

Impact of Remote Assessments During the COVID Pandemic

Lessons Learnt

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Disclosure

- Full time employee and stockholder of Signant Health

Remote assessments during COVID pandemic

- Is there impact of ad-hoc remote assessments on the data?
 - Change from baseline and prior visit
 - Variability
 - Reliability
- What is the impact of ad-hoc remote assessments on data quality?

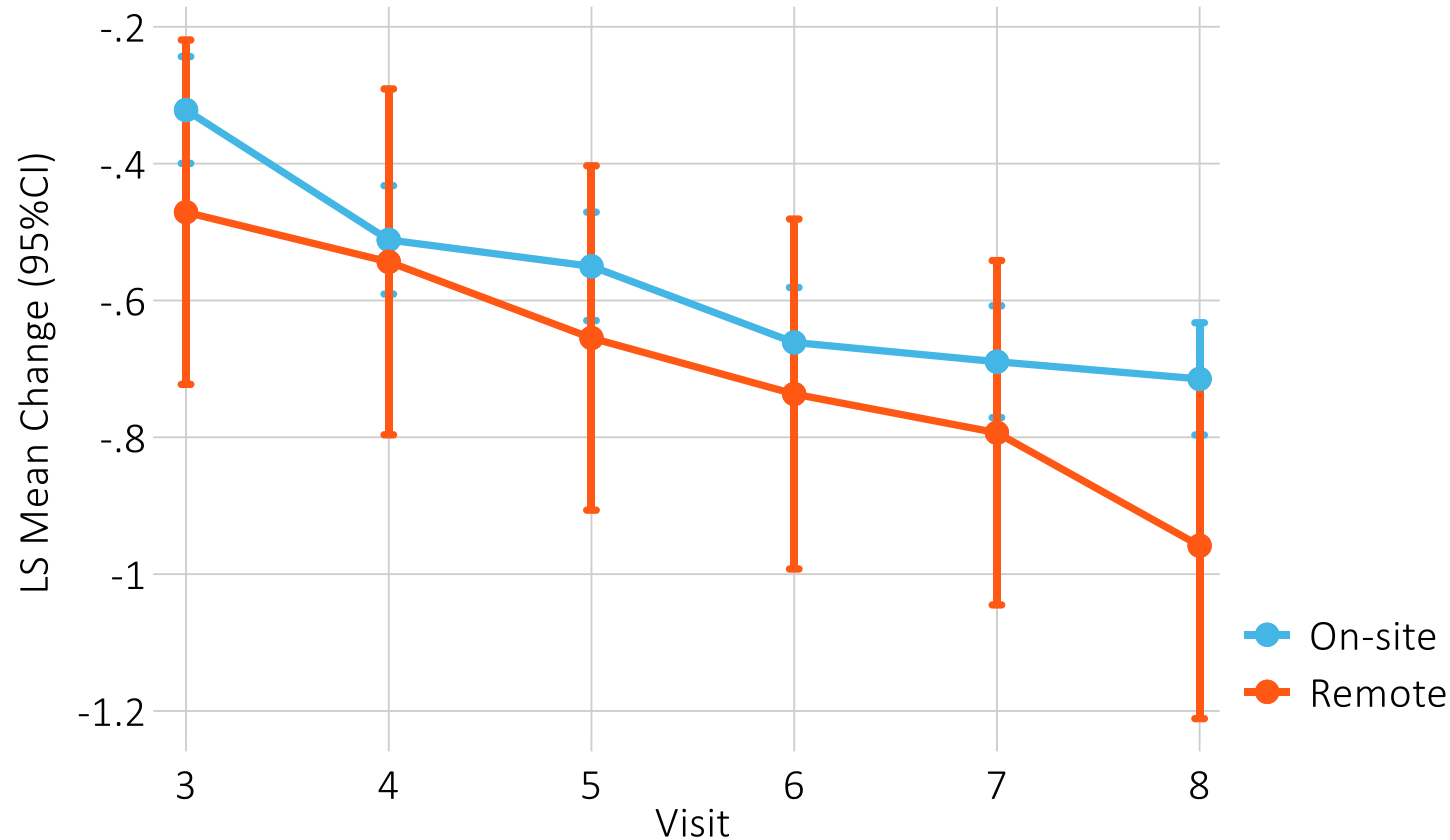
Challenges

- Defining the population:
 - Large regional and temporal differences in COVID impact on trials and trial subjects
 - Differences in study conduct even within the same visit (e.g. in-person and remote administration during the same visit)
- Mixed modes (in-person vs remote) of assessment
 - Inconsistent administration over time
 - Inconsistent tracking
 - Inconsistently administered within subject
 - Insufficient data to make inferences

