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Establishing normative physiological values among breastfeeding infants in Malawi for the development of a pneumonia dysphagia risk score

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ABSTRACT

Background Pneumonia is the leading infectious cause of death in children under 5 years of age in low- and middle-income countries (LMICs), with most deaths among infants. In children with pneumonia, aspiration events have been implicated in fatalities; however, physiological data on normative infant feeding patterns and validated techniques for detecting dysphagia and aspiration risk in LMICs are lacking. We aimed to establish a baseline of normative physiological and behavioural feeding-related variables in healthy, well, breastfeeding infants in Malawi to begin developing dysphagia risk scoring tools for infants with severe pneumonia.

Methods We enrolled healthy breastfeeding infants (<12 months) without known dysphagia risk factors who presented to a vaccination clinic in Lilongwe, Malawi. We incorporated key variables from the literature and expert opinion to create a feeding evaluation protocol. We collected sociodemographic and clinical information and evaluated infants during 5 minutes of breastfeeding. Descriptive statistics and distributions of feeding variables were used to develop two dysphagia risk scoring tools for predicting wet breath sounds during feeding, a proxy for increased aspiration risk. We assessed initial tool performance by calculating test statistics.

Results We enrolled 100 infants and analysed data from 95 healthy, well participants. The median age was 4 months (IQR 1–6) and 60% (57/95) were female. During feeding, 55% (52/95) had more than one wet breath sound and 17% (16/95) had more than one cough. The two scoring tools classified 2.1% (2/95) and 3.2% (3/95) of participants as 'at risk' for dysphagia. The specificity of each scoring tool was 100% in detecting wet breath sounds during feeding.

Conclusion We demonstrated that healthy, well Malawian infants exhibit variable vital signs and feeding behaviours during breastfeeding, and these data can be used to develop dysphagia risk scoring tools. Our next steps include evaluating and refining the tools to predict wet breath sounds in infants with severe pneumonia.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There are no standardised, validated techniques to assess dysphagia and aspiration risk in low-resource settings, and data on physiological values and feeding behaviours in healthy breastfeeding infants are lacking.

WHAT THIS STUDY ADDS

⇒ Establishing normative physiological values and behaviours in healthy breastfeeding infants is an essential step in developing a novel tool to identify dysphagia risk in infants with severe pneumonia.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A non-invasive dysphagia screening tool that can predict which infants with severe pneumonia are at risk of dysphagia, aspiration and death could improve pneumonia outcomes in low- and middle-income countries.

INTRODUCTION

Lower respiratory infections like pneumonia are the leading cause of death globally in children outside the neonatal period.[1] Despite overall declines in pneumonia-associated morbidity and mortality, the disproportionately high burden of childhood pneumonia persists in low- and middle-income countries (LMICs).[2] Severe disease incidence is highest in South Asia and Africa, and in sub-Saharan Africa, approximately 261 000 deaths from childhood pneumonia occurred in 2021.[3] In Malawi, one of the poorest countries in sub-Saharan Africa, pneumonia killed an estimated 2900 children under 5 years of age in 2021, resulting in a mortality rate of 106.3 deaths per 100 000 children under 5.[3]

In LMICs, some pneumonia-related deaths may be due to unrecognised aspiration events.[4] The national guidelines of many LMICs, including Malawi, have adopted and implemented the WHO hospital management guidelines for the care of children hospitalised with pneumonia. The guidelines define severe disease as cough and/or difficult breathing plus a general danger sign, signs of respiratory distress or hypoxaemia (peripheral arterial oxyhaemoglobin saturation (SpO_2) <90%).[5] Children who develop acute respiratory distress from pneumonia have an increased risk of aspiration from swallow dysfunction.[6] Interventions for pneumonia may also increase aspiration risk. Although the WHO guidelines recommend conventional low-flow oxygen and antibiotics for severe disease with hypoxaemia, some larger hospitals in LMICs use non-invasive ventilation (NIV) such as continuous positive airway pressure (CPAP),[7 8] which may place children at risk of swallowing difficulty or 'dysphagia' and subsequently aspiration.[9 10] In a randomised controlled trial conducted in Malawi, our group evaluated the use of bubble CPAP (bCPAP) for treating children with severe pneumonia and unexpectedly found a higher risk of mortality associated with bCPAP compared with conventional oxygen.[4] We hypothesised these unanticipated results may have been due to a higher frequency of aspiration events among bCPAP recipients. Children in high-income countries (HICs) with respiratory distress, including those receiving NIV, may be restricted from feeding orally. This practice is not routine in LMICs. The WHO guidelines recommend withholding oral feeding and providing nutrition with a nasogastric (NG) tube only for children who are unable to drink, lethargic, unconscious or having frequent convulsions.[5]

