Horizon Scanning Research & Intelligence Centre

New and emerging technologies for the diagnosis and monitoring of Chronic Obstructive Pulmonary Disease (COPD)

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EXECUTIVE SUMMARY

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity and mortality worldwide, leading to a large and increasing burden on patients, carers and health services. However, despite its significant impact, there remain several key issues facing the management of COPD. These include delays in diagnosis, meaning that patients miss out on appropriate care early in the development of their disease; and the empirical treatment of COPD exacerbations, which exposes some patients to inappropriate antibiotic and corticosteroid therapy, a particular concern given the increasing development of antibiotic resistance and the potentially significant side effects of corticosteroids.

This review sought to determine whether technologies currently in development could address these issues by identifying and reviewing new and emerging technologies for the diagnosis and monitoring of COPD. Technologies were identified by searching technology and bibliographic databases, clinical trial registries, commercial media, and other online sources, as well as consultation with clinical experts. A panel of clinical experts and patients with COPD then gave their views on each technology's degree of innovation, potential for impact, acceptability to users, and likelihood of adoption.

In total, 80 new and emerging diagnostic and monitoring technologies were identified and included in the report, of which 25 were considered to be particularly promising. These covered a wide variety of technology types, including telehealth, vital signs monitoring technologies, questionnaires, imaging modalities, biomarker tests, spirometry and wearable sensor technologies.

Biomarker tests were the largest identified field, and those based on a sample of sputum or saliva, providing advance warning of an exacerbation or identifying the cause of an exacerbation, and/or acting at the point of care were considered to be the most innovative and likely to offer patient benefit. Several wearable and other connected devices were identified that may offer patients the ability to self-monitor their disease and detect the early signs of an exacerbation, and some of these were considered to have a high potential for service and patient impact. A number of imaging technologies were also considered to be highly innovative, but were not thought to have wide application for routine COPD care in the NHS, while telehealth technologies were not considered promising due to the lack of demonstrable improvement in patient outcomes and a poor cost-benefit balance.

The most promising technologies identified by this review are recommended as a focus of future translational and clinical research funding, ultimately to facilitate their timely evaluation and adoption within the NHS. These technologies have the potential to meet a clearly identified unmet need in COPD care through supporting earlier diagnosis, the timely recognition of acute exacerbations, and improved targeting of treatment during exacerbations, potentially avoiding inappropriate use of antibiotics and corticosteroids.
ACKNOWLEDGEMENTS

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Miss Louise Dixon, Medical Student intercalating in Public Health.
Dr Derek Ward, Co-Director and Medical Advisor.
Mrs Joanna Smith, Senior Analyst.

Healthcare professionals
The following clinical experts kindly gave us their advice and views on relevant technologies:
- Karen Heslop, Respiratory Nurse Consultant, Chest Clinic, Royal Victoria Infirmary, Newcastle.
- Dr Steve Holmes, General Practitioner with Special Interest in COPD, Shepton Mallet, Somerset.
- Dr Nicholas Hopkinson, Clinical Senior Lecturer at Imperial College and Honorary Consultant Chest Physician, The Royal Brompton Hospital, London.
- Dr Colm Leonard, Consultant Respiratory Physician, University Hospital of South Manchester NHS Foundation Trust, Manchester.
- A further anonymous healthcare professional.

Statement of potential conflicts of interest: none declared.

Members of the public affected by COPD
Members of the Birmingham Lung Improvement Study (BLISS) Patient Advisory Group (PAG) kindly gave us their views on relevant technologies, and Dr Alexandra Enocson, University of Birmingham, helpfully facilitated their involvement.

The NIHR Horizon Scanning Research and Intelligence Centre is grateful to all those who helped us to include both a healthcare professionals’ and potential users’ perspective in this report. We thank them for their time and valuable contributions.

We would welcome your views on this report.
Please complete our brief online survey at this link:
https://www.surveymonkey.com/s/X7WW6QX
1. AIMS OF THE REVIEW

This review aimed to determine whether new and emerging technologies currently in development could address key identified research needs in the field of chronic obstructive pulmonary disease (COPD) in order to inform future research priorities and NHS evaluation activities. New and emerging technologies that claim to diagnose COPD, diagnose the cause of an acute exacerbation of COPD (AECOPD), and/or monitor the progression of COPD (both during stable disease and exacerbations) were identified. Clinical experts and patient representatives were then asked to comment on the technologies to determine those that were considered most innovative, acceptable and likely to make an impact on patients and health services in the future.

1.1 COPD

1.1.1 OVERVIEW OF THE CONDITION

COPD is a lifelong, incurable, disabling condition\(^1\) that is primarily caused by tobacco smoking and is characterised by an airflow obstruction that is not fully reversible\(^2\). Patients classically experience a progressive dyspnoea (shortness of breath), restricting activities of daily living and reducing quality of life\(^3\). Exacerbations of COPD result in an escalation of symptoms and possible hospitalisation. The resulting impact of COPD is that of a major cause of morbidity and mortality, which leads to a significant burden on patients, carers and health services worldwide\(^4\).

1.1.2 THE IMPACT OF COPD

In England and Wales, there were 1,530,763 adults registered with COPD in primary care during 2011, representing a crude prevalence of 2.42\(^%\)\(^5\). A model based on published literature and healthcare data by Stang \textit{et al}\(^6\), estimates a further three million people are living with undiagnosed COPD.

COPD commonly presents in the fifth and sixth decades of life with exertional dyspnoea, chronic cough productive of sputum, wheeze and frequent episodes of bronchitis\(^7\); symptoms vary over the course of the day and exhibit seasonal variation\(^8\). The disease may manifest as pulmonary hypertension\(^9\), lung cancer\(^10\), osteoporosis\(^11\), poor nutrition\(^12\), anaemia\(^13\), fatigue\(^14\), sexual dysfunction\(^15\), anxiety, and depression\(^16\). It has been estimated that 74.6\% of patient with COPD have a degree of depression and anxiety\(^17\), however the association is complex. The symptoms associated with COPD and resulting psychological anxiety are an important cause of reduced quality of life (QoL)\(^18\). It is theorised that anxiety may contribute to episodes of AECOPD\(^19\), therefore resulting in an anxiety-exacerbation cycle of causality\(^20\).
The severity of COPD and dyspnoea experienced by patients has been shown to have a marked impact on health related QoL. The greater the severity of airway obstruction, the worse the QoL. Moreover, in the event of an exacerbation of COPD, a significant reduction of QoL is observed\(^1\). However, QoL is associated more closely with the degree of dyspnoea as determined, for example, by the Medical Research Council (MRC) dyspnoea scale\(^2\).

### 1.1.3 THE MANAGEMENT OF COPD

The current care pathway for the diagnosis and management of COPD is outlined in recent guidelines produced by the National Institute for Health and Care Excellence (NICE)\(^3\). Patients presenting with at least one symptom of COPD, over the age of 35, and with at least one risk factor, are recommended for further investigation\(^4\). A definitive diagnosis is made by confirming airway obstruction using pulmonary function tests according to the European Respiratory Society 1993 reference values\(^5\): an FEV\(_1\)/FVC ratio <0.7 and FEV\(_1\) <80% predicted for age and sex is considered to represent airflow obstruction\(^6\). Spirometry is the most commonly used form of pulmonary function test, objectively measuring obstruction using a reliable, non-invasive device\(^7\).

Inhaled therapy is the mainstay of COPD treatment\(^8,9\). It is primarily used for symptomatic relief, although a recent literature review by Welte et al hypothesised that long acting bronchodilators may also limit the decline in lung function\(^10\). First line pharmacological therapy is an inhaled short-acting bronchodilator\(^11\) (β\(_2\) agonist or muscarinic antagonist) taken as required in order to relieve dyspnoea. If patients continue to experience persistent dyspnoea, a further inhaled agent (long acting muscarinic antagonist/β\(_2\) agonist/corticosteroid) should be introduced\(^12\). In addition to inhaled therapy, long-term oxygen therapy in more advanced disease stages has a clear role in modifying survival rates and reducing long-term lung function loss\(^13\).

The treatment of acute exacerbations of COPD has similarities to the treatment of stable COPD, in that worsening dyspnoea is treated using nebulised/inhaled bronchodilators in increasing doses. Unless contraindicated, oral corticosteroids are recommended in all patients. Systemic corticosteroids are of benefit in exacerbations with underlying eosinophilic inflammation, estimated to be one third of cases, where they have been shown to reduce recovery time and treatment failure\(^14\). However, corticosteroids have a significant side effect profile, including weight gain, diabetes and secondary infections. Furthermore, the optimal

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\(^A\) FEV\(_1\) = the volume of air that the patient is able to exhale in the first second of forced expiration.

\(^\) FVC = the total volume of air that the patient can forcibly exhale in one breath.

\(^\) FEV\(_1\)/FVC ratio = the ratio of FEV\(_1\) to FVC, often expressed as a percentage.
duration and dosage has yet to be determined\(^ {35} \). If sputum is purulent, or there are clinical signs of pneumonia, empirical antibiotics are prescribed. The use of such therapy in exacerbations that do not originate from a confirmed bacterial infection results in patients receiving unnecessary treatment\(^ {36} \). In addition, inappropriate use of antibiotics gives rise to increasing resistance of organisms to treatment\(^ {37} \).

1.2 CURRENT ISSUES IN THE DIAGNOSIS AND MANAGEMENT OF COPD

Current issues in the diagnosis and management of COPD were identified through a search of the published medical literature and can be summarised as follows:

1.2.1 LIMITATIONS TO THE USE OF SPIROMETRY

A common consideration raised in the published literature concerns limitations in the use of spirometry for the diagnosis of COPD. Pistelli et al evaluated the use of spirometry and found elderly patients frequently encountered difficulties due to “fatigue, a lack of co-ordination and cognitive impairment”\(^ {38} \). Similarly, Lam et al conducted a systematic literature review evaluating the use of spirometry in COPD screening and diagnosis, finding the use of spirometry alone to be inadequate due to differing guidelines as to what constitutes COPD\(^ {39} \). In addition, Fromer cites a lack of awareness and knowledge of the use of spirometry in the investigation of COPD amongst general practitioners leading to the delayed diagnosis of many patients, particularly in non-smoking subgroups\(^ {40} \).

1.2.2 EARLY DIAGNOSIS AND DIFFERENTIATING COPD FROM OTHER DIAGNOSES

Fromer et al further recognised an issue in diagnosing patients with COPD where asthma co-exists\(^ {41} \). Similarly, Barnes identified the need for diagnostic criteria to differentiate asthma from COPD as a research need; arising from the observation of the tendency for physicians to treat both as the same disease in cases where they co-exist, despite current medications having different efficacies in the different disease states\(^ {42} \). Roche et al appraised current COPD care, concluding that emphasis should be on the early detection of disease\(^ {43} \). There is an unmet need for a reliable method of diagnosis that would enable accurate recognition of COPD and early differentiation of COPD from other respiratory diagnoses prompting the provision of appropriate treatment that could improve symptoms and slow or prevent disease progression\(^ {44} \).
1.2.3 MONITORING OF COPD PROGRESSION AND DETERIORATION

With the publication of their 2010 COPD guideline, NICE recommended the optimal method for monitoring of COPD for deterioration into an acute exacerbation as a research need\textsuperscript{45}. It was hypothesised that a single, multidimensional assessment may be a quicker and more practical alternative to the monitoring of FEV\textsubscript{1} or using the BODE index\textsuperscript{8}. Monitoring is commonly undertaken by health care professionals, although patients may also benefit from monitoring their disease themselves. A randomised controlled trial (RCT) of a comprehensive COPD self-monitoring programme by Bischoff et al found that it helped patients to more capably manage an acute exacerbation\textsuperscript{46}. Furthermore, the King’s Fund recommends the use of self-monitoring and management in chronic conditions more widely to reduce preventable hospital admissions\textsuperscript{47}.

1.2.4 IDENTIFICATION OF THE CAUSE OF COPD EXACERBATIONS

Several commentators recognise that developing methods to determine the cause of an exacerbation is a key research need; this would enable treatment to be tailored to the underlying pathology\textsuperscript{48}. Correspondingly, a review of the NICE Database of Uncertainties about the Effects of Treatments (DUET) highlights the use of corticosteroids\textsuperscript{49} and antibiotics\textsuperscript{50} for COPD exacerbations as treatment uncertainties. With approximately only half of acute exacerbations due to an underlying bacterial infection, antibiotics are not always necessary and their side effects and complications could therefore be avoided in many patients\textsuperscript{51}. Moreover, with only around one third of COPD exacerbations demonstrating eosinophilic inflammation, corticosteroid use may also be of limited benefit for many patients, who experience their adverse effects for no gain\textsuperscript{52,53}. A diagnostic test, biomarker or similar alternative that could identify the causative agent or pathological process underlying COPD exacerbations would allow antibiotic and corticosteroid therapy to be prescribed more appropriately.

In conclusion, there is a need for novel approaches, including tests that can be used at the point of care (POC), to diagnose COPD, diagnose the cause of acute exacerbations, and to monitor progression of the disease. Technologies able to address these needs would enable COPD treatment to be more appropriately targeted to the patient’s needs, help reduce avoidable hospitalisations and the frequency of exacerbations, and reduce unnecessary prescribing of antibiotics and corticosteroids.

\textsuperscript{8} BODE index – a multidimensional indicator of disease severity and prognosis that incorporates the measurement of body mass index (BMI), airflow obstruction, dyspnoea and exercise capacity.
2. METHODS

2.1 SEARCH STRATEGY

We sought to identify new and emerging technologies for the diagnosis and monitoring of COPD by searching a range of online sources, including commercial media, research funding agency websites, clinical trial registries, scientific publications, conference reports, commercial databases of research and development, professional and patient group websites, and health technology assessment agency websites (Appendix 1). Sources were further supplemented by a general internet search. Searches were conducted according to pre-defined search terms representing synonyms for COPD as well as diagnostic and monitoring technologies in development (Appendix 2). In addition, contributing experts (section 2.2) were asked to suggest any further technologies in development or current research that they were aware of, but which were not already identified.

Technologies were filtered to select for those which were within the review’s scope. Those fulfilling either of the following criteria were included in the review:

- New technology: already licensed and CE marked or launched in the UK for 24 months or less, launch stage or early post-marketing or early diffusion stages.
- Emerging technology: technology in development and expected to be CE marked within the next 18 months, phase ≥ II clinical trial, pre-launch or pre-marketing stage.

The resulting technologies were then prioritised with the assistance of the HSRIC review medical advisor to select those which were innovative. Technologies were included if they met either of the following criteria:\(^{\text{c}}\):

- A completely new technology with no direct comparators.
- A significant incremental innovation to similar existing technologies.

2.2 CLINICAL AND PATIENT ASSESSMENT

Technologies were considered by a panel of clinical experts and patients. The clinical expert panel comprised five clinicians, representing general practitioners, respiratory nurse consultants and consultant respiratory physicians. They were asked to provide comments on specific aspects of each individual identified technology (Table 1). In addition, they were encouraged to add any additional comments that may be relevant to the review aims.

\(^{\text{c}}\) Technologies were not excluded at this stage in cases where their innovativeness could not be determined without input from experts.
**Table 1: Fields for analysis by clinician panel**

<table>
<thead>
<tr>
<th>Analysis topic</th>
<th>Detailed questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>What features do you believe are innovative?</td>
</tr>
<tr>
<td></td>
<td>Are these innovations significant?</td>
</tr>
<tr>
<td>Impact</td>
<td>Is this technology likely to have a significant impact on patient outcomes or NHS systems and resources?</td>
</tr>
<tr>
<td></td>
<td>Are there any other potential impacts of this technology?</td>
</tr>
<tr>
<td>Adoption</td>
<td>Does this technology seem likely to be adopted into UK practise?</td>
</tr>
<tr>
<td></td>
<td>What barriers to its adoption can you foresee?</td>
</tr>
<tr>
<td>Missing technologies</td>
<td>Are there any related technologies that are missing?</td>
</tr>
</tbody>
</table>

A patient panel, comprising two patients with COPD from the Birmingham Lung Improvement Study (BLISS) Patient Advisory Group (PAG), were also asked to provide comments on specific aspects of each individual identified technology (Table 2).

**Table 2: Fields for analysis by patient panel**

<table>
<thead>
<tr>
<th>Analysis topic</th>
<th>Detailed questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>What features do you believe are new?</td>
</tr>
<tr>
<td>Impact</td>
<td>Is this technology likely to have a significant impact on you?</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Would you be willing to use this technology?</td>
</tr>
</tbody>
</table>
3. RESULTS

A total of 140 technologies were found in the initial identification stage (Figure 1). Searches produced a varying number of relevant technologies depending on the source (Appendix 3).

A review of the technology names, developers and clinical trial identifiers led to 12 of the initial list being identified as duplicates. In addition, 36 technologies were removed at the filtration stage while a further 12 were removed at prioritisation. No further technologies were identified by the expert or patient panel. A total of 80 new and emerging technologies met the inclusion criteria. These technologies are summarised in Appendix 4 and referred to by the corresponding number throughout the text. The technologies are grouped by technology type into eight subgroups (Table 3). Grouping the technologies ensured the final table was manageable and approachable to the expert and patient panels, as well as allowing comparison between similar technologies within each section.

**Table 3: Number of technologies by subgroup.**

<table>
<thead>
<tr>
<th>Technology subgroup</th>
<th>Number of technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wearable monitoring technologies</td>
<td>6</td>
</tr>
<tr>
<td>Biomarker technologies</td>
<td>31</td>
</tr>
<tr>
<td>Sample used:</td>
<td></td>
</tr>
<tr>
<td>Blood 17</td>
<td></td>
</tr>
<tr>
<td>Sputum 4</td>
<td></td>
</tr>
<tr>
<td>Saliva 2</td>
<td></td>
</tr>
<tr>
<td>Breath 5</td>
<td></td>
</tr>
<tr>
<td>Other 3</td>
<td></td>
</tr>
<tr>
<td>Telehealth technologies</td>
<td>21</td>
</tr>
<tr>
<td>Imaging technologies</td>
<td>6</td>
</tr>
<tr>
<td>Vital sign monitoring technologies</td>
<td>4</td>
</tr>
<tr>
<td>Spirometry technologies</td>
<td>3</td>
</tr>
<tr>
<td>Questionnaire based technologies</td>
<td>4</td>
</tr>
<tr>
<td>Other technologies</td>
<td>5</td>
</tr>
<tr>
<td>Total number of technologies</td>
<td>80</td>
</tr>
</tbody>
</table>
Search hits 
(n = 4171) -> Non-relevant hits 
(n = 4031) -> Technologies identified 
(n = 140) -> Duplicates removed 
(n = 12) -> Technologies filtered 
(n = 128) -> Technologies excluded 
(n = 36) -> Technologies prioritised 
(n = 92) -> Technologies excluded 
(n = 12) -> Technologies assessed 
(n = 80) -> Additional technologies identified by clinical experts 
(n = 0) -> Technologies included in the final report 
(n = 80)
3.1 RESULTS BY SUBGROUP

3.1.1 WEARABLE TECHNOLOGIES

All identified wearable technologies aimed to monitor stable COPD through devices worn either across the chest or on the wrist. They all demonstrated some degree of innovation. Although devices monitoring respiratory rate, wheeze, blood oxygenation and/or temperature are already in use, several devices enabled self-monitoring at home with remote access by clinicians. However, the impact of the WHolter (1), Breeze@home (2) and VigilCare (4) devices was judged to be minimal, with one expert commenting that they had “limited benefit in the real world”. Furthermore, the feasibility of multiple clinicians interpreting large volumes of recorded data was questioned and the patient panel commented that users may be unwilling to wear a “cumbersome” looking device, and they expressed concern about “the idea of having the restriction of a band around [their] chest”.