Case study

- Ad-hoc remote assessments due to COVID after randomization in the study
 - Administered at 3.3% of all post-baseline visits
 - Affected a total of 9.0% of all randomized study participants

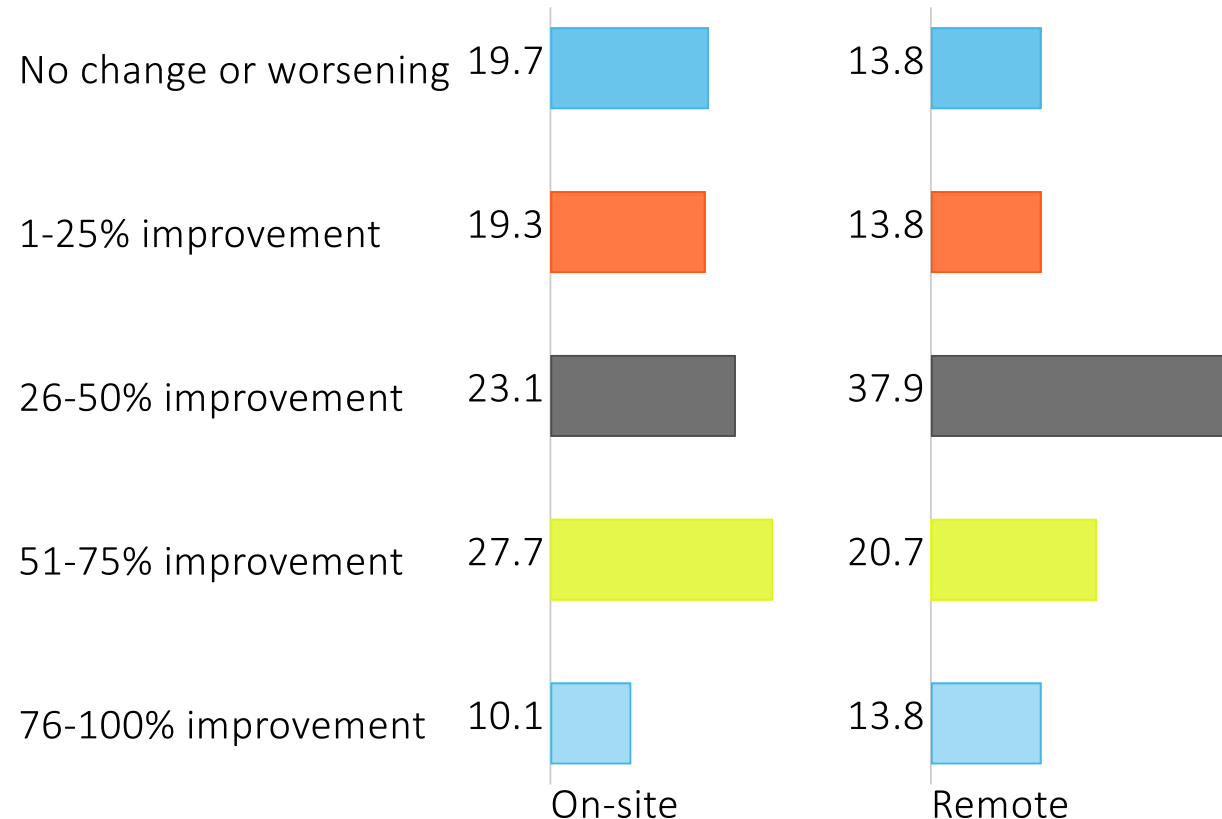
LS Mean Change from Baseline



No difference in change from baseline between subjects assessed fully on-site vs. subjects with remote assessments

Comparing change from baseline in subjects assessed completely on site and subjects with at least 1 remote assessment