In HICs, children who demonstrate signs of dysphagia typically receive a clinical feeding evaluation to assess aspiration risk.[11 12] These evaluations include observation for clinical signs of dysphagia during feeding (eg, coughing, noisy breathing). Some clinical evaluations use cervical auscultation, a technique that involves placing a stethoscope on the neck at the level of the pharynx and listening to swallowing sounds.[13] When clinical or acoustic signs of aspiration are identified, a resource-intensive instrumental swallow study (eg, videofluoroscopic swallow study (VFSS) or flexible endoscopic evaluation of swallowing (FEES)) is typically conducted to evaluate for dysphagia and aspiration.[14 15] Clinical and instrumental swallow evaluations rarely occur in resource-limited African settings. Effective and feasible clinical techniques for resource-limited settings are needed for assessing aspiration risk among infants with severe pneumonia. To our knowledge, feeding assessment guidelines for infants are not available for sub-Saharan Africa. Determining dysphagia and aspiration risk in patients with pneumonia can help guide safer feeding practices, such as feeding via NG tube, until the acute illness improves.

An early step in developing a contextually appropriate screening tool for identifying infants at risk for aspiration in sub-Saharan Africa is to evaluate physiological parameters and feeding behaviours of healthy breastfeeding infants in this region. One approach used for developing diagnostic tools is to derive normative thresholds from a healthy population representative of the target population.[16] Based on this rationale, our goals were to (1) describe the range of physiological parameters and behaviours of healthy, well Malawian infants during breastfeeding and (2) begin development of novel tools based on the extremes of these normative data that could be used in future studies to identify infants with severe pneumonia at risk for dysphagia.

METHODS

Study design and setting

We conducted a cross-sectional study in Lilongwe, Malawi, from December 2022 to April 2023. Infants who presented with their mothers for routine immunisations or weight checks to Bwaila District Hospital in Lilongwe, the capital city of Malawi, were screened for eligibility criteria. Infants were eligible if they were <12 months of age, breastfed, free of respiratory signs (including cough, difficulty breathing, tachypnoea, head nodding, nasal flaring, grunting, tracheal tugging, chest wall indrawing, stridor or cyanosis) and had a normal mental status based on the Blantyre Coma Score.[5] Infants born before 37 weeks' gestation were included if healthy and well, as prematurity in Malawi is typically based on the mother's recollection of her last menstrual period or fundal height during obstetric evaluation, rather than ultrasound findings. Infants with craniofacial anomalies, including cleft lip and palate, or neurological disorders, including hydrocephalus, were ineligible for this study because these conditions are already known to be associated with an increased risk of dysphagia and were not the focus of this research.[17]

Our objective was to assess healthy, well, breastfeeding infants. We therefore excluded enrolled participants with fever (≥38°C), severe malnutrition (WHO weight-for-age Z-score <−3 SD of the median) or a prior hospitalisation for breathing difficulty (online supplemental figure).

Feeding evaluation protocol development and outcome ascertainment

A protocol for evaluating feeding that uses cervical auscultation was created using the expert opinions of two speech-language pathologists (MAL-G, PS-F) and a paediatric pulmonologist (EDMcC) (online supplemental file). Key feeding-related physiological and behavioural variables were selected, including vital signs (temperature, heart rate, respiratory rate, SpO_2), cough, vocal changes, wet breath sounds, emesis and changes in work of breathing. We defined 'vocal change' as a wet-sounding vocalisation or cry, a 'wet breath sound' as a wet-sounding inhalation or exhalation, 'emesis' as vomiting or spit-up and a 'change in work of breathing' as the development of chest retractions, nasal flaring or head bobbing during feeding. A paediatrician (NEH) was trained to perform cervical auscultation by two speech-language pathologists (MAL-G, PS-F) who specialise in paediatric dysphagia. Cervical auscultation was used to identify swallowing sounds, including wet breath sounds and vocal changes.

