Horizon Scan Report 0015 **Date 20 June 2011**

Diagnostic Technology: Spirometry in primary care for COPD case finding, self-monitoring and remote technology.

Clinical Questions:

1. Can self-monitoring or remote monitoring with spirometry lead to early detection of acute exacerbations of COPD (AECOPD) and/or enhance decision making regarding need for admission?
2. Does self-testing by spirometry and intervention improve outcomes in COPD management compared with usual care or with other interventions such as education, management plans or symptom scoring? (Examples of beneficial primary outcomes include reduced attendance at emergency departments, hospital admissions, and reduced decline in long-term lung function).
3. Does early detection by case finding or screening improve outcomes for patients with COPD?

Advantages over Existing Technology:

1. Symptom scoring

Classification of COPD using symptoms

The 2010 update to NICE guidance on COPD has brought spirometric measurement criteria for COPD in line with GOLD classification (i.e. FEV1>80% predicted and FEV1/FVC ratio < 0.7). However there is one important difference; GOLD does not require the presence of subjective symptoms (cough, sputum production, shortness of breath), whereas NICE guidance states that symptoms are a requirement for diagnosis and classification of COPD.(1)

This continuing discrepancy between national and international guidance is unhelpful for patients, doctors, policy makers and researchers because there is substantial evidence that reported symptoms are unreliable for diagnosis. For example, among 5000 people from those included in the Third National Health and Nutrition Examination survey in the US, 70% of those with undiagnosed early airways obstruction (and up to 50% of undiagnosed stage 3 COPD) denied having cough or phlegm and 40% denied a wheeze (2). A longitudinal study of over 2000 patients with COPD, from 12 different countries, found that 'among subjects with severe airflow obstruction, a substantial proportion did not report symptoms'. About 40% of those in the GOLD severe category denied being breathless (modified MRC dyspnoea scale 0(10%) or 1(30%)) (3). Likewise, among a large population survey in China of 20 000 people over 40 years of age, 8% were found to have COPD of whom 35% had no symptoms (they said 'no' to the questions- 'do you have cough, phlegm wheeze or breathlessness?') (4).

Case finding using symptom scores

Symptom scoring has been used as method of case finding but as outlined above, symptom reporting alone is not a reliable means of determining a diagnosis of irreversible airways obstruction or for staging airways disease. Symptom questionnaires have the disadvantage of missing those who deny or are unaware of symptoms (when clinically they are dyspnoeic, wheezing or have a cough) or have no symptoms but have measurable impairment of lung function. One recently published symptom-scoring tool has been developed and validated in a US population. Although they found reasonable sensitivity (80%), the tool has poor specificity (<50%) (5). Therefore even a validated symptom scoring tool failed to detect 20% of people who have the disease (but deny/do not have symptoms) and produced a large number of false positives (those who had symptoms but did not have COPD).

The presence of large numbers of people with undiagnosed symptomatic and asymptomatic COPD in many different populations poses a dilemma. The US Preventive Service Task Force is firmly against screening with the rationale that there is no early treatment except smoking cessation, and early detection medicalises those with mild and asymptomatic disease (6). However, recent evidence points towards better smoking cessation with early detection and confrontation with results (7). There is a paucity of other evidence for the benefits of early or pre-symptomatic detection of COPD.

Diagnosis of exacerbation using symptoms

Clinical presentation of exacerbation of COPD is a common problem in primary care and currently detection and treatment relies on patients reporting symptoms of worsening cough, phlegm (quantity or discolouration), wheezing or shortness of breath. The National Institute of Health and Clinical Excellence evidence based guidance on the diagnosis and management of COPD exacerbations supports the practice of using symptoms to start steroids and/ or antibiotics (and guidance on criteria for admission using clinical and laboratory results such as hypercapnia) (8).