Last Visit Response Rates

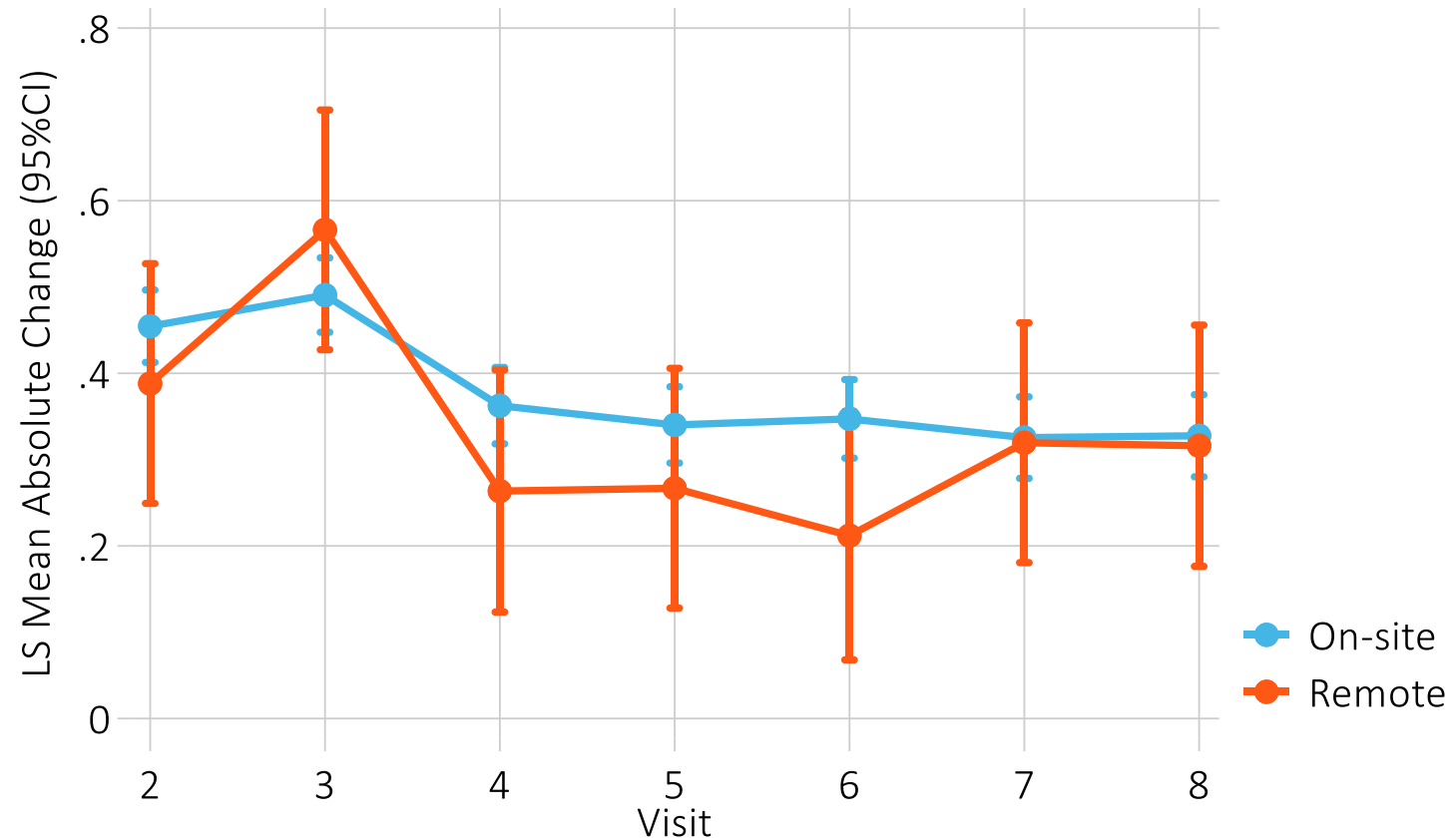


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No difference in response rates between subjects assessed fully on-site vs. subjects with remote assessments

Comparing change from baseline in subjects assessed completely on site and subjects with at least 1 remote assessment