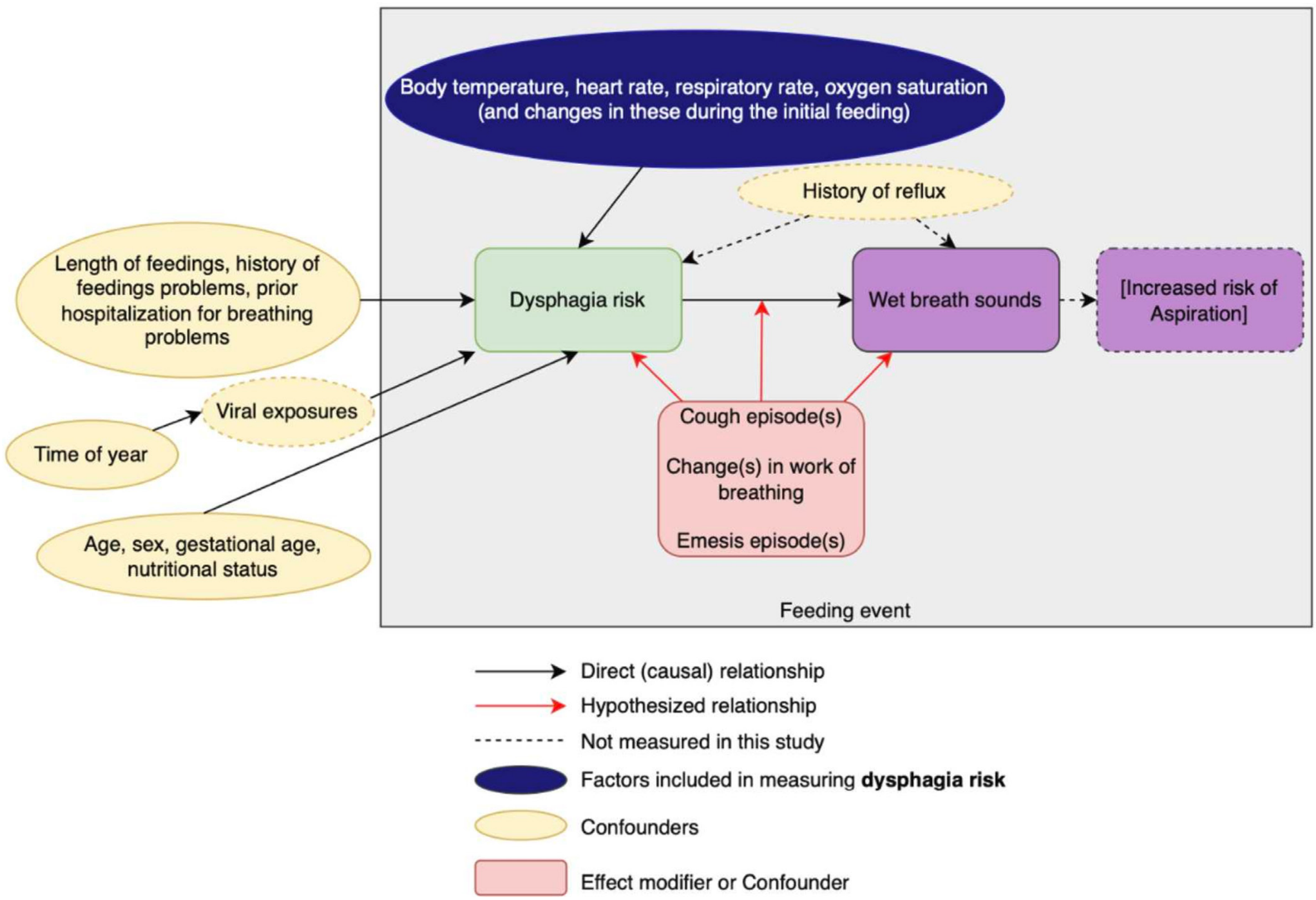

Figure 1 Conceptual representation of the causal relationship between demographic and feeding variables and increased aspiration risk.