RESpeck (6), received mixed reviews from the panels; one expert remarked “long term ambulatory monitoring in a form that is tolerable to patients is highly desirable”. In contrast others commented “not useful in my opinion” and “adoption: unlikely”. Again, the issue of requiring a clinician to interpret the data was raised as a barrier to use.

The Wrist-based pulse oximeter (3) and BuddyWOTCH (5) devices are new alternatives to existing fingertip pulse oximeters, providing continuous monitoring of blood oxygenation without limiting movement of the user’s hands. In addition, BuddyWOTCH captures physical activity, temperature and heart rate. Both technologies were considered promising, with patients keen to try a more compact, watch style device. Experts considered them “potentially useful… for longer term monitoring… in vulnerable groups… [and] for pulmonary rehabilitation”. Concerns were expressed regarding the reliability of wrist-based monitoring, however a “potentially large” impact could be expected if they were “more reliable than…standard finger pulse oximeters”.

3.1.2 BIOMARKER TECHNOLOGIES

Of the 31 biomarker tests identified, the majority were based on blood samples. Alternative samples included sputum, bronchial aspirate, saliva and volatile organic compounds from breath samples.

Biomarkers for the diagnosis of COPD

Diagnostic biomarkers accounted for the largest number of biomarker technologies. An array of blood based biomarkers were dismissed by experts as not being of any true clinical value,
saying “possibly as a research tool rather than clinical”, despite some cases being “highly innovative”. AlphaKit Quickscreen Device (20), a POC test for α₁-anti-trypsin deficiency, was also disregarded by experts, due to the lack of a clinical requirement.

Fourier transform infrared spectroscopic (FTIR) monitoring (27) used a sputum sample to rapidly diagnose COPD; experts commented that this was “interesting and if effective then impact and adoption [are] possibly significant”. A further biomarker panel using sputum to diagnose asthma-COPD overlap (26) was considered to be “of interest in secondary care clinics”. Of particular interest was COPD-SPOC (28), a novel, saliva based POC test for the diagnosis of COPD incorporating three biomarkers, which experts said had the “potential to change practice”.

Five breath based diagnostic biomarkers were identified (30-34). Experts were ambivalent towards these developments however, saying that although the technology is of “moderate innovation”, it is “miles away from any likelihood of impact/adoption”.

Aα-Val<sup>360</sup> (8) was the most promising biomarker in this category, having been proposed as a method to identify patients with early COPD at risk of progression. Experts commented that it was “highly innovative… targeting high risk individuals”.

**Biomarkers for COPD monitoring**

Several inflammatory blood biomarkers were proposed for monitoring COPD for risk of an acute exacerbation. However, fibrinogen, alone or with C-reactive protein (CRP) and leukocyte count (10 and 12) were noted to be “non-specific indicators of inflammation” and therefore “unlikely to be much impact or [have much] chance of adoption in the NHS”. Serum uric acid (21), although being researched as a potential low-cost biomarker, was similarly dismissed due to poor specificity for COPD<sup>55</sup>, as was a saliva CRP test (29).

The Home-use sputum test (24) claims to provide advance warning of an AECOPD in the community. Experts were highly optimistic, commenting “this would be useful and may help identify pathogens early so treatment can be commenced”, and highlighting the potential to “reduce antibiotic use”. Patients commented on its potential to “reassure patients”. A possible restriction of the technology however, was that “identifying a bacterium does not always mean that the cause of symptoms is identified”.

**Biomarkers for diagnosing an AECOPD**

Although being developed to diagnose an AECOPD, neither the serum procalcitonin-Q (14) nor hydrogen sulphide (22) biomarkers were thought to have promise. Clinical trials found that
despite the possibility of rapid results, PCT-Q was poorly correlated with clinical outcome. Likewise, little evidence was found to support the reliability of a hydrogen sulphide biomarker.

**Biomarkers to determine the cause of an AECOPD**

Technologies in this category aimed to identify the cause of an AECOPD in order to better direct specific management. Peripheral blood eosinophil count (7) was proposed as a biomarker to direct corticosteroid therapy; experts were favourable, commenting “the test is very easily undertaken…worth exploring more”. Conversely, the impact of the technology was judged to be “unclear, as most exacerbations are in the community and will need a blood test for this biomarker”. The CRP POC test (9) was applauded for its innovation in providing an accessible finger prick test to community care. One expert remarked “yes to innovation, yes to potential impact and adoption is a strong possibility if [it is] shown to help decision making”. Where CRP had previously been criticised for poor specificity, the procalcitonin (PCT) biomarker (13) was commended for being a “more specific marker of infection”. Researchers claimed it was able to differentiate between a bacterial and non-bacterial cause of an AECOPD, prompting an expert to report “there is a strong chance of high impact (more appropriate exposure to antibiotics) and adoption”.

### 3.1.3 TELEHEALTH TECHNOLOGIES

Telehealth is a popular area of development for chronic disease and represented a large number of all technologies reviewed. Many of the devices were in the late stages of development from established commercial developers and had already obtained a CE mark, making them more likely to come to market within the specified timeframe.

The clinician panel’s assessment of telehealth was generally negative, with comments aimed at the category as a whole, rather than individual technologies. One expert cited Pinnock et al., who undertook a UK multicentre RCT to evaluate the effectiveness of touchscreen telemonitoring; “the current best evidence is that cost per quality-adjusted life-year for telehealth in COPD is ~£130,000”. A further expert cited a Cochrane review and meta-analysis by McLean et al., concluding that although telehealth did reduce the odds of A&E attendance and hospitalisation (OR=0.27; 95% CI 0.11-0.66 and OR=0.46; 95% CI 0.33-0.65), it did not improve COPD QoL (mean difference -6.57; 95% CI -13.62-0.48) nor the odds of death (OR=1.05; 95% CI 0.63-1.75). As in the assessment of wearable monitoring technologies, concern was expressed regarding the increased burden on clinicians; “the problem with this kind of technology is that you need a healthcare professional to look at the data. This is often the problem”.

Most of these monitoring devices are intended for use in the home. The Care Innovations Guide (38), Intel® Health Guide PHS6000 (39), Alere HomeLink (40), CHROMED monitoring
Three technologies were identified which use sensors to automatically monitor patients, without relying on user input. The Virtual Medical Assistant version 2.0 (41) uses an under-the-mattress sensor to wirelessly detect heart rate, respiratory rate, and patient movement. The technology is able to transmit data to any wireless network and can be integrated with other software applications, a progression from the developer, Sensiotec Inc.’s version 1.0. Experts considered the technology innovative, and of potential use in frail/elderly patients or those in single hospital rooms as an early warning system. However, concerns regarding the likelihood of false alarms meant that it had limited utility and widespread adoption of the technology was deemed unlikely. Correspondingly, the Smart inhaler (54) uses an innovative inhaler mounted sensor to remotely monitor medication use. Highlighted as “useful for trials...to monitor compliance and early signs of an AECOPD”, experts agreed with the patient panel and commented on the high potential impact and likely adoption of this technology. The semi-automated cough classifier (57) uses novel technology to monitor COPD through cough frequency. Although the expert panel were in agreement that the technology was innovative, the usefulness of the device was in doubt, with no known association between cough frequency and disease severity.

### 3.1.4 Imaging Technologies

The majority of imaging technologies were considered innovative by the panels, but exhibited little potential for impact across the wider NHS, and therefore experts predicted their uptake would be limited. Although developers claimed that Mobile SPECT imaging (60) has the...
potential to detect early changes in COPD, experts commented “[it is] hard to see that this would catch on for diagnosing early disease compared to existing technologies” and “I am not optimistic about [the] impact and adoption in [the] current NHS climate”. Similarly, the CT perfusion scan (61), aimed at the early diagnosis of COPD, received little enthusiasm from experts. It was suggested that it may have more impact as a specialist tool for the targeted treatment of emphysema.

The PRM™ (parametric response map) COPD (59), quantitative CT scan (62), and human lung regional ventilation defect severity measuring MRI (64), despite being marketed for diagnosis and monitoring, were thought to be of more use for clinical research rather than routine care. Only the diagnostic transthoracic parametric pulsed doppler ultrasound system (63), received any positive feedback from experts, one commenting that it is “interesting, innovative, [with] potential for impact and adoption in [the] NHS”. However, another contradicted this with “impact – low. Adoption [in] specialised centres only”. Overall, this category showed innovation, however, no technologies are expected to have a significant wide scale impact on the clinical diagnosis or monitoring of COPD in routine care.

3.1.5 VITAL SIGN MONITORING TECHNOLOGIES

The vital sign category included four devices, all of which offered novel methods of monitoring COPD. Both the Respiratory Holter-COPD (66) and the EverOn™ monitor (65) monitored respiratory rate, and one expert noted, “technology for the accurate long-term measurement of respiratory rate in hospital/home may be useful”. However, neither were particularly new and experts were “not sure how [they] will be useful in the real world of patients and clinical practise”.

The Nonin Bluetooth Smart Model 3230 finger pulse oximeter (67) is claimed to be the first technology of its kind by the developer. Although the device “may provide some additional useful connectivity on certain contexts, e.g. with smartphone apps”, and a potential user from the panel commented “a good idea. I would use it.”, others said it would have “no significant impact compared to available devices. Adoption: minimal”. A similar device, Capno-Pulse (68), developed as a non-invasive carbon dioxide monitor was also considered, “not especially novel” and was expected to have, “minimal impact” by experts.

3.1.6 SPIROMETRY TECHNOLOGIES

All three spirometry devices (69-71) use a smartphone mounted, handheld device for home monitoring of COPD. Reviews were mostly encouraging, with good potential for use in conjunction with training and follow-up by respiratory nurse specialists. Patients thought they “could have [a] considerable impact” and were “definitely” acceptable to users. Poor user
technique could be a possible limitation to the effectiveness of the devices, leading to unreliable results. Resp.io’s smartphone spirometer (71) incorporated the further innovation of using smartphone accelerometers to ensure optimal posture during spirometry and thereby promoting good technique. Two devices were also Bluetooth connected (69 and 70). However, as for many telehealth technologies, their use was ultimately expected to be limited due to the requirement for an interpreting clinician and/or patients capable of self-management in response to the results.

### 3.1.7 QUESTIONNAIRE-BASED TECHNOLOGIES

Questionnaire use was generally acceptable to the patient panel with the caveat of them not being too long as “patients do get tired of filling in forms”. Two questionnaires aimed to monitor the severity of exacerbations in order to inform clinical decisions regarding care. The DECAF score (72) was seen as a “useful innovation to predict safe early discharge”. Similarly, the DOSE index (75) is “well validated as an option (Jones et al⁶⁸)...I do find it difficult to see why [it is] not used more as [there is] plenty of other evidence”. Two further questionnaires focussed on diagnosis, particularly the COPD screening questionnaire (74). By quantifying smoking history and symptoms, it aimed to identify those “at risk of COPD” to facilitate early diagnosis. Experts were divided in their opinions; one felt it was “a useful way to identify and encourage people to get spirometry done” whereas another said it was “not novel, tools already exist”. Correspondingly, expert opinions of the asthma-COPD overlap syndrome (ACOS) questionnaire (73) were contradictory. One expert commented “possibly a useful tool for clinical practice”; however a further expert noted “limited utility, low potential impact or adoption”.

### 3.1.8 OTHER TECHNOLOGIES

The Short Physical Performance Battery (SPPB) (76) was described as “simple yet innovative and has the potential for impact and adoption”. This timed walking test aims to monitor COPD, particularly for risk of admission and mortality. Experts specified its use “in [a] frail/co-morbid population”.

Three further technologies aimed to diagnose the cause of an AECOPD to enable tailored treatment regimes. The developer of RESPOC (78), a POC test, claimed that it is capable of identifying respiratory viruses within one hour, with an equivalent accuracy to that of standard laboratory tests. Multiplex-PCR (80) used similar technology to diagnose viral infections using samples of tracheal or nasal aspirate. HIRA-TAN semi-quantitative PCT (79) is a similar technology, providing a quick and sensitive identification of bacterial infections. All three technologies received positive reviews from experts; “innovative… potential for impact and adoption”.

20
4. DISCUSSION

Research in the field of COPD is advancing rapidly. This review identified developing technologies focussed on early accurate diagnosis in order to offer appropriate treatment and early smoking cessation advice; reliable monitoring in order to guide prognostic predictions or identify the early signs of an AECOPD; and determination of the cause of exacerbations to tailor therapy, ensuring antibiotics and oral corticosteroids are not used in circumstances where they offer no benefit.

4.1 ADDRESSING THE REVIEW AIMS

Searches identified 80 potentially innovative new and emerging technologies, of which 25 were evaluated as having a high degree of innovation and potential for impact and adoption in the NHS (Table 4). These technologies broadly addressed the areas which were identified as current issues in COPD care: novel approaches and POC tests able to accurately diagnose COPD, determine the cause of COPD exacerbations, and monitor the progression of the disease.

Biomarkers offer a possible alternative to spirometry in the diagnosis of COPD, with innovative markers using samples of saliva or sputum able to offer less invasive testing and earlier diagnosis. Non-invasive sputum biomarkers further addressed a specific issue identified as a research need, the diagnosis of asthma-COPD overlap.

The issue of availability and usability of lung function testing may be improved with the use of the identified mobile phone based spirometers. Although not intended for diagnostic purposes, these technologies offered innovative methods for self-monitoring, a recurring theme across many of the technologies found. Self-monitoring was also a feature of telehealth, vital sign monitoring technologies and even biomarkers – with a home-use sputum test offering patients advance warning of an AECOPD.

Diagnosing the cause of an AECOPD was a key area of need that was addressed by six identified technologies, two of which offer this at the point of care. These may enable the targeted treatment of an AECOPD, avoiding the unnecessary use of antibiotics and corticosteroids.
Table 4: Promising technologies – those considered to demonstrate a high degree of innovation and potential for impact and adoption in the NHS

<table>
<thead>
<tr>
<th>Technology subgroup</th>
<th>Technology number and name</th>
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<td>Wearable technologies</td>
<td>3 - Wrist based pulse oximeter 5 - BuddyWOTCH</td>
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<tr>
<td>Biomarker technologies -</td>
<td>8 - Aα-Val(^{360}) biomarker</td>
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<tr>
<td>Diagnostic</td>
<td>26 - Biomarker panel: SP-A, sRAGE, MPO and NGAL for asthma-COPD overlap syndrome</td>
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<td></td>
<td>27 - Fourier transform infrared spectroscopic (FTIR) monitoring</td>
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<td></td>
<td>28 - COPD-SPOC (Saliva point of care) sensor</td>
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<td>Biomarker technologies -</td>
<td>24 - Home use sputum test</td>
</tr>
<tr>
<td>Monitoring</td>
<td></td>
</tr>
<tr>
<td>Biomarker technologies -</td>
<td>7 - Blood eosinophil biomarker</td>
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<tr>
<td>Determining the cause of</td>
<td>9 - CRP point of care test</td>
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<td>AECOPD</td>
<td>13 - Procalcitonin (PCT)</td>
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<td>Telehealth technologies</td>
<td>41 - Virtual Medical Assistant Version 2.0</td>
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<td>42 - Commander Flex</td>
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<tr>
<td></td>
<td>43 - MedVizer T400 Home Health Monitor</td>
</tr>
<tr>
<td></td>
<td>49 - ADAPT: After DischArge Pulmonary Tele-health</td>
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<td>50 - SmartScope System</td>
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<td>52 - Respiratory virtual clinics</td>
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<td>Spirometry technologies</td>
<td>69 - MySpi-roo</td>
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<tr>
<td></td>
<td>70 - MIR Smart One®</td>
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<td></td>
<td>71 - Smartphone spirometer</td>
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<td>Questionnaire technologies</td>
<td>72 - DECAF scoring system</td>
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<td>75 - DOSE index</td>
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<td>Other technologies</td>
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<td></td>
<td>78 - RESPOC Point-of-care testing for respiratory viruses</td>
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<td></td>
<td>79 - HIRA-TAN semi-quantitative PCR</td>
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<tr>
<td></td>
<td>80 - Multiplex PCR (mPCR)</td>
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</table>

4.2 ACCEPTABILITY OF TECHNOLOGIES

The use of a patient panel ensured that end-users’ perspectives on acceptability was incorporated into the consideration of each technology. In support of a systematic review of body worn sensors\(^{59}\), patients tended to prefer compact, simple devices that did not interfere with daily life. As a result, reviews of the wrist-worn devices were more positive than vest-like devices. Likewise, the three smartphone-mounted spirometry devices were favoured by the
patient panel for their ease of use and portability. The development of biomarkers that used samples other than blood or were applicable at the point of care were praised by both patients and clinicians as being more acceptable, practical, and less invasive.

### 4.3 TELEHEALTH DEVELOPMENTS FOR COPD

Clinicians did not consider developments in telehealth as generally useful or having widespread application, citing impracticality and cost as a barrier to use. In contrast, patients were in favour of devices that enabled them to self-monitor and communicate with their doctor or nurse. Experts noted the lack of evidence that variables such as cough frequency or inhaler use were associated with the risk of an AECOPD. Clinical trials of such systems were also generally measured in terms such as patient satisfaction, as opposed to conventional clinical outcomes, including spirometric values. In a field that is becoming increasingly saturated with similar products, yet experiencing little adoption within the NHS, it seems unlikely that telehealth will become a routine part of care for COPD until such technologies are demonstrated to improve patient outcomes and a feasible cost-benefit balance is achieved.

### 4.4 LIMITATIONS OF THE EVIDENCE

In many cases, clinicians were reluctant to comment on the potential of technologies to deliver on the claims made by developers, citing a lack of validation or clinical trial evidence. Although several technologies were reported to be within 18 months of launch or at/above phase II trials, little evidence of clinical validation for many of the technologies was found. Publication bias may have affected the available evidence, with trials demonstrating no significant benefit of a technology being less likely to be submitted for publication. Conversely, clinical trials with outcomes relevant to patients and the health service may not be occurring in the earlier stages of development, resulting in a lack of evidence (including economic evaluations) to support subsequent commercialisation and adoption.

