Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

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<th>Topic:</th>
<th>Point-of-care smartphone applications (ResAppDx-EU) for the diagnosis of acute respiratory disease</th>
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<td>Topic exploration report number:</td>
<td>TER198</td>
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Introduction and aims

Diagnosis of respiratory disease is currently performed using a combination of clinical observation, lung auscultation using a stethoscope, imaging (chest x-ray, CT), spirometry, blood and/or sputum tests. Telehealth platforms have the potential to provide more convenient and quicker access to diagnosis and further treatment for patients, and to allow this to be done remotely.

ResAppDx-EU is a smartphone app that can be used in both traditional (face-to-face) and virtual clinical practice. The app uses machine learning (artificial intelligence) to diagnose disease based on the sound of a person’s cough. There are two versions for ResAppDx-EU (version 1 and version 2).

Health Technology Wales researchers searched for evidence on digital applications (such as the ResApp) for the diagnosis of acute respiratory disease.

According to the technology developer, ResAppDx-EU holds a class IIa CE mark certification for use as an aid to diagnosis by a clinician in:

- Lower Respiratory Tract Disease (in people aged 29 days and over)
- Asthma (aged 12 years or less)
- Asthma exacerbations (in people aged 12 years or more with a prior diagnosis of asthma)
- COPD exacerbations is (in people aged 22 years or more with a prior diagnosis of COPD)
- Pneumonia (in people aged 29 days and over).
- Bronchiolitis (in children aged between 29 days and 2 years old)
- Croup (in children aged between 29 days and 12 years old)
**Summary of evidence**

The ResAppDx-EU is a digital health technology and was determined to be a Tier 3b technology according to the *Evidence Standards Framework for Digital Health Technologies*. This classification covers technologies with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. For technologies of this classification, it is recommended that high-quality randomised controlled study or studies are produced to demonstrate effectiveness of the technology.

**Secondary evidence**

We identified several guidelines for the diagnosis and management of relevant populations outlining current recommended care (see Brief Literature Search results), but no secondary evidence or economic evidence was identified for ResAppDx-EU or similar applications.

**Primary evidence**

We identified three primary studies on use of smartphone interventions for respiratory conditions. One study was based on ResAppDx-EU, whereas the other two papers reported different technologies.

Porter et al. (2019) reports a prospective, multicentre study evaluating the diagnostic accuracy of ResAppDx-EU for common respiratory disorders in children (n = 585). Children were between 29 days and 12 years old. Five cough sounds were analysed using cough data and reported symptoms, and compared against diagnoses made by a panel of paediatricians (using hospital charts and all available investigations). The authors reported positive and negative agreement between the cough analyser and clinician diagnoses, which ranged between 80% and 97%. However, statistical evaluation of the level of agreement was not reported. The conditions diagnosed were upper or lower respiratory tract disease, croup, asthma, bronchiolitis or pneumonia.

A second study outlined the development of TussisWatch, a smartphone application, to record and process coughs for the early identification of chronic obstructive pulmonary disorder and congestive heart failure (Windmon et al. 2019).

The third study evaluated the development of a smartphone-based detection system aimed to detect coughs continuously, with limited impact on smartphone battery life. The authors reported 88.94% sensitivity and 98.64% specificity for cough detection in noisy environments.

In addition to the published evidence, the technology developer highlighted two conference posters for ResAppDx-EU. Both reported the percentage agreement between ResAppDx-EU algorithms using a non-standard reference test: one evaluated diagnosis of COPD exacerbations in known COPD cases, and the second evaluated diagnosis of COPD in a mixed-disease acute care cohort (outpatients with COPD, inpatients with acute respiratory symptoms and asymptomatic). Whole cohort agreement levels ranged from 78% to 91%. Again, statistical evaluation on the level of agreement was not reported.

**Ongoing evidence**

A page on the [technology developers’s website](#) lists six clinical studies and includes links to trial registry entries for these. The majority are listed as completed, but it is unclear whether results of all are yet available.

The technology developer states that they are currently undertaking further evidence generation. They are awaiting ethical approval to run health economic studies at a range of
teaching hospitals in the South East of England. The paediatric study includes five sites and the adult study includes three sites.

