Modelling of hypothetical SARS-CoV-2 point of care tests for routine testing in residential care homes: rapid cost-effectiveness analysis

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Scientific summary

SARS-CoV-2 POCTs in residential care

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Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which was identified in China in 2019, is the virus that causes coronavirus disease 2019 (COVID-19). Worldwide, at the time of writing (January 2021), the number of cases of COVID-19 was greater than 100 million and more than 2.25 million deaths were attributable to it. In the UK, the corresponding numbers were over 3.8 million cases and over 100,000 deaths. SARS-CoV-2 appears to be highly transmissible and is spread primarily through secretions from the nose or mouth, which can occur when coughing, sneezing or talking.

The risk of infection within a residential care facility could bear grave consequences, particularly for vulnerable elderly residents with comorbidities. Currently, laboratory-based testing is relied on to detect infections; however, it takes a considerable turnaround time to receive a test result. During this time, a decision needs to be made on whether or not to isolate residents. Incorrectly isolating residents can have an impact on their well-being, but incorrectly failing to isolate residents can result in the rapid spread of SARS-CoV-2.

The Medicines and Healthcare products Regulatory Agency has released target product profiles for point-of-care tests for SARS-CoV-2 that have a much quicker turnaround time to receive a test result than laboratory-based testing, albeit with lower diagnostic accuracy. Desirable and acceptable target product profiles were released; however, the clinical effectiveness and cost-effectiveness of these target product profiles were unknown.

Objective

The objective of this study is to evaluate the expected clinical effectiveness and cost-effectiveness of hypothetical point-of-care tests for SARS-CoV-2 when these are introduced into a residential care home for routine testing of residents and staff, and to evaluate different strategies related to the use of SARS-CoV-2 point-of-care tests and laboratory-based SARS-CoV-2 tests.

Methods

As the tests were hypothetical, no systematic reviews of diagnostic accuracy were performed. As the research was conducted to demanding deadlines, in agreement with the National Institute for Health and Care Excellence, no systematic reviews were performed. Instead, scanning of published literature and discussions with clinical experts were undertaken to identify literature sources for use in the modelling. New evidence was being published continually and this would not have been picked up using standard systematic review techniques.

A mathematical model was constructed using an individual patient simulation methodology to allow for interactions (and the possible spread of infection) between residents, from residents to staff, from staff to residents and between staff. The model was populated from data identified in the non-systematic review. Outputs from a mathematical model included the number of infections among residents and staff, the number of days spent in isolation, the numbers of simulated deaths from COVID-19, the numbers of critical, non-fatal, cases of COVID-19, and the costs of testing. Calibration techniques were used to ensure that the proportion of residents and staff infected associated with using the testing strategy in place at the start of the COVID-19 pandemic was in line with published evidence. Thirteen strategies using SARS-CoV-2

tests were initially modelled for four possible combinations of care homes (i.e. whether this was en suite or had shared facilities, and whether the model started with an index SARS-CoV-2-infected resident or not) and whether or not early release on receipt of a negative SARS-CoV-2 test was permitted. Ten additional sensitivity analyses that varied parameter values were explored.

Owing to the large number of strategies evaluated and the potential that incremental cost-effectiveness ratios may provide misleading results when there are very small absolute differences in terms of costs and health benefits, a net monetary benefit approach was adopted, although full incremental analyses were also presented. Strategies were evaluated that altered the assumed time to SARS-CoV-2 test results and laboratory-based SARS-CoV-2 tests, and the assumed diagnostic accuracy.

Results

Strategies with desirable target product profiles were most cost-effective, all other things being equal, as were SARS-CoV-2 tests with better diagnostic accuracy. If a point-of-care test with the characteristic of the desirable target product profile was available, then this would have a high net monetary benefit regardless of whether or not early release from isolation was permitted. The acceptable SARS-CoV-2 point-of-care test target profile product typically had lower net monetary benefit than both the desirable target product profile and real-world evidence because of the increased number of days spent in isolation by residents. The results remained robust with sensitivity analyses varying population age, the prevalence of symptoms falsely suggesting COVID-19, the proportion of asymptomatic cases and the proportion of residential care facilities that would be penetrated by SARS-CoV-2. However, the net monetary benefit of a test was sensitive to its costs and the assumed efficacy of vaccination, in addition to diagnostic accuracy and time to result. Some strategies, for example those that have the acceptable target product profiles, have small numbers of infections, but at the expense of markedly more days in isolation for residents, which is likely to be associated with detrimental impacts on the residents. Exploratory analyses assessing the potential of lateral flow testing show promising results; however, more data, including diagnostic accuracy and failure rate data, particularly within a residential care facility setting, and more certainty in the costs of a lateral flow test are needed to increase the robustness of these results.

Discussion

There was considerable uncertainty relating to parameters contained within the model, although this was mitigated to some degree by the calibration undertaken. However, the results produced should not be taken as definitive, but indicative only, with small levels of Monte Carlo sampling error remaining. It is not certain the extent to which SARS-CoV-2 point-of-care tests would reduce the test turnaround time, nor is it clear what the diagnostic accuracy of these tests will be; therefore, the results remain hypothetical. It is noted that both factors are important drivers of the clinical effectiveness and cost-effectiveness of SARS-CoV-2 point-of-care tests. The relative cost of point-of-care tests to laboratory-based tests can also influence the estimated cost-effectiveness. However, a structure is in place to quickly evaluate new SARS-CoV-2 point-of-care tests as these become available.

Conclusions

Given the heterogeneity of residential care facilities, no blanket result can be provided. This report contains information that should be useful for decision-makers in assessing their own specific problem. The modelling structure developed is anticipated to be useful for assessing the cost-effectiveness of SARS-CoV-2 point-of-care tests as further information on the costs, turnaround times and diagnostic accuracy of these tests becomes available.

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This report

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