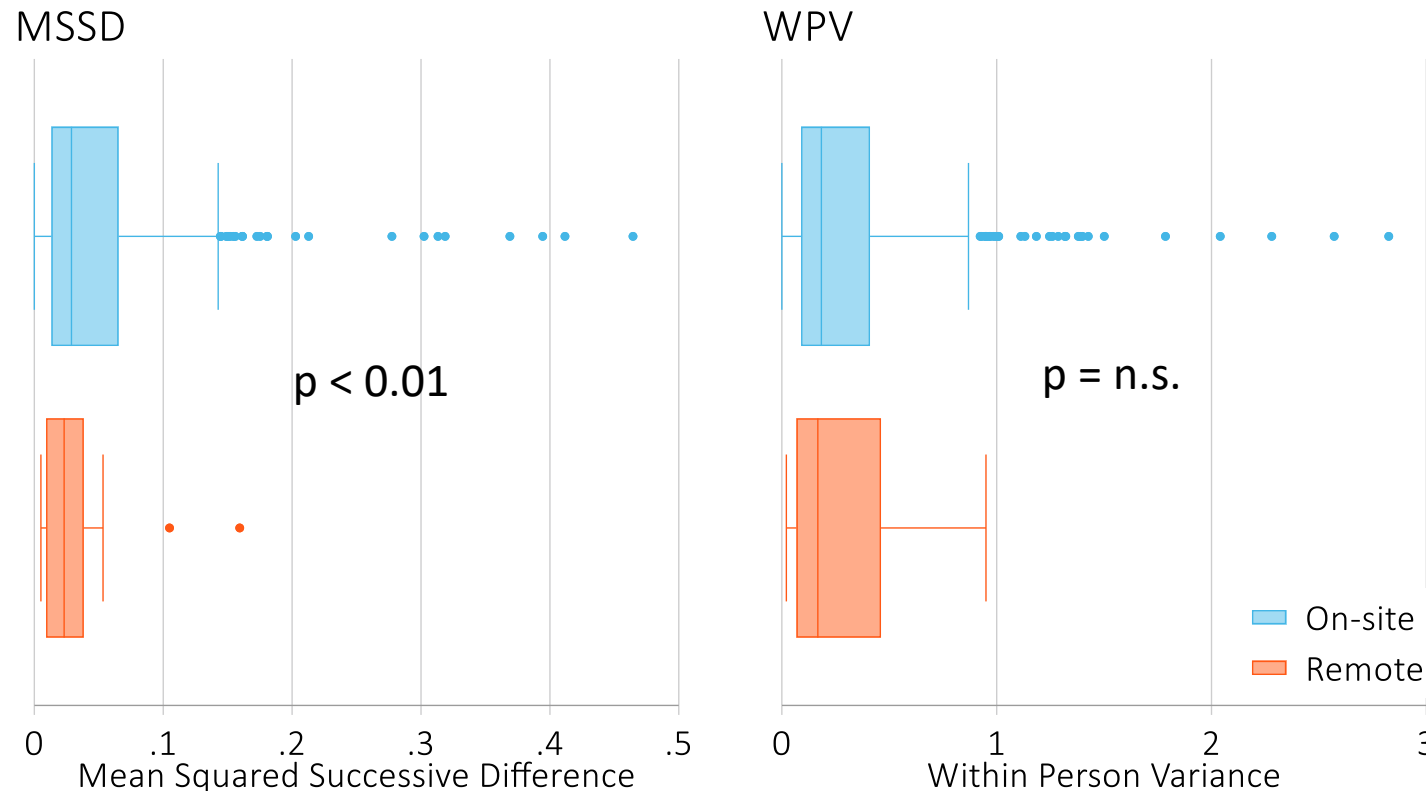
LS Mean Absolute Change from Prior



No difference in absolute change from prior visit between subjects assessed fully on-site vs. subjects with remote assessments