The clinical outcome of 'wet breath sounds' was selected as a surrogate marker of increased aspiration risk in infants, given instrumental swallow studies were unavailable in Malawi (figure 1).

Vocal changes and wet breath sounds were included in the definition of 'wet breath sounds' as both findings are acoustic markers of dysphagia.[18–20] We created six categories for the outcome 'wet breath sounds': zero, one, two or more, three or more, four or more and five or more events during the 5 minute breastfeeding evaluation. These categories represent escalating threshold values (eg, ≥2, ≥3, ≥4, etc) rather than discrete counts (eg, 2, 3, 4, etc), based on the assumption that more frequent wet breath sound events are associated with a greater likelihood of dysphagia.

Data collection

A baseline set of vital signs, demographic information, medical history and clinical data were obtained. Participants were observed for the first 5 minutes of breastfeeding. During this time, SpO_2 and heart rate were continuously monitored using a pulse oximeter (RadG, Masimo, Irvine, California, USA). A paediatrician (NEH) trained in cervical auscultation continuously listened for swallow sounds using a conventional stethoscope placed on the neck, while simultaneously recording sounds with a digital stethoscope (Sonavi Labs, Baltimore, Maryland, USA) (online supplemental file). A 5 minute feeding duration was chosen considering feasibility and resource constraints in settings with high patient volumes and limited clinical staff. This approach allowed us to capture a standardised interval of feeding across subjects. Digital stethoscope recordings were not included in this analysis. Feeding variables, including vital signs, were systematically documented during the feeding period. Immediately after breastfeeding, another set of vital signs was recorded and a physical examination was performed. The quality of the pulse oximeter plethysmograph was noted for SpO_2 and heart rate values and classified as adequate if the waveform and SpO_2 signal quality bar were regular with consistent and sufficiently high amplitudes, according to the paediatrician's judgement.

Statistical analysis

Descriptive statistics were used to summarise demographic information, medical history, clinical data, wet breath sound events and selected feeding variables. Heart rate and SpO_2 values from low-quality measurements were excluded from the analysis. As a sensitivity analysis, we compared the demographic information, medical history and clinical data of participants with missing prefeed or postfeed pulse oximeter measurements (SpO_2 or heart rate) with those with complete prefeed and postfeed pulse oximeter measurements using the Wilcoxon rank-sum test. An additional sensitivity analysis compared feeding variables between participants born at term and those born preterm, also using the Wilcoxon rank-sum test.

Dysphagia risk score development and performance

The frequencies and distributions of feeding variables were examined, and expert specialist opinion (MAL-G, EDMcC) was applied to develop two dysphagia risk scoring tools intended to identify infants with wet breath sounds. The first scoring tool, the 'Practical Scoring Tool', was created using variables that can be feasibly measured in low-resource, high-volume settings by clinical staff with limited paediatric training. The second scoring tool, the 'Comprehensive Scoring Tool', was created using variables that are deemed clinically important in identifying aspiration risk in HICs but more difficult to routinely collect in low-resource settings. Scoring tools based on feeding variables were created because monitoring for wet breath sounds through cervical auscultation requires specialised training that is often unavailable in many LMICs.

Points were allocated to each variable based on the distribution in the study population. For normally distributed variables, we assigned 1 point if the participant's value was >1 SD through 2 SD from the mean of the study population, and 2 points if the value was >2 SD. For non-normally distributed variables, we assigned 1 point if the participant's value was greater than the 90th percentile through the 95th percentile of the study population, and 2 points if value was greater than the 95th percentile. For each participant, the points assigned for each variable were summed and an overall numeric score was generated. The distribution of participant summed scores was calculated for each scoring tool to create a final classification. For each scoring tool, participants were classified as 'at risk' for dysphagia if their summed score was greater than the 95th percentile of participant summed scores. The 95th percentile threshold was selected based on existing literature on defining normative thresholds in other paediatric conditions.[21]

We assessed the performance of each tool by calculating sensitivity, specificity, false positive rate, false negative rate, positive predictive value and negative predictive value performance statistics for six categories of wet breath sound events in healthy, well infant participants.

