An easy-to-implement Clinical Trial-Frailty Index based on accumulation of deficits: validation in zoster clinical trials

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Methods
Post-hoc analysis using data from 2 clinical trials of the adjuvanted recombinant zoster vaccine (ZOE-50 [NCT01165177] and ZOE-70 [NCT01165229])

41 possible deficits assessed
- baseline medical history: 12
- SF-36: 25
- EQ-5D: 4

each deficit scored: 0 to 1

Validation
- Distribution of FI (expected gamma distribution)
- Association with mortality (using Cox regression)
- Robustness to in/exclusion of specific deficits (Jackknife and Bootstrap re-sampling on survival association)

CT-FI that we have developed can be used to evaluate clinical outcomes by frailty status in other clinical trials, retrospectively or prospectively

Results
The CT-FI was calculated for >99% of the 26,976 vaccinated participants
The CT-FI distribution followed a gamma distribution with a range of 0 to 0.695 and shifted to the right with age, consistent with previous FIs

Frailty increased with age and was higher for women than men, consistent with previous FIs

Annual deficit accumulation rate

Frailty was a robust indicator for mortality

Significant predictors of mortality
- FI
- Age
- Sex

CT-FI was not sensitive to inclusion/exclusion of specific individual or groups of variables, as shown by re-sampling methods

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