Feasibility and acceptability of spirometry and FeNO testing in children treated for asthma in primary care

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maara

CIRCASSIA
Importance

• 5.4 million people in the UK have been diagnosed with asthma

• 1.1 million children - child admitted to hospital every 20 minutes because of asthma *(Asthma UK, 2017)*

• Absence of any single ‘gold standard’ test to confirm (or manage) asthma

• Children with asthma managed poorly become adults with poorly controlled asthma *(Tai et al, 2014)*

• Emphasis on **objective measures** to diagnose and monitor asthma
Headline news?

Asthma: More than 1 MILLION people may have been wrongly diagnosed with the incurable condition

Wednesday 28 January 2015 08:44 GMT

More than 1m people in UK may have been wrongly diagnosed with asthma amid concerns about overdiagnosis

Children's asthma inhalers given out 'like fashion accessories': Report says doctors are wrongly taking the slightest wheeze as sign

Overdiagnosis of asthma in children in primary care: a retrospective analysis.

Looijmans-van den Akker J¹, van Luijn K¹, Verheij T².
Importance

- Under-diagnosis and under-treatment of childhood asthma in primary care have been reported from several European countries including the UK (Lai 2009; Kuprys-Lipinska 2010; Luks 2010; Heffler 2015; Looijmans-van den Akker 2016; Aaron 2017; Yang C 2017)

- National Asthma Education and Prevention Program (NAEPP, 2007) and Global initiative for asthma (GINA, 2017) recommends that a diagnosis of asthma should be made on:
  1. the basis of episodic symptoms consistent with asthma
  2. exclusion of an alternative diagnosis AND
  3. objective evidence of airflow obstruction with reversibility

- British Thoracic Society (BTS, 2016)
  ‘Spirometry with bronchodilator reversibility, is the preferred initial test for investigating intermediate probability of asthma in adults, and in children’
Why does getting the diagnosis right matter?

• Asthma medication could be reduced/discontinued
  • Overuse of bronchodilators and underuse of inhaled corticosteroids
    *(Bush & Fleming, 2016)*

• Inappropriate prescriptions
  • Medicinal side effects and ongoing morbidity
    *(LindenSmith et al, 2004)*

• Early treatment may improve long term symptoms later in life and reduce risk of developing COPD
  *(van Schayck et al, 2000; Tai et al, 2014)*

• Financial implications for NHS
  *(Karin & Pijnenburg, 2015)*
3 Key documents

• National Review of Asthma Deaths (NRAD)
  www.rcplondon.ac.uk/sites/default/files/why-asthma-still-kills-full-report.pdf

• NICE diagnostics guidance 12
  nitric oxide concentration in asthma: NIOX MINO, NIOX VERO and NObreath. www.nice.org.uk/guidance/dg12

• NICE draft guidelines for diagnosis and monitoring of asthma
  National Institute for Health and Care Excellence (NICE) (2015) Diagnosis and monitoring of asthma in adults,
  Consultation. NICE, London.
NRAD (1)

- Review all asthma deaths in UK in 2012
- 195 deaths investigated – 28 children
- 1000 recommendations!

- Age group of the 28 children:
  - <10 years old n=10 (5%)
  - 10–19 years n=18 (9%)
Key findings

• 43% - No evidence of *asthma review in general practice* in last 12 mths

• Likely that many patients treated as mild or moderate asthma had poorly controlled undertreated asthma

• Particularly in young people, *poor recognition of risk* of signs of deteriorating/worsening asthma was found to be an important *avoidable* factor in primary care

• Evidence of *excessive prescribing of reliever medication*
  • 39% prescribed >12 short-acting MDIs in the year before they died
  • 4% prescribed >50 reliever inhalers

• Evidence of *under-prescribing of preventer medication*
  • 38% issues with < 4
Fraction of exhaled Nitric Oxide (2)

- Nitric oxide is produced in the lungs and is present in exhaled breath
- Inflammatory mediator in the lungs and airways
- Proposed as a non-invasive marker of airway inflammation in asthma
- FeNO levels are raised in many people with asthma and can be lowered by effective treatment with corticosteroids
Recommendations

• FeNO testing is recommended as an option to help diagnose asthma in adults and children

• Who, after initial clinical examination, are considered to have an intermediate probability of having asthma by BTS

• Further investigation recommended when FeNO test negative because a negative result does not exclude asthma
This guideline covers adults, children and young people who are being investigated for suspected asthma, or who have been diagnosed with asthma and are having their condition monitored.
Key priorities for implementation

