability.

The TOM ILO and TOM CC were adapted by a specialist SLT (Siobhan Ludlow) in line with the RCSLT guidance and guided by TOMs developed for other disciplines (Figures 1 and 2). Siobhan Ludlow is a consultant SLT who has been working in the field of upper airways for over 10 years.

The adapted TOMs were emailed to 10 specialist SLTs working with upper airway conditions including ILO and CC and responses were gathered from all 10 SLT professionals. Changes were made and the newly adapted scales were sent to Pamela Enderby and Alexandra John for review and to ensure that the scale were in line with the principles of TOMs.

Inducible Laryngeal Obstruction (ILO)

Identify descriptor that is “best fit”. The patient does not have to have each feature mentioned. Use 0.5 to indicate if patient is slightly better or worse than a descriptor.

IMPAIRMENT

0 – Profound persistent breathlessness as a result of ILO. Feeling like being strangled, unable to control symptoms.

1 – Severe consistent breathlessness episodes as a result of ILO. Episodes come on suddenly. Consistent irritation in the larynx (pain, dysphonia, cough, choking episodes). Rarely able to control symptoms.

2 – Severe/ Moderate breathlessness as a result of ILO. Regular irritation in the larynx (dryness, globus pharyngeous, ache, need to throat clear). Can use strategies to manage symptoms occasionally.

3 – Moderate breathlessness as a result of ILO. Less frequent episodes of breathlessness, (occurring less than once a day). Occasional irritation in the larynx. Can often use strategies to manage symptoms.

4 – Mild breathlessness episodes as a result of ILO. Episodes are occasional (occurring less than once a week). Minimal upper airway symptoms and good voluntary control.

5 – No breathlessness as a result of ILO. Episodes are rare and if occurs are fully controlled.

ACTIVITY

0 – ILO occurs in all situations and affects all activity. Patients are often wheelchair bound as they are symptomatic with any level of exertion and symptoms can occur at rest. Requires regular assistance with activities of daily living. Dependent on others for all tasks. Tasks are extremely slow and inefficient.

1 – ILO occurs in most situations except occasionally in modified environments and affects all activity to a marked degree e.g., walking a few yards, transferring from chair to standing. Needs assistance with some activities of daily living. There are minimal tasks performed independently. Tasks are slow with a lot of inefficiency.

2 – ILO is managed in modified environments. Most activity completed independently. Requires occasional assistance with activities of daily living. Prompting often needed to use control exercises e.g., walking up hills/ stairs. Most tasks are performed independently. Tasks are completed slowly in an efficient manner

3 – ILO is mostly controlled but can be unpredictable in some situations. Needs minimal assistance with activities of daily living. Needs occasional prompting to complete control exercises. Most tasks are performed independently. Tasks are completed in a timely and efficient manner with some pacing needed.

4 – ILO is controlled on most occasions. Fully dependent with activities of daily living. Control exercises rarely needed/ completed spontaneously. All tasks are performed independently. Tasks are completed in a timely and efficient manner with some pacing needed.

5 – ILO rarely/ never experienced but able to function without any effect on activity. All tasks performed independently. Tasks are completed in a timely and efficient manner.

Figure 1. TOM ILO.

PARTICIPATION

0 – Profound difficulty in participating. Unable to participate in any social/ educational/ family role. No social integration.

1 – Severe difficulty in participating. Very low opinion of themselves. Very little confidence. Doesn't mix socially. Doesn't take advantage of any opportunities around them. Cannot achieve potential in any situation.

2 – Moderate difficulty in participating. Some self-confidence will mix socially in familiar situations. Makes some decisions and influences control in familiar situations.

3 – Moderate / Mild difficulty in participating. Reasonably confident. Will mix socially in certain environments. Participates in educational/ recreational activities but needs a lot of support and encouragement. Will occasionally make the most of opportunities but needs encouragement to achieve potential.

4 – Mild difficulty in participating. Generally self-confident and willing to mix socially in most environments. Participates in family/ social/ educational decision making. Will make the most of opportunities but occasionally seeks reassurance.

5 – No difficulty in participating. Fully confident and able to fulfil social, educational and family role.

WELLBEING/DISTRESS

0 – Severe constant: High and constant levels of distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Unable to express or control emotions appropriately.

1 – Frequently severe: Moderate distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Becomes concerned easily, requires constant reassurance/support, needs clear/tight limits and structure, loses emotional control easily

2 – Moderate consistent: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy in unfamiliar situations. Frequent emotional encouragement and support required.

3 – Moderate frequent: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Controls emotions with assistance, emotionally dependent on some occasions, vulnerable to change in routine etc., spontaneously uses methods to assist emotional control.

4 – Mild occasional: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Able to control feelings in most situations, generally well-adjusted/stable (most of the time/most situations), and occasional emotional support/encouragement needed.

5 – Not inappropriate: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Well-adjusted, stable and able to cope with most situations, good insight, accepts and understands own limitations.

Refer to using the scale of the carer well-being.

Figure 1. Continued

The iterative process of designing the measure and testing the validity and reliability was followed to produce a measure that functioned as intended (Figure 3).

Sample and recruitment***Eligibility criteria******Inclusion criteria for patient recruits (stage 1)***

- Patient with a diagnosis of ILO or CC and undergoing speech and language therapy
- Patients aged 17 and above

Inclusion criteria for professional recruits (stage 1, stage 2)

- Medical professionals working in the NHS with respiratory patients
- Medical professionals who understand ILO and CC (diagnosing and treating themselves or part of an MDT team who diagnose and treat) who can give a fair judgement on the relevance of TOMs domains.
- Specialist SLTs who are working in upper airway or ENT services and regularly diagnosing and treating ILO and CC
- Comprehension of English

Exclusion criteria for patient recruits (stage 1)

- Patients with a diagnosis of ILO and/or CC that is being managed by other professionals and not currently appropriate for speech and language therapy.

COUGH

Identify descriptor that is “best fit”. The patient does not have to have each feature mentioned. Use 0.5 to indicate if patient is slightly better or worse than a descriptor.

IMPAIRMENT

0 – Severe persistent cough Unable to control, constant cough with few periods of respite. Can cause vomiting, incontinence, or fainting.

1 – Consistent cough. Rarely able to avoid/ control coughing, can cause incontinence and panic. Rarely able to suppress cough

2 – Moderate cough. Occasionally able to avoid/control coughing. Can use strategies to manage occasionally.

3 – Moderate/mild cough. Less frequent episodes of coughing (e.g., occurs some time each day/or slight persistent “throat clearing”

4 – Mild cough Occasional episodes of coughing occurring e, g. on a weekly basis or less.

5 – No cough Cough occurs rarely and if does has good voluntary control.

ACTIVITY

0 – Coughing occurs in all situations and affects all activity. Unable to initiate or complete activities due to coughing. Dependent on others for initiation or completion of all activities

1 – Coughing occurs in most situations except occasionally in modified environments and affects all activity to a marked degree. Needs regular assistance for initiation or completion of activities

2 – Coughing is manageable in modified environments (e.g., quiet situations, familiar situations). Can initiate and complete some activities in some environments independently. Occasionally able to suppress cough

3 – Coughing is mostly avoidable but can be unpredictable in some situations. Cough suppression requires less personal attention and effort in most situations. Mostly independent but may require assistance for particular activities in some environments

4 – Cough suppression is effective on most occasions. Rarely effortful. Very occasional difficulties experienced.

5 – No chronic coughing experienced, able to function without effect on activity.

Figure 2. TOM CC.

PARTICIPATION

0 – Unable to fulfil any social/educational/family role. Not involved in decision making/no autonomy/no control over environment. No social integration.

1 – Low self-confidence/ poor self-esteem/limited social integration/ socially isolated/contributes to some basic and limited decisions. Cannot achieve potential in any situation.