Patient and public involvement

The public was sensitised to the development, design, recruitment, conduct and results of this research through meetings held by the study group in Lilongwe, Malawi.

Ethics

This study was approved by the National Health Science Research Committee of Malawi (reference: 22/04/2902) and the University of North Carolina at Chapel Hill Institutional Review Board (reference: 22–0975). Caregivers

Table 1 Description of demographics, medical history and clinical features of study participants

Characteristics	Participants (n=95)
Demographics	
Age (months)	
0–2	39 (41%)
3–6	36 (38%)
7–11	20 (21%)
Median age, IQR (months)	4 (1, 6)
Females	57 (60%)
Medical history	
Premature*	4 (4%)
Gestational age (median (IQR))	29 (28, 31)
No history of asthma or wheezing	95 (100%)
No prior treatment for tuberculosis†	94 (100%)
No history of feeding problems‡	95 (100%)
Clinical features	
WHO WAZ§	
Not underweight (WAZ≥−2)	94 (100%)
Moderate underweight (−3≤WAZ<−2)	0
Severe underweight (WAZ<−3)	0
Not currently on treatment for tuberculosis	95 (100%)
HIV status	
Negative	1 (1%)
Exposed	30 (32%)
Unknown¶	64 (67%)
Cumulative wet breath sound events during feeding evaluation	
0	43 (45%)
1	23 (24%)
≥2	30 (31%)
≥3	20 (21%)
≥4	14 (15%)
≥5	9 (9%)

*In one of the 95 participants, the information on prematurity was not documented.
†In one of the 95 participants, the information on prior treatment for tuberculosis was not documented.
‡Mothers were asked about infant's history of feeding problems, issues gaining weight, breathing problems with feeding.
§In one of the 95 participants, weight was not documented.
¶HIV status was documented as 'unknown' unless both mother and infant presented a documented test result.
WAZ, weight-for-age Z-score.

of eligible infants provided written informed consent to participate.

RESULTS

From December 2022 to April 2023, a total of 100 participants were enrolled and 95 met inclusion criteria for analysis (online supplemental figure). The study population is summarised in table 1.

The average number of wet breath sound events during the feeding evaluation was 1 with an SD of 2. The number of participants with each category of wet breath sound events during 5 minutes of breastfeeding is summarised in table 1. Online supplemental table 1 details the number of participants with each discrete count of wet breath sound events during feeding.

Among 95 participants, 16 (17%) had at least one cough, 5 (5%) had an episode of increased work of breathing and 2 (2%) had one episode of emesis during feeding. The distributions of feeding variables are summarised in table 2.

Sensitivity analyses comparing participants with missing prefeed or postfeed pulse oximeter measurements (SpO_2 or heart rate) and those with complete pulse oximeter measurements showed no significant differences in demographic information, medical history and clinical data (online supplemental table 2). Similarly, comparisons between term and preterm participants demonstrated no significant differences in the mean and median of each feeding variable, supporting the inclusion of preterm infants in the primary analysis (online supplemental table 3).

After application of the Practical Scoring Tool (table 3), 2.1% (2/95) of participants scored greater than the 95th percentile of summed scores and thus were classified as ‘at risk’ for dysphagia (online supplemental tables 4 and 5).

After application of the Comprehensive Scoring Tool (table 3), 3.2% (3/95) of participants scored greater than the 95th percentile of summed scores and thus were classified as ‘at risk’ for dysphagia (online supplemental tables 4 and 5). No participants were classified as ‘at risk’ by both scoring tools.

The specificity of each scoring tool was 100% for each category of wet breath sound events (table 4). The negative predictive value of both scoring tools was >85% for the categories of four or more and five or more wet breath sound events.