OBJECTIVE TESTS:

• Use spirometry as the first-line investigation (test 1)

• Bronchodilator reversibility (BDR) test to >5yrs with obstructive spirometry (test 2)

• Offer a FeNO test if >5yrs if a diagnosis of asthma is considered (test 3)

• Serial peak flow monitoring for 2-4 weeks – Positive >20% diurnal variation (test 4)

• Offer a direct bronchial challenge test in > 16 if there is diagnostic uncertainty

• Use spirometry (FEV1) or peak flow variability to monitor asthma at each annual asthma review and consider using a validated symptom questionnaire (ACT)

• Recommendation – 2 positive tests needed to make the diagnosis of asthma
Recommendation (1) - Spirometry

• Regard a FEV1/FVC ratio of less than 70% as a positive test for obstruction

• Recognised that it is technically difficult for young children to breathe out for long enough to achieve an accurate FVC, making it difficult to obtain the FEV1/FVC ratio cut off

• The ability to perform spirometry will vary from child to child

• Agreed that spirometry should be ‘attempted’ in children aged 5 years and older
Recommendation (2) - Reversibility

- Offer a bronchodilator reversibility (BDR) test to children aged 5-16 years with obstructive spirometry (FEV1/FVC ratio less than 70%)

- Regard an improvement in FEV1 of 12% or more, together with an increase in volume of 200 ml or more, as a positive test
Recommendation (3) - FeNO

- **Offer a FeNO test in children aged 5-16 years** if there is diagnostic uncertainty after initial assessment and they have either:
  - normal spirometry or
  - obstructive spirometry with negative BDR

- **Regard a FeNO level of 35 ppb or more** as a positive test
Diagnostic algorithm C – objective tests for children aged 5-16 years

From diagnostic algorithm A: children aged 5-16 years undertake spirometry
- Obstructive spirometry: FEV₁/FVC ratio less than 70%
- Normal spirometry: FEV₁/FVC ratio is 70% or more

normal spirometry       obstructive spirometry

Offer a FeNO test. Regard a FeNO level of 35 ppb or more as a positive test.

-ve FeNO               +ve FeNO
Monitor peak flow variability for 2-4 weeks. Regard a value of more than 20% variability as a positive test.

-ve PEFv               +ve PEFv
Review³
³after 6 weeks repeat abnormal test and review symptoms

Consider alternative diagnoses

Suspect asthma
Do not rule out other diagnoses if symptom control remains poor after treatment
Review³ the diagnosis
³after 6 weeks repeat abnormal tests and review symptoms

Diagnose with asthma

Refer for specialist assessment

Suspect asthma
Do not rule out other diagnoses if symptom control remains poor after treatment
Review³ the diagnosis
³after 6 weeks repeat abnormal tests and review symptoms

Diagnose with asthma

Do not offer as diagnostic tests:
- skin prick tests to aeroallergens
- serum total and specific IgE
- peripheral blood eosinophil count.
Aim

To implement spirometry and FeNO into General Practice for the management of children with suspected or existing diagnosis of asthma

- Participating practices will invite children (5-16yrs) who:
  - Either have documented exacerbation of wheeze in last 12 mths
  - Are prescribed regular inhaled corticosteroids
  - Have been prescribed 2 or more Salbutamol MDI’s in last 12 mths
Outcome Measures

• Training needs - No. of tests to feel competent (perform and/or interpret)

• Clinical capacity - Barriers to change, useable data (stratified by age), time to perform tests

• Usefulness to staff - Did it change asthma review outcome or clinical decision making

• Acceptability to children and families – What do the children/parents think about the tests
Methods – Training

- Children and their carer(s) were invited to attend the surgery for an asthma review at a specially set-up children’s asthma review clinic

Staff Training:

- Prior to the first asthma review clinic the specialist nurse and/or clinical fellow will spend up to 2 hours with the practice nurse or health care assistant to discuss and teach incentive spirometry and FeNO testing

- The team will also teach the staff interpretation of spirometry tracing and interpretation of the FeNO test
Methods – Review clinic

The paediatric asthma review clinic:

• Children attending the clinic will have their diagnosis reviewed
• Children will be asked to perform (incentive) spirometry
• Given a personalised written asthma action plan
• Complete an asthma control test (ACT/PAQLQ)
• FeNO measurement
• Have inhaler technique checked
• Prescription record checked
Methods – Data Collection