2 – Some self-confidence/some social integration/makes some decisions and influences control in familiar situations.

3 – Some self-confidence, autonomy emerging. Makes decisions and has control of some aspects of life. Able to achieve some limited social integration/educational activities. Diffident over control over life. Needs encouragement to achieve potential.

4 – Mostly confident. Occasional difficulties integrating or in fulfilling social/role activity. Participating in all appropriate decisions. May have difficulty in achieving potential in some situations occasionally.

5 – Achieving potential. Autonomous and unrestricted. Able to fulfil social, educational, and family role.

WELLBEING/DISTRESS

0 – Severe constant: High and constant levels of distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Unable to express or control emotions appropriately.

1 – Frequently severe: Moderate distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Becomes concerned easily, requires constant reassurance/support, needs clear/tight limits and structure, loses emotional control easily

2 – Moderate consistent: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy in unfamiliar situations. Frequent emotional encouragement and support required.

3 – Moderate frequent: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Controls emotions with assistance, emotionally dependent on some occasions, vulnerable to change in routine etc., spontaneously uses methods to assist emotional control.

4 – Mild occasional: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Able to control feelings in most situations, generally well-adjusted/stable (most of the time/most situations), occasional emotional support/encouragement needed.

5 – Not inappropriate: Distress/upset/concern/frustration/anger/ embarrassment/withdrawal/severe depression/apathy. Well-adjusted, stable, and able to cope with most situations, good insight, accepts and understands own limitation.

Figure 2. Continued

Exclusion criteria for professional recruits (stage 1, stage 2)

- Medical professionals who do not work within respiratory or the NHS.
- Medical professionals who do not understand ILO or CC.
- Speech and Language Therapists who do not work within respiratory or ENT and do not manage upper airway conditions.

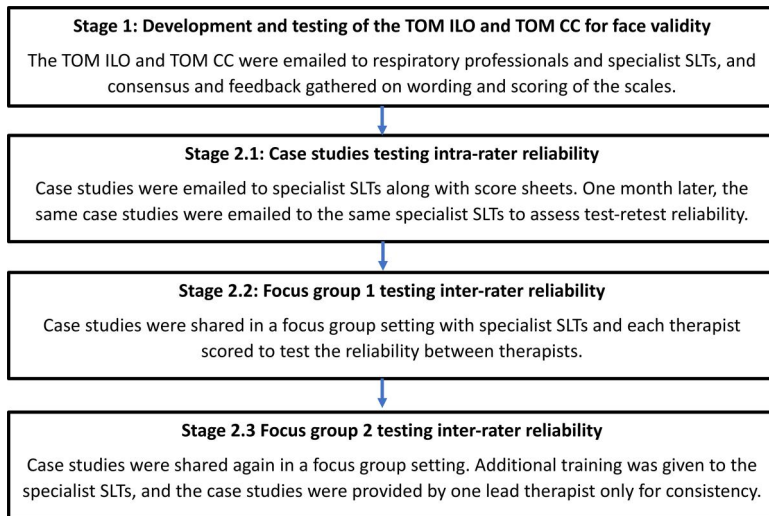


Figure 3. Stages of development and validation of the TOM ILO and TOM CC.

Ethical and regulatory considerations

We sought advice from Manchester University NHS Foundation Trust (MFT) Research and Innovation (R&I) team and Professor Pam Enderby who stated that as there no identifiable data was involved, and outcome measurement is part of routine practice, there was no need for ethical approval for this project.

Statistical methods

The statistical methods chosen (Cohen's Kappa co-efficient and Krippendorff alpha co-efficient) were decided on after advice and discussions with the MFT statisticians. Statistical analysis was performed in SPSS version 28.0.1.0

Recruitment

To test the TOM ILO and TOM CC for validity and reliability, a multidisciplinary group of respiratory professionals were recruited (Tables 2 and 3). Purposive sampling was used as these professionals are considered experts in the field of ILO and CC, have a deep understanding of the subject and a clear understanding of what needs to be measured.

Table 2. Professional groups.

Profession	Numbers
Speech and language therapist	15
Respiratory physician	6
Respiratory registrar	2
Clinical nurse specialist	3
Physiotherapist	3
Psychologist	2
Pharmacist	1

Table 3. Professional groups geographical areas represented.

NHS areas represented	Numbers
Manchester	20
Preston	4
London	3
Sheffield	1
Newcastle	1
Birmingham	1
Liverpool	1
Leicester	1

Stage 1: face validity

Once satisfied, the ILO and CC adapted TOMs were shared with the multi-professional groups by email to ensure all agreed with wording and scoring. Written feedback was returned by email. Feedback suggested that the TOM ILO and TOM CC had strong face validity and usability.

The ILO and CC adapted TOMs were trialled on 20 patients recruited from the Manchester SLTs to ensure that no further amendments needed to be made to wording or adaptive scales, then a reliability trial was completed.

Stage 2: reliability

Checking reliability is important as it represents the extent to which the adapted scale is understood consistently, and that the data collected is a correct representation. Intra-rater reliability refers to the consistency of the data recorded by one therapist over several trials. Inter-rater reliability is a measure of consistency used to evaluate the extent to which different professionals agree in their assessment decisions.

Stage 2.1: case studies

Intra-rater reliability was tested by producing 20 case studies (Appendixes A and B) (10 ILO, 10CC) which were shared with 10 specialist SLTs who were working within upper airway/ENT services and regularly seeing ILO

Table 4. Intra-rater reliability of TOMS ILO and TOMS CC using Cohen's Kappa co-efficient.

TOM	Rater	Kappa (k)	P	Classification Landis and Koch
CC	R1	0.183	0.237	Slight
	R2	0.182	0.238	Slight
	R3	-0.032	0.835	Poor
	R4	0.452	0.004	Moderate
	R5	0.225	0.144	Fair
	R6	0.254	0.094	Fair
	R7	0.262	0.097	Fair
	R8	0.246	0.119	Fair
	R9	0.271	0.084	Fair
	R10	0.158	0.291	Slight
ILO	R1	0.979	<0.001	Almost perfect
	R2	0.990	<0.001	Almost perfect
	R3	0.983	<0.001	Almost perfect
	R4	0.956	<0.001	Almost perfect
	R5	0.973	<0.001	Almost perfect
	R6	0.991	<0.001	Almost perfect
	R7	0.961	<0.001	Almost perfect
	R8	0.962	<0.001	Almost perfect
	R9	0.979	<0.001	Almost perfect
	R10	0.993	<0.001	Almost perfect

Table 5. Inter-rater reliability of TOMS ILO and TOMS CC from case histories and focus groups using Krippendorff alpha co-efficient.

TOM	Round	Krippendorff alpha	95% CI	Classification
CC	Stage 2.1 case studies ^a	0.797	0.780–0.814	Low
	Stage 2.2 Focus group 1 ^b	0.614	0.589–0.639	Very low
	Stage 2.3 Focus group 2 ^c	0.892	0.876–0.907	Strong
ILO	Stage 2.1 case studies	0.849	0.837–0.859	Strong
	Stage 2.2 Focus group 1	0.612	0.588–0.633	Very low
	Stage 2.3 Focus group 2	0.881	0.862–0.901	Strong

^aStage 2.1 Case studies. 10 ILO and 10 CC case studies were provided to 10 specialist SLTs and 2 time points (one month apart).

^bStage 2.2 Focus group 1p. Specialist SLTs attended a virtual focus group, and each provided 2 case studies (1 ILO and 1 CC) whilst the other SLT rated.

^cStage 2.3 Focus group 2. Further training was given to the specialist SLTs and a further focus group was completed.

and CC patients, along with score sheets (Appendixes E and F). All specialist SLTs were familiar with using TOMs for other disorders so no specific training was delivered at this time. Each therapist used the TOM ILO and TOM CC scales to rate the ILO and CC case studies. One month later, the therapists were asked to rate the same case studies again (without referring to their previous scoring 1st scores). This helped to measure if the adapted scale was consistent over time. Agreement was quantified for the TOM ILO and TOM CC scales using the Cohen's Kappa co-efficient (k) (Table 4). Inter-rater reliability was also tested on this data using the Krippendorff alpha co-efficient (Table 5).