### 4.5 WHAT THE REVIEW ADDS

This review identified several innovative technologies with the potential for impact in a disease that causes a significant burden to patients and health services in the UK and worldwide. Technologies have been identified with the potential to address several current key issues facing the management of COPD: innovative biomarkers for the early diagnosis of COPD provide an alternative to spirometry, while some new telehealth, wearable sensor, and
portable smartphone spirometer technologies may enable patients to monitor their own disease. Finally, biomarker tests and PCR technologies are in development to allow clinicians to determine the cause of an AECOPD at the point of care, allowing treatment to be tailored accordingly. Having identified key technologies in development, this review provides information that can contribute to ensuring future translational and clinical research funding is appropriately aimed at areas with the most potential to make a significant change to NHS COPD care and the quality of patients’ lives.

In addition, this review also identified developing technologies in the fields of telehealth and wearable devices which were thought to be less promising, impractical and/or poorly directed. Telehealth systems in particular have been subject to extensive evaluation. Research funding may therefore be better invested in alternative areas of COPD management.

A lack of appropriate validation for developer’s claims about the capability of their technologies was recognised. In several cases where validation trials had taken place, the measure of a technology’s efficacy was in unconventional terms. Those technologies without appropriate demonstration of efficacy will be limited in their ability to progress beyond the early development stages. Therefore, promising technologies should undergo early clinical validation using appropriate, conventional measures of disease state e.g. change in FEV₁ or BODE index, and incorporating economic measures, e.g. health resource utilisation, in order to facilitate the adoption of appropriate innovative technologies.
This review focused on selected aspects of the future of care for patients with COPD, the third leading cause of death in the world. A literature review, identified the need for innovative technologies to improve the diagnosis and monitoring of the disease. In total, 80 technologies were identified and determined to be both potentially innovative and either new or emerging. For each identified technology, the degree of innovation, potential for impact, and likelihood of adoption into NHS care was considered by panels of specialist clinicians and patients with COPD. Comments from the panels highlighted 25 promising technologies which are recommended as a focus of future translational and clinical research funding to facilitate their timely evaluation and adoption within the NHS. These technologies were considered to be the most promising for the future of COPD diagnostics and monitoring.
## APPENDICES

### APPENDIX 1: IDENTIFICATION SOURCES

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## APPENDIX 2: SEARCH TERMS

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## APPENDIX 3: IDENTIFIED TECHNOLOGIES BY SOURCE

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### APPENDIX 4: COMPLETE LIST OF TECHNOLOGIES IDENTIFIED WITH CLINICAL EXPERTS’ AND PATIENTS’ COMMENTS

#### 1) Wearable monitoring technologies

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<tr>
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<th>Description of technology</th>
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<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
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<td>1) WHolter</td>
<td>WHolter is a 24 hour ambulatory digital device intended for tracking wheeze and cough. The device consists of two sticky pads placed on the chest and a band placed around the chest. Three wires connect each sensor to a box which clips to clothing e.g. waistband/jacket. Sensors are specifically designed for lung-sound detection. It can be worn overnight or for 24 hours and then be returned to a specialised clinic that can analyse the recorded data. The acquired data is analysed using PulmoTrack software and searches for spectral patterns specific to certain lung sounds, marking their presence and duration on the graphical sonogram. Outside noises are cancelled out using patented ambient noise rejection techniques, to ensure the accuracy of physiological sound detection.</td>
<td>Product details: <a href="http://www.s-med.co.uk/s-med/media/s-med-pdf/iSonea_WHolter.pdf">http://www.s-med.co.uk/s-med/media/s-med-pdf/iSonea_WHolter.pdf</a> iSonea website: <a href="http://isonea.com/products/legacy-products/">http://isonea.com/products/legacy-products/</a></td>
<td>Monitoring of COPD</td>
<td>CE marked 04/08/2010. FDA approved 19/07/2010.</td>
<td>No trials found.</td>
</tr>
</tbody>
</table>

*Produced by iSonea Ltd., Israel. Formerly KarmelSonix Ltd.*
Expert comments:

- The algorithms may be innovative. Various other monitors available for cough, none I think for wheeze. Requires validation. Might be useful as an outcome measure in trials of treatments and conceivably for home monitoring more widely but would need evidence that performs better than symptom scores etc. Expert 1
- I think this would have limited benefit in the real world. It could be useful to establish baseline wheeze and cough but could encourage patients to focus on physical symptoms which may be unhelpful if these symptoms are part & parcel of the patient’s condition. Expert 2
- The use of sounds heard in the chest and their relevance to an acute exacerbation of COPD are not well established in acute and community settings. There is not a link between severity of wheeze and exacerbation (indeed in asthma very severe disease has a “silent chest”). Sound detection is likely to be tricky. I could find no validation of the use of the equipment that was published to indicate the equipment might be in any way reliable. Nothing here that would encourage me to invest further at this stage clinically. Expert 3
- Innovation: home monitoring for wheeze and cough is innovative but its place has yet to be defined in COPD. Our local cough clinic has developed and patented a cough monitor. Impact; hard to say, in theory it means a very active recording gets downloaded to clinic (primary or secondary care) and acted on but it still needs a human being to access the results and act on them. Adoption: In the current NHS climate the likelihood of staff being freed up to do this kind of thing is low unless some clear outcome benefits are shown such as avoiding hospital admissions or reducing intensity or duration of COPD exacerbations. Expert 4
- Innovation: Assessment of wheeze and cough during normal daily living. Distinguishing multiple breath sounds. No clinical trial data. Impact: Minimal impact to patient outcomes, but may be worth discussing with specialist cough centres. Adoption: Unlikely to be wholesale- cough centres. Expert 5

Patient comments:

- Innovation: Not seen or heard of this before – so think it’s new. Acceptability: Would not be willing to use this because I do not like the idea of having the restriction of a band around my chest.
- Not seen this before. Is it likely to be uncomfortable? I would wear it if it was considered necessary.
| Breeze@home | Breeze@home is a remote patient monitoring jacket intended for COPD patients. The patient wears the jacket, fastening with three clips and activates the on button. Using Vibration Response Imaging (VRI) Technology, the patient’s lung function is collected and transmitted to the clinician via a smart phone or tablet computer. The company claims the device is easy to use, low cost and provides real-time data.  

*Produced by Deep Breeze Ltd., Israel.* | YouTube video: [https://www.youtube.com/watch?v=Ux-8n6m2lzo](https://www.youtube.com/watch?v=Ux-8n6m2lzo)  


**Expert comments:**
- Not clear what this would be used for clinically - can’t be worn indefinitely. Maybe a use in clinical trials as an outcome measure. To date no evidence that remote monitoring in lung disease is useful. Expert 1
- Not likely to be of benefit in clinical practice. Expert 2
- VRI technology is not being used in general practice as far as I am aware and though a few published trials I am not sure that I can see when this would be used by patients in real clinical practice. Was not clear what exactly “lung function was being collected and transmitted”. This appears to be another using the same sort of technology as described in many of the prospective innovations. The technology measuring pulse oximetry and pulse rate would give some useful information; the use of steps to indicate an acute exacerbation is less informative as our steps reduction can be due to a number of issues. Temperature around the wrist is not going to be particularly useful – and none of the measurements will capture patient symptoms. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. Expert 3
- Same comments as above with additional one to say that I expect the jacket will be more reliable than the WHolter. Expert 4
- Innovation: Some physiological measurements can be made remotely and reviewed in another location, but the ability to measure lung function may be overstating the capabilities. ? Of use in children. Impact: Although providing some useful information the impact is likely to be minimal as collected data is unlikely to be used in isolation and will require additional investigations/review prior to changing any patient interventions. Important data correlating clinical symptoms with data is not available. Adoption: Unlikely as no clinical data. ? Of use in children. Expert 5
### Patient comments:
- **Impact:** Looks cumbersome, appears more suitable for housebound people. Acceptability: no does not appear to me at all.
- **This looks too cumbersome; I've already got enough which restricts my breathing. So no, I wouldn't wear this.**

### 3) Wrist Based Pulse Oximeter
A wireless, pulse oximeter which is worn on a patient’s wrist.

The technology is based on a photoplethysmography (PPG) sensor which detects the same amount of blood oxygen saturation information that conventional fingertip probes provide. It also uses a complementary blood flow sensor that allows continuous measurements of blood rheological parameters. The device would retail for ~$300.

*Produced by Oxitone Medical Ltd., Israel.*

<table>
<thead>
<tr>
<th>Expert comments:</th>
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</thead>
<tbody>
<tr>
<td><strong>Potentially useful if the measurements are actually accurate in clinical use and depending on battery life. For sleep studies and longer term monitoring. Same general point that so far there is no evidence that home physiological monitoring of COPD patients is useful. Abandoning the fingertip would be useful.</strong> Expert 1</td>
</tr>
<tr>
<td><strong>Could be a useful device for services such as pulmonary rehabilitation when patients are mobilising. Having a watch could be better than the normal finger pulse oximeter but this is much more expensive.</strong> Expert 2</td>
</tr>
<tr>
<td><strong>This appears to be another using the same sort of technology as described in many of the prospective innovations. The technology measuring pulse oximetry and pulse rate would give some useful information; the use of steps to indicate an acute exacerbation is less informative as our steps reduction can be due to a number of issues. Temperature at the wrist is not going to be particularly useful and none of the measurements will capture patient symptoms. Use of telehealth has had considerable investment within the UK and at the current time reviews of any benefit in COPD and other long term conditions are lacking, hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance.</strong> Expert 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medgadget:</th>
<th>Monitoring of COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxitone:</td>
<td>Patent pending.</td>
</tr>
<tr>
<td><a href="http://oxitone.com/products/">http://oxitone.com/products/</a></td>
<td>Estimated to reach UK market by end 2015. A fully functioning prototype, software and data centre have been developed.</td>
</tr>
<tr>
<td>YouTube marketing video of the product:</td>
<td>Clinical tests in Israel reported with &gt;300 successful measurements.</td>
</tr>
<tr>
<td><a href="https://www.youtube.com/watch?v=NdEHoiFlGcq">https://www.youtube.com/watch?v=NdEHoiFlGcq</a></td>
<td></td>
</tr>
</tbody>
</table>
In certain situations this could be very helpful but we currently discourage patients from buying their own pulse oximeters as they are prone to error but of course until now this refers to the use of fingertip probes. This device, if more reliable than the standard finger pulse oximeters, may be more useful. Innovative: yes. Impact: potentially large; for example, easy screening for sleep apnoea or picking up people slipping into COPD exacerbations. Adoption: same issue that it needs human beings to act on the readings. One will also have to be aware of confounding factors. For example, if a patient on home oxygen decides to sleep without his oxygen supply (as happens regularly due to partners being annoyed by noise of concentrator, or patient being irritated by the constant irritation of oxygen flow) then you get an alert that may not require an intervention. I think there needs to be a clear plan for target group and with outcome data to prove a benefit. Expert 4

Innovation: The innovation is in the way oximetry measurements are made, however pulse oximetry is not innovative in itself. The significance may lay in the reduction of motion artefact and may be more reliable in some groups e.g. for overnight oximetry/ambulatory assessments. Impact: No more than any other conventional method of measuring pulse oximetry. May be more convenient to some patients and specific indications as above. Adoption: Unlikely to have wide scale adoption, unless targeting specific uses as above and patients may prefer this technology. However, outcomes are not significantly different from current systems. Expert 5

Patient comments:

Innovation: As a watch type piece of equipment – looks new. Impact: Yes if it was compact enough. Acceptability: Yes would be willing to give it a go.
This seems good. I would wear it.

4) VigilCare
VigilCare is a wireless device intended for monitoring of patients suffering from COPD. It is designed to monitor the step activity and vital signs of patients remotely in real time. Patients wear a wireless monitor and sensors that send data to the server without the need for a PC or base station. Data is sent securely to medical professionals.

Produced by Agali Technologies, Inc., USA.

Product page: https://www.uml.edu/docs/Nick_Gildred%20Agali%20Final_tcm18-45828.pdf

Monitoring of COPD
Estimated UK launch October 2017
No trials found
Expert comments:
- Not clear exactly what is measured. Same general point that evidence so far is that home physiology monitoring doesn’t improve outcomes in COPD. Expert 1
- Could be useful as encouraging activity is really important for patients with respiratory problems. Patients often overestimate their levels of activity so this would be good to monitor. Expert 2
- Vital signs – it is not clear which signs are going to be monitored. Nor could I see how bulky the equipment is. This appears to be another using the same sort of technology as described in many of the prospective innovations. The technology measuring pulse oximetry and pulse rate would give some useful information; the use of steps to indicate an acute exacerbation is less informative as our steps reduction can be due to a number of issues. Temperature around the wrist is not going to be particularly useful – and none of the measurements will capture patient symptoms. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. Expert 3
- Innovative: yes. Impact: potentially but we need outcome data to prove that this technology changes outcomes i.e. reduces A&E attendances or hospital admissions etc. Adoption: It needs healthcare professionals to act on the findings and lots of potentially confounding issues, such as patient logs oximetry while off O₂ or just after exercise rather than after period of rest. Expert 4
- Innovation: The measurements being made are not innovative, other devices are available that make the same measurements. The only slight innovation is the forwarding of data wirelessly. Impact: Some impact as it could highlight to medical professionals a reduction in activity levels remotely and hence trigger intervention earlier. Clinical trial data in exercise programmes/pulmonary rehabilitation - etc. may be helpful. Adoption: Potential for adoption dependent on price and assessment of impact on patient care. Expert 5

Patient comments:
- Good idea. I would use this.
### BuddyWOTCH

BuddyWOTCH is a simple to use, wearable smartwatch intended for monitoring of blood oxygen levels in COPD patients in a home setting.

It is designed to continuously monitor and measure blood oxygenation levels using a sensor and automatically sends data from the wearer to the Cloud-based servers via cellular and wireless networks. It incorporates medical sensors for capturing: walking, oxygenation, temperature, chronicle (image capture of medication, food and liquids) and heart rate. It also includes pulse oximetry with continuous monitoring of SpO2 (blood oxygen saturation).

*Produced by Aseptika Ltd., UK.*

**Aseptika website:**

**Monitoring of COPD**

- Estimated launch October 2019.
- £1 million funding to accelerate the development of BuddyWOTCH recently secured through Phase II pre-procurement contract with NHS England’s SBRI Healthcare.

- The company intends to deliver its first production units to NHS clinical partners and beta test volunteers by the end of 2015.

**Expert comments:**

- **A device combining activity and oxygen saturations could be useful to produce more complex integrated algorithms for monitoring.**
  - **Expert 1**
- **Monitoring saturations is useful but can encourage some patients to focus on symptoms which can be unhelpful from a psychological viewpoint. It can be helpful when exacerbations are occurring & give useful clinical information in these circumstances.**
  - **Expert 2**
- **This appears to be another using the same sort of technology as described in many of the prospective innovations. The technology measuring pulse oximetry and pulse rate would give some useful information; the use of steps to indicate an acute exacerbation is less informative as our steps reduction can be due to a number of issues. Temperature at the wrist is not going to be particularly useful and none of the measurements will capture patient symptoms. Use of telehealth has had considerable investment within the UK and at the current time reviews of any benefit in COPD and other long term conditions are lacking, hence it would not seem appropriate to**
invest more research funding into a technology which has not demonstrated clinical applicability and relevance. Expert 3

- Same comments as above and reiterate the need for outcome data that will need to show some clinical impact if this is to be widely adopted in NHS i.e. A&E visits or hospital visits/admissions reduced. Expert 4

- Innovation: All the parameters can already be captured remotely. The innovation lies in the ability to transmit this data back to the healthcare professional for review. Impact: Could be impact through earlier warning of requirements for intervention from professionals outside of normal review - e.g. in vulnerable groups. Adoption: Potential market following confirmation of its ability to target healthcare utilisation particularly in vulnerable groups. E.g. Earlier intervention reducing the need for hospitalisation. Expert 5

Patient comments:

- New – interesting – easier monitoring – targeted Rx as needed. Yes I would use it.
- Seems a good idea. I would use it and would certainly like to trial it.

| 6) RESpeck | RESpeck is a wireless respiration and movement monitor. The company claims it to be the first system of its kind to successfully reconstruct respiratory waveforms from accelerometer data to enable wireless non-invasive monitoring of respiratory rates in COPD patients. Trials suggest there is a high degree of correlation between the respiratory rates measured by this device and by nasal cannula (in hospital patients).

RESpeck is intended for long-term wearing, with 12 month battery life, and easy to use, with data downloaded to the base-station when within range - no manual intervention is required.

Currently being developed at the Centre for Speckled Computing, University of Edinburgh, UK. |
| Monitoring of COPD |
| Monitoring of AECOPD |
| Prototype developed. |
| Pilot trials complete. |
| Pilot trial. |
Expert comments:

- Long term ambulatory respiratory rate monitoring in a form that is tolerable to patients is highly desirable particularly if integrated with physical activity. It may have a role as a trial outcome or for patient monitoring long term (subject to trials). Expert 1
- Not useful in my opinion. Expert 2
- Respiratory rate is considered to be the most sensitive of parameters for deterioration in a clinical condition – however if used at home respiratory rate will vary considerably depending on exertion. Alone not going to be useful. This appears to be another using the same sort of technology as described in many of the prospective innovations. The technology measuring pulse oximetry and pulse rate would give some useful information; the use of steps to indicate an acute exacerbation is less informative as our steps reduction can be due to a number of issues. Temperature around the wrist is not going to be particularly useful – and none of the measurements will capture patient symptoms. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. Expert 3
- Respiratory rate monitoring is probably of particular interest once it is accurate but again it needs medical professionals to act on it and we need to have outcome data. Expert 4
- Innovation: Long term monitoring of some physiological parameters. Impact: Minimal information gathered which, if the system highlights the need for intervention, will likely require more in depth monitoring of the patient. Adoption: unlikely. Expert 5

Patient comments:

- Impact: In an acute exacerbation – would be most useful. Acceptability – Yes.
## 2) Biomarker technologies

### a) Blood biomarkers

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
</tr>
</thead>
<tbody>
<tr>
<td>7) Blood eosinophil biomarker</td>
<td>The peripheral blood eosinophil count is a promising biomarker to direct corticosteroid therapy during COPD exacerbations, but larger studies are required. Research is underway, led by Prof Christopher Brightling, Glenfield Hospital, UK.</td>
<td>UKCRN database: <a href="http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=6667">http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=6667</a></td>
<td>Determining the cause of AECOPD</td>
<td>Follow up completed</td>
<td>BEAT:COPD study (ISRCTN92422949). Single centre study with 150 participants. Randomised biomarker-directed double-blind, corticosteroid versus standard therapy study.</td>
</tr>
<tr>
<td>8) Aα-Val&lt;sup&gt;360&lt;/sup&gt; biomarker</td>
<td>Aα-Val&lt;sup&gt;360&lt;/sup&gt; has been proposed as a novel biomarker for identifying patients with early COPD</td>
<td>UKCRN database: <a href="http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14954">http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14954</a></td>
<td>Identifying early COPD at risk of progression</td>
<td>In pilot/feasibility trial</td>
<td>Trial ID: UKCRN ID 14954. Currently open, due to close 07/31/2015.</td>
</tr>
</tbody>
</table>

**Expert comments:**

- **There is increased interest in use of blood eosinophil levels regarding use of ICS in obstructive lung disease (both asthma and COPD). The published study has challenged thinking and if a larger study is completed and supports use then the test is very easily undertaken. Worth exploring more.** Expert 3
- **Innovative: yes. Impact: unclear as most exacerbations are in the community and will need a blood test for this biomarker i.e. GP/nurse time. Adoption: Outcome data needed i.e. less steroid exposure with good outcomes, less hospital or A&E attendance.** Expert 4
- **Innovation: Targeted treatment. Impact: In some groups. Adoption: Unlikely to change practice for exacerbation management, but may have an impact on chronic management and understanding COPD phenotypes.** Expert 5
Research is underway led by Prof Robert Stockley, Queen Elizabeth Hospital, UK.


