**INTERPRETING SPIROMETRY (DIAG 2)**

<table>
<thead>
<tr>
<th>Ref ID 353</th>
<th>Study type</th>
<th>Study quality</th>
<th>Number of patients</th>
<th>Prevalence</th>
<th>Patient characteristics</th>
<th>Type of test</th>
<th>Reference standard</th>
<th>Sensitivity and specificity</th>
<th>PPV and NPV</th>
<th>Source of funding</th>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. R. Celli, R. J. Halbert, S. Isonaka, and B. Schau. Population impact of different definitions of airway obstruction. <em>European Respiratory Journal</em> 22 (2):268-273, 2003.</td>
<td>Cross-sectional study (diagnostic)</td>
<td>Multi centre: USA (NHANES III sample - 81 sites sampled using stratified clustered probability sample, to identify that could be extrapolated to the entire civilian noninstitutionalised population in the USA)</td>
<td>N=9838</td>
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<td>Inclusion criteria: A lower age cut-off of 30 years was used in order to reduce the confounding effects of asthma in younger people; therefore was adults aged 30-80 years with satisfactory spirometry test. Exclusion criteria: people aged &gt;80 years and not caucasian, African-American or Mexican-American were excluded because there were no reliable reference equations for spirometry results. Baseline characteristics: Age (mean) 48 yrs; post-BD FEV1/FVC ratio (mean) 77.6%</td>
<td>Post-BD FEV1/FVC &lt;70% GOLD definition (fixed) vs Post-BD FEV1/FVC ATS 1995 LLN equations (LLN)</td>
<td>GOLD stage IIA definition: FEV1/FVC &lt;70% and FEV1 &lt;80% predicted</td>
<td>Not given</td>
<td>Not given</td>
<td>Boehring Ingelheim GmbH</td>
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and was 96.6% predicted; FEV₁ 2.9 L (mean).

Additional results:

**Diagnosis of COPD using pre-BD FEV₁/FVC (<70%, fixed ratio vs LLN) vs physician diagnosis**

- In entire population the prevalence is estimated from the spirometry results of the sample as:
  - 8.5 million cases (77.3 per 1000 population) - physician diagnosis
  - 18.4 million cases (167.8 per 1000 population) - fixed ratio
  - 15.6 million (142.1 per 1000 population) – LLN
  - 8.6 million (78.7 per 1000 population) – fixed ratio GOLD stage IIA

- For persons aged <50 years, the LLN produced the highest estimates; for persons aged ≥55 years, the fixed ratio produced the highest rate estimates. For the more elderly population (aged 75-80 years) GOLD IIA identified less patients than the LLN, therefore GOLD IIA was a more conservative estimate. The GOLD Stage IIA definition for all age-groups and overall produced lower estimates than the other definitions (LLN and fixed ratio) and was more similar to the physician diagnosis than the other definitions.

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| Ref ID: 2561 |
|---|---|---|---|---|---|---|---|---|---|
| **Bibliographic reference** | **Study type** | **Study quality** | **Number of patients** | **Prevalence** | **Patient characteristics** | **Type of test** | **Reference standard** | **Sensitivity and specificity** | **Positive and Negative predictive value** | **Source of funding** | **Additional comments** |
| F. W. Ko, J. Woo, W. Tam, C. K. Lai, J. Ngai, T. Kwok, and D. S. Hui. | Cross-sectional study (diagnostic) | Multi centre: No mention of blinded investigators | N=1008 (originally recruited N=1149 but only 1008 were included) | **Inclusion criteria:** Elderly people (aged ≥60 years) selected randomly from Post-BD FEV₁/FVC <70% GOLD definition (fixed) | Doctor diagnosis – self-reported (clinical diagnosis) | Not given | Not given | Grants from the Hong Kong Lung Foundation and the | | |

**ID 2561**

| Hong Kong (Elderly Chinese people from several community centres) | • Participants not representative of the true population (all were elderly) | able to perform the spirometry according to ATS/ERS standards) | community centres. Baseline characteristics: Age (mean) 74 years; BMI mean 24.1 kg/m²; 3.6% had history of COPD; 4.2% had current asthma; post-BD FEV₁/FVC ratio (mean) 75.9%; FEV₁ (mean) 1.9L and 86.8% predicted. | vs Post-BD FEV₁/FVC Hong Kong LLN equations (LLN) vs University of Hong Kong |

**Additional results:**

**Diagnosis of COPD using post-BD FEV₁/FVC (<70%, fixed ratio vs LLN) vs physician diagnosis**

- n=36 (3.6%) – physician diagnosis
- n=361 (25.9%) – fixed ratio
- n=125 (12.4%) – LLN
- The difference in % diagnosed with COPD between the fixed and LLN ratios was more marked in older individuals (5.3% and 16.1% <70 years and ≥70 years)