Table 2 Distributions of feeding variables in healthy breastfed infants without feeding problems (n=95)

Feeding variable	N*	Missing	Mean±SD†	5%	10%	Median	90%	95%
Prefeed temperature‡	95	0	36.6±0.2	36.2	36.2	36.7	36.9	36.9
Prefeed heart rate‡	93	2	141.9±18.4	116.0	121.0	139.0	176.0	181.0
Postfeed heart rate‡	79	16	144.9±16.5	110.0	124.0	145.0	166.0	173.0
Highest heart rate‡	89	6	154.1±18.5	128.0	132.0	153.0	177.0	188.0
Change in heart rate§	87	8	11.7±16.8	−16.0	−5.0	10.0	34.0	41.0
Prefeed respiratory rate	94	1	44.7±11.1	31.0	32.0	42.5	59.0	64.0
Postfeed respiratory rate‡	94	1	46.3±11.5	30.0	33.0	45.0	62.0	68.0
Change in respiratory rate¶	93	2	1.8±12.0	−17.0	−11.0	2.0	14.0	20.0
Prefeed SpO_2	94	1	98.0±2.0	94.0	95.0	98.0	100.0	100.0
Postfeed SpO_2	80	15	98.3±1.6	95.0	95.5	99.0	100.0	100.0
Lowest SpO_2	88	7	97.1±2.0	94.0	95.0	98.0	99.0	100.0
Change in SpO_2‡**	87	8	−0.8±2.4	−5.0	−4.0	0.0	2.0	3.0
Drop in SpO_2≥3%††, yes/no, frequency (%)	87	8	19 (21.8%)				Yes	Yes
Drop in SpO_2≥3% and below 92%‡‡, yes/no, frequency (%)	88	7	2 (2.3%					
Cough episode count during feeding	95	0	0.2±0.4	0.0	0.0	0.0	1.0	1.0
Change in work of breathing count during feeding	95	0	0.0±0.2	0.0	0.0	0.0	0.0	1.0
Emesis count during feeding	95	0	0.0±0.1	0.0	0.0	0.0	0.0	0.0

*Number of participants with data on specific variables.
†Mean±SD unless otherwise specified.
‡Normally distributed variable.
§Highest heart rate during or after feed minus prefeed heart rate.
¶Postfeed respiratory rate minus prefeed respiratory rate.
**Lowest SpO_2 during or after feed minus prefeed SpO_2.
††Change in SpO_2 ≥−3%.
‡‡Change in SpO_2 ≥−3% *and* lowest SpO_2 <92%.
SpO_2, peripheral arterial oxyhaemoglobin saturation.

DISCUSSION

We quantified and characterised a range of physiological parameters and feeding behaviours in a population of healthy, well, breastfeeding infants in Malawi. These data were used for the initial development of two dysphagia risk scoring tools based on weighted normative values. Our subsequent goal is to further evaluate and refine these novel scoring tools to adequately predict wet breath sounds, a proxy for increased aspiration risk, among infants with severe pneumonia. We also plan to compare the tools with the gold standard for diagnosing dysphagia and aspiration, the VFSS or FEES.

Some vital sign measurements and behaviours observed during infant feeding may be indicative of dysphagia and aspiration risk, or they may be typical during feeding in healthy infants without dysphagia.[22] Our findings support that healthy infants exhibit variable feeding behaviours and vital signs during breastfeeding. We found that approximately 17% of healthy breastfeeding participants had at least one coughing episode during 5 minutes of feeding. This is consistent with a recent study showing that healthy, term, breastfed and bottle-fed infants coughed during an average of two feeds per day over the first month of life.[22] The study also highlighted significant variability in the frequency of coughing episodes among healthy infants, with some not coughing at all and others coughing during most feeds. In our study, vital sign changes and the number of coughs, changes in work of breathing and emesis during feeding were the feeding variables with the most variability. Clinically, coughing, increases in respiratory rate, and decreases in SpO_2 typically raise concerns for aspiration. Our study demonstrates that even healthy infants display a range of feeding behaviours and changes in vital signs during breastfeeding, which is an important consideration for the development of a score to detect infants at high risk for aspiration.