PhD thesis: [http://etheses.bham.ac.uk/4071/1/Carter13PhD.pdf](http://etheses.bham.ac.uk/4071/1/Carter13PhD.pdf)


### Expert comments:

- **Innovative:** yes. **Impact:** if effective at identifying those patients at high risk then it may be useful. **Adoption:** Only if shown to improve outcomes. **Expert 4**
- **Innovation:** Highly innovative - targeting high risk individuals. **Expert 5**

| **9) C-Reactive Protein (CRP) Point of Care Test** | Measures CRP levels from a finger prick blood sample. The test aims to improve antibiotic prescribing decisions for AECOPD in general practice, such that fewer antibiotics are prescribed overall without having adverse effects for patients. The test is simple, rapid and a single step process. It is | UK Clinical Trials Gateway: [http://www.ukctg.nihr.ac.uk/trialdetails/ISRCTN24346473](http://www.ukctg.nihr.ac.uk/trialdetails/ISRCTN24346473)  
NIHR Health Technology Assessment programme: [http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/130664/PRO-12-33-12.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/130664/PRO-12-33-12.pdf) | Point of care test to determine the cause of AECOPD | In trials since July 2014, due to publish trial in February 2018. | PACE study (Primary care use of a CRP point of care test to help target antibiotic prescribing to patients with acute exacerbation of COPD who are most likely to benefit). RCT recruiting 650 participants at 60 General Practices in Wales, Thames Valley & South London. |
intended for use in conjunction with a clinical assessment.

Research is underway by a team led by Prof Christopher Butler, Cardiff University, UK.

**Expert comments:**

- *The sensitivity and specificity is very important here. The data on community acquired pneumonia in hospital shows a very wide range of CRP values. If often a low CRP means we don't need antibiotics – then clinicians don't need to prescribe. If at times we should use an antibiotic even if CRP is low – then the test would have time implications and would not define if treatment needed or not – leaving us with a clinical decision. Expert 3*

- *This is widely available in hospital as part of venous blood sampling but a point of care finger prick test may be useful to speed up decision-making on referral for admission, decisions on antibiotics etc. Yes, to innovation, yes to potential impact and adoption is a strong possibility if shown to help decision making. Expert 4*

- *Innovation: CRP is not innovative but point of Care testing in the community may be. Impact: Depends on study data may have more impact if targeting community management to aid decision making regarding hospital admission or not. Adoption: has potential if study design and outcomes impact practice. Expert 5*

<table>
<thead>
<tr>
<th>Plasma fibrinogen biomarker</th>
<th>Plasma fibrinogen may be used as a biomarker for AECOPD. Levels ≥ 350 mg/dL identify COPD individuals at increased risk of exacerbations and death.</th>
<th>Published findings: <a href="http://journal.copdfoundation.org/">http://journal.copdfoundation.org/</a></th>
<th>Monitoring for risk of AECOPD</th>
<th>Submitted to FDA 10/09/2013.</th>
<th>14/08/2014: Meta-analysis of 4 studies with 6376 individuals.</th>
</tr>
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<tbody>
<tr>
<td>Expert comments:</td>
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<tr>
<td>This again is academically interesting – but fibrinogen levels are like CRP a non-specific indicator of inflammation. Not sure if we can rely on the test for interpreting risk of exacerbations or death (there is evidence of FEV₁ and a variety of other parameters that indicate a poor prognosis – exacerbation rate, continued smoking, severity of symptoms). Would not have thought high priority. Expert 3</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Innovative: yes, but unlikely to be much impact or chance of adoption in NHS, more of a research tool. Expert 4</td>
<td></td>
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<tr>
<td>Innovation: moderate. Impact: depends on clinic trial data- see comments in previous. Adoption: see comments in previous. Research and trial data &gt; clinical use. Expert 5</td>
<td></td>
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<table>
<thead>
<tr>
<th>11) Inflammatory biomarker panel</th>
<th>COPD is characterised by low-grade inflammation, the addition of inflammatory biomarkers to established predictive factors may improve the prediction of mortality. The inflammatory biomarker panel includes: white blood cell count, neutrophil count, and serum/plasma levels of fibrinogen, chemokine ligand 18, surfactant protein D, CRP and interleukin-6/8.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fierce diagnostics:</td>
<td><a href="http://www.fiercediagnostics.com/story/tracking-inflammation-copd/2012-03-20">http://www.fiercediagnostics.com/story/tracking-inflammation-copd/2012-03-20</a></td>
</tr>
<tr>
<td>Monitoring of COPD mortality</td>
<td>Test of hypothesis study.</td>
</tr>
<tr>
<td>Trial ID: NCT00292552: Three-year observational ECLIPSE study (for Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints) with 1,843 participants.</td>
<td></td>
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</tbody>
</table>

04/11/2011: Study with 201 participants in ECLIPSE cohort.
Kaplan-Meier survival analysis showed that inflammatory higher than the median in control participants were significantly associated with an increased risk of death at 3 years.

*Researched by ECLIPSE study - GlaxoSmithKline plc.*

**Expert comments:**
- Fascinating concept but not sure whether these measurements will change clinical practice. Expert 3
- It is innovative but can a positive test lead to an intervention that changes outcome? This is key question. Unless the answer is yes then it will not be adopted. Expert 4

### 12) CRP, fibrinogen and leukocyte count inflammatory biomarkers

Simultaneously elevated levels of inflammatory biomarkers (CRP, fibrinogen and leukocyte count) in individuals with stable COPD are associated with an increased risk of exacerbations, even in those without previous exacerbations. Researchers propose the use of an inflammatory biomarker panel to monitor for exacerbations of COPD.

*Currently being researched by Mette Thomsen, Copenhagen University Hospital, Denmark.*

| Monitoring for exacerbations of COPD |
| Test of hypothesis study. |
| Prospective observational study examined 61,650 participants from the Copenhagen City Heart Study (2001-2003) and the Copenhagen General Population Study (2003-2008). 6574 participants were then identified and included in the trial. |
Expert comments:
- Not sure if this has any clinical value – it is interesting but not specific enough to change clinical practice or manage patients differently from what I can see from this large study. Expert 2
- Same comment as above. Expert 4

| 13) Procalcitonin (PCT) | It is hypothesised that PCT will show a greater increase in bacterial lower respiratory tract infections than viral lower respiratory tract infections. PCT-based treatment decisions could lower the consumption of antibiotics without increasing the risk to patients of an adverse outcome. Research is being undertaken by Hans Ibsen, Holbæk Hospital, Denmark. | Published findings: [http://www.ncbi.nlm.nih.gov/pubmed/19738090?dopt=Abstract](http://www.ncbi.nlm.nih.gov/pubmed/19738090?dopt=Abstract) | Determining the cause of AECOPD | Phase IV trial | 1) Phase IV trial (Trial ID: NCT02171338): reported study completion date September 2014, but study still ongoing with 55 participants. 2) Phase II/III trial (Trial ID: NCT01950936): reported complete September 2013 with 120 participants. |

Expert comments:
- There are implications if this is accurate that would be sensible to avoid over use of antibiotics in people with COPD. Although not particularly well studied I am aware that people with COPD have commensals in their lungs – and Costelloe (Costelloe C, Metcalfe C, Lovering A, Mant D, Hay AD. Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: systematic review and meta-analysis. BMJ. 2010;340) has indicated a likely increased risk of further infection with even one course of antibiotics; many clinicians see patients using repeated antibiotics at increasing frequency – is this linked to our use of antibiotics when not needed initially or every time? Expert 3
- This is innovative as a more specific marker of infection and may improve care of inpatients with AECOPD. There is a strong chance of high impact (more appropriate exposure to antibiotics) and adoption. Expert 4

| 14) Serum procalcitonin (PCT-Q) | PCT-Q may be useful as a biomarker for AECOPD. While the PCT-Q level is only weakly correlated with the clinical outcome, the benefit of PCT-Q is short turnaround time.  
Researched by Dr. Theerasuk Kawamatawong, Ramathibodi Hospital, Bangkok. | Published findings:  
http://erj.ersjournals.com/content/42/Suppl_57/P2072.full.pdf+html?sid=30b1ec4c-39c8-4049-8499-be25d5a3035d  
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109646/  
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109646/  
http://www.ijabmr.org/article.asp?issn=2229-516X;year=2013;volume=3;issue=2;spage=77;epage=83;aulast=Kaw | Diagnosing AECOPD | Proof of concept study. | 2013: Prospective observational study with 40 participants. |

**Expert comments:**
- From the commentary provided this can be ignored as it doesn’t relate to clinical outcome. The fact that the test can be done easily (but is no use) does not help. Expert 3
- As above. Expert 4
### 15) HSP27 biomarker

<table>
<thead>
<tr>
<th>High levels of HSP27 in the blood may indicate lung damage in the early stages of COPD before a lung function test detects the reduction in lung volume. There is the potential HSP27 to be used as a case finding marker for COPD.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research by Hendrik Jan Ankersmit, University Department of Surgery at MedUni, Vienna.</strong></td>
</tr>
<tr>
<td><strong>Medical news today:</strong> <a href="http://www.medicalnewstoday.com/articles/244262.php">http://www.medicalnewstoday.com/articles/244262.php</a></td>
</tr>
<tr>
<td><strong>Published findings:</strong> <a href="http://www.karger.com/Article/FullText/336557">http://www.karger.com/Article/FullText/336557</a></td>
</tr>
<tr>
<td><strong>Diagnosis of early stage COPD</strong></td>
</tr>
<tr>
<td><strong>Test of hypothesis study.</strong></td>
</tr>
<tr>
<td><strong>Prospective observational study complete and published in 2012 with 94 participants</strong></td>
</tr>
</tbody>
</table>

**Expert comments:**
- The quoted paper appears to indicate that this correlates well with radiological evidence of COPD before lung function changes (not widely accepted in UK where we tend to use spirometry even though the study was CT based). Looking at the paper the range of those with disease would appear to show that many patients with disease could be falsely reassured. Expert 3
- Research tool only, innovative but low chance of impact and adoption in real world. Expert 4
- See above comments. Expert 5

### 16) EMP (endothelial microparticle) biomarkers

<table>
<thead>
<tr>
<th>Assessment of EMP levels may provide an early and inexpensive approach to identifying early evidence of emphysema without the radiation exposure associated with chest CT scans. Elevated levels may identify smokers with early emphysema at a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical news today:</strong> <a href="http://www.medicalnewstoday.com/releases/218787.php">http://www.medicalnewstoday.com/releases/218787.php</a></td>
</tr>
<tr>
<td><strong>Published findings:</strong> <a href="http://www.ncbi.nlm.nih.gov/pubmed/21471087">http://www.ncbi.nlm.nih.gov/pubmed/21471087</a></td>
</tr>
<tr>
<td><strong>Diagnosis of early stage emphysema</strong></td>
</tr>
<tr>
<td><strong>Test of hypothesis studies.</strong></td>
</tr>
<tr>
<td><strong>Observational studies with registry entries: NCT00224198 and NCT00224185 (each enrolling 196 participants).</strong></td>
</tr>
</tbody>
</table>
stage where intervention may prevent further permanent lung destruction.

*Researched by the Departments of Genetic Medicine and Pulmonary and Critical Care Medicine, Weill Cornell Medical College USA.*

**Expert comments:**
- Not seen enough evidence at present to support developing this in a clinical context. Expert 3
- Innovative; yes. Impact: yes, may encourage smoking cessation. Adoption: possible but likely to be more in secondary care COPD clinics and assumes that NHS will give resources (and that patients will participate) in a COPD screening programme. Expert 4

17) α-2 macro-globulin, haptoglobin, ceruloplasmin and hemopexin biomarkers

A panel of four blood-based, protein biomarkers used to discriminate between healthy controls, asthma and COPD. The selected biomarkers are all involved in the regulation of inflammation, usually functioning as anti-inflammatory proteins. Methods for quantifying these biomarker in blood are already currently available.


Published findings: [http://online.liebertpub.com/doi/abs/10.1089/omi.2010.0134](http://online.liebertpub.com/doi/abs/10.1089/omi.2010.0134)


Diagnosis of COPD

Proof of concept study.

Estimated UK launch January 2018.

Initial study with 43 participants. Diagnostic accuracy was validated in a further independent patient sample of 80.

Additional data from a second independent cohort of patients is currently being cross-validated.
### 18) ARHGEF1 (Rio guanine nucleotide exchange factor 1) biomarker

ARHGEF1 (Rio guanine nucleotide exchange factor [GEF] 1) is a biomarker which may be used to diagnose COPD and determine prognosis. ARHGEF1 expression levels are responsive to thromboxane receptor inhibitors specific to COPD.

- **Researched and produced by Lenimen, USA.**

<table>
<thead>
<tr>
<th>Expert comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unless this is diagnostic and reliably prognostic then not seeing this with clinical relevance at present in COPD – the evidence presented does not indicate this is likely yet. Expert 3</td>
</tr>
<tr>
<td>Purely an interesting research marker. Expert 4</td>
</tr>
</tbody>
</table>

### Expert comments:

- Not seeing this with clinical relevance at the current time in COPD. Expert 3
- Innovative but unless some beyond expectation results I think potential impact and likelihood of adoption is low. Expert 4
- Innovation: highly innovative. Impact: depends on further studies as to whether this is more a research rather than clinical tool. Adoption: as above. Expert 5

- **Innovation Center of the Rockies:** [http://www.innovationcenteroftherockies.com/CUCOPD.html](http://www.innovationcenteroftherockies.com/CUCOPD.html)
- **Company website:** [https://gust.com/companies/lenimen](https://gust.com/companies/lenimen)

- **Diagnosis of COPD**
- **Determine prognosis of COPD**
- **Estimated launch May 2016.**
- **No trials found.**
| 19) Autoantibody Antigen Array - COPD | Autoantibody antigen array - COPD is a biomarker based test intended for the diagnosis and prognostic assessment of COPD. It is designed to detect auto-antibodies reactive to a broad spectrum of self-antigens reportedly specific to COPD from a patient's serum sample. Research is underway at the University of Colorado, USA. | Published findings: [http://www.ncbi.nlm.nih.gov/pubmed/22941590](http://www.ncbi.nlm.nih.gov/pubmed/22941590) | Diagnosis of COPD Determine the prognosis of COPD | Estimated launch May 2016. | Autoantibody identification trial with 21 participants. |

**Expert comments:**
- *Unless this is diagnostic and reliably prognostic then not seeing this with clinical relevance at present in COPD – the evidence presented does not indicate this is likely yet. Expert 3*
- *Truly a research area, no likelihood of clinical impact or adoption in NHS for foreseeable future. Expert 4*

| --- | --- | --- |

**Expert comments:**
- *Point of care diagnostic test not really required for A1AT – but a careful consideration and work up – therefore not really interested. Expert 3*
- *Tiny percentage of COPD is alpha 1, I don’t see the benefit of a point of care test for alpha 1 deficiency. Expert 4*

<table>
<thead>
<tr>
<th>21) Serum uric acid biomarker</th>
<th>Serum uric acid may be used as a biomarker to predict AECOPD - it was associated with increased 30-day mortality and risk for AECOPD and hospitalisations in a 1-year follow-up. This low-cost biomarker may allow identification of high-risk patients that could benefit from intensive management. <em>Researched by Konstantinos Bartzikas, University of Athens, Greece.</em></th>
<th>Published findings: <a href="http://erj.ersjournals.com/content/43/1/43.full?sid=0b086a42-7708-49c2-a4de-20178573846b">http://erj.ersjournals.com/content/43/1/43.full?sid=0b086a42-7708-49c2-a4de-20178573846b</a> <a href="http://www.ejbronchology.eu/article.asp?issn=1687-8426;year=2014;volume=8;issue=2;spage=115;epage=120;aulast=Embarak">http://www.ejbronchology.eu/article.asp?issn=1687-8426;year=2014;volume=8;issue=2;spage=115;epage=120;aulast=Embarak</a> <a href="http://www.medsci.org/v08p0470.htm">http://www.medsci.org/v08p0470.htm</a></th>
<th>Identification of patients at high risk of AECOPD</th>
<th>Test of concept study.</th>
<th>2014: 115 participants.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013: test of concept study, 314 participants.</td>
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<tr>
<td>2011: 2917 participants, spirometry values compared to serum uric acid levels.</td>
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</tbody>
</table>
Expert comments:

- Quite a challenge as several other areas associated with increased urate levels (what would be the number needed to test to reliably pick up patients – and how many would we miss) Note plenty of research in cardiology too – and hence are we looking at long term conditions rather than the just COPD. Palmer TM, Nordestgaard BG, Benn M, et al. Association of plasma uric acid with ischaemic heart disease and blood pressure: mendelian randomisation analysis of two large cohorts. BMJ. 2013;347. Expert 3

22) Hydrogen sulphide biomarker

<table>
<thead>
<tr>
<th>Serum hydrogen sulphide may serve as a biomarker in exacerbation of COPD but more studies are required to arrive at a definite conclusion. Researched by Debraj Jash, N.R.S. Medical College, India.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Published findings: <a href="http://erj.ersjournals.com/content/44/Suppl_58/P3983.abstract?sid=165a1244-aa56-48da-bba7-0797b2902609">http://erj.ersjournals.com/content/44/Suppl_58/P3983.abstract?sid=165a1244-aa56-48da-bba7-0797b2902609</a></td>
</tr>
<tr>
<td><a href="http://biohorizons.oxfordjournals.org/content/6/hzt009.full">http://biohorizons.oxfordjournals.org/content/6/hzt009.full</a></td>
</tr>
<tr>
<td><a href="http://erj.ersjournals.com/content/44/Suppl_58/P3984">http://erj.ersjournals.com/content/44/Suppl_58/P3984</a></td>
</tr>
</tbody>
</table>

Expert comments:

- The trial quoted in ERJ is 25 patients distinguishing smokers from non-smokers. Again not sure of reliability here. Too early to know or use clinically. Expert 3

- Too early to make any comments, need some sense that it can help care and alter management? Expert 4

23) Neutrophil/lymphocyte (NLR) ratio

<table>
<thead>
<tr>
<th>The NLR shows a highly prognostic accuracy for infectious AECOPD. NLR is a widely available measurement, and</th>
</tr>
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<tbody>
<tr>
<td>Published findings: <a href="http://erj.ersjournals.com/content/44/Suppl_58/P3997.abstract?sid=60c0342f-edff-4bb1-978c-99798d668f71">http://erj.ersjournals.com/content/44/Suppl_58/P3997.abstract?sid=60c0342f-edff-4bb1-978c-99798d668f71</a></td>
</tr>
<tr>
<td>Determining the cause of AECOPD</td>
</tr>
<tr>
<td>Proof of concept study.</td>
</tr>
<tr>
<td>2014: 269 participants, retrospective study.</td>
</tr>
<tr>
<td>2014: 40 participants.</td>
</tr>
</tbody>
</table>
therefore could be a cost-effective approach for clinical practice.