In summary, the use of symptoms is useful for clinical management of exacerbations of COPD, but the use of symptom scoring cannot reliably exclude COPD or be used as a screening tool for case finding. The different approaches to case finding and the advantages and disadvantages of each is summarised in a recent review (9).

2. Self-management interventions

A Cochrane review of self-management interventions in those with COPD found 14 studies fulfilling the predetermined quality criteria. They concluded that self-management programmes may be effective in improving confidence and reducing admissions (10). However, there was no significant improvement in exacerbations, emergency department visits, lung function, exercise capacity or days lost from work. There was a significant drop in hospital admissions. To prevent one extra admission, the number needed to treat (NNT) in severe COPD was 10 (95% CI: 6-35) and 24 (95% CI: 16-80) in mild to moderate COPD. Most programmes included education, anxiety reduction, relaxation techniques and aerobic exercises but the interventions were too heterogeneous to combine results for meta-analysis. No programme included self-monitoring with spirometry or pulse oximetry.

3. Pulse oximetry as a guide to management

Pulse oximeters are increasingly available in primary care but the place of oximetry in primary care monitoring and diagnosis of COPD is not yet clearly established.

Pulse oximeters are not able to measure the CO_2 levels or pH, which are crucial determinants of the need for hospital intervention such as non-invasive ventilation (NIV). Early disease does not cause hypoxia and therefore pulse oximetry cannot be used for early detection. However, oximetry has been used as a guide to determine which patients with severe COPD should be considered for long-term oxygen therapy (11). There is a paucity of published research about the use of pulse oximetry in primary care regarding COPD diagnosis or as an aid to decision making during exacerbation (12; 13).

Further detailed consideration of pulse oximetry use in Primary Care is contained in the MaDOx reports online (http://madox.org/horizon-scanning-reports).

4. Peak flow measurement

Peak flow is not reliable for either diagnosis or monitoring of COPD (14; 15; 16). The standard of using spirometry for diagnosis and severity is well established in ERS, BTS, ATS and GOLD, although the impact of the disease on an individual cannot be measured with spirometry in isolation (8).

Details of the Technology:

Chronic obstructive pulmonary disease is characterised by progressive, largely irreversible, obstruction to airflow. This can be quantified using a spirometer, which measures volume and rate of airflow using a number of different types of sensor (listed below). Severity of COPD is classified on the basis of spirometry results (including FEV1 [percent of predicted value], FVC, and FEV1/FVC) compared to standardised reference tables.

Over the past 10 years the desktop and hand-held technology of spirometers has advanced with a wide choice and price range depending on type of device, data entry, data storage and outputs including data interpretation and printout capability. Many studies have shown that these primary care devices can deliver readings (of FEV1, FVC, FEV1/FVC etc.), which are comparable to those from the respiratory laboratory (17-22).

New guidelines and the advent of nGMS quality and outcomes framework (QOF) have led to widespread use of spirometry in primary care. All new diagnoses of COPD are expected to include confirmation by spirometry. Annual testing of FEV1 is encouraged by the QOF and NICE guidance but without any clearly defined goal (8).

Competent use of the technology currently available needs training, experience, patient cooperation and interpretation to obtain accurate and reproducible results. Advances in technology and more widespread availability of the Internet and mobile phones has opened the possibility of automated transfer of data from community or home based spirometry to the primary care team (or respiratory support team).

Types of spirometer

The devices considered in this review are detailed in Table 1 and include:
N-spire Piko-1 (nSpire Health Ltd., Hertford UK), Vitalograph Diary 2110 (Vitalograph Ltd., Maids Moreton Buckingham), Micromedical MicroDL (Cardinal Health UK 232 Ltd., Basingstoke UK), Easyone (NDD Medizintechnik, Zurich, Switzerland), Datospir120, Datospir70 (Sibelmed, Spain), Microloop (Micromedical, UK), OneFlow (Clement Clarke, UK), Pneumotrac (Vitalograph, UK), Simplicity (Puritan Bennett, USA), Spirobank (Medical International Research, Italy), SpiroPro (SensorMedics, USA), SpiroStar (Medikro, Finland), Diagnosa (Diagnosa; Cyberscope, Cape Town, South Africa), and Vitalograph R (Vitalograph, England).