• 10 GP surgeries of different sizes and demographics
• Pre and post implementation data collected from GP staff
• Paediatric spirometry/eNO training provided (theory + practical)
• Spirometry and eNO testing are attempted in all children
• Record of time taken to perform tests, length of training until competent, feedback from the child/parent/staff after each review
• Patient data (medications, exacerbations, asthma diagnosis, ACT/PAQLQ) collected at baseline and at 6 months
### Demographics of Children Recruited to Date (n = 586)

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Count/Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of males (%)</td>
<td>312 (53.5)</td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>9.9 (3.3)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>81% White, 3% Black, 12% Asian, 4% Other</td>
</tr>
<tr>
<td>No. of children with existing asthma diagnosis (%)</td>
<td>434 (74)</td>
</tr>
<tr>
<td>No. of children performing spirometry for 1st time (%)</td>
<td>534 (91)</td>
</tr>
</tbody>
</table>
Feedback from child and family

• Parent/carer – ‘how likely are you to recommend these tests to friends and family if their children needed an asthma review at this practice?’

  • 514/528 (97%) said they would be likely or extremely likely to recommend

    ‘A fantastic idea to hold these tests in a GP surgery!’
    ‘Very reassuring to parent and child that heir breathing is being monitored’
    ‘Tests should be used yearly to ensure nothing is being missed or diagnosed as something else!’

• Child/teenager – ‘would you be happy to try these tests again?’

  • 462/531 (87%) said they would be happy to try these tests again (12% didn’t mind)

    ‘This is really fun’      ‘I like the video game!’
    ‘It felt like playing a video games, didn’t see it as being a test’
    ‘It was really interesting’
Feedback from staff (pre-implementation)

Anonymous questionnaire highlighted concerns regarding:

- Funding (n=10/36, 27%)
- Workload/staffing (n=21/36, 58%)
- Training (n=13/36, 36%)

“All we need to do now, Andrew, is explain it to the public.”
Feedback from staff

• Staff were asked ‘did you find the tests useful in helping with your diagnosis/management decision?’

  • 470/508 (92%) felt the tests did help their management decision during the child’s asthma review

• Staff were asked ‘would your plan have been different if you did NOT have spirometry and/or eNO results available to you?’

  • 130/542 (24%) would have changed their management plan if the tests results were not available
Can children perform the tests?

Percentage of children able to perform usable lung function by age (n=586)
Mean time to perform spirometry in minutes (SD) = 4.3 (1.3)
Mean time to perform FeNO in minutes (SD) = 2.4 (1.0)

N.B. An extra 15 mins were added to allow for reversibility testing if lung function demonstrated obstruction
Lung function results

<table>
<thead>
<tr>
<th></th>
<th>Existing Asthma Diagnosis (n = 408)</th>
<th>No Existing Asthma Diagnosis (n = 141)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Spirometry (%)</td>
<td>287 (70.3)</td>
<td>96 (68.1)</td>
</tr>
<tr>
<td>Obstructed (%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reversible ≥12%</td>
<td>40 (9.8)</td>
<td>12 (8.5)</td>
</tr>
<tr>
<td>Not Reversible ≥12%</td>
<td>77 (18.9)</td>
<td>32 (22.7)</td>
</tr>
<tr>
<td>Restrictive Spirometry (%)</td>
<td>4 (1.0)</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

* Standardised reference values for spirometry based on Global Lung Initiative (GLI)  *(Quanjer et al, 2012)*
Does an asthma diagnosis predict airway obstruction?

<table>
<thead>
<tr>
<th></th>
<th>Asthma Diagnosed (QOF)</th>
<th>Asthma Not Diagnosed (QOF)</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstructed Spirometry</td>
<td>123/408 (30.1%)</td>
<td>44/141 (31.2%)</td>
<td>167/549 (30.4%)</td>
<td>0.81</td>
</tr>
<tr>
<td>eNO ≥35ppb</td>
<td>133/345 (38.6%)</td>
<td>25/105 (23.8%)</td>
<td>156/450 (34.7%)</td>
<td><strong>0.006</strong></td>
</tr>
</tbody>
</table>
Does ACT<20 predict airway obstruction

<table>
<thead>
<tr>
<th></th>
<th>Controlled (ACT ≥20)</th>
<th>Not Controlled (ACT &lt;20)</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Obstructed Spirometry</strong></td>
<td>76/319 (23.8%)</td>
<td>91/225 (40.4%)</td>
<td>167/544</td>
<td>0.0000349</td>
</tr>
<tr>
<td><strong>eNO ≥35ppb</strong></td>
<td>94/266 (35.3%)</td>
<td>64/184 (34.8%)</td>
<td>158/450</td>
<td>0.90</td>
</tr>
</tbody>
</table>
Does a raised eNO predict airway obstruction

