CFHealthHub: Using the Leeds criteria and clinicians' decision to determine the Pseudomonas status among the 64 adults with cystic fibrosis in the two centre CFHH pilot study

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BACKGROUND:

P. aeruginosa (Psae) status influences the decision for long-term inhaled antibiotics and the denominator for calculating normative adherence with inhaled therapies among people with CF.[1] Determining Psae status accurately is therefore crucial for a nebuliser adherence clinical trial, such as CFHealthHub (CFHH).

However, there is no gold standard definition for Psae status among people with CF. The most commonly used definition in a CF research setting is the Leeds criteria.[2] The Leeds criteria is highly specific for chronic Psae infection. However, studies using PCR techniques have shown that it may lack sensitivity, with a tendency to under-diagnose chronic Psae as intermittent infection.[3,4]

An alternative to the Leeds criteria is asking clinicians to assimilate all relevant information, e.g. microbiological results (including information on strain typing) and Pseudomonas antibody results, to make a decision on Psae status. In an earlier abstract, we have demonstrated the inter-rater reliability and face validity of clinicians´ consensus for Psae status among adults with CF.[5] In another abstract, we have also demonstrated that the Leeds criteria is specific but lacks sensitivity for chronic Psae infection when compared against clinicians' consensus.[6]

The Leeds criteria are objective and simple to apply, whereas clinicians' decision is less likely to under-diagnose chronic Psae infection. A pragmatic method to determine Psae status is therefore to use the Leeds criteria in conjunction with clinicians' decision.

AIM:

To describe how the Leeds criteria was used in conjunction with clinicians' decision to determine Psae status in the CFHH pilot

METHODS:

CFHH is a NIHR-funded programme comparing a complex intervention to support self-care and nebuliser adherence vs standard care among adults with CF. The pilot trial ran in Nottingham and Southampton.

Two data collection methods were used for Psae status:

1. Microbiological data for 12 months pre-recruitment were recorded to apply the Leeds criteria[2]
2. Local Principal Investigators (LPI) were asked to independently decide on the Psae status of all their participants

If LPI agreed with the Leeds criteria or "over-estimated" Psae status in relation to the Leeds criteria, LPI decision was accepted as the 'final' Psae status. If the Leeds criteria suggested intermittent Psae but LPI suggested no Psae, the Leeds criteria is accepted. If the Leeds criteria suggested chronic Psae but LPI disagreed, this was resolved between the Chief Investigator (CI) and LPI.

RATIONALE FOR THE METHODS USED:

Our earlier study demonstrated that where there was disagreement between the two methods, the Leeds criteria always under-estimated the Psae category in comparison to clinicians' decision.[6] Therefore, if the Leeds criteria agreed with LPI's decision or "under-estimated" Psae status, the LPI decision was accepted as the 'final' Psae status.

If LPI suggested no Psae but the Leeds criteria suggested intermittent Psae (i.e. at least x1 positive Psae culture in the previous 12 months), the participant is still considered as intermittent Psae because an adult with CF is not considered free from Psae unless 12 months has elapsed since the last positive Psae culture. If the Leeds criteria suggested chronic Psae but LPI disagreed, resolution with the CI is required because the Leeds criteria may very occasionally misdiagnosed intermittent Psae as chronic if most of the microbiological samples were collected within a short time interval prior to an effective Psae eradication therapy.

RESULTS:

Psae results were available for 63 out of 64 participants in the CFHH pilot. 34 participants have chronic Psae, 7 have intermittent Psae and 22 have no Psae. Only 1 participant required resolution of the 'final' Psae status between CI and LPI.

LPI decision vs the Leeds criteria in the CFHH pilot:

The Leeds criteria Psae status, n	Psae status according to LPI decision, n		
	No Psae	Intermittent	Chronic
No Psae	22	1	2
Intermittent	1	4	3
Chronic	0	1	29

CONCLUSIONS:

Pragmatically determining Psae status by combining clinicians´ decision with Leeds criteria was easy to use and acceptable across two separate adult pilot centres, allowing Psae status to be determined for all participants with data.

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