Stage 2.2: focus group 1

Inter-rater reliability was tested by inviting all specialist upper airway SLTs to attend a virtual focus group which was completed on Microsoft Teams. Some of these specialist SLTs ($n = 6$) were the same therapists that completed stage 2.1 (case studies). Each therapist who attended was asked to provide two case studies (1 ILO, 1 CC) and take turns to share their computer screen, whilst the other therapists rated the case studies using the adapted scales separately and without collusion (Table 4).

Stage 2.3: focus group 2

As the inter-rater reliability was poor on the first focus group. Further training was given to the specialist upper airway SLTs. This was completed online and involved more detailed explanation about TOMs and their use, including reminders about the scale (11-point), allowing scores between descriptors to be given (e.g. 1.5, 2.5), and use of more detailed case study descriptions. The lead therapist (Siobhan Ludlow-Consultant SLT) revised all case studies to keep consistency, and these were shared with the therapists before they attended the focus group. The therapists were able to ask any additional questions during the focus group and each therapist rated the case study using the adapted scales without collusion (Appendixes C and D).

Results

Most comments were supportive of the adapted measures with a few changes on wording including terminology of the varying levels of breathlessness on the TOM ILO, including independence level, pace and efficiency on the TOM ILO and including more detail on social ability on the TOM CC which were all made. The TOMS ILO showed 'almost perfect' intra-rater reliability with a Kappa (k) greater than 0.9 by each therapist. The TOMS CC co-efficient was less reliable with the highest percentage of therapists (50%) showing 'fair' intra-rater reliability with a Kappa (k) of between 0.21–0.40 (Table 4)

Where case studies were shared with 10 therapists via email twice (one month apart), the TOMS ILO showed a strong inter-rater reliability with a Krippendorff alpha co-efficient greater than 0.849. The TOMS CC showed moderate inter-rater reliability with a Krippendorff alpha co-efficient of 0.797 (Table 5). The TOMS ILO and TOMS CC on the first focus group showed poor inter-rater reliability with a Krippendorff alpha co-efficient of 0.614 (TOMS CC) and 0.612 (TOMS ILO). The TOMS ILO and TOMS CC on the second focus group showed strong inter-rater reliability with a Krippendorff alpha co-efficient of 0.892 (TOMS CC) and 0.881 (TOMS ILO).

Discussion

Therapy outcome measures provide quantifiable data and insights into a patient's well-being, symptoms and functioning allowing therapists to track progress and make informed decisions about treatment approaches. The first iteration of the TOM ILO and TOM CC have been tested for face validity, intra-rater reliability and inter-rater reliability between specialist SLT's. Initial findings suggest that both scales have strong face validity. The TOM ILO had strong intra-rater and inter-rater reliability. The TOM CC had poor intra-rater but strong inter-rater reliability. In previous reliability testing of TOM, the limitations of testing inter-rater reliability using patient case histories have been highlighted because information can be inadequate or reveal information in such a way as to prime judges (Enderby et al., 2013). Several of the specialist SLTs completed stage 2.1 (case studies), stage 2.2 (focus group 1) and stage 2.3 (focus group 2) therefore had seen the TOM ILO and TOM CC several times and may have had bias over those who were seeing the TOM ILO and TOM CC for the first time. Case histories are known to have difficulties in inter-rater reliability trials. However, they are resource efficient and allow presentation of data, using the full range of severities of conditions to test scoring systems. In preparing the case histories on the second focus group, more detail was given in the case histories and additional training given to the therapists prior to the focus group. The therapists were able to ask further questions if needed of the therapist presenting the case history.

The TOM CC poor intra-rater reliability could have been due to the nature of case histories and rating a second time without additional clinical information could cause bias. It has been reported that using the TOM in real life situations where professionals can explore patient-experiences and choose appropriate scores is easier than rating from case histories (John and Enderby 2000). Most therapists will see patients several times during their care therefore it is likely that the reliability in the clinic will be likely to be better than in this trial. All respiratory SLTs who were involved in this project felt positively towards these measures and realised the importance of collecting reliable data appropriate for their services to inform commissioning and service improvement. We are hopeful that the TOM ILO and TOM CC can now be used as validated outcome measure and can be published in future editions of TOMs book.

The effectiveness of any therapeutic intervention has many dimensions including clinical effectiveness of the intervention and the benefit felt by the patient as a direct result of having the intervention. Capturing the direct patient perspective on functional status, health related quality of life, symptoms, symptom burden, activity, participation and contextual impact complements therapy outcomes and provides a patient centred approach to care. There are several patient reported outcome measures (PROMs)

used in chronic cough (Birring et al., 2003; French et al., 2002; Morice et al., 2011) but a specific ILO PROM is required in the future.

Conclusion

In conclusion, the TOM ILO and TOM CC scales have been shown to have strong reliability and validity. They can now be used for clinical and research purposes by therapists who have received the TOMs training. Future work is needed to develop and validate a patient reported outcome measure for ILO to be used alongside the TOMs.

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Appendix A. ILO case studies V1

Case study 1

Name	HB
Age	45
Diagnosis	Asthma, ILO, Breathing Pattern Disorder
Context	Referred from Respiratory Consultant at North Manchester for one stop assessment

Female patient referred with ongoing SOB.

Diagnosed with asthma aged 15 years.

Diagnosed with ILO on top of her asthma back in 2008. Unfortunately she did not receive any speech and language therapy due to non-attendance.

Recently her asthma control has become poor with monthly visits to A&E. The symptoms are mainly upper chest and throat, and are thought to be driven by her ILO.

Her triggers are fragrance, strong smells, cold weather, emotions, if she talks for long time, and walking short distances.

When she gets her symptoms she finds they come on suddenly and she feels that she cannot breathe in or out.

She does not get any relief from her inhalers.

Sometimes the symptoms can last for a very short period, sometimes for longer, up to 10 minutes.

She does sometimes have choking symptoms with food.

HB explained she feels 'scared' to go anywhere without her son and rarely leaves the house.

The flow volume loop showed a marked flattening of the inspiratory curve in line with ILO symptoms.

Her FeNO in paediatric setting was 5 ppb.

On laryngoscopy today there was evidence of ILO on inspiration. It was glottic and supraglottic in nature.

VCDQ: 50

Block of SLT arranged for ILO.

Case study 2

Name	RT
Age	67
Diagnosis	Inducible laryngeal Obstruction (ILO)
Context	Patient known to Severe Asthma Service and referred for an upper airways assessment

Male patient referred with increased SOB, feeling different from normal and originating in the upper airway.

He localises at lot of his symptoms. The attacks come on suddenly.

On laryngoscopy, the nasal passages were normal. On voice challenge (increasing volume) RT showed signs of laryngeal tension with some inspiratory adduction on forced inspiration in keeping with ILO.

RT used to be extremely active, playing rugby in NZ. He now continues to try and go to the gym a few times a week. He is trying to lose weight and has dropped from 120 down to 103 kg. He enjoys socialising with friends and family.

VCDQ: 35

Block of SLT arranged for ILO. Follow up in the severe asthma clinic in due course as we are considering biologic treatment for his underlying severe eosinophilic asthma.

Case study 3

Name	NY
Age	36
Diagnosis	ILO, BPD
Context	Referred from Respiratory Consultant, Wrexham for upper airway assessment

Female patient referred with increased dysphonia and SOB over the last year. She has had periods of aphonia.

She has also had to stop going to the gym due to breathlessness symptoms.

NY is currently not working. She used to work as a cleaner.