Hand-held and desk-top spirometers detect flow volume and rates using one of a variety of flow sensors including turbine (Datospir 70, Microloop, Spirobank), heated or non-heated Fleisch pneumotachograph (Datospir 120, Pneumotrac) and ultrasonics (Easyone) (22).

Some devices have been designed with the ability for data transfer by telephone, e.g. Spirotel (land line or mobile phone) (23). Many have data storage capacity and allow use in the field (for surveys or patient use), from which data can be downloaded at a later date for analysis (e.g. EasyOne) (24). However, such devices cannot be used for remote real time monitoring of patients.

Patient Group and Use:

1. Diagnosis and screening

Measuring FEV1 and FEV/FVC is essential to the diagnosis of COPD (8). A quarter of smokers develop chronic obstructive pulmonary disease (COPD), which is the fourth most common cause of death worldwide.

Inaccurate prevalence rates

There is good evidence that there is a discrepancy between current QOF prevalence rates of COPD and prevalence rates based on survey data. Cross sectional surveys using portable hand-held devices have COPD detection rates of between 13 and 18% (previously un-diagnosed cases) (25; 26). Pre-selection using symptom scoring increases the rates of positive spirometry but misses half of the cases. Approximately 60% of smokers over the age of 60 years, who also have a chronic cough, will have COPD on spirometry (25).

In the United Kingdom, there are a total of over 800,000 (prevalence 1.5%) people on General Practice COPD registers (QOF data) (27). However, cross sectional studies and extrapolation of data indicate that the actual prevalence should be nearer to 4%. More than half of the people with chronic obstructive pulmonary disease are currently not identified (23; 25; 26; 28). Therefore, a General Practice population of 10 000 patients should have about 400 people on the COPD register but QOF data (2008-9 NHS Information Centre Data) indicate that on average 150 (1.5%) have been detected (27; 29; 30) In other words a GP with a list of 2000 patients should have about 80 patients (4%) who have regular monitoring

of this chronic condition but currently only has a record of between 30 and 40 (1.5-2%) on the COPD register. One or two patients on each GP's COPD register may die each year and 4 or 5 may be admitted to hospital with exacerbations. One in 8 admissions to hospital are due to COPD and of those 15% will die during or within 3 months of admission (31).

National and International recommendations for screening

Currently there are no UK National recommendations for screening. There is increasing support for more active case finding but these inevitably tend to concentrate on those with symptoms. The British Lung Foundation has been campaigning for more widespread testing to detect COPD as emphasised in the annual World COPD day 17th November 2010 (www.lunguk.org/media-and-campaigning/world-copd-day/index).

NICE has recommended case finding for those over 35 and the Consultation on a Strategy for Services for COPD in England states that 'further work needs to be undertaken to appraise the cost and benefits of systematic case finding at the age of 25 and 40 and if appropriate ask the UK National Screening Committee to advise (recommendation number 187)' (32).

Other developed countries have rejected calls for screening for COPD. The USPSTF (United States Preventive Services Task Force) (http://www.uspreventiveservicestaskforce.org/) in their 2008 review of the evidence concluded that screening for COPD 'using spirometry is likely to identify a predominance of patients with mild to moderate airflow obstruction who would not experience additional health benefits if labeled as having COPD. Hundreds of patients would need to undergo spirometry to defer a single exacerbation' (33; 34).

The BOLD initiative has among its objectives 'to measure the prevalence and burden of chronic obstructive lung disease across the world using high quality spirometry' and 'use prevalence and burden of disease data to support the Global Initiative for Chronic Obstructive Lung Disease (GOLD) (http://www.goldcopd.com) and the WHO Global Alliance Against Respiratory Disease (GARD) Program'(http://www.boldstudy.org). The GOLD 2009 updated guidance on the global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease states that 'the benefits of community-based spirometric screening, of either the general population or smokers, are still unclear' (35).