*Researched by Nikoletta Rovina, Athens Medical School.*


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**Expert comments:**

- *Looking at the trial methodology not sure this is worth pursuing at present.* Expert 3
- *Already available on simple FBC, low chance of impact or adoption.* Expert 4
### b) Sputum biomarkers

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
</tr>
</thead>
</table>
| 24) **Home use sputum test** | A home use test that measures the level of activity of 9 respiratory pathogens in the lungs from a sputum sample to provide advance warning of an exacerbation. *The technology is produced by Aseptika Ltd., UK.* | SBRI healthcare: [http://www.sbrihealthcare.co.uk/case-studies/aseptika/](http://www.sbrihealthcare.co.uk/case-studies/aseptika/)  
Business weekly news source: [http://www.businessweekly.co.uk/biomedtech/15975-aseptika-secures-uk-patent-for-diy-lung-infection-test](http://www.businessweekly.co.uk/biomedtech/15975-aseptika-secures-uk-patent-for-diy-lung-infection-test) | Monitoring for AECOPD  
Determining the cause of AECOPD | Forecast NHS sales will start 2017 following publication of RCT results.  
Awarded £1,242,500 by SBRI healthcare  
Aseptika won first place for “Promising eHealth EU SME” eHealth solution 2014 developed by an early-stage European SME. | Phase III trials. |

**Expert comments:**

- Yes this would be useful & may help identify pathogens early so treatment can be commenced. Expert 2
- The use of identifying respiratory potential pathogens in the lungs on a test is interesting – but like skin commensals and bacteriuria in older women identifying a bacterium does not always mean that the cause of symptoms is identified. In many DGH sputum culture is no longer performed for COPD. Expert 3
- Innovative: yes. Impact: if it allows early intervention with less use of hospital resources then impact will be high. Adoption: If trials pan out then yes, potential for adoption. Expert 4
- Innovation: highly innovative. Impact: potential to change practice and reduce antibiotic use. Adoption: depends on clinical trial data, cost and ease of use. Expert 5
<table>
<thead>
<tr>
<th>25) Sputum rheology</th>
<th>The application of existing rheology technology to differentiate between COPD patients and non-COPD patients. This technology could potentially provide a cheap, rapid, easy to access and non-invasive method of COPD diagnosis. <em>It is being researched by TA Instruments, USA.</em></th>
<th>Company website: <a href="http://www.tainstruments.com/lpage.aspx?id=290&amp;n=1&amp;siteid=1">http://www.tainstruments.com/lp age.aspx?id=290&amp;n=1&amp;siteid=1</a></th>
<th>Diagnosis of COPD</th>
<th>Technology is already available but is not currently used for this indication.</th>
<th>COPD-ANT trial (registry ID: ISRCTN82911859). Cross-sectional study followed by a longitudinal cohort study with 200 participants. End date 08/12/2015.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expert comments:</strong></td>
<td>- Too soon to have any strong views on this. Expert 3</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>26) SP-A, sRAGE, MPO and NGAL biomarker panel.</td>
<td>A panel of biomarkers (SP-A, sRAGE, MPO and NGAL) to be used to diagnose COPD-asthma overlap. The biomarkers are measured by enzyme immunoassay/ELISA in sputum and plasma. In patients with COPD-asthma overlap, sputum MPO and plasma SP-A are significantly elevated whereas plasma sRAGE levels are reduced compared with asthma alone. Sputum NGAL is elevated in COPD-asthma overlap compared with COPD and could be used to differentiate patients with overlap</td>
<td>Published findings: <a href="http://erj.ersjournals.com/content/43/2/421.full?sid=0b086a42-7708-49c2-a4de-20178573846b">http://erj.ersjournals.com/content/43/2/421.full?sid=0b086a42-7708-49c2-a4de-20178573846b</a></td>
<td>Diagnosis of COPD-asthma overlap</td>
<td>Proof of concept study.</td>
<td>2013: Study investigating biomarker panel with 134 participants.</td>
</tr>
</tbody>
</table>
from those with COPD alone.  

*In research by Hiroshi Iwamoto, University of Helsinki, Finland.*

**Expert comments:**
- Too experimental not sure of any value to progress yet. Expert 3
- Possibly of interest in secondary care respiratory clinics but outcome data needed, i.e. will care be better if someone is labelled Asthma/COPD vs Asthma Vs COPD. That is far from clear. Expert 4

| 27) Fourier transform infrared spectroscopic (FTIR) monitoring | Glyconics Ltd has developed a hand-held device that uses infrared (IR) spectroscopy to provide sensitive analysis of the composition of sputum from patients with COPD. A small sputum sample is applied onto a disposable sample strip. The IR device determines the sample’s infrared spectrum and the pattern of the spectrum analysed. The entire analysis takes less than 10 minutes. FTIR sputum profiling produces spectral signatures that can differentiate COPD or predict exacerbation presence. Significant differences are observed in the published findings: [http://thorax.bmj.com/content/65/Suppl_4/A124.2.abstract](http://thorax.bmj.com/content/65/Suppl_4/A124.2.abstract) [http://tar.sagepub.com/content/2/1/23.long](http://tar.sagepub.com/content/2/1/23.long) Glyconics website: [http://www.glyconics.com/](http://www.glyconics.com/) | Published findings: [http://thorax.bmj.com/content/65/Suppl_4/A124.2.abstract](http://thorax.bmj.com/content/65/Suppl_4/A124.2.abstract) [http://tar.sagepub.com/content/2/1/23.long](http://tar.sagepub.com/content/2/1/23.long) Glyconics website: [http://www.glyconics.com/](http://www.glyconics.com/) | Diagnosis of COPD Monitoring of COPD | Large validation trial. | 2009: Trial ID: UKCRN 5127. Single-centre, observational study with 200 participants. 2008: Proof of concept study with 30 participants. |
sputum from patients with stable disease compared to those with exacerbations, and between those with COPD and with other respiratory pathologies.

*Produced by Glyconics, UK.*

**Expert comments:**
- Not yet. Expert 3
- Interesting and if effective then impact and adoption possibly significant. Expert 4
<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
</tr>
</thead>
</table>
| 28) COPDSPOC (saliva point of care) sensor | COPDSPOC is a novel saliva based point of care biosensor for COPD. Biomarkers assessed are: C-reactive protein (CRP), procalcitonin and neutrophil elastase.  

The biomarkers are integrated into a saliva-based detection platform on one portable system, which eventually will be miniaturised into a hand-held monitor called ‘COPDSPOC sensor’. The research team claim this monitor will be the first of its kind in COPD care enabling routine self-assessment for early prediction of exacerbations.  

*Product is being researched by a team led by Prof Monica Spiteri, University Hospital of North Staffordshire, UK.* | Foundation for Assistive Technology: [http://www.fastuk.org/research/projview.php?id=1682](http://www.fastuk.org/research/projview.php?id=1682)  
NIHR i4i programme: [http://www.nihr.ac.uk/funding/funded-research/funded-research.htm?postid=1846](http://www.nihr.ac.uk/funding/funded-research/funded-research.htm?postid=1846)  
Single-centre, observational, pilot/feasibility study, 80 participants. |
**Expert comments:**

- Could be useful if it works. Expert 2
- Early – wait for results of pilot first. Expert 3
- Possible interest, impact and adoption but outcome data needed. Expert 4
- Innovation: highly innovative. Impact: potential to change practice, and reduce antibiotic use. Adoption: depends on the ease of use and comparison with current predictors. Expert 5

| 29) Saliva CRP and PCT biomarkers | Saliva samples may be used to monitor levels of CRP and PCT in order to identify the risk of an AECOPD. Salivary CRP and PCT concentrations strongly correlate with serum counterparts and breathing scores. *Research by N Patel, University Hospital of North Staffordshire, UK.* | Published findings: [http://thorax.bmj.com/content/69/Suppl_2/A102.2.full.pdf+html?sid=915237f2-57b3-45d5-89c0-f4d843e1930](http://thorax.bmj.com/content/69/Suppl_2/A102.2.full.pdf+html?sid=915237f2-57b3-45d5-89c0-f4d843e1930) | Monitoring for AECOPD | Test of concept. | 2014: Prospective case-control study. 139 participants. |

**Expert comments:**

- No idea of likely costs, no idea of reliability from this small pilot. Expert 3
- As above. Expert 4
### d) Breath biomarkers

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
</tr>
</thead>
</table>
| 30) Volatile organic compounds (VOC) Diagnostic Assay | An immunodiagnostic assay intended for the diagnosis of COPD. It is designed to detect the presence of VOCs specific to COPD from exhaled breath samples. It is based on XVOC Technology. *Produced by XAir Diagnostics B.V.* | Market reports: [http://www.marketreportsonline.com/213564.html](http://www.marketreportsonline.com/213564.html)  
Published findings: [http://www.sciencedirect.com/science/article/pii/S095461109003515](http://www.sciencedirect.com/science/article/pii/S095461109003515) | Diagnosis of COPD | Estimated UK launch April 2016 | In a trial of 79 participants, 6 VOCs correctly classified 92% of the COPD subjects (sensitivity: 98%, specificity: 88%) and 91% of the control subjects (sensitivity: 100%, specificity: 81%). |

**Expert comments:**
- Aware of the development into VOC and in the longer term this is likely to be the way forward (dogs and smell research in cancer, UTI etc.) we can smell some things, dogs a lot more if we can match the complexity of aroma we may open a lot of diagnostic areas. *Expert 3*
- Innovation: moderate. Impact: will need comparison with existing methods. Adoption: depends on the ease of use and comparison as above. *Expert 5*

| 31) Exhaled volatile organic compounds (VOCs) | The patient exhales a full breath into the sampler through a disposable mouthpiece. After sample collection, the mouthpiece is removed and replaced with the plunger which displaces the air into a thermal desorption tube containing a suitable sorbent(s) that is mounted onto the outlet end of the Bio-VOC sampler. | Published findings: [http://www.mdpi.com/2218-1989/4/2/300/htm](http://www.mdpi.com/2218-1989/4/2/300/htm) | Diagnosis of COPD | Monitoring of COPD | Current study exploring the application of the existing technology for use in COPD.  
Cross-sectional study (ISRCTN82911859) followed by a longitudinal cohort study of the use of this technology to diagnose and monitor COPD. Study end date 08/12/2015. |
The sorbent tube can either be analysed straight away or sealed with long-term storage caps for testing at a later date. 

Produced by Markes International Ltd., UK.

**Expert comments:**
- Very early. Aware of the development into VOC and in the longer term this is likely to be the way forward (dogs and smell research in cancer, UTI etc.) we can smell some things, dogs a lot more if we can match the complexity of aroma we may open a lot of diagnostic areas. Expert 3
- Possible utility in monitoring of COPD. Expert 4

### 32) $^{13}$C-Methacetin Breath Test (MBT)

**Clinical trials registry:**
- Diagnosis of COPD
- Monitoring of COPD

**Phase II/III trial.** Trial reportedly is ongoing (NCT01205074).

**Expert comments:**
- Wait for further trials. Expert 3
- Research plaything, miles away from any likelihood of impact or adoption. Expert 4

Breath test is based on CO$_2$ production. Subject with COPD may have abnormal CO$_2$ production. However, several other factors are thought to affect the MBT, including smoking, age, CYP450 1A2 inhibitors in drugs and food, alcohol, and beta-blockers.

*Being researched at the Hadassah Medical Centre, Israel.*
| 33) Spirometrix Fenom™ Point of Care test | Spirometrix Fenom is a point-of-care breath analyser which measures nitric oxide, a biomarker of respiratory diseases. The sensor system works similarly to a spirometer; the user exhales into the device for 10 seconds results are returned in a minute. The test will be used both as an initial diagnostic test and to predict exacerbations.

The company suggest data will be transmitted to patients and physicians via the cloud. The sensor device will also include standard sensors like a peak flow meter, GPS, and an environmental sensor for pollen counts.


**Expert comments:**

- *This appears to be a FENO test for COPD. Most of the literature I have seen is with allergic rhinitis and asthma – but this is still controversial. We don’t need a point of care test immediately until the science is proven.*  
  
  **Expert 3**

- *Innovative: yes in terms of COPD but FeNO has been used mainly in research studies in asthma for years. I would be surprised if this gets used in COPD in real world as it hasn’t found its way into everyday practice in Asthma, where there has been data for a long time.*  
  
  **Expert 4**
| **34) Breath PulmoHealth “Check” COPD detector** | The Breath PulmoHealth “Check” COPD detector identifies biomarkers that signal the breakdown of lung tissue in patients with COPD. The assays are based on the company’s proprietary MicroParticle Catalysed Biosensor Technology that facilitates the rapid analysis of a test subject’s breath condensate sample. These products are packaged in a small tube, through which a patient can comfortably blow for several seconds. In reactive, positive samples, the microparticles form a complex with the specific biomarker present in the breath, which leads to an easy-to-view colour change. 


**Expert comments:**
- Very early – await other trials. Expert 3
- Innovative, yes; Impact and adoption will depend on outcome data becoming available. Expert 4
<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
<th>Sample required</th>
</tr>
</thead>
</table>

**Expert comments:**

- Very early – await trials. Expert 3
- Innovative. Impact may occur if it aids the diagnosis of COPD. But I suspect this will be small. Adoption likely to be low unless the test is included in national or international diagnostic guidelines Expert 4

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
<th>Sample required</th>
</tr>
</thead>
<tbody>
<tr>
<td>36) L-LDH biomarker</td>
<td>Samples of bronchial aspirate can be analysed for L-LDH in order to evaluate lung tissue damage and estimate bacterial infection in the lungs.</td>
<td>Published findings: <a href="http://erj.ersjournals.com/content/42/Suppl_57/P2703.full.pdf+html?sid=cc84a177-1d54-4543-b7e5-7233b46fe2e1">http://erj.ersjournals.com/content/42/Suppl_57/P2703.full.pdf+html?sid=cc84a177-1d54-4543-b7e5-7233b46fe2e1</a></td>
<td>Diagnosing the cause of AECOPD</td>
<td>Proof of concept study.</td>
<td>Trial with 84 participants. In patients from whom bacteria were isolated, median L-LDH is</td>
<td>Bronchial aspirate</td>
</tr>
<tr>
<td>Expert comments:</td>
<td>1.9 x median L-LDH of group with no bacteria isolated (p&lt;0.001).</td>
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<tr>
<td><strong>37) Hyaluronic acid and heparan sulfate biomarkers</strong></td>
<td>Acute exacerbations are associated with differential expression of specific glycosaminoglycans (hyaluronic acid and heparan sulfate). These molecules may be potential biomarkers and alternative targets for pharmacological interventions.</td>
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</tr>
<tr>
<td>Researched by Eleni Papakonstantinou, University Hospital Basel, Switzerland.</td>
<td>Published findings: <a href="http://erj.ersjournals.com/content/44/Suppl_58/P843.abstract?sid=60c0342f-edff-4bb1-978c-99798d668f71">http://erj.ersjournals.com/content/44/Suppl_58/P843.abstract?sid=60c0342f-edff-4bb1-978c-99798d668f71</a></td>
<td></td>
<td></td>
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<tr>
<td>Monitoring for AECOPD</td>
<td>Proof of concept study.</td>
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</tr>
<tr>
<td>2014: 94 participants.</td>
<td>Bronchial aspirate</td>
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</tr>
<tr>
<td>Expert comments:</td>
<td><strong>Very early – await trials. Expert 3</strong></td>
<td></td>
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<td></td>
<td><strong>Already available, not innovative, no likely impact or adoption. Expert 4</strong></td>
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<td><strong>Potential as research tool. Expert 5</strong></td>
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### 3) Telehealth technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
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<tbody>
<tr>
<td><strong>38) Care Innovations Guide</strong></td>
<td>Care Innovations Guide is a comprehensive, next-generation remote health management device intended to monitor chronically ill patients such as those with COPD. Through the use of the touch screen, tablet device, it provides an online interface allowing clinicians to monitor patients and remotely manage care. The company claims the device is easy to use with audio and graphic capabilities. The device can be personalised for the patient’s individual needs. In addition, patient education can be provided when needed for each particular patient through a video or image. Data collected can be transmitted through a secure connection with a health care practitioner. If needed, a teleconference can be held between doctor and patient through the device. <em>Produced by Intel-GE Care Innovations LLC., USA.</em></td>
<td>Product page: <a href="http://www.careinnovations.com/intel-ge-care-innovations-guide-goes-live-introducing-virtual-care-coordination/">http://www.careinnovations.com/intel-ge-care-innovations-guide-goes-live-introducing-virtual-care-coordination/</a></td>
<td>Monitoring of COPD</td>
<td>Estimated launch date May 2011. FDA approved March 2011. Unknown if CE marked.</td>
<td>No trials found.</td>
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</table>

**Expert comments:**

- *Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. Expert 1*
- *The problem with this kind of technology is that you need a health care professional to look at the data. This is often the problem. Expert 2*
Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Appears to have been launched in May 2011 – hence suggest check on results of trials that would warrant further assessment. Expert 3

Innovative with potential for impact and adoption but does require healthcare professional to interact with patient. Useful in remote areas especially but with adequate staffing could be applicable widely. Expert 4

Innovation: Remote real-time interaction with patients. Impact: Potentially significant if proved that system results in reduced attendances/admissions and thus a reduction in healthcare utilisation. High risk individuals. Adoption: Could be adopted if the NHS IT infrastructure allows for secure and reliable connections. Expert 5

Patient comments:

Innovation: Viewed and used some telemonitoring devices for the NHS. A few years ago. Impact: Yes – am using something similar at home now. Acceptability: Yes.

I have seen during a session with four devices. Concept is brilliant – I think it should be implemented ASAP. I would use it.