We selected wet breath sounds as a surrogate marker of increased aspiration risk in infants with severe pneumonia based on feasibility, expert opinion, current evidence and in anticipation of future studies. First, instrumental diagnostic tools such as VFSS and FEES that identify dysphagia and aspiration are not available in Malawi, as they require substantial resources and expertise. Second, the presence of wet-sounding breaths or vocalisations associated with swallowing serves as an acoustic marker

Table 3 Dysphagia risk scoring tools: point allocations for feeding variable values

Feeding evaluation variable	1 Point rationale	1 Point	2 Point rationale	2 Points
Practical Scoring Tool				
Prefeed temperature	>1 SD–2 SD	>36.8–37	>2 SD	>37
Prefeed heart rate	>1 SD–2 SD	>160–178	>2 SD	>178
Prefeed respiratory rate	>90–95 percentile	>59–64	>95 percentile	>64
Prefeed SpO_2	<10–5 percentile	<95–94	<5 percentile	<94
Postfeed heart rate	>1 SD–2 SD	>161–177	>2 SD	>177
Postfeed respiratory rate	>1 SD–2 SD	>57.8–69	>2 SD	>69
Postfeed SpO_2	<10–5 percentile	95	<5 percentile	<95
Comprehensive Scoring Tool				
Highest heart rate	>1 SD–2 SD	>172–191	>2 SD	>191
Change in heart rate*	>90–95 percentile	>34–41	>95 percentile	>41
Change in respiratory rate¶	>90–95 percentile	>14–20	>95 percentile	>20
Lowest SpO_2	<10–5 percentile	<95–94	<5 percentile	<94
Change in SpO_2†	<(−1 SD)–(−2 SD)	<(−3)–(−5)	<(−2 SD)	<(−5)
Drop in SpO_2≥3%‡ (yes/no)	>90 percentile	Yes		
Drop in SpO_2≥3% and below 92%§ (yes/no)			>95 percentile	Yes
Cough episode count during feeding	>90 percentile	>1		
Change in work of breathing count during feeding			>95 percentile	>0
Emesis count during feeding			>95 percentile	>0

*Highest heart rate during or after feed minus prefeed heart rate.
†Lowest SpO_2 during or after feed minus prefeed SpO_2.
‡Change in SpO_2 ≥−3%.
§Change in SpO_2 ≥−3% and lowest SpO_2 <92%.
¶Postfeed respiratory rate minus prefeed respiratory rate.
SpO_2, peripheral arterial oxyhaemoglobin saturation.

Table 4 Performance of practical and comprehensive scoring tools for detecting wet breath sound outcomes in healthy, well infants (n=95)

Wet breath sound events (*n/N)	Se (%)	Sp (%)	FP (%)	FN (%)	PPV (%)	NPV (%)
Practical Scoring Tool (2/95 at risk of dysphagia)						
0 (43/95)	0	100	0	45.3	0	54.7
1 (23/95)	0	100	0	24.2	0	75.8
≥2 (30/95)	6.7	100	0	30.1	100	69.9
≥3 (20/95)	10	100	0	19.4	100	80.6
≥4 (14/95)	14.3	100	0	12.9	100	87.1
≥5 (9/95)	0	100	0	9.5	0	90.5
Comprehensive Scoring Tool (3/95 at risk of dysphagia)						
0 (43/95)	2.3	100	0	44.7	100	55.3
1 (23/95)	0	100	0	24.2	0	75.8
≥2 (30/95)	6.7	100	0	30.1	100	69.9
≥3 (20/95)	0	100	0	21.1	0	78.9
≥4 (14/95)	0	100	0	14.7	0	85.3
≥5 (9/95)	0	100	0	9.5	0	90.5

*Prevalence in study population.
FN, false negative; FP, false positive; NPV, negative predictive value; PPV, positive predictive value; Se, sensitivity; Sp, specificity.

predictive of aspiration.[18–20] Children at risk for aspiration who underwent VFSS with simultaneously recorded cervical auscultation sounds demonstrated wet breath sounds following swallows with aspiration twice as often as swallows without aspiration.[20] To our knowledge, the frequency of wet breath sounds during feeding in healthy breastfeeding infants without dysphagia has not been reported. Our study addresses this evidence gap by showing that approximately half of healthy infants exhibit at least one wet breath sound during 5 minutes of feeding. Thus, our data provide key evidence that it is not uncommon for wet breath sounds to occur in well, healthy Malawian infants. We found that only 9% of infants had five or more wet breath sound events during feeding, suggesting persistent or repeated wet breath sounds are less common in healthy infants during breastfeeding. The frequency of wet breath sounds in infants with respiratory distress from severe pneumonia remains unknown.