She has been investigated by her local hospital in Wrexham which has not turned up anything in her lungs.

NY is an ex-smoker of the past three years. She did smoke cannabis 6–7 spliffs a day and quit three years ago.

She has had a difficult childhood, having been in foster care and then adopted. She suffered sexual abuse by her adopted father (NY openly informed the team of this). She is currently having counselling for this.

In clinic, her spirometry was an FEV1 of 2.66 L, 85% predicted with an FVC of 3.07 L, 101.4% predicted. Her FEV1/FVC ratio was 69%. Her FENO was 16 p/b.

On laryngoscopy she had marked circumferential constriction with inspiratory ILO features post phonation.

VCDQ: 50

Block of SLT arranged for ILO and block of physiotherapy for BPD.

Case study 4

Name	CM
Age	31
Diagnosis	ILO, asthma
Context	Referred from GP with increased SOB

Female patient, referred from GP with increased SOB.
 She has a background history of asthma diagnosed by her GP but previously very well controlled until a caving incident about four years ago. She along with some friends got trapped down a cave at that stage and she had a severe episode of breathlessness.
 Since then she has been having frequent similar episodes occurring sometimes daily. They come on suddenly but resolve quickly.
 Salbutamol doesn't help these episodes.
 Triggers include exercise, stress, change in temperature (especially cold), smoke, perfumes and dust. She has had few admissions with these episodes.
 At laryngoscopy nasal appearances were normal. She did not have any evidence of laryngopharyngeal reflux. Laryngeal appearances were normal at baseline but closed on inspiration after triggering with deodorant spray, confirming the diagnosis of inducible laryngeal obstruction.
 VCDQ: 35
 Block of SLT arranged for ILO

Case study 5

Name	OO
Age	29
Diagnosis	ILO, tracheobronchomalacia, asthma
Context	Referred from the severe asthma service for review of upper airway

Female patient referred with increased SOB originating from her larynx. Feeling different to her usual asthma symptoms.
 She has been struggling with a cough, tightness in her throat, wheeze on breathing in and also out.
 Triggers: cleaning products, perfumes in shops, environmental change and also when she tries to sleep.
 Inhalers are making her cough.
 Currently working as an IT trainer. Struggling to do presentations/ speak on the phone due to dysphonia and SOB.
 Rarely socialises with friends due to breathlessness and fatigue.
 Losing interest in hobbies such as knitting/ attending music gigs.
 Laryngoscopy confirmed glottic inspiratory ILO. Partial closure seen post aerosol challenge.
 VCDQ: 45
 Plan: to treat ILO first and then consider hypertonic saline for TBM.

Case study 6

Name	SR
Age	57
Diagnosis	ILO
Context	Referred from GP with increased SOB

Female patient referred with unexplained breathlessness
 Lots of investigations for asthma – all normal.
 When she gets breathless she has a feeling of tightness around the throat and sometimes has a problem with her voice associated with it.
 Triggers for her breathlessness include cleaning products, aerosols, cold weather, fires and smoke and talking.
 She has a previous history of mitral valve repair, chronic fatigue syndrome, and multiple drug intolerances.
 Patient is retired, she continues to socialise regularly with friends. No A + E attendances for breathlessness
 Laryngoscopy confirmed glottic inspiratory ILO post exposure to cleaning products.
 VCDQ: 32
 Plan: block of SLT

Case study 7

Name	CL
Age	42
Diagnosis	ILO and asthma
Context	Referred from the severe asthma service for review of upper airway

Male patient referred with uncontrolled breathlessness originating from upper airway.
 She gives an interesting history of having two types of breathlessness, one in the lower thorax and one around her throat and upper thorax.
 Since starting on Methotrexate her asthma has been well controlled. She still suffers from breathlessness.
 She suffers with intermittent voice changes and gets a burning type sensation in her larynx.
 Sometimes she gets a choking sensation.
 Symptoms can vary from week to week. She regularly cancels social events and avoids attending certain situations in case her symptoms occur.
 Her flow volume loop appears to have a flattened inspiratory loop indicative to ILO.
 On laryngoscopy, without even provoking her, she had evidence of tension in her arytenoids and partial closure of her vocal cords on inspiration. She has got definite inducible laryngeal obstruction.
 There was a normal laryngeal structure and no evidence of reflux.
 VCDQ: 40
 Plan: block of SLT. Asthma team to continue to manage

Case study 8

Name	UF
Age	51
Diagnosis	ILO and asthma
Context	Referred from the severe asthma service for review of upper airway

Female patient referred with increased SOB and dry cough

She has had problems with breathlessness for a couple of years. This was initially associated with a cough that in particular affected her at night.

She has since been diagnosed with asthma on the basis of reversibility, blood eosinophilia and atopy. She has improved significantly since starting Fostair.

She is still left with episodes of breathlessness that occur acutely triggered by for example cough and exertion.

She continues to work as a HCA. She continues to regularly socialise with friends and family.

At laryngoscopy the nose looked normal apart from some septal deviation. She had very narrow nasal passages. Laryngeal appearances were normal at baseline and after vocalisation and after an episode of coughing she developed clear signs of inducible laryngeal obstruction. This fits in with her report of breathlessness after coughing and exertion.

VCDQ: 35

Plan: block of SLT for ILO

Case study 9

Name	CM
Age	57
Diagnosis	ILO and asthma
Context	Referred from the severe asthma service for review of upper airway

Female patient referred from the severe asthma service. She is atopic and was put on Xolair back in 2015. She responded very well over the first 12 to 18 months with a significant decrease in her steroid requirement.

However in the past two to three years there has been a steady deterioration again. This is somewhat different with episodes of breathlessness originating from larynx.

She has now stopped socialising as frequently.

She has had several days off work.

She has had 1 visit to A + E.

The new episodes are triggered often by inhaled irritants such as the deodorant spray. She gets episode of throat spasm with this that then can lead to panic.

At laryngoscopy today she had expiratory laryngeal obstruction on first placing the scope. After triggering with deodorant spray this developed into combined inspiratory and expiratory ILO which she was able to control with supervision.

Her lung function test today good and exhaled nitric oxide again low.

VCDQ:40

Plan: Block of SLT for ILO

Case study 10

Name	RD
Age	34
Diagnosis	ILO
Context	Referred from GP with suspected EILO

Male patient, under investigation for breathlessness symptoms especially when he is playing football.

He gives a history of inspiratory and expiratory obstruction when he undertakes extreme exercise. This is a problem as he is a semi-professional footballer and affects him during matches. He often has to come off the pitch during matches.

He also had a period when he was doing his exams at A level when he would get similar symptoms.

The onset is sudden in his upper chest and throat. The symptoms last for about 10–15 min.

He has some symptoms of laryngeal sensitivity such as a dry and tight sensation with a lot of throat clearing.

On laryngoscopy the larynx was initially normal. He was provoked on a bike challenge. After 4 min of heavy cycling his symptoms developed. He developed inspiratory supraglottic EILO.

VCDQ: 30

Plan: Block of SLT

Appendix B. Chronic cough case studies V1

Case study 1

Name	CC
Age	69
Diagnosis	Cough hypersensitivity syndrome
Context	Referred to SLT from cough clinic

Female patient with a chronic cough for over 20 years. Started after three back to back chest infections.

She finds it extremely distressing in social situations. She was hoping that would improve when she retired two years ago as a head teacher but unfortunately there has been no change to her cough. She feels that her cough did slightly ease in the summer holidays when she was not working and she is aware that stress/anxiety is a trigger of her cough.

She has had multiple investigations for her cough including CT chest, chest x-rays, full breathing tests and ENT investigations which have all been reported as normal. She has laryngeal hypersensitivity and sensations of tickle, dryness, dysphonia and globus pharyngeus.