39) Intel® Health Guide PHS6000
The Intel Health Guide is a comprehensive, next-generation remote patient monitoring solution. It may be used by patients to monitor for AECOPD. It combines a touch-screen, in-home patient device, the Intel® Health Guide PHS6000, with the Intel® Health Care Management Suite, an online interface that allows clinicians to monitor and communicate with patients and remotely manage their care.

Produced by Intel Corporation.

UKCRN registry:

eHealth insider news:
http://www.ehi.co.uk/features/item.cfm?docId=284

Monitoring of COPD
Phase III trial.
FDA 510(k) approved and CE marked.
Single centre, cohort study with 20 participants. Currently open. Due to close 03/31/2015.

Phase II trial completed 09/25/2014.
Information from company:

Youtube marketing video:
https://www.youtube.com/watch?v=6u-bhsXd0OA

Expert comments:
- Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. Expert 1
- Again this has staffing implications to check the data. Expert 2
- Not sure why would use this – much health care input and would hope that clinician relationship would do better in a real trial. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Same comments as above. Expert 4
- Innovation: There are other similar products on the market or ready to be marketed so little innovation. Impact: As with all telehealth, there is a potential impact but this relies on proven reductions in healthcare utilisation and clinician confidence that effective patient management can be conducted remotely and comparisons with existing technologies. Adoption: Very much dependent on the impact as above. Expert 5

Patient comments:
- Innovation: Viewed and used some telemonitoring devices for the NHS. A few years ago. Impact: Yes – am using something similar at home now. Acceptability: Yes.
- I have seen during a session with 4 devices. Concept is brilliant – I think it should be implemented ASAP. I would use it.
| **40) Alere HomeLink** | The Alere HomeLink is a comprehensive health information connectivity solution that effectively links patients to their healthcare providers and electronic medical records through the cloud. Patients self-testing at home can easily send collected test results to their healthcare providers. The device also supports questions and answers that can provide further information about the patient's current health status. The company claim that the platform enables healthcare practitioners to extend their services to a broader patient population, and achieve the proactive, cost avoidance benefits and efficiencies associated with remote health monitoring. The devices allow automated transmission of health information and provide secure integration with a variety of online health record systems.  

**Expert comments:**
- *Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful (the “cost avoidance and efficiencies are largely imaginary in an NHS context). Expert 1*
- *As above – staffing implications. Could work in rural areas. Expert 2*
- *Not sure why would use this – much health care input and would hope that clinician relationship would do better in a real trial. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings*

- Same as above. Expert 4
- Innovation: There are other similar products on the market or ready to be marketed so little innovation. Impact: As with all tele-health, there is a potential impact but this relies on proven reductions in healthcare utilisation and clinician confidence that effective patient management can be conducted remotely. Comparison with existing technologies. Adoption: Very much dependent on the impact as above. Expert 5

Patient comments:
- Innovation: Viewed and used some telemonitoring devices for the NHS. A few years ago. Impact: Yes – am using something similar at home now. Acceptability: Yes.
- Not sure I’ve seen this before. Concept is brilliant – I think it should be implemented ASAP. I would use it.

| 41) Virtual Medical Assistant (VMA) Version 2.0 | VMA version 2.0 is a wireless, digital under-the-mattress sensor that detects the heart rate, respiration rate, breathing pattern and movement of patients. It comes with matching bedside display units and nurse station monitors to monitor patients’ condition. It requires no contact with the patient to monitor vital signs. Using ultra wideband technology with excellent penetration, the sensor panel sends out electronic pulses that are streamed continuously via any wireless network, decoded by an algorithm, and ultimately transmitted to computers, smartphones, and tablets through which caregivers can view patients’ data and receive status alerts. | Monitoring of COPD | Planning clinical trials. | No existing trials found. |
| **Patient comments:** |
| - Innovation: Viewed and used some telemonitoring devices for the NHS. A few years ago. Impact: Yes – am using something similar at home now. Acceptability: Yes. |
| - Not sure I’ve seen this before. Concept is brilliant – I think it should be implemented ASAP. I would use it. |

Medgadget: [https://www.medgadget.com/2014/02/sensiotec.html](https://www.medgadget.com/2014/02/sensiotec.html)


YouTube marketing video for version 1.0: [https://www.youtube.com/watch?v=El88VU6dYdo](https://www.youtube.com/watch?v=El88VU6dYdo)
to further expand the platform’s integration capabilities with a special focus on enabling developers to use the information from the patented Bed Sensor Panel in their own applications, products and services.

Produced by Sensiotec Inc., USA.

Expert comments:
- Could be a way to improve respiratory rate assessment in hospital and trigger early warning which could have a big impact on in-patient care. Trend towards single rooms makes this sort of thing more desirable. Expert 1
- Not sure why would use this – much health care input and would hope that clinician relationship would do better in a real trial. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Innovative yes, but limited utility as requires healthcare workers to respond to abnormal signals or absent signals e.g. patient downstairs having a cup of tea rather than in bed. Lots of false alarms I expect. I am not optimistic about impact or potential for adoption. Expert 4
- Innovation: Innovative in the technology and what it is being used for. Impact: If only under the bed then this impacts on the utility of the system to monitor patient health when not in bed. However, it may still have some use in monitoring the patients’ health status e.g. frail elderly/in hospital/wandering patients. Adoption: Unlikely unless compelling impact on health care utilisation or target groups defined. Expert 5

Patient comments:
- I have seen during a session with four devices. Concept is brilliant – I think it should be implemented ASAP. Seem good that patients don’t require input. I would use it.
| 42) Commander Flex | An interactive home telehealth wireless tablet device intended for patient monitoring. The company claim it simplifies home telehealth management and education for patients with complex conditions. It uses Bluetooth and cellular technology to provide health status of a patient wirelessly and its modular design allows patient to select vital sign measurement devices. Its features include:

- **Active Voice**: optimises the patient's experience and ease of use by asking questions in a clear, friendly voice and written prompts.
- **Branching Logic**: It allows the healthcare provider to pinpoint the patient’s symptoms and symptom severity.
- **Two-Way Messaging**: Two-way messaging enables healthcare providers to send unique, customised communications to individual patients or select groups.


**Expert comments:**

- *Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful.* Expert 1
- *All of these products have staffing implications.* Expert 2
- *Not sure why would use this – much health care input and would hope that clinician relationship would do better in a real trial. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has*

- Somewhat useful for patients in remote settings or with difficulty accessing healthcare, but still requires healthcare provider to act on abnormal readings. Some potential impact but hard to see widespread adoption in current NHS climate. Not especially useful in COPD as does not seem to have an option for respiratory rate monitoring. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

Patient comments:
- Innovation: The ability to be able to ask questions through the device is new to me. Impact: Yes I like the idea of it. Acceptability – yes!
- Good idea to be able to ask questions. I would use this.

| 43) MedVizer T400 Home Health Monitor | ViTelCare’s MedVizer T400 Home Health Monitor is a non-invasive, cost effective, portable device intended to monitor chronically ill patients such as those with COPD. It is a touch screen tablet device, designed to support daily patient health assessment, disease education and vital sign capture. It alerts a patient’s healthcare provider of potential health problems before they become critical. Features:
- Supports automatic or manual entry of vital sign collection
- Provides disease-specific alerts based on vital signs and health assessment data | ViTelCare product page: [http://www.vitelnet.com/Mobile-Health](http://www.vitelnet.com/Mobile-Health)
Published findings:
- Integrates disease-specific random education during the health assessment interaction to promote better patient self-care.
- Easy to configure and set up the monitor for each patient. Transmits data over standard telephone lines, LAN/WAN or broadband platforms.

Produced by Visual Telecommunication Network, Inc., USA.


Expert comments:
- **Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful.** Expert 1
- **Similar to above.** Expert 2
- **Not sure why would use this – much health care input and would hope that clinician relationship would do better in a real trial. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance.** The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. First publication suggests “However, no statistically significant differences were observed between intervention and control groups in terms of changes in physical health, inpatient admissions, bed days of care, emergency department visits, or general satisfaction with home care services.” Might have helped mental health. Expert 3
- **This is innovative and has evidence of benefit in terms of documented impact on hospital attendances being reduced so this has potential to be adopted, albeit the data is American and one always wonders how this transfers to the UK context.** Expert 4
- **Low innovation: as per comments for all telehealth.** Expert 5
**Patient comments:**
- **Innovation:** Similar devices on the market so not new to me. **Impact:** Already using something similar. **Acceptability:** Yes, already am.
- Good idea to be able to ask questions. I would use this.

| 44) CHROMED monitoring system | The CHROMED system is a home monitoring system for patients with multimorbidities including COPD. It is comprised of three elements: Resmonpro (Respiratory monitoring device), Medic4all wrist clinic (a wireless vital signs monitoring device), and a touch-screen PC (to remind for drugs and symptom monitoring). The system is researched by Prof A Niroshan Siriwardena, University of Lincoln, UK. | JoinUp: https://joinup.ec.europa.eu/node/134941 CHROMED website: http://www.chromed.eu/ | Monitoring of COPD | In pilot/feasibility trial | Trial registry ID NCT01960907. Feasibility trial with 300 participants followed by international multicentric RCT in five European countries (UK, Sweden, Estonia, Spain and Slovenia). Estimated primary trial completion March 2016. |

**Expert comments:**
- Possibly a wrist worn long term monitoring system would be useful but current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. Expert 1
- I would wait until results are available for projects such as this. Expert 2
- Plenty of trials awaited – hopefully good methodology. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Similar potential to the MedVizer T400 device above but we need outcome data similar or better to the Medvizer T400 if an impact is to be realised and technology adopted. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

Patient comments:
- **Innovation**: Similar devices on the market so not new to me. **Impact**: Already using something similar. **Acceptability**: Yes, already am.
- Yet again a very good idea. I would use this.

| 45) eHealth Diary | The eHealth diary is a form of telemonitoring of patients with advanced COPD within specialised home care. It is based on the patient’s participation in their own care. The product is simple to use - the patient keeps a health diary at home where they monitor specific health parameters that are important for their disease. The diary is kept on ordinary paper, but the patient uses a digital pen that automatically reads values written on paper. The scanned information is transferred from the pen to the central system and is thereby available to the staff of the care giver. The patient can also write messages to the caregiver. Because the caregiver is continuously provided with information about the patient’s health, it is possible to have an effective monitoring of a large number of patients and facilitates early identification of patients with worsening health. **It is produced by Phoniro systems, Sweden.** | Phoniro systems website: [http://www.phonirosystems.se/en/solutions/e-health](http://www.phonirosystems.se/en/solutions/e-health) | Monitoring of COPD Pilot/feasibility trial. | Trial registry ID: ISRCTN34252610. Interventional, non-randomised, single-centre, clinical study in Sweden. Trial due to end 30/11/16. Target sample size 130. |
**Expert comments:**

- **Might be useful for communication but trials needed. No evidence so far that home monitoring is effective in COPD.** Expert 1
- **All these technologies do have staffing implications. Could be useful for rural areas. Identification of exacerbations is important so this could be possibly a good idea.** Expert 2
- **Trials awaited. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance.** The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- **Innovative but still needs healthcare providers to act on this information. I am not enthused about this technology’s potential impact or adoption.** Expert 4
- **Low innovation: as per comments for all telehealth.** Expert 5

**Patient comments:**

- **Innovation: new to me. Impact: Could have if used correctly. Acceptability: Yes.**
- **Seems a good idea.**

| 46) i-DSMP (Internet-based Dyspnoea Self-management Program) | iDSMP is a system for the monitoring of patients for signs of AECOPD. It incorporates technological enhancements to support earlier recognition of worsening symptoms through real-time monitoring, prompt feedback, and convenient access to information and support. Patients use the iDSMP to submit real-time information about their symptoms (dyspnoea, cough, and sputum) and exercise (mode, duration, and intensity). | Published findings: [http://www.ncbi.nlm.nih.gov/pubmed/18417444](http://www.ncbi.nlm.nih.gov/pubmed/18417444) [http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD01425/pdf](http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD01425/pdf) | Monitoring for AECOPD | Phase II trial | Trial registry ID: NCT00461162. 125 participants. |
worst dyspnoea) using their desktop computer or smartphone. It is being researched at the University of California, USA.

Expert comments:
- Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. Expert 1
- All these technologies do have staffing implications. Could be useful for rural areas. Identification of exacerbations is important so this could be possibly a good idea. Expert 2
- Trial results awaited. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Innovative yes, potential for impact yes, potential for adoption yes assuming that outcome data supports improved care. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

Patient comments:
- Very similar to other devices, not sure it has any more to offer.
- Seems a good idea.

| 47) TLC-COPD (Telephone-linked computer - COPD) | The TLC system is a computer-based telecommunications system that can monitor, educate, and counsel patients through regular automated conversations in patients' homes. In previous studies, the applicability of TLC technology in the clinical monitoring of adults with chronic disease conditions such as hypertension and | Study concept: [http://www.ncbi.nlm.nih.gov/pubmed/11348968](http://www.ncbi.nlm.nih.gov/pubmed/11348968) | Monitoring of COPD | Phase IV trial | Trial registry ID: NCT00012805. 300 participants. Study complete, although no results published. |
hypercholesterolemia has been demonstrated. It is proposed that the TLC system can be utilised for the monitoring of patients for AECOPD.

Researched by David William Sparrow, VA Boston Health Care System, USA.

Expert comments:
- Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. Expert 1
- Could be useful. Expert 2
- Trial results awaited. Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Outcome data on improved patient care needed before commenting on likely impact or potential for adoption. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

Patient comments:
- Very similar to other devices, not sure it has any more to offer.
- Seems a good idea.

48) InterSpace: Web based supported self-
A website developed in collaboration with both experts in pulmonary rehabilitation and patients to be used as a self-management programme to patients with COPD. It is intended for use over a period

Patient info sheet:

Monitoring of COPD following an AECOPD
Feasibility study
Trial registry ID: ISRCTN13081008. Single centre non-randomised feasibility study,
A management programme of 3 months after discharge from hospital using tablet computers to help, guide, support and encourage patients to better understand and manage their condition and thereby reduce unnecessary readmission to hospital.

It will act as a web-based version of the SPACE for COPD programme and offer face-to-face video conferencing with clinicians/nurses.

*It is being researched at the University hospitals of Leicester, UK.*

**planned recruitment of 80 participants. Trial still recruiting and due to end 30/01/2016**

**Expert comments:**

- Technology that actually facilitates face to face contact may be useful. Expert 1
- Possibly very useful – would be interested in the trial results. You hope educating patients can help self-management but again has staffing implications. Expert 2
- I can’t see the evidence of the research published. This has been available for some time hence I am unclear how much benefit we will gain. A method using a single centre, non-randomised feasibility study of 80 patients in a unit which has probably several thousand per year is not a representative group? Useful to ask about evidence base behind SPACE and PR recently published in BMJ which was not positive. Greening NJ, Williams JEA, Hussain SF, et al. An early rehabilitation intervention to enhance recovery during hospital admission for an exacerbation of chronic respiratory disease: randomised controlled trial. British Medical Journal. 2014;349. Expert 3
- Yes, innovative, potential for impact and adoption if outcome data support this. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

**Patient comments:**

- Innovation: This is new to me – I like it. Impact: I think it would benefit patients and improve quality of life. Acceptability: Yes.
- A very good idea. Something we’ve needed for some time. I would like to use this.
It is hypothesised that the introduction of a short-term intensive telemonitoring programme followed by a less intensive ‘step-down’ approach to telemonitoring for patients discharged from hospital after an AECOPD reduces subsequent hospital re-admission.

ADAPT will provide the ability to interact with the Chronic Disease Management Team via the telemonitoring devices following discharge from hospital for an acute exacerbation of their COPD.

The Tm is composed of three stages:
1. **High Level Tm (gold)**: daily tele-consultation (preferably via video consultation or telephone if not possible), pulse oximetry and daily (six) symptom management questions for 10 working days after discharge.
2. **Moderate Level Tm (silver)**: daily pulse oximetry and six symptom management questions for up to 12 weeks after discharge.
3. **Low Level Tm (bronze)**: optional six symptom management questions and behaviour prompts via text messages or website links for up to 12 months after discharge.

Patients can be transferred between these levels (both up and down) according to Tm results and clinical discretion.

Research is led by Dr Keir Lewis, Prince Phillip Hospital, Llanelli, UK.

**Expert comments:**
- Intensive post-exacerbation input may be effective – trial results needed. Might help to refine resource utilisation so that those who are recovering well need less visitation and vice versa. Expert 1
- Possibly useful in initial stages of a discharge from hospital. The trial results will be interesting. Expert 2
- Await results from the Llanelli unit. Expert 3
- This is interesting for post-discharge monitoring of patients to try and prevent readmission. This certainly has potential for impact and NHS adoption. Expert 4

**Patient comments:**
- Innovation: New – regarding tailoring advice on 3 levels. Impact: Co-operation between patient and medical team has to be of benefit to patient. Acceptability – Yes.
- Don’t know anything about this. Could be good. I would use this.

| 50) SmartScope System | SmartScope System is a remotely used software application system intended for remote patient monitoring. It is designed to transfer health-related information of patients with COPD over a secure network by connecting the patient to care provider remotely. It enables clinicians to analyse data and give feedback while also improving communication and efficiency of care between patient and clinician through the transfer of health-centred data over a secure network. It encompasses software components for smartphone and tablet devices that transmits and stores data through a server application. It works on IOS (iPhone OS) system. | Biz journals: [http://www.bizjournals.com/philadelphia/blog/health-care/2013/08/smartphone-app-to-help-copd-patients.html](http://www.bizjournals.com/philadelphia/blog/health-care/2013/08/smartphone-app-to-help-copd-patients.html) | Monitoring of COPD | Pilot study. Estimated launch May 2016. | Pilot study complete with 30 patients in 2014. Plans for a larger scale study with 120 participants. |
Expert comments:

- Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. A technology looking for a problem. Expert 1
- Could be useful to improve communication & especially helpful for rural patients. I would wait until all of the results from pilot studies are available. Expert 2
- Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- This is innovative, has potential for impact and adoption. Expert 4
- Innovation: two way communication is a good idea. Potential for impact and adoption. Expert 5

Patient comments:

- Good as long as the patient is prepared to play their part and give regular feedback I would try it, but it wouldn’t work for everyone.
- They are all very good. I would try to use them all.

51) GaitTrack App

The GaitTrack app is a smartphone app used in conjunction with a pulse oximeter to monitor gait, heart rate and blood oxygenation. It was found that the GaitTrack app was able to accurately predict a patient’s FEV₁ spirometry test.

It takes advantage of accelerometers built into modern smartphones, obtaining more

Medgadget: https://www.medgadget.com/2014/05/gaittrack-smartphone-app-a-medical-device-for-automatic-gait-assessment.html

University of Illinois news:

Monitoring of COPD

Pilot study
05/06/2014: Team hoped to have the app available for download within months.

Pilot study complete with 30 patients in 2014.

Plans for a larger scale study with 120
comprehensive data than provided by traditional pedometers.

Producers claim the app is more accurate, and cheaper, than medical accelerometers already used in medicine.