In this work, we used data from healthy breastfeeding infants to develop two scoring tools that may identify elevated dysphagia risk. We acknowledge that our score development approach, which uses extreme values of normative data, differs from other score development approaches that use statistical modelling of larger datasets. Given that cervical auscultation is a novel technique in settings like Malawi and requires an expert for data collection, we were inherently restricted to a smaller dataset and therefore opted for this unique score development approach. To evaluate our approach and explore the performance of the scoring tools, we applied each tool to our healthy breastfeeding infant population and evaluated test statistics for the outcome of wet breath sounds. We found that <4% of participants were classified as being 'at risk' with either tool. Interestingly, we observed no overlap between the tools, as no participants were identified as 'at risk' with both tools. A potential explanation is that the two scoring tools incorporated unique sets of variables, with SpO_2 changes during feeding mainly contributing to points accumulated by participants in the 'Comprehensive Scoring Tool'. While it remains unclear which variables are most important for identifying dysphagia and aspiration risk, this exercise provided potential reassurance. Both tools demonstrated high specificity and relatively low false negative rates with more frequent wet breath sound events. In a healthy, well population with likely infrequent wet breath sound events, the scoring tools would ideally identify wet breath sounds when present, or 'true positives'. Therefore, the 'Practical Scoring Tool' may be the more optimal tool as it had a specificity of 100% and false negative rate of 12.9% for the outcome of four or more wet breath sound events during feeding. We would not expect either scoring tool to have high sensitivity in healthy infants who are well and without current signs of dysphagia. Ultimately, the performance of each scoring tool and the optimal wet breath sound frequency threshold need to be evaluated and refined in the intended target population of infants with severe pneumonia and compared with the gold standard for diagnosing dysphagia and aspiration, the VFSS or FEES.

We acknowledge that our use of wet breathing sounds as a proxy for increased aspiration risk has several limitations. First, as previously mentioned, the frequency of wet breathing during feeding in infants with dysphagia and aspiration remains unknown. Additionally, various confounding variables, such as the presence of reflux, may impact wet breathing (figure 1). Furthermore, relying on wet breath sounds may fail to identify infants with silent aspiration. However, most infants with silent aspiration identified through instrumental swallow studies were evaluated due to dysphagia concerns, indicating they were high risk. We also considered using the changes in SpO_2 measurement during feeding as an end point. However, we opted against this because many hospitalised infants with severe pneumonia in low-resource settings are placed on oxygen regardless of their SpO_2 levels, potentially masking low SpO_2 values associated with aspiration during feeding. Notably, we included changes in SpO_2 as a parameter in the 'Comprehensive Scoring Tool', which did yield points for participants. Despite these limitations, we believe that wet breath sounds remain the most appropriate end point, given the unavailability of instrumental swallow studies to diagnose dysphagia and aspiration in Malawi. Additionally, the prevalence of wet breath sounds in this study is based on a single paediatrician's examination. To mitigate this limitation, the paediatrician received training in the cervical auscultation technique before the study.

In sum, defining normative feeding behaviours in healthy breastfeeding infants in Malawi is an essential step in developing a novel screening tool to identify dysphagia risk and predict aspiration risk in infants with severe pneumonia. By conducting future studies that include sick infants and further optimising these tools, we aim to identify infants with respiratory distress who are at elevated risk of aspiration in LMICs with high infant pneumonia mortality.

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Contributors NEH, MAL-G and EDMcC conceptualised and designed the study. TM was responsible for project administration. NEH and CP collected the data, and NEH curated it. HS and MC conducted the data analysis. NEH, MAL-G, HS, MC and EDMcC interpreted the data. NEH wrote the original draft. NEH, HS, MC, PS-F, CP, TM, MAL-G and EDMcC contributed to writing, review and editing. NEH is the guarantor.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods' section for further details.

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