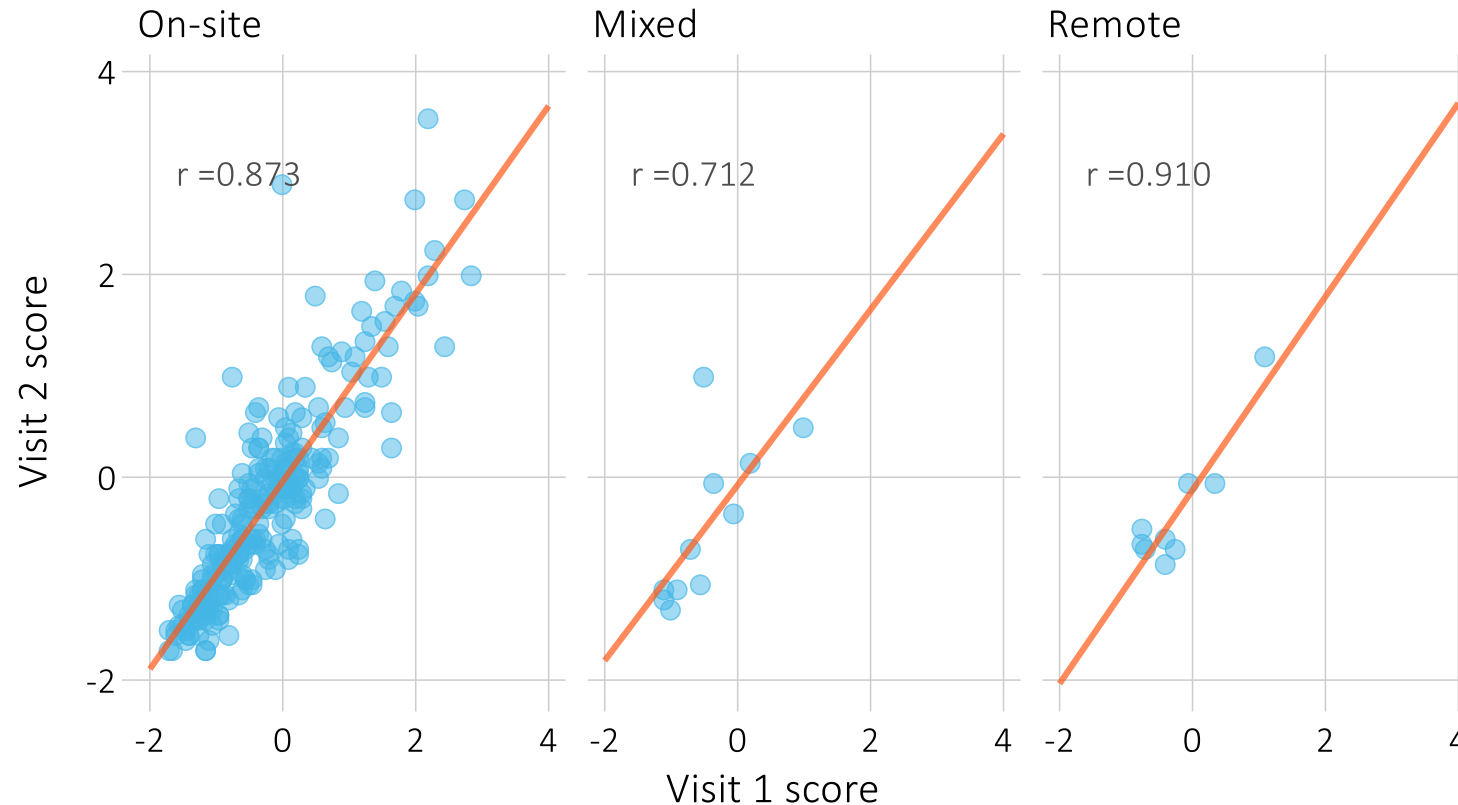
Comparing change from prior visit in subjects assessed completely on site and subjects with at least 1 remote assessment