*It is produced by Bruce Schatz, University of Illinois, USA.*

**Expert comments:**

- I think by predict they mean correlate with. Note that only works if smartphone carried (i.e. not indoors). May be useful for promoting exercise but pedometers are very cheap. Expert 1
- I would wait until all of the results from pilot studies are available. Expert 2
- Not sure of the value of steps – where is the evidence? Use of telehealth has had considerable investment within the UK – and at the current time reviews of any benefit in COPD and other long term conditions are lacking – hence it would not seem appropriate to invest more research funding into a technology which has not demonstrated clinical applicability and relevance. The COPD data is summarised by McLean S, Nurmatov U, Liu JLY, Pagliari C, Car J, Sheikh A. Telehealthcare for chronic obstructive pulmonary disease: Cochrane Review and meta-analysis. British Journal of General Practice. 2012;62(604):e739-e749, but it should be noted a positive result from DH funded research in the BMJ Steventon A, Bardsley M, Billings J, Dixon J, Doll H, Hirani S. Effect of telehealth on use of secondary care and mortality: findings from the whole systems demonstrator cluster randomized trial. British Medical Journal. 2012;344:e3874. Expert 3
- Innovative but I am not optimistic about impact or adoption until there is data showing that tracking gait patterns results in a change for the better in patient outcomes. Expert 4

**Patient comments:**


**Expert comments:**

- *This has potential to rapidly drive high value care – address over and under-prescription and misdiagnosis with big resource/value benefits for NHS.* Expert 1
- *This is an interesting project & hopefully could improve care.* Expert 2
- *Plenty of similar unpublished work ongoing but not aware of publication which either means of little value or working quietly behind the scenes.* Expert 3
- *This is innovative and has potential impact (less ICS usage, less pneumonia), and potential for adoption. This is exciting.* Expert 4
- *Low innovation unlikely to have widespread adoption.* Expert 5

**Patient comments:**
- **Innovation:** new idea – I like it. **Impact:** Think it is more likely to be used with newly diagnosed patients. **Acceptability:** I would be willing to give it a try.
- **Good idea.**

| 53) mACEWS (mobile Acute Care Early Warning System) | The mACEWS system is a mobile monitoring solution to help clinicians predict declining health in acute and critically ill patients. It will collect and translate structured and unstructured data via the AirStrip ONE® platform, and deliver real-time analytics on that data using IBM® InfoSphere® Streams, an advanced analytic platform that can be used in most any industry and with multiple types of data, that allows customer-developed applications to quickly ingest, analyse and correlate millions of data points per second as they arrive from thousands of real-time sources. The AirStrip mACEWS system’s resulting predictive care insights would then be ready for clinicians who use AirStrip’s mobile applications on Apple, Android and Windows devices. *Produced by Airstrip Technologies Inc., USA.* | Fierce medical devices: [http://www.fiercemedicaldevices.com/press-releases/airstrip-provide-mobile-monitoring-and-early-patient-warning-technology-usi-0](http://www.fiercemedicaldevices.com/press-releases/airstrip-provide-mobile-monitoring-and-early-patient-warning-technology-usi-0) Airstrip website: [http://www.airstrip.com/](http://www.airstrip.com/) | Monitoring of COPD for AECOPD | Partnership between Airstrip and IBM for technology announced October 2014. | No trials found. |

**Expert comments:**
- I like the detail on this software. I think this is innovative and has potential impact and adoption in NHS. As with all of these remote monitoring technologies, it will be very important to have outcome data of better care, lower hospital utilisation etc. to drive adoption. **Expert 4**
- Low innovation and impact. **Expert 5**
### Patient comments:
- Good – the earlier the better.

### 54) Smart Inhaler

An inhaler sensor serves as a remote monitor of drug use. It feeds into a smartphone app that tracks and analyses medication use.

The app predicts when patients are likely to have an AECOPD, based on prior experience, and can be used to ensure proper inhaler usage.

*Produced by Propeller Health (formerly Asthmapolis), USA.*

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<tr>
<th>Expert comments:</th>
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<tr>
<td>In general devices to monitor inhaler use (when and how devices used) will be useful for trials and possibly also for patients. Too early to comment on whether it is actually useful. Expert 1</td>
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<tr>
<td>Potentially could be useful to monitor compliance and early signs of an AECOPD. Expert 2</td>
</tr>
<tr>
<td>Innovative way of tracking compliance and also tracking rescue inhaler usage. This has potential impact and adoption but to drive this we need outcome data proving the benefit. Expert 4</td>
</tr>
<tr>
<td>Innovation: yes. Impact? For targeting individuals e.g. compliance. Adoption: potential. Expert 5</td>
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<th>Expert comments:</th>
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<tr>
<td>Innovation: New – good idea. Impact: Yes will make sure inhalers are used to maximum benefit. Acceptability: Yes I would use it.</td>
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<td>Good – the earlier the better.</td>
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<th>Fierce medical devices:</th>
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<th>Monitoring of COPD</th>
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<td>FDA approved.</td>
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<th>Estimated market launch</th>
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<th>No trials found.</th>
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<th>Propeller health website:</th>
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<th>Eye for pharma:</th>
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| 55) Health-e-Connect System | Health-e-Connect System is an internet-based patient monitoring system intended for remote nebuliser compressor monitoring. It is designed to enable physicians and caregivers to monitor the use of the nebuliser, including the duration of nebuliser use, in people who suffer from COPD.

The system is composed of application software and hardware devices. The hardware consists of the CHC (Constant Health Companion) connected to nebuliser models that include connectivity, and a transmission modem.


**Expert comments:**
- Could be useful to monitor compliance as with inhaler technology. Expert 1
- No- nebulisers are not routinely used in the community for COPD in this country. Expert 2
- Why spend so much on nebuliser use (duration) if the patient knows could they just set the machine off? Can they monitor the number of prescriptions? Expert 3
- Not especially exciting and low likelihood of impact or adoption. I guess neb use might predict exacerbation but compared with other technologies shown in this document it is pretty unexciting. Expert 4
- Low innovation: as per comments for all telehealth. Expert 5

**Patient comments:**
- Innovation: Completely new to me. Impact: Could have, I only use my own nebuliser during an exacerbation. Acceptability: Yes.

and follow up of patients with COPD based on a combination of biomedical sensors, smart phones, databases and software; in addition, it can also evaluate disease progression and provide predictive design for personalised recommendations for treatment by assessment of pulmonary symptoms and lung function.

*Produced by CareTelCom AB, Sweden.*

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**Expert comments:**
- Potentially could be useful to monitor compliance and early signs of an AECOPD. Expert 2
- Wait for results of trial. Expert 3
- This is innovative, has potential impact and adoption possibilities depending on the outcome data from the trial. Expert 4

**Patient comments:**
- Innovation: new. Impact: Could have a significant impact on patients. Acceptability: Yes.
- The earlier the better.

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| 57) Semi-automated cough classifier (Philips ambient system) | Daily cough monitoring using ambient sound recording system (Philips) and a novel semi-automated cough classifier intended for use in monitoring cough in COPD patients as a marker for AECOPD. Researchers claim the technology is an effective and unobtrusive method of objectively monitoring trends in cough frequency in COPD patients. *Researched by Michael Crooks, Hull York Medical School, UK.* | Published findings: [http://erj.ersjournals.com/content/44/Suppl_58/P4008.abstract?sid=c934b8c-de16-4d31-b8a8-30e1696f0fdd](http://erj.ersjournals.com/content/44/Suppl_58/P4008.abstract?sid=c934b8c-de16-4d31-b8a8-30e1696f0fdd) | Monitoring of COPD | Pilot study | Pilot study monitored 13 participants over 45 days. |
Expert comments:
- May be useful for research evaluating therapies and for the investigation of people with difficult cough. Expert 1
- Possibly useful – more studies are needed. Expert 2
- Why monitor cough in AECOPD? Does it indicate severity? How applicable will it be for an individual? Expert 3
- Innovative but cough alone is not an especially good indicator to drive interventions. I am not enthusiastic about the potential impact or adoption in NHS. Expert 4

Patient comments:
- Acceptability: Would be prepared to give it a try.
- Good idea. I would use this.

| 58) Microsoft® Kinect™ based telemedicine programme | A Microsoft Kinect based telemedicine system used in order to monitor patients with COPD. Kinect is a television based device which, using a built in sensor, is able to monitor the patient’s movements. Patients answer a symptom questionnaire, send data on pulse oximetry and temperature and perform upper arms exercises controlled by Kinect®.

Researchers claim the programme is viable and very well accepted by patients resulting in fewer and less severe AECOPD.

Researched by David Bravo, HUA Txagorritxu, Spain. |

Published findings: [http://erj.ersjournals.com/content/42/Suppl_57/P4906.full.pdf+html?sid=5cc09e9e-afa0-4877-adbc-811206701cad](http://erj.ersjournals.com/content/42/Suppl_57/P4906.full.pdf+html?sid=5cc09e9e-afa0-4877-adbc-811206701cad) | Monitoring of COPD | Pilot study | Pilot study involved 5 participants. Daily adherence was 97% and all participants were able to learn how to use the technology. |

Expert comments:
- Current best evidence (Pinnock et al) is that cost per QALY for telehealth in COPD is £130k. This sort of intermittent home monitoring is unlikely to be useful. Expert 1
- Need further studies. Expert 2
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<th>Patient comments:</th>
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<td>Seems good.</td>
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4) Imaging technologies

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<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
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| 59) PRM™ (parametric response map) COPD | PRM™ COPD is a software technology that has been developed to distinguish areas of normal tissue, emphysema and chronic bronchitis in CT images of the lungs of people with chronic obstructive pulmonary disease (COPD). The software produces a colour coded image of the lungs by quantifying changes between inspiratory and expiratory CT images using a technique called Parametric Response Mapping™. The image produced is intended to show areas of normal tissue in green, chronic bronchitis in yellow and emphysema in red. The company state the software can be used with existing imaging equipment as most modern CT scanners have a high enough resolution. 


**Expert comments:**

- *Quantifying CT appearances may be useful for trials and for patient selection for lung volume reduction approaches. Difficult to say which will be better – depends on cost, ease of use, forward and back compatibility and features like fissure analysis.* Expert 1
- *Wait for publication on system – should be plenty of these available soon compared against.* Expert 3
- *Interesting and innovative but I don’t see how this will change outcomes for patients and therefore I think impact is low and*
likelihood of adoption is low. Expert 4


| 60) Mobile SPECT imaging | Mobile SPECT (single-photon emission computed tomography): CT imaging suitable for acute care, bedside or clinics remote from tertiary centres could be used for the diagnosis of COPD.

Mobile SPECT is sensitive to early changes in COPD and has the possibility of identifying comorbid disease.

*Researched by Professor Brian Hutton, UK.*  |
| Science Daily: [http://www.sciencedaily.com/releases/2013/04/13041111549.htm](http://www.sciencedaily.com/releases/2013/04/13041111549.htm)  |
| Published findings: [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC370634/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC370634/)  |
| Diagnosis of COPD  |
| 2013: system currently under development for use as a SPECT insert for MRI. Prototype to be installed early 2016  |
| 2013: Trial of 10 participants concluded that further clinical studies are required.  |
| 2011: Trial of 30 participants.  |

**Expert comments:**

- Hard to see that this would catch on for diagnosing early disease compared to existing technologies. Expert 1
- 40 patients over 4 years – not sure how applicable yet. Expert 3
- Interesting and innovative but is there really a problem with diagnosis of COPD. Not really. Yes, detecting comorbid cancer or other disease is useful but I am not optimistic about impact and adoption in current NHS climate. Expert 4

| 61) CT perfusion scan | CT perfusion scans may be used in order to determine physiological disease severity in COPD. The technology may offer earlier identification of patients at risk, as well as provide regional detailed information on lung function with the prospect of more targeted treatment.

*Researched by Dr John Murchison, University of Edinburgh, UK.*  |
| Diagnosis of early COPD and those at risk of disease progression  |
| In pilot/feasibility trial  |
| Trial due to close 31/12/2015. Single centre, interventional, pilot/feasibility trial with 30 participants.  |
Expert comments:
- May have a role but needs to be evaluated against CT. Expert 1
- Again too far in the future. Expert 3
- Low enthusiasm for this. Easy ways already of knowing patients at risk based on lung function, CT scan, history of exacerbation etc. Moderately innovative but low impact and low likelihood of adoption in NHS. Expert 4
- Innovation moderate. Impact potentially for targeted treatment for emphysema. Adoption- will depend on comparison with current techniques- highly specialised units. Expert 5

| 62) Quantitative CT scans | Quantitative CT can be used to measure inflammation as determined by thickness of airway walls and the amount of tissue destruction or emphysema. Greater airway wall thickness and emphysema were both associated with more frequent exacerbations; each 1mm increase in bronchial wall thickness was associated with a 1.84-fold increase in annual exacerbation rate. Emphysema became a factor only if it involved 35% or more of the lungs. Beyond the 35% involvement, each 5% increase in emphysema was associated with a 1.18-fold increase in exacerbations. Greater lung emphysema and airway wall thickness were associated with COPD exacerbations, independent of the severity of airflow obstruction. Quantitative CT may help identify subgroups of patients with COPD who experience exacerbations for targeted research and therapy | Medical news today: [http://www.medicalnewstoday.com/releases/239855.php](http://www.medicalnewstoday.com/releases/239855.php) Published findings: [http://pubs.rsna.org/doi/abs/10.1148/radiol.1110173](http://pubs.rsna.org/doi/abs/10.1148/radiol.1110173) [http://www.atsjournals.org/doi/full/10.1513/pats.200804-034QC#.VMoY1CusWSU](http://www.atsjournals.org/doi/full/10.1513/pats.200804-034QC#.VMoY1CusWSU) | Monitoring for the likelihood of AECOPD Technology widely available but not widely used for this indication. Technology widely available but not widely used for this indication. 2011: Study completed and published (1002 participants). |
development for individual phenotypes.

*Researched by James D. Crapo, Professor of Medicine at National Jewish Health, USA.*

**Expert comments:**
- Quantifying CT appearances may be useful for trials and for patient selection for lung volume reduction approaches. Difficult to say which will be better – depends on cost, ease of use, forward and back compatibility and features like fissure analysis. Expert 1
- Too far in the distance in UK general practice. Expert 3
- Research tool not something that will impact on patient care of be adopted in NHS. Expert 4
- Innovation: moderate. Impact could be used as a tool to study targeted therapy. Adoption unlikely. Expert 5

| 63) Transthoracic Parametric Doppler (TPD)/Pulsed Doppler Ultrasound System | A non-invasive and non-imaging ultrasound Doppler and signal processing technology capable of extracting parametric information regarding both the coronary arteries and the pulmonary system. Three modes: 1. **P–Mode:** TPD measures Doppler shifts due to the movement of the border between the pulmonary blood vessel walls and the alveoli that surround them. The signals, which are obtained by a simple non-invasive procedure of short duration (a few minutes), provide highly significant clinical information regarding changes in lung parenchyma indicative of pulmonary diseases such as COPD, | Company website: [http://www.echosense.co.il/Index.aspx](http://www.echosense.co.il/Index.aspx)  
fibrosis, emphysema and sarcoidosis.

2. **PBP-Mode**: A variant of P-Mode dedicated to measurement of Pulmonary Blood Pressure. The ability to carry out pulmonary pressure measurements in a non-invasive simple, 5 minute procedure will most likely turn to be a standard in physical examination in internal medicine.

3. **C-Mode**: Evaluation of the functional integrity of the coronary circulation.

*Produced by EchoSense Ltd., Israel.*

**Expert comments:**
- Too far in the distance for UK general practice. Expert 3
- Interesting, innovative, potential for impact and adoption in NHS but I think more data is needed; the attached publications have modest evidence for the benefits. The data needs to be much more mature. Expert 4
- Innovation moderate. Impact - low. Adoption specialised centres only and would need to be compared with current technologies. Expert 5

| **64) Human Lung Regional Ventilation Defect Severity Measured by Fluorine-19 Gas MRI** | MRI using inert perfluorinated gases mixed with oxygen for regional assessment of pulmonary function. In the case of these perfluorinated/oxygen mixtures, the availability of multi-litre quantities allows for wash-in/wash-out image acquisition and analysis allowing direct measures of gas trapping in a manner not easily achieved with any existing modality. | Clinical trials.gov: [https://clinicaltrials.gov/ct2/show/NCT01640288](https://clinicaltrials.gov/ct2/show/NCT01640288) | Monitoring of COPD Phase II trial | Trial estimated completion date June 2017. |
This technology is intended for use in the monitoring for progression of COPD.

Researched by Cecil Charles, Duke University Medical Center, USA.

**Expert comments:**
- Likely to be very expensive so limited to clinical trial applications rather than clinical practice. Expert 1
- Too far in the distance for UK general practice - need robust some data. Expert 3
- This is a research tool and has low likelihood for impact or adoption in NHS for the foreseeable future. Expert 4
- Innovation high. Impact has potential depending on the ease of use and reliability of data. Adoption potential for specialised centres. Expert 5
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<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
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<tr>
<td><strong>Product</strong></td>
<td><strong>Description</strong></td>
<td><strong>Company</strong></td>
<td><strong>Website</strong></td>
<td><strong>Preliminary Validation Stages</strong></td>
<td><strong>Diagnosis of COPD</strong></td>
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<td><strong>Respiratory Holter - COPD</strong></td>
<td>Respiratory Holter - COPD is intended for the diagnosis of respiratory diseases. It is designed to measure respiratory rate by estimating dispersion of QT interval in patients suffering from COPD. <em>Developed by Nicrem S.r.l., Italy.</em></td>
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**Expert comments:**
- Technology for the accurate long term measurement of respiratory rate in hospital or at home may be useful. Depends on the practicalities of the patient interface. Expert 1
- No great evidence to support use in any way. Expert 3
- This appears novel and RR monitoring is an important way of tracking respiratory risk. However, compared to other technologies in

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**Patient comments:**
- Innovation: Have heard of this or something similar. Impact: Seems more suited in nursing homes and hospitals. Acceptability: maybe.
- Seems very versatile. If the company is right. Once again good that it gives earlier detection.
This document this product is less interesting and has very modest potential for impact and adoption in the NHS. Again, as with all these technologies, outcome data from trials would be necessary to support adoption. Expert 4
- **Innovation:** Low. **Impact:** Low. **Adoption:** Unlikely. Expert 5

**Patient comments:**
- **Innovation:** new to me. **Impact:** I think it could have a great impact. **Acceptability:** Yes definitely.
- **I would use it.**

<table>
<thead>
<tr>
<th>67) Nonin Bluetooth® Smart Model 3230 Finger Pulse Oximeter</th>
<th>Nonin’s Model 3230 is the first finger pulse oximeter with Bluetooth Smart wireless technology, which provides a simplified pairing for vital information exchange over a secure wireless connection. Nonin’s clinically proven accuracy provides precise readings. Nonin claims to be the only company with has SmartPoint™ capture and send and CorrectCheck™ technologies to provide advanced information.</th>
<th>Fierce medical devices: <a href="http://www.fiercemedicaldevices.com/press-releases/nonin-medical-announces-fda-clearance-nonin-bluetooth-smart-model-3230-fing-0">http://www.fiercemedicaldevices.com/press-releases/nonin-medical-announces-fda-clearance-nonin-bluetooth-smart-model-3230-fing-0</a> Nonin Medical website: <a href="http://www.nonin.com/EMSolutions/Nonin_3230_Bluetooth_SMART">http://www.nonin.com/EMSolutions/Nonin_3230_Bluetooth_SMART</a> YouTube video of product: <a href="https://www.youtube.com/watch?v=qO6tL8OF3Yk">https://www.youtube.com/watch?v=qO6tL8OF3Yk</a></th>
<th>Monitoring of COPD</th>
<th>FDA approved. Launched in 2013. Awarded 2014 Bluetooth Breakthrough Award in the Product Category. The award recognises products that have a large market appeal and are innovative, easy to use, convenient and reliable.</th>
<th>No trials found</th>
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**Expert comments:**
- **May provide some additional useful connectivity on certain contexts e.g. with smartphone apps.** Expert 1
- **Company well known and accepted as measure of pulse and oximetry. Blue tooth technology useful to computer and onwards. Not sure how much use it will be though in real world.** Expert 3
- **Innovative; outcome data needed but may have impact and potential for NHS adoption as a means of monitoring COPD patients via**
Capno-Pulse is a continuous, non-invasive respiratory monitoring device intended for the monitoring of asthma and COPD.