**Areas of uncertainty**

The published evidence for ResAppDx-EU (Porter et al. 2019) has evaluated ResAppDx-EU in children; it is unclear at this time if the evidence is transferable to an adult population. Some evidence is also available in adults but at the time of writing this is limited to conference abstracts rather than full publications and only assessed diagnosis of COPD.

The evidence identified reported applications intended for continuous and non-continuous use (ResAppDx-EU is non-continuous use) and further, more detailed work would be required to assess the advantages and disadvantages of continuous versus non-continuous use applications.

**Conclusions**

Published evidence for the effectiveness of ResAppDx-EU as a tool to diagnose acute respiratory disease, including pneumonia, is available from one published diagnostic study in children. Additional evidence for adults is available from unpublished conference posters, but these only measured COPD diagnosis. The evidence found for ResAppDx-EU reports a diagnostic outcome (percentage agreement). We did not identify any evidence, on other outcomes, such as influence on changes in patient management after diagnosis, or assessments of cost effectiveness. Further studies into the clinical and cost effectiveness of ResAppDx EU are ongoing.
### Brief literature search results

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<th>Resource</th>
<th>Results</th>
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| **HTA organisations**                         | **Healthcare Improvement Scotland**  
We did not identify any publications on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.  

We did identify the following point-of-care test.  
**SHTG 008-18 C-reactive protein point-of-care testing.**  
Advice for NHS Scotland:  
Using C-reactive protein (CRP) point-of-care testing as part of the holistic clinical assessment of adult patients attending primary care with symptoms of lower respiratory tract infection shows potential as a cost-effective way to target antibiotic prescribing. However, the size of the reduction in antibiotic prescribing and the likely impact on clinical practice is unknown. There is little published evidence on the use of the test in children or older people. Additional piloting, with monitoring and evaluation, should be undertaken by the organisations in Scotland with responsibility for diagnostic testing, prior to any widespread implementation of CRP testing.  

**Health Technology Assessment Group**  
We did not identify specific evidence on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.  

We identified the following condition pages for various respiratory conditions and their diagnosis:  
- Respiratory tract infection: [https://www.hse.ie/eng/health/az/r/respiratory-tract-infection/](https://www.hse.ie/eng/health/az/r/respiratory-tract-infection/)  
| **Health Information and Quality Authority**  | We did not identify any evidence for this topic.                                                                                                                                                                                                                                                                                    |
| **UK guidelines and guidance**                | **SIGN**  
We did not identify any evidence for this topic.                                                                                                                                                                                                                                                                                    |
| **NICE**                                      | We did not identify specific evidence on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.  

We identified the following guidelines for relevant conditions:  
- Chronic obstructive pulmonary disease in over 16s: diagnosis and management (NG115). [https://www.nice.org.uk/guidance/ng115](https://www.nice.org.uk/guidance/ng115)  
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<th>Secondary literature and economic evaluations</th>
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<tr>
<td><strong>ECRI</strong></td>
<td>We did not identify any evidence for this topic.</td>
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<tr>
<td><strong>Cochrane library</strong></td>
<td>We did not identify any evidence on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.</td>
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<td><strong>Medline (Ovid)</strong></td>
<td>We did not identify any evidence on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.</td>
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<td><strong>Cochrane library</strong></td>
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<tr>
<th>Ongoing primary or secondary research</th>
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<td><strong>PROSPERO database</strong></td>
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<tr>
<td><strong>Clinicaltrials.gov</strong></td>
<td>We did not identify any evidence on point-of-care smartphone platforms for the diagnosis of acute respiratory disease.</td>
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<th>Other</th>
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| **Additional evidence submitted by the topic proposer** | In additional to the Porter et al. study above, the manufacturer submitted the following documents:  
- Conference poster: Diagnosis of Chronic Obstructive Pulmonary Disease (COPD) using a smartphone based, cough centred algorithm in a mixed disease acute care cohort. |
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<th><strong>Date of search:</strong></th>
<th>March 2020</th>
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<tr>
<td><strong>Concepts used:</strong></td>
<td>ResApp, ResAppDx, telehealth,</td>
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