<table>
<thead>
<tr>
<th></th>
<th>Obstructed Spirometry</th>
<th>Normal Spirometry</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raised eNO ≥35ppb</td>
<td>68/156 (43.6%)</td>
<td>88/156 (56.4%)</td>
<td>156/438 (35.6%)</td>
<td></td>
</tr>
<tr>
<td>Normal eNO &lt;35ppb</td>
<td>74/282 (26.2%)</td>
<td>208/282 (73.8%)</td>
<td>282/438 (64.4%)</td>
<td>0.000204</td>
</tr>
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</table>
### Staff training – To deemed competent

<table>
<thead>
<tr>
<th></th>
<th>No. of clinics</th>
<th>No. of tests performed (Spiro/eNO)</th>
<th>No. of tests interpreted (Spiro/eNO)</th>
<th>No. of children seen</th>
<th>Time taken hands-on testing of children in mins (hrs)</th>
</tr>
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<tbody>
<tr>
<td><strong>Nurses trained (n=27)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.4</td>
<td>9/10</td>
<td>22/22</td>
<td>25</td>
<td>617 (10)</td>
</tr>
<tr>
<td>- Practice Nurse (n=9)</td>
<td>6</td>
<td>7/9</td>
<td>20/19</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>- Nurse Practitioners (n=6)</td>
<td>6.2</td>
<td>-</td>
<td>26/25</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>- Healthcare Assistants (n=12)</td>
<td>4.6</td>
<td>15/15</td>
<td>-</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

‘Prior to training I did not feel that children were competent at performing the tests, but clearly they are and I feel much more confident in performing and interpreting them’ - Nurse Practitioner

‘The tests have enhanced the diagnosis and given me confidence in my diagnosing’ - Practice Nurse

‘I am able to explain better to parents and make the diagnosis’ - Practice Nurse

‘Easier to test children than first imagined, children more cooperative than I thought!’ - HCA
ARTP Accreditation (1)

Improving the quality of diagnostic spirometry in adults: the National Register of certified professionals and operators

- National Register of all health professionals who perform spirometry
  - Three levels of training
    1. Full - perform and interpret
    2. Foundation – perform only
    3. Interpretation only
  - Phased implementation by 2021
  - Must demonstrate regular spirometry and certify every 3 years
  - Assessment by ARTP approved provider

Improving the quality of diagnostic spirometry in adults: the National Register of certified professionals and operators

Full assessment will involve

• Observed practical assessment
• Submission of professional portfolio
• 10 spiro tests (covering range of scenarios)
• Written assignment

Experienced Practitioner Scheme

• Assessment without attending training
• Recognition of previous spiro experience
• Assessment includes all of the above plus an interpretation type viva – in the workplace!

• *NHS England et al. 2016*
Key findings (1)

• Spirometry and eNO are possible (and acceptable) to perform in primary care for children as young as 5, but are more successful from age 8

• Objective lung function impacts on clinical decision making 1/4 of the time

• Overall 1/3 of children had abnormal lung function

• These tests confirmed an asthma diagnosis in 9% of those without an existing diagnosis
Key findings (2)

• People reporting poor control by ACT were also more likely to have abnormal lung function (40%), however, even those reporting good control, a 1/4 have abnormal lung function.

• Abnormal eNO is correlated with poor lung function.

• Children with existing diagnosis are likely to have higher eNO.

• No difference in lung function for those with/without diagnosis.

• 1% of those with “asthma” had restrictive defect.
To conclude

• Children (as young as 5, mostly 8!) can perform useable lung function!

• Implementing these tests could be time consuming and costly – so we need to get it right!

• More age specific research studies needed into the value and interpretation of these lung function tests in children

• Careful and accurate history taking, alongside clear education remain key to good asthma control - consider objective tests to support/inform

• Await outcome of NICE proposed algorithm – still mainly adult based!

• The person making the recordings is every bit as important as the spirometer!
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- Andrew Wilson  
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- Special thanks to all the lovely nurses we trained in primary care !!!
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• Van Schayck CP, van der Heijden FM et al. (2000) Under diagnosis of asthma: is the doctor or the patient to blame? The DIMCA project. Thorax 55:562-565