Data Variability by Mode of Assessment



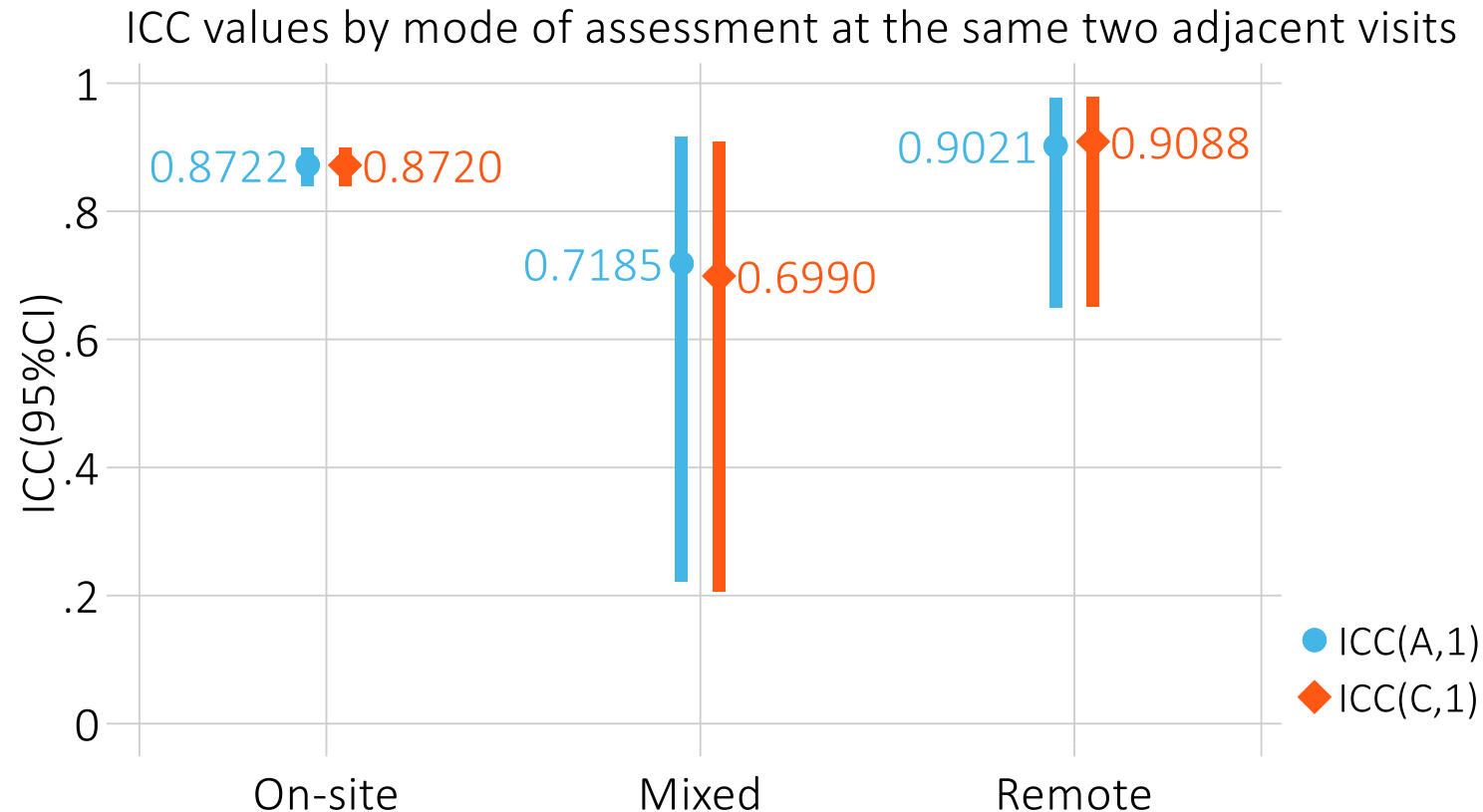
Significant differences in MSSD but not WPV between the groups