As well as stress she feels that talking on the phone being in a quiet environment, changes in temperature, aerosols, strong smells and when walking up hills are also triggers of the cough. She is okay exercising when on the flat and she is trying to increase her walking to lose some weight.

She takes Morphine 10 mg one daily which has improved her cough 'slightly'.

VAS score 7/10 for severity on initial assessment (10 being the worst).

Leicester cough questionnaire score today was 10.9 (4.5, 3.1 and 3.3).

On laryngoscopy structure and function of the larynx was normal. There was a mild sensitivity throughout the procedure and there was circumferential constriction throughout.

Patient listed for a block of SLT.

Case study 2

Name	RS
Age	69
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from the cough clinic

Female patient with a chronic cough for over 10 years.

Cough is mostly dry and occurs intermittently.

She is aware that that it can be triggered by eating (especially spicy foods), talking and she can become short of breath which then lead to coughing when walking uphill.

She has laryngeal sensitivity in the form of tickle, dryness and globus pharyngeus but no dysphonia, pain or burning. She has no symptoms of reflux or postnasal drip.

She has had multiple investigations for her cough including chest x-ray, ENT assessment, CT scan which are all reported as normal.

Shas trialled Morphine for over 12 months with no benefit.

She feels that sucking polo mints can help her cough. She has avoided going to quiet environments with her friends, e.g. cinema/ theatre for fear she may cough.

Her Leicester cough questionnaire score was 12.5 (6.0, 2.7, 3.8).

On laryngoscopy there was a normal laryngeal structure and function. She had mild sensitivity throughout the procedure. There was no production of mucus when coughed.

Patient listed for a block of SLT.

Case study 3

Name	AC
Age	58
Diagnosis	Asthma and cough hypersensitivity syndrome
Context	Referred from chronic cough clinic

Female patient, whose cough started in December 2017 following a suspected viral infection. The cough has continued and has been productive at times. Cough mostly dry over the last few weeks. She has had multiple investigations including chest x-ray, CT scan and breathing test which supported the diagnosis of asthma.

She does have heightened laryngeal sensitivity in the form of intermittent dysphonia throat clearing, burning, dryness and globus pharyngeus.

She feels triggers of her cough include talking for long periods, cleaning products and changes in temperature.

She does have a diagnosis of asthma and continues to take inhalers for this.

She has tried Morphine previously for her cough but this made her symptoms worse and therefore has stopped taking it.

Her Leicester cough questionnaire score today was 19.6 (6.4, 7.0, 6.3).

On laryngoscopy, the structure and function of her larynx was normal. There were no secretions in the laryngeal vestibule. She had severe sensitivity throughout the procedure and there were circumferential constriction.

Patient listed for a block of SLT.

Case study 4

Name	PS
Age	67
Diagnosis	Asbestosis and chronic cough
Context	Referred from North Manchester General Hospital to the One Stop assessment clinic

Male patient with a chronic dry cough for three years. On a couple of occasions it has resulted in a presyncopal episode. The last episode was over 12 months ago now and has had to inform the DVLA.

He does not have any other chest symptoms such as breathlessness or chest pain. He does not get breathless or dizziness on exertion. Regarding the blackouts he has not had any new problems with his vision and he does not get morning headaches. He does not have any other neurological symptoms.

CT chest showed some early scarring of the lining of the lung and possibly some very minor scarring at the bottom of the lungs. This is likely due to exposure of asbestos.

He has previously been diagnosed with reflux and treated for this but did not really find that this made a difference to his cough. The only treatment that he thinks has helped his cough temporarily is some dry cough medicine from the pharmacist.

His cough is aggregated particularly by dry crumbly foods such as biscuits.

On laryngoscopy nasal appearances were normal. He had heightened laryngeal sensitivity throughout.

After CT chest was discussed with a respiratory consultant, it was agreed patient was to be seen for cough hypersensitivity syndrome by SLT.

Patient listed for a block of SLT.

Case study 5

Name	JT
Age	56
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from the chronic cough clinic

Male patient with a chronic cough for 8 years.

Triggers of his cough include perfumes, aerosols, changes in temperature, talking for long periods and strong smells.

He continues to work as a painter and decorator. He socialises with friends regularly.

He has had problems with his sinuses in the past and has had increased nose bleeds over the last year. He has been diagnosed with laryngopharyngeal reflux previously and continues to take Omeprazole for this.

He has laryngeal symptoms of globus pharyngeus soreness, dryness and an intermittent burn.

On laryngoscopy the structure and function of the larynx was normal. He had mild sensitivity throughout and there was mild inflammation in his nose. (He already takes Avamys nasal spray for this).

His Leicester cough questionnaire today was 13.1 (4.0, 4.6, 4.5).

Patient listed for a block of SLT.

Case study 6

Name	PA
Age	57
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from chronic cough team

Male patient with a chronic cough for 10 years.

Cough is generally dry but he can regurgitate food if a coughing attack happens immediately post eating.

He is aware that his cough is triggered by shouting when exposed to fumes, mouth wash, eating quickly (especially crumbly foods) and when blowing a whistle.

He has symptoms of heightened of laryngeal sensitivity in the form of tightness, globus pharyngeus, dry cough and intermittent dysphonia.

He has had several investigations previously including laryngoscopy by ENT, gastroscopy, CT scan, bronchoscopy and barium swallow.

He has had various treatment trials including Omeprazole, Morphine and a short trial of Pregabalin. He feels that he was not consistent with the taking of his Pregabalin but did not notice any improvements on the short term he was on these tablets.

PA explained that his cough can be extremely debilitating. He is a senior teacher and he finds that it affects him at work especially when shouting with children.

Laryngoscopy showed normal structure and function. Laryngeal sensitivity was evident throughout. There were no signs of inducible laryngeal obstruction but he does get episodes of throat closure following a coughing attack so this will be kept in mind during therapy.

Leicester cough questionnaire was 12.4 (5.3, 3.4, 3.8).

Patient listed for a block of SLT.

Case study 7

Name	AR
Age	46
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from the chronic cough team

Female patient suffering with a cough for over 20 years but it has deteriorated in the last 10.

Investigations including Bronchoscopy, HRTC thorax and PFTs were all within normal limits.

Treatment trials have been extensive and the only one that has really had any impact is on her oxycontin (she was unable to tolerate Morphine).

She doesn't have any voice difficulties and has some mild laryngeal sensory symptoms. She does have a history of reflux but she is on Omeprazole 20 mg twice daily which she feels controls this.

She doesn't have any particularly difficulty breathing but does take a regular nasal steroid Avamys which helps.

She works as a solicitor and manages at work. She struggles reading her children a bedtime story at times.

Her baseline LCQ today is 11.7 (5.0, 3.7, 3.0).

No abnormalities were seen on laryngoscopy and structure and function were normal.

She currently feels she has no control really over her cough and is keen for some intervention.

Patient listed for a block of SLT.

Case study 8

Name	SF
Age	71
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from chronic cough clinic

Male patient with a cough for over 15 years

He feels that this is triggered by crumbly foods, strong juices, laughing, talking and when walking up steep hills. He feels that there are times where it is worse than others and there have been a few occasions where he felt he was going to collapse due to being unable to get enough inspiratory breath.

He has increased laryngeal sensitivity in the form of laryngeal tickle, dryness and globus pharyngeus.

SF used to play golf with his friends weekly but has now had to stop this due to his cough. His children are now texting him rather than calling as speaking on the phone can trigger his cough. This upsets SF as he enjoyed speaking to his family on the phone.

He has trialled several medications for his cough, with him recently trying MST and Esomeprazole 40 mg twice daily. Unfortunately these did not help his cough and his GP discontinued these a few weeks ago. Mr Fraser feels that the only thing that has helped to control his cough is by taking fluids to relieve the dryness and suppress his cough.

