BACKGROUND

• Evidence is quickly accumulating on the use of IGRAs in many pre-defined settings.
• Several advantages of IGRAs over tuberculin skin test are widely recognized.
• Recent guidelines allow for the use of IGRAs instead of TST in the diagnosis of TB infection

CDC, MMWR June 25, 2010 / Vol. 59 / No. RR-5
• How does the QuantiFERON-TB In Tube (QFT-IT) test perform in the routine clinical practice of a university hospital in a low TB burden country?

• What is the fluctuation of QFT-IT results in repeated tests in a non-predefined setting?

METHODS

• Study design: retrospective
• Site: University Hospital of Modena (Italy)
• Anonymised electronic records of all consecutive QFT-IT tests performed in inpatients and health care workers from the same hospital in nearly five years
• Single laboratory
• QFT-IT according to manufacturer instruction
RESULTS

- Period: May 2006 – December 2010
- 5,293 tests
- 4,299 subjects
  - Mean age ± SD: 48 ± 20 years
  - Male: 50.4%
- 711 subjects with multiple tests
  - Mean age ± SD: 46 ± 18 years
  - Male: 54.6%

QFT-IT RESULTS (1)

- Negative
- Positive
- Indeterminate
- Inadequate

- All tests (n=5,293)
- Subjects with single testing (n=3,588)
QFT-IT RESULTS (2)

<table>
<thead>
<tr>
<th>Category</th>
<th>1st of repeated tests (n=711)</th>
<th>Subjects with single testing (n=3,588)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>72.7%</td>
<td>63.3%</td>
</tr>
<tr>
<td>Positive</td>
<td>16.3% 21.0%</td>
<td></td>
</tr>
<tr>
<td>Indeterminate</td>
<td>10.0% 12.7%</td>
<td></td>
</tr>
<tr>
<td>Inadequate</td>
<td>1.0% 3%</td>
<td></td>
</tr>
</tbody>
</table>

p = 0.03

REPEATED QFT-IT TESTS

- **1705 repeated QFT-IT tests**
- **711 subjects**
  - Mean age ± SD: 46 ± 18 years
  - Male: 54.6%
- Number of repeated tests:
  - 1 repeat n=504
  - 2 repeats n=155
  - 3 repeats n=36
  - ≥ 4 repeats n=16
### REPEATED QFT-IT TESTS

<table>
<thead>
<tr>
<th></th>
<th>1st of repeated tests (n=711)</th>
<th>All repeats (n=994)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>45.5%</td>
<td>46.3%</td>
</tr>
<tr>
<td>Positive</td>
<td>51.7%</td>
<td>51.5%</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>2.8%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Inadequate</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

- 70% of repeated QFT give concordant valid results

### HOW DID THE QFT-IT RESULTS CHANGE IN REPEATED TESTS?

<table>
<thead>
<tr>
<th></th>
<th>FIRST REPEAT</th>
<th>ALL REPEATS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concordant negative</td>
<td>58.6%</td>
<td>59.2%</td>
</tr>
<tr>
<td>Concordant positive</td>
<td>13.9%</td>
<td>14.9%</td>
</tr>
<tr>
<td>Concordant indeterminate</td>
<td>5.2%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Reversion (from pos. to neg.)</td>
<td>3.5%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Conversion (from neg. to pos.)</td>
<td>6.7%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Indeterminate to negative</td>
<td>6.9%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Indeterminate to positive</td>
<td>0.8%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

- p < 0.0001

In approx. 4.0% of cases a negative result became indeterminate in subsequent testing.
WHERE WERE THE SAMPLES COMING FROM?

HCW SUBGROUP

- **1401 QFT-IT tests**
- **1093 subjects**
  - Mean age ± SD: 36 ± 10 years
  - Male: 28.6%

- **204 subjects with multiple tests**
  - Mean age ± SD: 36 ± 9 years
  - Male: 29.9%
**DISTRIBUTION OF QFT-IT RESULTS AMONG HCW**

<table>
<thead>
<tr>
<th></th>
<th>FIRST REPEAT</th>
<th>ALL REPLACES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concordant negative</td>
<td>66.3%</td>
<td>67.3%</td>
</tr>
<tr>
<td>Concordant positive</td>
<td>16.3%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Reversion (from pos. to neg.)</td>
<td>11.4%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Conversion (from neg. to pos.)</td>
<td>4.0%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Concordant indeterminate</td>
<td>0.5%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Indeterminate to negative</td>
<td>1.5%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Indeterminate to positive</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

> 80% of repeated QFT give concordant valid results

Reversion occurred more frequently than conversion

Indeterminate QFT-IT results became negative in all but one case
CONCLUSION

• In this non-experimental hospital setting, repeated QFT-IT confirmed previous results in most cases.
  → Little additional clinical information from repeated tests.

• Indeterminate QFT-IT results were more frequently negative than positive at repeated testing.
  → Most indeterminate results do not mask a positive result.

• Indeterminate results among HCW are negligible.
  → Excellent technical performance of QFT-IT among HCW in a low TB prevalence area.

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