Between Visits Relationship by Mode of Assessment



No statistical difference in rho between the modalities

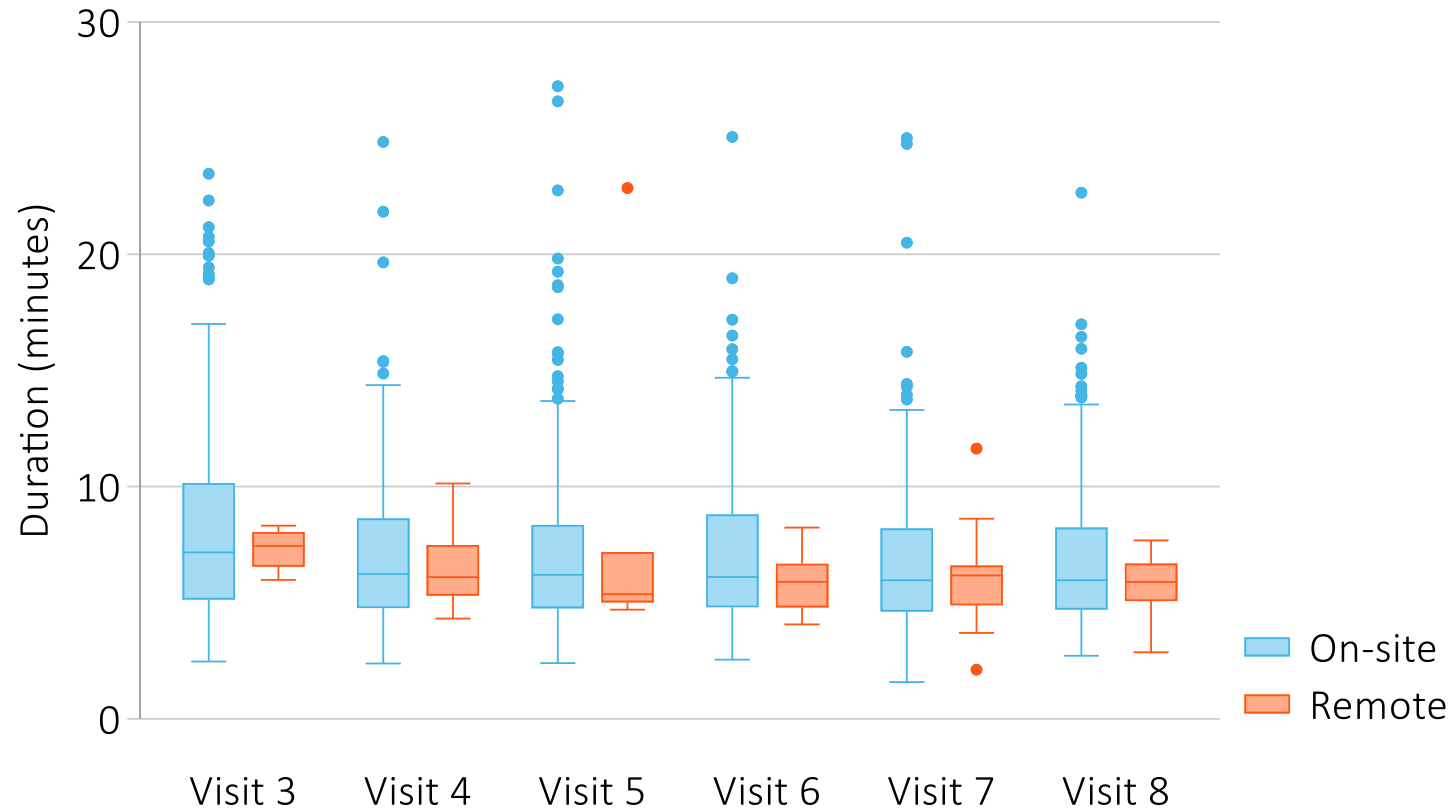
Between Visits ICC by Mode of Assessment