On laryngoscopy today he showed a normal laryngeal structure and function. He did have an enlarged uvula which may lead to heightened sensitivity and he also had heightened laryngeal sensitivity throughout the procedure. There was some sign of oedema but as he has already been trialled on a high dose reflux medication I do not feel that he needs to be trialled on anything further at present.

His Leicester Cough Questionnaire today was 7.7 (3.4; 2.1;2.3).

Patient listed for a block of SLT.

Case study 9

Name	DP
Age	67
Diagnosis	Cough hypersensitivity syndrome
Context	Referred from chronic cough clinic

Female patient with cough for 14 years. She feels that this has gotten worse over the last few years. DP feels that her cough is productive but this is of small amounts of white clear sputum. She has had respiratory investigations including chest x-ray and chest CT and breathing tests which have all been normal.

She does have some symptoms of reflux disease and continues to take Ranitidine 150 mg bd. She describes some symptoms of post nasal drip but none of this was seen on laryngoscopy.

DP describes laryngeal symptoms of dryness, tickle, globus pharyngeus, intermittent dysphonia and laryngeal ache. She feels triggers of her cough include aerosols, perfumes, talking, hairdryers and when anxious.

She has tried inhalers for her cough but these did not help but has never had any treatment trials of Morphine or Pregabalin.

She feels that when she drinks water this helps her cough or when sucking sugar free sweets. She worries about her cough and avoids going out for meals with her friends.

On laryngoscopy she revealed a normal laryngeal structure and function. There was some mild anterior to posterior constriction seen on phonation. No sensitivity was observed during the procedure and there was no evidence of mucus.

Her Leicester cough questionnaire score today was total 8.7(2.8, 2.7, 3.3).

Patient listed for a block of SLT

Case study 10

Name	JH
Age	49
Diagnosis	Cough hypersensitivity, recurrent pleurisy
Context	Referred from cough clinic

Female patient, cough for 11 years. Attributes the on-set to when she had pleurisy during pregnancy.

She has symptoms in keeping with cough hypersensitivity and the cough is consistent, is dry in nature and is triggered by changes in temperature and smells.

She has had a background of recurrent chest infections and has had pleurisy on a couple of occasions. This has been investigated and she now has rescue azithromycin due to a low immune system.

Investigations wise that she has had an HRCT which was normal and ENT examination and PH manometry which were normal. She has declined bronchoscopy.

She has marked symptoms of heightened laryngeal sensitivity which she thinks gets worse with stress (for which she has quite a lot on in her person life). She does feel that she can intermittently suffer with reflux but takes Omeprazole and feels this controls it effectively. She has no difficulties with rhinosinusitis.

Control wise at the moment she takes Beclomethasone and Salbutamol. She feels this in part helps along with sips of water and cough sweets.

She avoids certain environments and social situations due to the embarrassment of coughing. She is currently not working.

Laryngoscopy was normal but she was sensitive to the procedure.

Her baseline Leicester cough questionnaire was 5.4 (3.0,1.4,1.0).

After discussion in MDT, agreed for block of SLT

Appendix C. ILO case histories V2

77. y/o Female. Retired. Lives with husband

PMHx: Asthma (well controlled on ICS), reflux, IBS, OA

Respiratory investigations: in keeping with asthma. No recent exacerbations.

Referred to SLT from Asthma clinic

Reports sx which feels separate to asthma over the past few years – feels like throat closing when people spray aerosols/cleaning the house. Can happen with/without cough. Initially felt like ‘going to die’ but very transient, resolves after a few minutes when ‘calms down,’ tends to sit, breathe through

Happening approximately weekly

No benefit if takes salbutamol

Voice feels ‘different’ – lower pitch, hoarse

No dysphagia

Avoids all aerosol triggers, nothing in the house anymore. Worries about being symptomatic in shops, i.e. avoids perfume aisle etc.

Questioning whether related to stress – husband having memory clinic/dementia investigations

As happened a few times now, acknowledges not life threatening but just wants diagnosis/explanation of what is going on

Laryngoscopy = unable to trigger typical symptoms but, in absence of respiratory concern, to treat empirically for ILO

60. y/o Female. Retired nurse. Lives with husband

PMHx: Fibromyalgia, Sjogrens. No respiratory diagnoses.

Respiratory investigations = no evidence of lower airways disease

Referred to SLT from Allergy clinic

Long-standing history of? anaphylaxis to multiple drugs but no evidence of allergy on formal testing and so Allergy clinic keen for MDT discussions and SLT input.

Traumatic episode following COVID jab – throat tightness, SOB, stridor. Ended up ventilated in ICU.

Since then, has been experiencing similar symptoms ‘out of the blue’ and in response to environmental triggers and stress. Taking up to x10 epi-pens a day, with little effect.

Baseline mild inspiratory wheeze (chest clear)

Seeing psychology for trauma post-ICU

Debilitating currently – scared to leave the house. Convinced having spontaneous episodes of anaphylaxis and reliant on adrenalin. Huge impact on quality of life.

Strained voice quality

Swallowing feels ‘tight’

No reflux/rhinitis concerns

Laryngoscopy = significant tension at baseline with clear ILO even before provocation. For SLT.

28. y/o Female. Student

PMHx: severe asthma (on Benralizumab), anxiety.

Respiratory investigations: asthma since childhood. Previously difficult to manage with recurrent exacerbations, but now well controlled on biologic.

Referred to SLT by Severe Asthma service

Has recently been experiencing episodes of throat closure – taking excessive amounts of salbutamol as a result but no benefit. Associated palpitations, worsen anxiety.

Triggers: aerosols, stress – overthinking/overinterpreting of symptoms ‘hyperaware’ of any laryngeal sensations now

Very anxious as has had bad asthma attacks in the past – frightened.

Impacting quality of life – happened once on night out and distressed/embarassed/friend called ambulance as they thought it was asthma. Makes her want to avoid some social settings.

No dysphonia/dysphagia/reflux/rhinitis concerns

Laryngoscopy = structurally and functionally normal at baseline. Intermittent vocal cord adduction on provocation with aerosols. Triggered typical sx. For SLT therapy alongside normal asthma management.

58. y/o Male. Stopped working as result of sx. Difficult social situation at home

PMHx: anxiety/depression, HTN, reflux, nil other significant

Respiratory investigations: no evidence of lower airways disease.? BPD but no self-reported SOB concerns

Referred to SLT from local Allergy Clinic

Multiple calls for ambulances, A&E attendance due to throat tightness and subjective feeling of swelling/tingling

Allergy testing – normal. Have written multiple letters encouraging him not to carry an epi-pen

Bounced between services; Resp/Gastro/Allergy/ENT and hard to engage

Patient convinced allergic to multiple foods and avoiding++, therefore difficult for him to consider differential diagnoses. Open to stress/anxiety impact on overall sx however.

Previous ENT scope in A&E = no laryngeal oedema

Very dysphonic (mod-severe rough, strained)

Eating and drinking normally aside from avoidance behaviours

Laryngoscopy = intermittent ILO at baseline. Declined provocation. For SLT input with ongoing liaison with allergy team.

48. y/o Female. Not working (own choice). Lives with partner

PMHx: TBM, obesity, chronic pain

Respiratory investigations: bronch for TBM diagnosis. Otherwise no lower airways disease. Encouraged to lose weight.

Referred to SLT by Physio as did not feel sx entirely explained by TBM. Managing ACT advice well and no recent chest infections.

Barking cough secondary to TBM but can find when cough++ that throat 'shuts off' and 'can't get any air in' – lasts seconds but partner can get worried

Patient not distressed but wants to know how to manage these episodes when they happen (few times a month). Googled ILO/VCD, sounds like what she is experiencing.

Episodes always start with cough and if can't settle can get throat closure

Triggers: exertion, unaware of any other

Musculoskeletal pain secondary to coughing – no cardiac concerns for upper chest pain

Laryngoscopy = no concerns at baseline. Circumferential tension, generalised oedema (likely due to BMI). Provocation with exertion = ++cough which progressed to ILO. For SLT therapy.