Whilst there remains a paucity of clear evidence to support very early detection of COPD there is an increasing interest in researching new ways to slow deterioration (e.g. through medication) (36) and a concentration of effort to promote early detection of COPD so that smoking cessation strategies can be used early in the disease (7; 9).

2. Decisions about admission

There is very limited research on the value of using self-testing or remote monitoring of FEV1 to predict exacerbations, guide treatment options or prevent admission.

A US based study produced spirometry based guidance for admission from an emergency department. This prospective observational study of 83 COPD patients studied the value of using the percent of predicted values of FEV1 to guide discharge or admission (37). A post treatment FEV1 of less than 40% (of predicted) identified patients who required hospital admission or who relapsed following discharge with a sensitivity of 96% and a specificity of 58%. Nearly a third of patients discharged home from the hospital with an FEV1 of less than 40% (of predicted normal) relapsed within 48 hours. They concluded that those with a post treatment FEV1 of over 40% (of predicted normal) or clinical absence of respiratory distress despite an FEV1 under 40% predicted can be safely discharged. This study used the Spiroscan 1000 (Brentwood Instruments) spirometer.

3. Self-testing and remote monitoring

In the context of COPD, the technology has been used in trials of self-monitoring and remote monitoring of patients with high risk of acute exacerbation (29; 38; 39).
Spirometers have also been used for early detection of lung transplant rejection, neuro-muscle disorders and monitoring of other chronic respiratory diseases.

Pilot studies have been done in the UK with remote self-testing and real time monitoring of spirometry results and symptom scores transmitted via PDA and Internet links (39). In a 6 month feasibility study of 18 patients with known moderate to severe COPD (mean FEV1 36% predicted), patients recorded daily symptoms and spirometry. Criteria to detect exacerbation were predetermined. An arbitrary 10% reduction of FEV1 was regarded as a deterioration requiring intervention. A total of 75 exacerbations were recorded of which 55 were detected by the remote monitoring. Among the study group there were 6 admissions (average 0.33/patient) to hospital compared to 14 admissions (0.78/patient) for the same six months in the previous year.

Technology, which can enhance patient autonomy, self-monitoring, control of disease and early recognition of worsening disease or acute exacerbations could improve management and reduce admissions.

Importance:

- Spirometry is an essential tool for initial diagnosis of COPD (8).
- NICE recommends monitoring COPD using spirometry annually in mild and moderate disease and bi-annually in severe disease (8).
- NICE guidance does not mention use of FEV1 (or a change in measurement) in the detection of acute exacerbations or assessment of severity or need for hospital admission.

Previous Research:

Accuracy compared to existing technology

Many of the handheld or desktop devices developed in the past 15 years have evidence for good accuracy compared to respiratory laboratory standards.(17; 18; 20-22). See Table 1 for a list of devices with published research evidence and comparisons where available with laboratory-standard spirometry. Results of accuracy are reported with heterogenous statistical methods including coefficient of variation (CV) (20;40), limits of precision (22) or correlation coefficient (21), which prevent combining results of different trials (see Table 1).

Impact compared to existing technology

The increased availability of spirometers outside specialist hospital departments has led to improved access in primary care and the potential for wider use (38). Newer spirometers are user-friendly and have the capacity for self-monitoring and, with the advent of telemedicine and computer transmission of data, many more patients could have access to a diagnostic screening and/or monitoring service. However there are no direct sales to the public and all the devices require a period of supervised training prior to home use. There are no devices for self-detection through fitness games or programmes e.g. Wii fit. There is no published research to test the efficacy of using spirometry for population self-screening e.g. in a community pharmacy.

Guidelines and Recommendations:

NICE recommends confirmation and monitoring COPD using spirometry annually in mild and moderate disease and bi-annually in severe disease (8).