**Agreement between measurements*:**

- **Fixed (GOLD) vs LLN:** κ coefficient 0.58 (0.52 to 0.64), p<0.001 *Moderate agreement*
- **Fixed (GOLD) vs physician diagnosis:** κ coefficient 0.66 (0.02 to 0.11), p=0.001 *Poor agreement*
- **LLN vs physician diagnosis:** κ coefficient 0.05 (-0.02 to 0.11), p=0.069 *Poor agreement*
- Only 6.9% and 6.4% of people with fixed ratio and LLN ratio (respectively) had doctor diagnosed COPD

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Interpretation of Kappa.

- Poor agreement = Less than 0.20
- Fair agreement = 0.20 to 0.40
- Moderate agreement = 0.40 to 0.60
- Good agreement = 0.60 to 0.80
- Very good agreement = 0.80 to 1.00

<table>
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<tr>
<th>Ref ID: 2559</th>
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<tr>
<td>N. Roche, F. Dalmay, T. Perez, C. Kuntz, A. Vergnenegre, F. Neukirch, J. P. Giordanella, and G. Huchon.</td>
<td>Cross-sectional study (diagnostic)</td>
<td>Multi centre: France (several health centres)</td>
<td>N=4764 (N=5008 people participated but only 4764 had adequate data)</td>
<td>Inclusion criteria: Consecutive people presenting to health centres; aged ≥45 years. Baseline characteristics: Age (mean) 59.9 yrs; Already known chronic respiratory diseases: asthma (9.1%), chronic airflow obstruction (2.6%) and chronic bronchitis (5.8%) ie. 8.4% had ‘COPD’ previous diagnosis Post-BD FEV1/FVC &lt;70% ATS-GOLD definition (fixed) vs Post-BD FEV1/FVC ECCS LLN equations – using ERS definition (LLN1) vs Post-BD FEV1/FVC study population Doctor diagnosis – self-reported (clinical diagnosis)</td>
<td>Not given</td>
<td>Not given</td>
<td>Authors receive fees for consultation and educational grant from several Pharma companies</td>
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ID 2559

**Additional results:**

**Diagnosis of COPD using post-BD FEV₁/FVC (<70%, fixed ratio vs LLN) vs physician diagnosis**

- 8.4% – physician diagnosis
- n=415 (8.7%) – fixed ratio
- n=305 (6.4%) – LLN1 (ERS definition using ECCS equations)
- n=379 (7.96%) – LLN2 (ERS definition using study population equations)

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<td>P. Shirtcliffe, M. Weatherall, S. Marsh, J. Travers, A. Hansell, A. McNaughton,</td>
<td>Cross-sectional study (diagnostic)</td>
<td>Single centre:</td>
<td>N=749 (N= 3500 sent questionnaire, n=1017)</td>
<td>Inclusion criteria: Random selection of NZ individuals equally divided among 5 groups according to age.</td>
<td>Post-BD FEV₁/FVC &lt;70% GOLD definition (fixed) vs</td>
<td>Doctor diagnosis – self-reported (clinical diagnosis)</td>
<td>Not given</td>
<td>Not given</td>
<td>Grants from GSK and Wellcome Trust</td>
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Additional results:

**Baseline characteristics:**
- Age (mean) 54.9 yrs;
- Female (mean) 45%;
- Already known chronic respiratory diseases: asthma (24%), emphysema (0.8%) and chronic bronchitis (13.9%)

**Post-BD FEV1/FVC**
- Marsh LLN equations for NZ population – using ATS definition (LLN)

**Additional results:**

**Diagnosis of COPD using post-BD FEV1/FVC (<70%, fixed ratio vs LLN) vs physician diagnosis**
- n=79 (10.6%) – physician diagnosis
- n=116 (15.5%) – fixed ratio
- n=78 (10.4%) – LLN1 (ATS definition using Marsh NZ population equations)

**Agreement between measurements***:
- **Fixed (GOLD) vs LLN:** \( \kappa \) coefficient 0.74 (0.67 to 0.81) **Good agreement**
- **Fixed (GOLD) vs physician diagnosis:** \( \kappa \) coefficient 0.06 (-0.02 to 0.13) **Poor agreement**
- **LLN vs physician diagnosis:** \( \kappa \) coefficient 0.09 (0.007 to 0.18) **Poor agreement**

Only 15% of individuals who met GOLD criteria had a doctor’s diagnosis of COPD; 85% of people met GOLD criteria but did not report a doctor’s diagnosis of COPD.

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*Interpretation of Kappa.
- Poor agreement = Less than 0.20
- Fair agreement = 0.20 to 0.40
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