35. y/o Nurse. Off sick as A&E nurse currently. Lives with partner

PMHx: nil significant past medical history. Generally fit and well.

Respiratory investigations: thoroughly investigated and normal CXR/HRCT/PFTs

Never used to have any problems but over the last 12 month has struggled to breathe around cleaning fluids at work, i.e. ChlorClean

Experiences throat tightness, chest tightness wheeze – became unmanageable at work and colleagues advised her to get it investigated. Currently signed off as result.

Has trialed inhalers but no benefit

Low mood since being signed off from work, keen to go back as financial concerns

Acknowledges stress at work but contextual

Laryngoscopy = evident baseline tension but no structural concerns. Provocation with cleaning products resulted in usual symptoms and intermittent ILO. For SLT therapy.

46. y/o Mail. Works in IT. Lives alone

PMHx: Asthma (on ICS), reflux, fusion of cervical spine with associated chronic pain
Respiratory investigations: mild asthma as per investigations and reversibility testing

Referred to SLT by asthma nurses

Adherent to ICS and no change to asthma management plan indicated

Patient reporting episodes of SOB and throat tightness +/- wheeze which are unresponsive to inhalers or previous courses of OCS. Can differentiate well between upper and lower airway sx.

Laryngeal sx mainly happen on exertion but can also be when talking fast

Taking excessive amounts of salbutamol as doesn't know what else to do

Feels like these sx caused the breakdown of his relationship as they frightened partner

Wants to get back into exercise but feels limited because of his symptoms

Laryngoscopy = no structural/functional concerns at baseline. On provocation with exertion, evidence of BPD and ILO. For SLT and Physio treatment.

55. y/o Female. Works as a teacher (currently on sick leave). Lives with parents

PMHx: anxiety, IBS, migraines

Respiratory investigations: NAD

Referred to SLT by local Allergy clinic

Following investigations, allergy clinic did not feel any true allergic response. Possible spontaneous angioedema of the lips and urticaria. Referred to psychology team.

No hospital admissions but GP prescribed epi-pen (infrequent use) – now stopped by Allergy team.

Very aware of own symptoms; lists, constantly looking for 'allergens' (i.e. convinced allergic to onions so will avoid completely).

Reporting instances where food/cooking smells cause her SOB, wheeze and throat tightness. No cough. When symptomatic 'can't get air in or out' but can settle in 30–45 mins if focuses on breathing. Can sometimes lose voice completely.

Now avoids eating out or socialising with friends. Potential to become quite isolated.

Feels like can't eat in staff room/around pupils and currently – not confident to go back to work until resolved/knows what is going on and how to manage it.

Laryngoscopy: baseline circumferential tension, increased on phonation. Evidence of ILO on exposure to cooking spices. For SLT therapy and ongoing Psychology for anxiety.

83. y/o Male. Retired. Lives with wife

PMHx: HTN, bilateral hip replacements, Crohn's (managed on biologics)

Respiratory investigations: normal CXR, HRCT, PFTs

No SOB/sputum concerns

Reports long-standing dry, laryngeal cough which worsened post COVID. Can cough to the point of choking which can be frightening (happens approx. once a week). Has also fallen over a few times as result and ended up in A&E. Self-rated 8/10 but variable.

Referred to SLT from Consultant Cough clinic

Typically episodes of choking/throat tightness always start with cough

Intermittent reflux – started on treatment

No rhinitis/PND concerns

No dysphagia and voice quality WNL for patient

Triggers: strong smells, i.e. candles/incense at daughters house. Can sometimes happen 'out of the blue'

Laryngoscopy = signs of reflux. Otherwise structurally and functionally normal at baseline. Provocation with scents = immediate cough++ which progressed to ILO. For SLT treatment.

19. y/o Female. Student. Lives with parents

PMHx: severe asthma (on Omalizumab), rhinitis, polyps

Respiratory investigations: PFTS, HRCT in line with severe asthma diagnosis

No sputum burden or recent infections

Referred to SLT by Severe Asthma service

Patient reporting when having a 'bad day' with asthma, throat can feel tight and 'harder to breath in.' Only occasional GP previously prescribed rescue pack for this but didn't improve sx. Confused as to why people keep saying it's her asthma when she clearly feels the tightness in her throat.

Not overly concerned, life-long asthmatic and knows how to manage symptoms but feels throat has become tighter, more uncomfortable in the past few years and wants to know why.

No specific triggers

No reflux, ENT removed polyps, takes nasal spray daily for rhinitis

Good adherence with medications/inhaler hygiene etc.

Laryngoscopy = no structural concerns but held very tight at baseline. Unable to trigger typical episode but 'simulated' how it feels – demonstrated stridor and paradoxical closure. For SLT treatment based on history alongside usual asthma treatment.

Appendix D. Chronic cough case histories V2**82. y/o Male – retired. No previous occupational exposures. Lives at home with son**

PMHx: chronic neck and back pain, nil else

Generally fit and well.

Respiratory investigations: CT thorax, PFTs = NAD

Referred to SLT from Consultant Cough clinic
Reporting intermittent dry laryngeal cough since 2019. No apparent precipitating event/trigger.

No secondary benefit to cough from Gabapentin for neck/back pain

No concerns re: reflux (managed on PPIs)/rhinitis/PND/localised pain/dysphagia/dysphonia/SOB

Cough mainly characterised by globus, chronic throat clearing – ‘annoying’ but ‘just gets on with it’

Not limiting day-to-day activities just irritating

Self-rated 5/10

Laryngoscopy = mild A-P squeeze on phonation otherwise NAD. SLT therapy for globus, hypersensitivity.

59. y/o Female – works in admin. Lives at home with husband

PMHx: Mild bronchiectasis, mild emphysema, EDAC, Fibromyalgia, memory investigations

Respiratory investigations: HRCT as above, PFTs = normal, No sputum concerns on bronch

No recent chest infections

Sx out of proportion for respiratory disease

Referred to SLT from Consultant Cough clinic

No secondary impact to cough from Gabapentin/Amitriptyline/Fentanyl patches for chronic pain

Dry cough, constant last 18 months – finding it difficult to manage in context of COVID. Avoiding social situations. Frustrated, tearful in consultation.

No specific triggers but worse when talking. Self-rated 9/10.

Denies chest focused sx and no recent infections

No dysphonia/dysphagia/reflux/rhinitis/PND/SOB concerns

Laryngoscopy = No structural/functional concerns. For SLT therapy.

49. y/o Female – works as healthcare assistant. Lives with husband

PMHx: recurrent tonsillitis and ear infections, breast cancer (1996, 2018) with ongoing reconstructive surgeries, skin cancer (2019) tx with radiotherapy, now discharged.

Respiratory investigations: A/w full PFTs, normal HRCT thorax. Pt denies any chest-focused sx or SOB. No mucus or chest infections.

Referred to SLT from Consultant Cough clinic

Dry, laryngeal cough (before Breast Ca in 1990s). Variable throughout the year. No pattern. Self-rated 8/10.

Much better on holiday – husband even thought about moving abroad as patient exasperated with it.

Would like to try and avoid antitussives and trial SLT first.

Triggers to cough = temperature change, talking, lying flat, strong smells

Initially cough improved ‘a bit’ with the addition of PPIs, no overt reflux

A lot of health related stress previously but very pragmatic, level-headed. Not limiting activities but can feel embarrassed.

No rhinitis/PND/dysphagia

Previous ENT surgery to widen R nostril. This side now more uncomfortable due to radiotherapy in this area for previous skin cancer.

Voice can feel 'croaky' when cough is bad, can lose easily.

Laryngoscopy = No structural/functional concerns at baseline. A-P and L-M squeeze on phonation. For SLT therapy.