NICE excludes a diagnosis of COPD in people without symptoms when FEV1/FVC is <0.7 and FEV1is>80% predicted (GOLD classifies these as mild COPD even without symptoms) (1). The continuing discrepancy between NICE and GOLD guidance is unhelpful for patients, doctors, policy makers and researchers because there is substantial evidence that reported symptoms are unreliable for diagnosis.

Cost-effectiveness and economic impact:

Estimates of cost-effectiveness have been conducted (see below). NICE has recommended case finding for those over 35 and the Consultation on a Strategy for Services for COPD in England states that ‘further work needs to be undertaken to appraise the cost and benefits of systematic case finding at the age of 25 and 40 and if appropriate ask the UK National Screening Committee to advise (recommendation number 187)’ (32).

Respiratory disease costs the NHS and society £6.6 billion: £3 billion in costs to the care system, £1.9 billion in mortality costs and £1.7 billion in illness costs (BTS report). According to the National Clinical Guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care, COPD costs the NHS and society £486-982 million. The analysis takes account of assumptions about the impact of early diagnosis and improved smoking cessation rates. Under the base case analysis, the cost per life year gained was £713.16 and the cost per quality adjusted life year gained is £814.56. Their conclusion was that "under current decision making conditions, this is a very favourable cost effectiveness ratio." (NICE guideline CG101 Chronic obstructive pulmonary disease). An important caveat to the model is the asumption that spirometry has 100% sensitivity and specificity and is carried out by staff who are trained and competent in its use and interpretation.

Research Questions:

1. Does spirometry self-monitoring (with or without electronic transmission to a clinical support service) permit early detection of acute exacerbation of COPD (AECOPD)? (e.g. reduced admissions or long term rate of decline in lung function)
2. Do changes in FEV1 predict AECOPD?
3. Can the use of spirometry prevent unnecessary admission during exacerbations of COPD (AECOPD)?
4. Would wider availability of lung function testing (self testing or community screening of smokers/ex smokers) be beneficial?
5. Is there scope for better user-friendly technology with wider personal or community availability (e.g. home testing kits, or via pharmacy or fitness centres/gyms)?
6. Does early detection of COPD have long-term beneficial outcomes? (e.g. reduced rate of lung function decline and reduced smoking rates)

Suggested next step:

1. Development of a systematic review of literature of the predictors of Acute Exacerbation of COPD including use of symptom scoring, lung function oxygen saturation and educational interventions.

2. Pilot study of community screening for COPD in smokers and ex smokers (via pharmacy outlets, smoking cessation programmes etc) using user-friendly technology and telemedicine. The usefulness of this programme would include an element of audit and quality assurance via laboratory checking to confirm findings/diagnosis.

Expected outcomes:

1. Wider availability and use of spirometry in settings that are more patient centred and convenient.
2. Further innovations to allow ease of gathering data and transmission to monitoring centres (with audit and quality control safeguards).
3. Development of telehealth based decision making tools to improve control and encourage early intervention to reduce morbidity and admissions for COPD related complications.
4. Increased detection of COPD at an earlier stage.
5. Reduction in smoking prevalence.
6. Improvements in technology and increased interest in remote monitoring and telehealth for increasing numbers of elderly or housebound individuals, in the context of increasing costs of inpatient care.
7. Reduction of burden (to the NHS) and inconvenience (to patients) of recurrent admissions of those with severe COPD.

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Comments:

NICE guidance clearly states that, before discharge all patients admitted with a diagnosis of COPD exacerbation should have spirometry (8). However the National Audit (2008) of over 9000 admissions with exacerbation of COPD revealed that only 55% had a record of FEV1 within the preceding 5 years (41). This was compared to the unlikely and unacceptable idea that a patient could be admitted to hospital with chest pain and not have at least one ECG. This figure had not improved since the previous audit of 2003. Clearly there is room for improvement.

