

Further Positive Preliminary Results from Current Clinical Study

High accuracy achieved for the diagnosis of additional respiratory diseases as well as the differential diagnosis of respiratory disease

- **100% accuracy for distinguishing patients with bronchiolitis from subjects with no discernible respiratory disease**
- **99% accuracy for distinguishing patients with croup from subjects with no discernible respiratory disease**
- **96% accuracy (with the addition of existence of fever to the algorithm) for distinguishing patients with upper respiratory tract infection (URTI) from subjects with no discernible respiratory disease**
- **97% accuracy for distinguishing patients with viral pneumonia from subjects with no discernible respiratory disease on a larger dataset than previously reported**
- **Successfully demonstrated differentiating patients with a particular respiratory disease from patients with other respiratory diseases with accuracy in the range of 89% to 99%**

Perth, Western Australia, 10 November 2015 -- ResApp Health Limited (ASX: RAP), the developer of smartphone medical applications for the diagnosis and management of respiratory disease, today announced further positive preliminary results from its paediatric clinical study underway at Joondalup Health Campus (JHC) and Princess Margaret Hospital (PMH) in Perth, Australia. These preliminary results, prepared by the team led by Associate Professor Udantha Abeyratne at The University of Queensland (UQ), are based on an updated 338 subject dataset.

These new results expand the platform to diagnose bronchiolitis, croup and upper respiratory tract infection (URTI) at very high levels of accuracy (greater than 96%) and show accurate (89-99%) differential diagnosis of patients with one respiratory disease from patients with other respiratory diseases. The new diseases (plus viral pneumonia and asthma/viral-induced wheeze reported in our previous release) cover the majority of respiratory conditions that commonly occur in children. Bronchiolitis is the most common reason for admission to hospital in children under 12 months in developed countries and forms a large proportion of the workload to General Practitioners and emergency departments during the winter months. Croup is also a common condition that accounts for approximately 15% of clinic and emergency department visits for paediatric respiratory tract infections.

“These results demonstrate the potential to accurately differentially diagnose respiratory disease in children in a novel way with meaningful consequences for selecting the correct treatment option,” said Dr Paul Porter, Paediatric Emergency Physician, Princess Margaret Hospital and Clinical Advisor to ResApp. “The results also point to the possibility to better define lower airway involvement in respiratory disease more accurately than current clinical practice.”

“The release of this additional data is another significant step forward in our development of a complete respiratory disease diagnostic tool that provides instant answers and seamlessly integrates into telehealth platforms,” said Dr Tony Keating,

CEO and Managing Director of ResApp Health. “These results demonstrate the power of the platform that Dr Abeyratne and his team have developed and provide an excellent foundation for our continuing regulatory and commercial discussions.”

The performance of the algorithm was evaluated using the method of leave-one-out cross-validation against the clinical diagnosis provided by the JHC and PMH medical team. The diagnosis was based on the clinical presentations, auscultation (listening to the internal sounds of the body with a stethoscope) findings and imaging as well as laboratory test results when clinically indicated for the diagnosis of a given respiratory illness. As some of these groups do not have a gold standard diagnosis, we have used the overall clinical diagnosis as a reference standard of comparison.

Table of respiratory disease groups

Normal Group (51 subjects, increased from 39)	Subjects with no discernible respiratory illness at the time of measurement.
Viral Pneumonia Group (35 subjects, increased from 25)	Patients with a diagnostic classification of viral pneumonia alone or with *comorbidities of URTI and/or viral-induced wheeze. Only X-ray confirmed viral pneumonias are considered.
Bronchiolitis Group (32 subjects)	Patients with a diagnostic classification of bronchiolitis with or without URTI as a comorbidity. Bronchiolitis is clinically taken as pneumonias/severe viral infections in children below 12 months.
Croup Group (17 subjects)	Patients with a diagnostic classification of croup, with or without URTI as a comorbidity.
URTI Group (20 subjects)	Patients with URTI alone without medically discernible lower respiratory tract involvement at the time of measurement.

**Comorbidity is the simultaneous appearance of two or more physical illnesses.*

Table of preliminary results, respiratory disease versus subjects with no discernible respiratory disease

Target Group	Control Group	Sensitivity	Specificity	Accuracy
Viral Pneumonia	Normal	100%	95%	97%
Bronchiolitis	Normal	100%	100%	100%
Croup	Normal	94%	100%	99%
URTI	Normal	94%	88%	90%
URTI	Normal	100%	95%	96%

(with the addition of presence of fever to the algorithm)

Table of preliminary results, target diseases versus URTI

Target Group	Control Group	Sensitivity	Specificity	Accuracy
†Viral Pneumonia	URTI	86%	90%	87%
†Viral Pneumonia	URTI	89%	90%	89%

