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Understanding FEV₁ for the purpose of CF registry comparisons: Are UK annual review FEV₁ only collected when subjects are well?

Authors (Last Name, First Name): Hoo, ZH ², ¹; Curley, R ¹, ²; Campbell, MJ ²; Walters, SJ ²; Wildman, MJ ¹, ²

Institutions (All): ¹. Sheffield Adult CF Centre, Northern General Hospital, Sheffield, S Yorkshire, United Kingdom.
². ScHARR, University of Sheffield, Sheffield, S Yorkshire, United Kingdom.

Abstract Body:

Background
Comparisons of health outcomes between countries can potentially identify variation in care but are dependent on data quality.

The recent US-UK FEV₁ comparison found superior FEV₁ in the US, especially among those aged 6-25 years.[1] Encounter-based FEV₁ were collected in the US whereas once yearly FEV₁ were collected in the UK during annual reviews. To mirror the UK data, one clinically stable FEV₁ reading was selected from each US study subject.[1] This is based on the assumption that annual reviews in the UK are only done when subjects are well. If this assumption does not hold, results of FEV₁ comparisons will be biased in favour of registries with encounter-based FEV₁.

Aims
1. Determine the discrepancy between annual review vs matched clinically stable FEV₁ using prospective 2016 Sheffield encounter-based data
2. Determine if the differences observed in Sheffield also apply to the wider UK data using the 2014 UK CF registry data

Methods
Clinicians’ opinion of health status and Fuchs’ criteria[2] were recorded during every encounter involving a clinician review in Sheffield during 2016. Annual reviews were performed in accordance with usual practice. Every annual review FEV₁ was matched to another FEV₁ performed during a period of clinical stability that was closest to the annual review. Mean paired difference and paired t-test p-value were calculated.

Differences between annual review and best annual FEV₁ for Sheffield and the UK registry data were similarly analysed.

Results - Sheffield data
Annual review FEV₁ were significantly lower than matched clinically stable FEV₁. Among 63 adults who were reviewed by a clinician during their annual review, 13 (20.6%) were deemed clinically unstable. Annual review FEV₁ were also significantly lower than best annual FEV₁, with larger discrepancy among those deemed clinically unstable during annual review.

Results - UK registry data
Discrepancy between annual review and best annual FEV₁ were similar to Sheffield.

Conclusions
The Sheffield data suggests that discrepancy between annual review and best annual FEV\textsubscript{1} is a surrogate for the proportion of annual reviews performed during periods of clinical stability – a smaller discrepancy indicates a higher proportion of annual review performed during periods of stability and vice versa. The discrepancy between annual review and best annual FEV\textsubscript{1} in Sheffield is similar to the UK registry, hence it is likely that the proportion of annual reviews performed during periods of stability around the UK was similar to Sheffield.

Annual review FEV\textsubscript{1} underestimated lung health of study subjects in comparison to FEV\textsubscript{1} captured during periods of clinical stability and could potentially explain the superior FEV\textsubscript{1} observed in the US.

References

**TABLE:**

*Note: The PDF table below is only an approximation of the HTML content and may not match formatting exactly.*

<table>
<thead>
<tr>
<th></th>
<th>Sheffield data: Annual review FEV\textsubscript{1} vs matched clinically stable FEV\textsubscript{1} (n = 173)</th>
<th>Sheffield data, subset analysis: Clinically stable annual review FEV\textsubscript{1} vs best annual FEV\textsubscript{1} (n = 50)</th>
<th>Sheffield data, subset analysis: Clinically unstable annual review FEV\textsubscript{1} vs best annual FEV\textsubscript{1} (n = 13)</th>
<th>Sheffield data: Annual review FEV\textsubscript{1} vs best annual FEV\textsubscript{1} (n = 174)</th>
<th>UK CF registry data: Annual review FEV\textsubscript{1} vs best annual FEV\textsubscript{1} (n = 2995)</th>
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<tbody>
<tr>
<td>Paired mean difference in %FEV\textsubscript{1} (95% CI)</td>
<td>–2.9 (–3.8 to –1.9)</td>
<td>–8.0 (–11.2 to –4.9)</td>
<td>–2.5 (–3.9 to –1.2)</td>
<td>–6.1 (–7.1 to –5.1)</td>
<td>–5.6 (–5.9 to –5.4)</td>
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<tr>
<td>Paired t-test p-value</td>
<td>&lt; 0.001</td>
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φ Health status of adults during 111 annual reviews was unknown because annual reviews in Sheffield do not always involve a formal clinical review

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