Spirometry should be considered in all adults who have risk factors (smokers, ex-smokers, occupational exposure) and those who have symptoms suggestive of lung disease. It could be used as part of the screening during NHS Health Checks ([1] www.nhs.uk/Planners/NHSHealthCheck). Initial testing can be in many community or primary care locations but diagnosis should be confirmed by trained health professionals using post-bronchodilation measurements and in line with NICE and BTS recommendations.

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Table 1. Overview of diagnostic accuracy studies for Spirometry devices.

Model	Handheld (H), desk top (DT)	Sensor (NH=not heated) (H=heated)	Ref.	Participants	Laboratory comparison	Statistics	Data storage capacity (no. of patients)	Data transfer	Approximate cost	Supplier
Datospir 120	DT	Fleisch pneumotacho-graph (H)	22	399 spirometry naïve healthy and COPD patients tested by expert technicians	yes	95% limits of precision 0.14 *	PC/internet unlimited	Internet	<£2000	Sibelmed, Spain. www.sibelmed.es
Datospir70	HH	Turbine				95% limits of precision 0.12 *	800	PC	<£700	
Microloop	DT	Turbine				95% limits of precision 0.18 *	PC storage	PC	<£1500	www.micromedical.co.uk
OneFlow	HH	Differential pressure				95% limits of precision 0.15 *	120	PC	<£300	Clement Clarke, UK. www.clement-clarke.com
Pneumotrac	DT	Fleisch pneumotacho-graph (NH)				95% limits of precision 0.13*	PC storage	PC	<£1000	www.vitalograph.co. uk
Simplicity	DT	Plastic screen				95% limits of precision 0.29 *	N/A	prints results	<£1000	Puritan Bennett, USA. http://respiratorysolutions.covidien.com
Spirobank	HH	Turbine				95% limits of precision 0.15 *	2000		<£500	Medical Internatinal Research, Italy. www.spirometry.com
SpiroPro	HH	Differential pressure (NH)				95% limits of precision 0.16 *	250	PC	POA	SensorMedics, USA. www.carefusion.com
SpiroStar†	DT	Plastic screen				95% limits of precision 0.17*	PC storage	PC	POA	Medikro, Finland. www.medikro.com
EasyOne ‡	HH	Ultrasound technology				95% limits of precision 0.19 *	700	PC	<£1500	NDD Medizintechnik , Zurich, Switzerland. www.ndd.ch
			42	chest clinic patients: 1041 patient tests and 75 calibration checks	syringe calibration tests	100% calibrations met criteria of 3.00+/- 0.105 L	700			
			20	24 spirometry naïve volunteers	yes	95% limits of agreement for FEV1 0.18 L, CV for FEV1 2.6	700			
			40	13 staff volunteers	no	Compared variablity of 4 meters, coefficient of variation of FEV1 , p value 0.009	700			
N-spire Piko-1	HH	metal spring					98	PC	<£50	www.nspirehealth.com
Vitalograph Diary 2110	HH	Fleisch pneumotacho-graph					540	PC	<£500	www.vitalograph.co. uk
MicroDL	HH	Rotary turbine					500	PC	<£700	Micro Medical, Ltd www.micromedical.co.uk
Diagnosa†	DT	Orifice plate pneumotacho-meter	21	45 supervised patients (normal, obstructive or restrictive defect)	yes	correlation coefficient test vs control machine: r = 0.92-0.99	PC storage	internet	POA	Diagnosa; Cyberscope, Cape Town, South Africa. www.cyberscope.co.za
Vitalograph R	HH		18	10 healthy volunteers + 10 patients with a1-antitrypsin deficiency.	yes	unclear	currently available model Vitalograph 2120	PC	<£2000 (for Model 2120)	www.vitalograph.co. uk

*Laboratory standard 0.14; †No UK distributor; ‡Confirms claim that device does not need calibration for at least 26 weeks