78. y/o Female – retired. Lives with husband

PMHx: Asthma (stable on low-dose ICS), GERD, ex-smoker (stopped 25 years ago)

Respiratory investigations: no change to PFTs, peak flows. No asthma concerns. HRCT = in keeping with mild asthma.

Reports intermittent 'choking' laryngeal cough for the past 3 years. Self-rated 6/10.

Predominantly dry but can feel more productive in the mornings

Referred to SLT from Consultant Cough clinic

Previous adverse reaction to Morphone so declined antitussives

Triggers = exertion, smells, laughing, talking

Subjectively feels no change to asthma, no SOB concerns. Rarely uses salbutamol.

No benefit to cough with changes to inhalers/PPIs/OCS

Feels occasionally things can go 'wrong way' because cough at meal times (but describes as normal irritative cough interrupting meals when trying to talk to husband at same time). Can find this upsetting when out with friends. No dysphagia concerns. No hx of infections.

Presbyphonic sounding voice but no patient concerns

Reflux managed on PPIs, variable PND sx

Laryngoscopy = evidence of PND – requested Avamys via GP. Otherwise no structural/functional concerns. For SLT therapy.

53. y/o Female – full time mum, 2 young children. Lives with partner

PMHx: IBS, Fibromyalgia, ME,? mild asthma, previous Breast Ca – now discharged, neuralgia, endometriosis

Respiratory investigations: HRCT thorax = mild bronchiectasis. A/w full PFTs. Referred to Physio to trial ACT +/- hypertonic saline. Consideration for bronch if no change.

Cough started around same time as COVID ~2019

Denies any sputum burden and cough always feels dry, localises to larynx++. Self-rated 8/10.

Reports? chest infections but no current evidence – just describes increased periods of dry cough

Working diagnosis = combination of lower + upper airway symptoms (?upper > lower)

Referred to SLT from Consultant Cough clinic

No benefit to cough with antibiotics/OCS/ICS – coughs more trying to use her Fostair.

Describes generalised laryngeal irritation, globus, no pain

No specific triggers, random

Can get chest 'heaviness' but? musculoskeletal as constant coughing

Reflux well controlled on PPIs

No dysphagia/dysphonia/rhinitis/PND concerns

Feels 'going round in circles', frustrated, cough aggravates Fibro, ME, 'exhausted.' Low mood. Doesn't really go out much because of cough. Sleeping in separate room to partner.

Laryngoscopy = normal larynx but difficult to establish LHS/CRC as refused procedure unless lidocaine spray used. Likely LHS/CRC component based on history but advised complete Resp investigations +/- bronch first then re-refer SLT.

63. y/o Female – retired. Lives alone, husband recently passed away

PMHx: HTN, otherwise fit and well.

Long-standing cough, variably dry/productive; 'as long as I can remember'. Self-rated 6/10.

Respiratory investigations = HRCT, PFTs normal. Bronch: raised neutrophils and eosinophils.

Treated with Azithromycin, resolved productive component of cough. Ongoing dry, irritative.

Referred to SLT from Consultant Cough clinic

Cough localised to throat/upper chest. Generalised irritation, feels like 'flap in throat catches' and causes cough

No specific triggers

No reflux/localised pain/dysphonia/dysphagia

Had FESS with ENT in 2020 – ongoing PND despite Dymista

As a result of cough staying at home a lot. Worried people will think she has COVID. Referred to local services for anxiety support/management.

Laryngoscopy = rhinitis and PND. Requested CNS review of nasal treatment and technique. SLT for hypersensitivity.

68. y/o Male – retired. No previous occupational exposures. Lives with wife

PMHx: previous hiatus hernia, reflux (managed on PPIs + Gaviscon), IBS

Respiratory investigations: HRCT thorax, PFTs = NAD. No lower airways concerns.

Reported some exertional breathlessness but resp/cardiac investigations normal and attributed to deconditioning.

Cough started prior to surgery for hiatus hernia (2018) when reflux was really bad

Can cough until retching but doesn't happen that often any more

Referred to SLT from Consultant Cough clinic

On 5 mg MST BD – tolerating. Would ideally like to stop this in future.

Initially sought referral as wife concerned, but not overly bothered himself. Self-rated 4/10.

Intermittent throat-focused cough and throat clearing++

Triggers: none specific, worse with masks

Reflux now well controlled.? PND but nasal sprays gave him nosebleeds so stopped.

No dysphagia/dysphonia concerns
Laryngoscopy = LHS/CRC. No concerns. For SLT therapy.

48. y/o Female – off sick because of cough. Lives alone

PMHx: reflux, rhinitis, OA, spinal stenosis, restless legs

Respiratory investigations: ground glass changes? after bad infection approx. 5 years ago. No other concerns. PFTs, auscultation normal. No evidence asthma.

Denies SOB/sputum

Cough started 2019 after a bad virus/infection. Dry, laryngeal.

Can cough until dizzy/vomits, feels like about to pass out but no actual cough syncope. Very distressed. Self-rated 10/10. Currently not working as result.

Referred to SLT from Consultant Cough clinic

No response to antitussives – frustrated, just wants ‘magic pill’

Triggers: environmental smells, stress/anxiety, smoke, cold air, spicy foods

Limiting daily activities as very anxious about people looking at her when symptomatic

Referred for local anxiety management

No reflux concerns

Voice – moderately strained. No dysphagia.

Rhinitis feels well managed on Dymista.

Laryngoscopy = structurally and functionally normal at baseline but evidently sensitive. Significant A-P and L-M squeeze on phonation. For SLT therapy.

55. y/o Female. Works as nurse. Lives with husband

PMHx: nasal polyps, nil other significant

Reports low-level irritation in larynx +/- cough. Unsure of duration. Dry, Self-rated 2/10.

Respiratory investigations = normal CXR, HRCT, PFTs

No response to sx with previous trials of ICS, PPIs

Referred to SLT from Consultant Cough clinic

Could not tolerate antitussives – woozy, nauseous. Unable to work as a nurse with side effects so discontinued.

No SOB/dysphonia/dysphagia/localised pain/reflux

Ran out of Beconase and didn't renew prescription – ongoing PND

Frequent throat clearing and finds it ‘annoying.’ Not really much impact on QoL – more aware of it in quiet environments, i.e. theatre

Laryngoscopy = rhinitis, advised restart nasal spray. Mild circumferential tension.

No structural or functional concerns. For SLT therapy.

52. y/o Male. Works in IT. Lives with wife

PMHx: cataracts, T2DM

Respiratory investigations; normal PFTs, CXR, HRCT. No lower airways concerns.

Laryngeal cough for approximately 15 years. Self-rated 5/10.

Referred to SLT from Consultant cough clinic

Currently 10mg MST BD – tolerating

SOB but felt due to BPD as avoids taking deep breath due to cough – feels he breathes differently to compensate. For consideration of Physio after SLT.

Feels globus and secretions in throat which often triggers cough. Otherwise, no exacerbating factors. Feels less confident – cough makes him feels self-conscious, especially at work.

Swallowing feels more 'effortful' but more in keeping with laryngeal tension than dysphagia

No chest infections

Voice feels 'gravelly'

No reflux/rhinitis/PND

Laryngoscopy = PND – for nasal spray via GP. Moderate circumferential tension (likely due to posture/BPD). No structural/functional concerns. For SLT therapy

Appendix E. TOM ILO score sheet

Therapy outcome measure instructions and scoring sheet

You have been provided with 10 case studies to rate using the **TOMs ILO**. Please refer to the descriptors when rating the case studies

Thank you!

Case study	Impairment	Activity	Participation	Well-being/distress
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Appendix F. TOM CC score sheet

Therapy outcome measure instructions and scoring sheet

You have been provided with 10 case studies to rate using the **TOMs COUGH**. Please refer to the descriptors when rating the case studies

Thank you!

Case study	Impairment	Activity	Participation	Well-being/distress
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				