Absence of bias
regardless of mode of
assessment

Highest ICC seen in
consecutive remote
assessments

Interview Duration

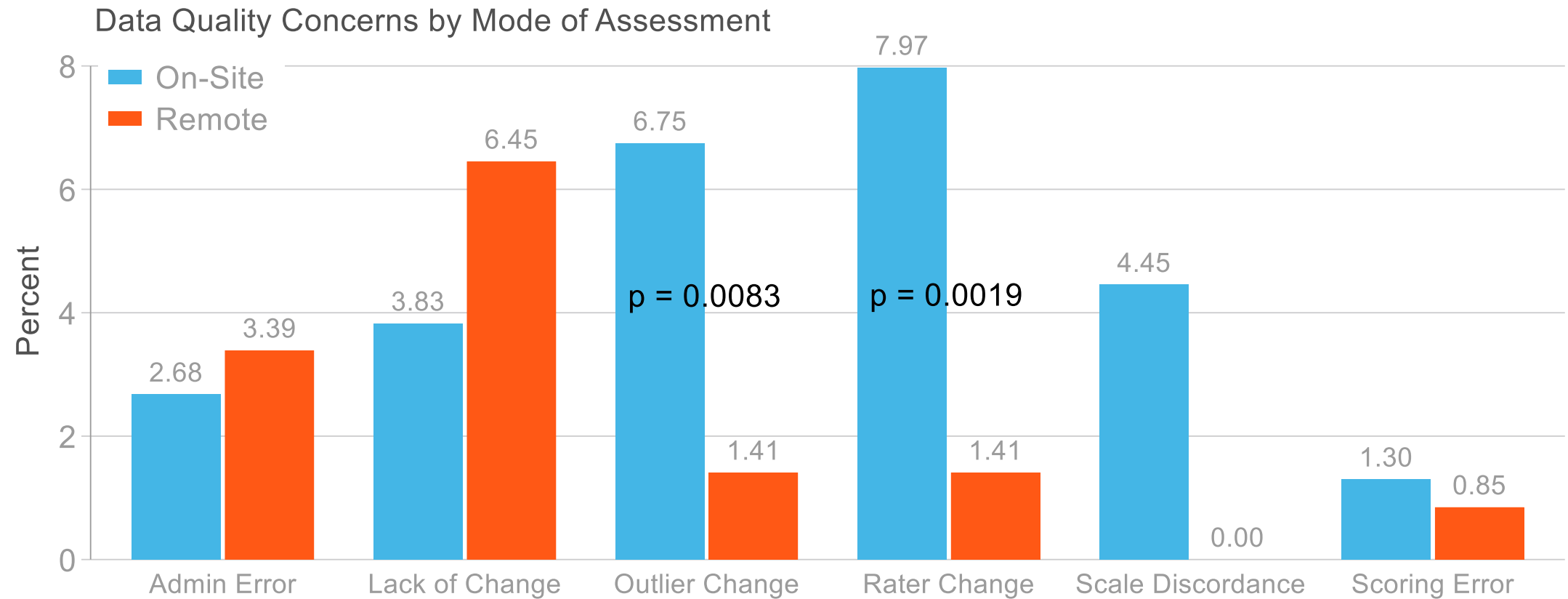


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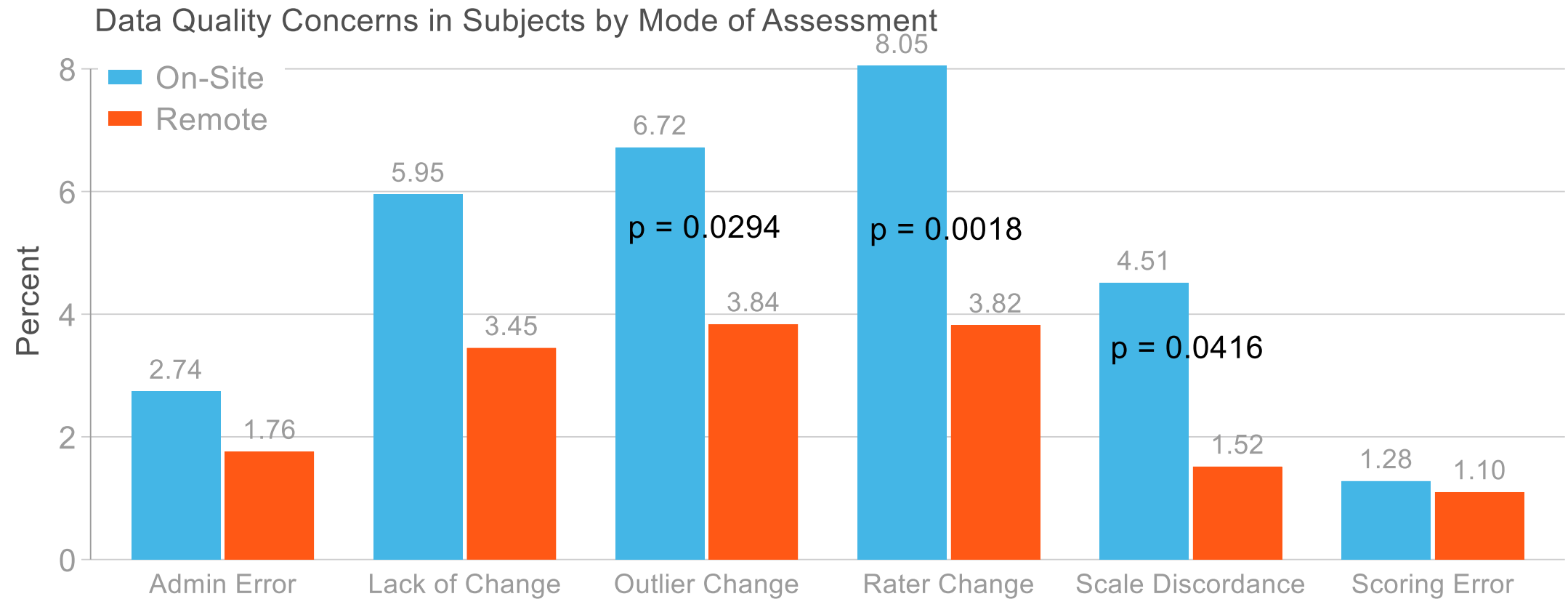
On-site assessments
longer than remote
assessments

The difference is not
statistically significant

Data Quality Concerns



Data Quality Concerns cont.



Conclusions

- Ad hoc remote assessments were relatively infrequent in the early stages of COVID pandemic and basically absent in 2021
- Based on available data no impact on change from baseline
- Change from prior visit was not-significantly reduced
- ICCs favourable but were lowest in case of switches between modes of assessments
 - ICCs did not identify any major bias in the remote assessments
- Data quality seemed better during remote assessments as well as in subjects who had at least one remote assessment

Thank you