(with the addition of patient age to the algorithm)

Bronchiolitis	URTI	100%	95%	98%
Croup	URTI	94%	95%	95%

†URTI, viral-induced wheeze and viral pneumonia are considered a spectrum of illnesses. Even in a tertiary hospital setting, it is difficult to differentiate between viral pneumonia and viral-induced wheeze due to the clinical overlap. Wheeze is not always detectable in a given clinical examination, and for these reasons mild cases of viral pneumonia and viral-induced wheeze may be clinically classified as URTI. Whilst the addition of patient age to the algorithm improves sensitivity, specificity and accuracy, increased patient numbers are needed to better evaluate (and potentially improve) the performance of the algorithms within this difficult to clinically diagnose spectrum.

Table of preliminary results, differential diagnosis of respiratory disease

Target Group	Control Group	Sensitivity	Specificity	Accuracy
Viral Pneumonia + Bronchiolitis + Croup + URTI	Normal	92%	90%	92%
‡Croup	Viral Pneumonia + Bronchiolitis + URTI	94%	97%	96%
Viral Pneumonia + Bronchiolitis	URT I	93%	85%	91%
Bronchiolitis	Croup	100%	94%	98%
Bronchiolitis	Viral Pneumonia	91%	80%	85%
§Bronchiolitis (with the addition of patient age to the algorithm)	Viral Pneumonia	100%	97%	99%
Pneumonia	Croup	100%	94%	98%

‡Croup is a very common condition in children and treatment using oral steroids is very effective. Treatment of croup with steroids has decreased intensive care unit admissions dramatically over the past 10 years. As steroids are not used for bronchiolitis, URTI or pneumonia an accurate differential diagnosis is critical in the treatment of these diseases.

§Bronchiolitis and viral pneumonia are clinically separated largely by age. Bronchiolitis is defined in children below the age of 12 months and viral pneumonia when the age is above 12 months. This cut-off differs between countries. Note that cough alone has been shown here to separate bronchiolitis from viral pneumonia.

The Company notes that these results are preliminary and may change as the study progresses and more patients are added to the dataset. Larger datasets and prospective studies will be needed to produce results with higher statistical validity. The size of the present dataset did not allow us to gender or age match subjects in different disease groups. ResApp is continuing the clinical study at both JHC and PMH and the UQ-JHC research team is continuing to improve the technology platform. The addition of further clinical study sites is planned in the coming months providing faster patient recruitment rates and commencement of adult studies.

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About Paediatric Acute Respiratory Diseases

Paediatric acute respiratory disease can be classified as upper respiratory tract or lower respiratory tract disease. Upper respiratory tract infections (URTI) are one of the most common infectious diseases and include the common cold, laryngitis and pharyngitis. Pneumonia is either a viral or bacterial infection that inflames the air sacs of one or both of the lungs. Bronchiolitis is an infection that causes congestion in the bronchioles, the small airways in the lungs; it is clinically taken as pneumonias/severe viral infections in children below 12 months in Australia, however in some countries 18 months and 24 months are used as the age cut-off. Croup is the result of inflammation around the larynx, trachea and bronchi.

About Leave-One-Out Cross-Validation

Cross-validation is a statistical method to evaluate the predictive performance (generalisation error) of a model. In leave-one-out cross-validation a dataset of size n is partitioned into a model training dataset of size $n-1$ and a model testing dataset of size 1. The training data is used to train the model and the testing data is used to assess the predictive performance. This process is repeated n times until each sample in the overall dataset of size n is used exactly once as the testing data. The performance of the model is then computed over all of the n repetitions of the process. In the assessment of the cough-based diagnostic model leave-one-out validation was performed at the subject level.

About Sensitivity, Specificity and Accuracy Measures

Sensitivity is the proportion of patients with the disease who test positive. Specificity is the proportion of patients without the disease who receive a negative test result. Accuracy is a measure of both categories.

About ResApp Health Limited

ResApp Health Limited, founded in 2014, is developing smartphone medical applications for the diagnosis and management of respiratory disease. The technology, exclusively licensed from The University of Queensland (UQ), is based on a machine learning algorithm that uses sound alone without the need for additional hardware to diagnose and measure the severity of respiratory conditions. The algorithms have been successfully tested for pneumonia and asthma diagnosis in a clinical proof of concept study by UQ through funding from the Bill and Melinda Gates Foundation. Addressable markets for this technology include licensing to large telehealth service providers for 'in consultation' point of care diagnosis, at-home diagnosis and management of respiratory disease through direct sales to consumers and healthcare providers, and working with global aid and humanitarian organisations to deliver tools for low-cost diagnosis in the developing world.

For more information on ResApp, visit www.resapphealth.com.au