It is designed to measure partial pressure of carbon dioxide (PaCO₂) in the arterial blood and is based on Capno-Pulse Technology. It can be combined with pulse oximeter and multi-parameter patient monitoring unit in the hospitals.

Produced by Neetour Medical Ltd., Israel.

Expert comments:

- Accurate non-invasive CO₂ measurement would be useful to identify people at high risk for needing NIV and for sleep monitoring. Depends how it performs against existing technology. Expert 1
- Not sure how much use this will be if proven as we don’t usually measure pp CO₂. Expert 3
- This seems to be for use in hospitals and is not especially novel as CO₂ monitors have been around for a while. It is a useful parameter to measure and avoids the need for blood gases in some patients and can track improvement or deterioration in patients with type II respiratory failure exacerbations. Some potential for impact and NHS adoption, just not especially novel and not a home monitoring device. Expert 4
- Innovation: Relatively innovative technology with capabilities of measuring the same parameters as other devices on the market. Would need to demonstrate its uniqueness in comparison to other readily available devices. Impact: Minimal impact in light of

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<td>YouTube video of product: <a href="https://www.youtube.com/watch?v=GJ_rD-09vZ4">https://www.youtube.com/watch?v=GJ_rD-09vZ4</a></td>
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existing technology that already performs the same task. Adoption: dependent on cost and efficiency compared to existing technology. Expert 5

Patient comments:
- **Innovation:** Not heard of it. **Impact:** looks more suited for inpatient use. **Acceptability:** Would give it a try.
- **Sounds good although don’t know anything about this.**
## 6) Spirometry technologies

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<th>Technology</th>
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<th>Stage of development</th>
<th>Trial details</th>
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| 69) MySpiroo | An ultra-portable, handheld, mobile spirometer that attaches to a mobile device via an audio jack/Bluetooth to monitor COPD/asthma. Comes in a PRO version with spirometry functions, reports and statistics, or a HOME version with patient friendly functions. Comes with a mobile app which plots change in spirometry over time. *Produced by MySpiroo, Poland.* | Company website: [http://www.myspiroo.com/#intro](http://www.myspiroo.com/#intro)  
Behance news: [https://www.behance.net/gallery/13586829/MySpiroo-Medical-device-Mobile-App](https://www.behance.net/gallery/13586829/MySpiroo-Medical-device-Mobile-App)  

**Expert comments:**
- **Costs, use is important here. If accurate could be used as screen at home. Not sure much benefit unless measure FEV₁ and PEFR at home.** *Expert 1*
- **We have been giving patients post-lung transplant home spirometers for years. This device is novel due to the Bluetooth technology but it still needs the patient to do the spirometry (our transplant patients get less compliant with self-recording over time) and someone to act on the readings in the hospital. This could be useful to COPD nurses but poor technique will be a limiting factor in some patients and reliability of readings may be low. Respiratory nurse specialists may value this but I suspect that monitoring RR and oximetry may be a more useful tool and the ability to remotely ‘see’ patient as some of other products can deliver, make this particular product of limited utility.** *Expert 4*
- **Innovation:** this is an innovative product via the ability to be used with a smartphone. This is significant innovation with regards the ability for spirometry to be performed by the patient in any setting. Reservations are the training of the patient to perform the manoeuvre to acceptable standards of reproducibility to ensure accuracy of results. **Impact:** impact likely to be minimal due to necessary training requirements to ensure accuracy of results. **Adoption:** Unlikely due to standards that need to be adhered to which will require input from healthcare professionals and hence no significant improvement to current system. Expert 5

**Patient comments:**
- **Innovation:** new. **Impact:** Possibly. **Acceptability:** Yes would give it a try.
- This is a good idea. I'd like to see it working. I would use it.

| 70) MIR Smart One® | MIR Smart One® is a smartphone based spirometer capable of measuring peak flow and FEV1. Test results include history with Peak Flow, traffic light health indicator, symptoms scoring and notes. It connects wirelessly to Bluetooth Smart and Bluetooth Smart Ready devices with extremely low battery consumption. With two common alkaline batteries it can run up to 5-10 years on standby mode with more than one thousand tests performed. MIR Smart One® comes with an App that includes an incentive for both adults and children. The incentive program shown directly on the screen is helpful in improving children’s compliance during testing. *Produced by MIR (Medical International Research), Italy.* | Product pages: [http://www.spirometry.com/ENG/products/smartone.asp](http://www.spirometry.com/ENG/products/smartone.asp) [http://clearlinemedical.com/MIR_New_Catalog_2015%20CLM.pdf](http://clearlinemedical.com/MIR_New_Catalog_2015%20CLM.pdf) YouTube video of product: [https://www.youtube.com/watch?v=JX27xfm0wwE](https://www.youtube.com/watch?v=JX27xfm0wwE) | Monitoring of COPD | Launched November 2014 | No trials found |
**Expert comments:**

- Not sure why this is needed rather than a hand held and normal email/communications systems? Expert 3
- Innovative, some potential for impact and adoption but relies on patient being self-motivated and happy and capable of self-management. Expert 4
- Innovation: Only through integration with smart phone technology and not significant. Impact: Due to level of training required to ensure test are conducted appropriately the impact is going to be minimal. Adoption: unlikely to be adopted as not a significant improvement on systems that are already available and the requirement for healthcare professional input into training to ensure standards and quality of outcomes are maintained. Expert 5

**Patient comments:**

- Innovation: new to me. Impact: Could have considerable impact. Acceptability: Yes definitely.
- I like this one and would use it.

| **71) Smartphone spirometer** | Respio's smartphone spirometer takes spirometric readings through a disposable mouthpiece using laser sensors, taking several thousand measurements per second and connects to a smartphone. 

The mobile spirometer uses a smartphone’s sensors to ensure proper body posture during the measurement, and adjust the collected data based on environmental conditions such as pressure and temperature. Using GPS recording, it is able to collect and localise areas dangerous to the patient's respiratory capabilities, and predict their lung capacity.

With the app, you can visualise spirometry data and easily understand a patient's respiratory condition. In a single touch you can browse |
<table>
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<tr>
<td></td>
<td>Monitoring of COPD</td>
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<td>Unknown</td>
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<td></td>
<td>No trials found</td>
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through history and see how medication increases lung functionality. From the palm of your hand you can send the data and advise on medication in real time.

Produced by Resp.io, USA.

**Expert comments:**
- Which spirometric readings and why do I need them online… basic figures and patients symptoms have the evidence. Expert 3
- Innovative but spirometry has its limitations and of course you need the healthcare professional to act on it and patient to comply with doing the spirometry manoeuvres. Outcome data specific to this device is needed in terms of reducing exacerbations or hospital visits etc. Expert 4
- See comments above to other similar technologies. Expert 5

**Patient comments:**
- I like this one and would use it.
<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology</th>
<th>Information sources</th>
<th>Place in management</th>
<th>Stage of development</th>
<th>Trial details</th>
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**Expert comments:**
- Could be a useful innovation to predict safe early discharge – trial results awaited. Expert 1
- Innovative, potential impact and also potential for adoption in hospital setting as it helps risk stratify patients. Expert 4

**Patient comments:**
- This sounds good. I would use it.
<table>
<thead>
<tr>
<th><strong>73) Asthma-COPD Overlap Syndrome (ACOS) Questionnaire</strong></th>
<th><strong>Consultant 360:</strong> <a href="http://www.consultant360.com/articles/diagnosing-asthma-copd-overlap-syndrome">http://www.consultant360.com/articles/diagnosing-asthma-copd-overlap-syndrome</a></th>
<th><strong>Diagnosis of COPD where asthma co-exists</strong></th>
<th><strong>Phase II trial</strong></th>
<th><strong>Trial registry ID:</strong> NCT02302417. Currently recruiting participants (planned recruitment, 1,000). Estimated trial completion date April 2015.</th>
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<tr>
<td>The ACOS questionnaire is a 41 item questionnaire which has been developed to elicit specific details of the respiratory history. It includes the following: bronchodilator use, disease progression, variation in symptoms, atopic history, symptom triggers, vagal bias, burden of disease, symptom presentation, co morbidities and age of onset. The questionnaire aims to identify subjects With features of both asthma and COPD. <em>Developed by US GSK Clinical Trials Call Center, USA.</em></td>
<td><a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3966158/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3966158/</a></td>
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**Expert comments:**
- This is at an early stage – may help with phenotyping for trials. Would need to show that it actually influences management in real life. 41 is a lot of items. Expert 1
- Possibly a useful tool for clinical practice. Expert 2
- Not sure about this one at all. This is a condition managed by GP for decades and only recently a guideline for specialist. It needs to be really practical if we use any questionnaire. Expert 3
- Limited utility, low potential impact or adoption. Expert 4

**Patient comments:**
- Innovation: not new. Acceptability: Yes if it would be of any help.
- This is a long questionnaire and patients do get tired of filling forms. Is there no other way? I would use it if I had to.
| 74) COPD screening questionnaire | COPD screening questionnaire is a questionnaire on smoking status and symptoms of COPD. It aims to identify those in need of investigation. If patients were smokers or former smokers, or if morning cough with sputum and/or dyspnoea was present, subjects are defined as "at risk of COPD" and are invited to undergo spirometry examination. Developed by Anne Marie Lyngsø, Bispebjerg University Hospital, Denmark. | Published findings: [http://informahealthcare.com/doi/full/10.3109/1541255.2012.714426](http://informahealthcare.com/doi/full/10.3109/1541255.2012.714426) | Early diagnosis of COPD | Effectiveness evaluation study | April 2013: Effectiveness evaluation study, 7103 participants. |

**Expert comments:**
- Could be a useful way to identify and encourage people to get spirometry done. Depends how many questions and if it performs better than "clinical" cough sputum breathlessness questions. Expert 1
- Possibly a useful tool for clinical practice. Expert 2
- Would suggest use microspirometry rather than questionnaire too much evidence to continue to use questionnaires. Expert 3
- Not novel, tools already exist, low impact and low likelihood of adoption. Expert 4

**Patient comments:**
- Any early pick up and detection of patients would be beneficial.
- Any means of earlier diagnosis of COPD is good.

| 75) DOSE index | The DOSE index is a multicomponent index and has the potential to predict important future outcome in patients with COPD better than the FEV1. | Published findings: [http://www.ncbi.nlm.nih.gov/pubmed/23538702](http://www.ncbi.nlm.nih.gov/pubmed/23538702) | COPD severity scoring and prognostic indicator | Validation study | A prospective cohort study with data from 209 participants in primary and... |
A DOSE score ≥4 has the ability to identify COPD patients with a greater risk on future worsening in health status and hospitalisation risk.

*Developed by Dr. Lisette van den Bemt, Radboud University Nijmegen, Netherlands.*

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<th>Expert comments:</th>
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<td>These scores are useful for stratifying for trials but of little use to individual patients or in clinical care. Expert 1</td>
</tr>
<tr>
<td>Possibly a useful tool for clinical practice. Expert 2</td>
</tr>
<tr>
<td>This was developed by Rupert Jones and colleagues including Neils Chavannes and is well validated as an option Jones RC, Donaldson GC, Chavannes NH, et al. Derivation and Validation of a Composite Index of Severity in Chronic Obstructive Pulmonary Disease: The DOSE Index. Am. J. Respir. Crit. Care Med. 2009;180(12):1189-1195. I do find it difficult to see why not used more as plenty of other evidence. Expert 3</td>
</tr>
<tr>
<td>Not clear to me that it is any advance over existing risk assessment tools with more robust evidence such as BODE index etc. low potential for impact or adoption. Expert 4</td>
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secondary care.
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<tr>
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<th>Description of technology</th>
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**Expert comments:**

- *May be useful in frail/co-morbid population – limit to more general use is floor and ceiling effects. Expert 1*
- *Wait for peer reviewed results. If works in a time rich environment like Brompton/Harefield needs evaluation in the pressured environment of primary care – can the authors indicate which 50% of already measured parameters should be discarded for this? What outcomes? Expert 3*
- *This is simple yet innovative and has potential for impact and adoption. It will be nice to see some hard data. Expert 4*

**Patient comments:**

- *If a patient has a 4 metre flat uncluttered floor area I think this would work – so would try it.*
- *4 metres is a big space!***
| 77) SonicSense | SonicSense is a unique new approach to gas sensing which radically cuts costs, size and power consumption. The ultrasonic sensor uses patent-pending TTP technology to precisely measure the speed of sound in a gas to determine its composition. It has the potential to disrupt a broad range of healthcare sensing applications such as respiratory monitoring, capnography, anaesthesia and COPD monitoring.  


**Expert comments:**
- Await trials. Expert 3
- Novel, but too early to say whether it will have impact or potential for adoption as no data. Expert 4

| 78) RESPOC Point-of-care testing for respiratory viruses | RESPOC is a fast, cost-effective and user-friendly molecular diagnostic point of care instrument for near-patient use. New rapid tests for respiratory viruses have been developed that can be done in admission units and give results within 1 hour. These tests have equivalent accuracy to the standard laboratory tests. | Product pages: [http://respoc.eu/#benefits](http://respoc.eu/#benefits), [http://ateknea.com/uncategorized/respoc-launch/](http://ateknea.com/uncategorized/respoc-launch/) | Point of care test to determine the cause of AECOPD Expected commercial launch 2016. Developers claim the technology is “licensed for clinical use in Europe and ResPOC trial (registry ID: ISRCTN90211642, protocol number: RHM MED 1217). An RCT at University Hospitals Southampton Foundation NHS Trust (UK) with 400 participants planned.” |
Introducing these new tests to admission units may improve the identification and management of patients infected with respiratory viruses and could also improve infection control practices to stop the spread of viruses within hospitals.

Identifying viruses at an early stage of a patient's care might also lead to a reduction in antibiotic use, which is important in reducing the spread of antibiotic resistance in hospitals.

*Developed by Ateknea Solutions, Hungary.*

**Expert comments:**
- Await trials. Expert 3
- Novel, with potential impact and adoption but we need some data. Expert 4

**Patient comments:**
- Innovation: New. Impact: Could have a great impact and avoid the overuse of antibiotics and give earlier access to antivirals. Acceptability: Yes.

<p>| 79) HIRA-TAN semi-quantitative PCR | PCR method is quick and sensitive to detect microorganisms but is difficult in discriminating pathogens from colonizers. A recently developed semi-quantitative PCR method, HIRA-TAN, can be used to detect microorganisms using an organism-to-organism comparison. | Published findings: <a href="http://erj.ersjournals.com/content/42/Suppl_57/3323.full.pdf+html?sid=1fb644f5-af8b-41bb-b3f8-7e0c8f70646a">http://erj.ersjournals.com/content/42/Suppl_57/3323.full.pdf+html?sid=1fb644f5-af8b-41bb-b3f8-7e0c8f70646a</a> | Determining the cause of AECOPD Validation study | 2014 trial (ID: UMIN000001694) with 568 participants. 2013 trial with 254 participants. |</p>
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<th>80) Multiplex PCR (mPCR)</th>
<th>Highly sensitive mPCR is a useful and rapid technique for detecting respiratory viruses from tracheal aspirate and nasal pharyngeal aspirate samples.</th>
<th>Published findings: <a href="http://erj.ersjournals.com/content/42/Suppl_57/P1882.full.pdf+html?sid=99b2ffe-cad9-47d0-9cbd-15d48ebe73c6">http://erj.ersjournals.com/content/42/Suppl_57/P1882.full.pdf+html?sid=99b2ffe-cad9-47d0-9cbd-15d48ebe73c6</a></th>
<th>Diagnosing the cause of AECOPD</th>
<th>Proof of concept study</th>
<th>2013: study with 137 participants.</th>
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<tr>
<td>Human cell DNA copy number ratio as an index for their pathogenic role.</td>
<td>HIRA-TAN is useful to identify bacteria responsible for comorbid airway infections in COPD including: H. influenza, P. aeruginosa, K. pneumonia, M. catarrhalis, E. coli, MRSA and S. pneumonia. Overall the HIRA-TAN procedure is able to identify the causative pathogens of pneumonia in 60% of the cases. The test is rapid, accurate, easily performed, and cost-effective.</td>
<td><a href="http://www.ncbi.nlm.nih.gov/pubmed/24411834">http://www.ncbi.nlm.nih.gov/pubmed/24411834</a></td>
<td>Researched by Dr. Shohei, Minezaki, Saitama Medical University, Japan.</td>
<td>Expert comments:</td>
<td>Patient comments:</td>
</tr>
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<td>• Await trials. Expert 3</td>
<td>• A great idea – would definitely welcome this one.</td>
<td></td>
<td>Innovative, may have impact of more rapid and appropriate targeting of antibiotics, yes it has potential for impact and adoption. Expert 4</td>
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This technology may prove helpful in early detection of the aetiology of AECOPD.

*Researched by Mr. Arvind, All India Institute of Medical Sciences, India.*

**Expert comments:**
- Await trials. Expert 3
- Useful tool potentially but limited utility as even if you find a virus that does not rule out a bacterial co-infection. Expert 4

**Patient comments:**
- Any community based technology which gives rapid diagnosis of a virus is excellent.
REFERENCES


42 Barnes PJ. Addressing unmet medical need in COPD management. Future Medicine 2011.


50 NICE DUETs. Antibiotics for exacerbations of chronic obstructive pulmonary disease. Updated 31/12/12. Available from:


