

The Liverpool Mass Asymptomatic Testing Pilot Study and Measuring Sensitivity in the Real World

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Liverpool asymptomatic testing



<https://www.liverpool.ac.uk/coronavirus/research-and-analysis/covid-smart-pilot/>



Liverpool asymptomatic testing

- November 2020 – MAST (Mass Asymptomatic Serial Testing) pilot opened in Liverpool, while in Tier 3
- Asymptomatic testing sites set up throughout the city, staffed by military personnel
- December 2020 – Liverpool moves to Tier 2, handover from military, MAST becomes SMART (Systematic Meaningful Asymptomatic Repeated Testing)
- SMART focused on test-to-protect, test-to-release, test-to-enable

Data flow - CIPHA



- Population health management platform
- Established in 3 months across Cheshire & Merseyside to help the health and care system manage the Coronavirus crisis and to drive its recovery
- Collaboration involving NHS, local government and University of Liverpool
- Near real-time person level linked dataset including demographic and health information, test results and medication
- Pseudonymised data – data sets could be linked using pseudo-IDs, no identifiable information available to researchers
- <https://www.cipha.nhs.uk/>

Liverpool asymptomatic testing – QA study

- Asymptomatic people attending testing sites in Liverpool between 8th and 29th November 2020 were invited to take part
- Recruitment for this study rotated between 48 test sites with two days recruitment, or 200 participants at each test site
- Participants received swabs for both an Innova LFT and an RT-qPCR test, self-administered under supervision, taken within minutes of each other
- PCR sent to a Lighthouse laboratory
- Site team (military personnel) processed the LFT sample

Liverpool QA study

QA dataset		RT-qPCR Result			
		Negative	Positive	Void	Total (%)
LFT Result	Negative	5431	42	341	5814 (99.1%)
	Positive	3	28	2	33 (0.6%)
	Void	18	4	0	22 (0.4%)
	Total	5452	74	343	5869
	(%)	(92.9%)	(1.3%)	(5.8%)	

Sensitivity = 40.0% (28.5% to 52.4%; 28/70)

Specificity = 99.9% (99.8% to 99.99%; 5,431/5,434)

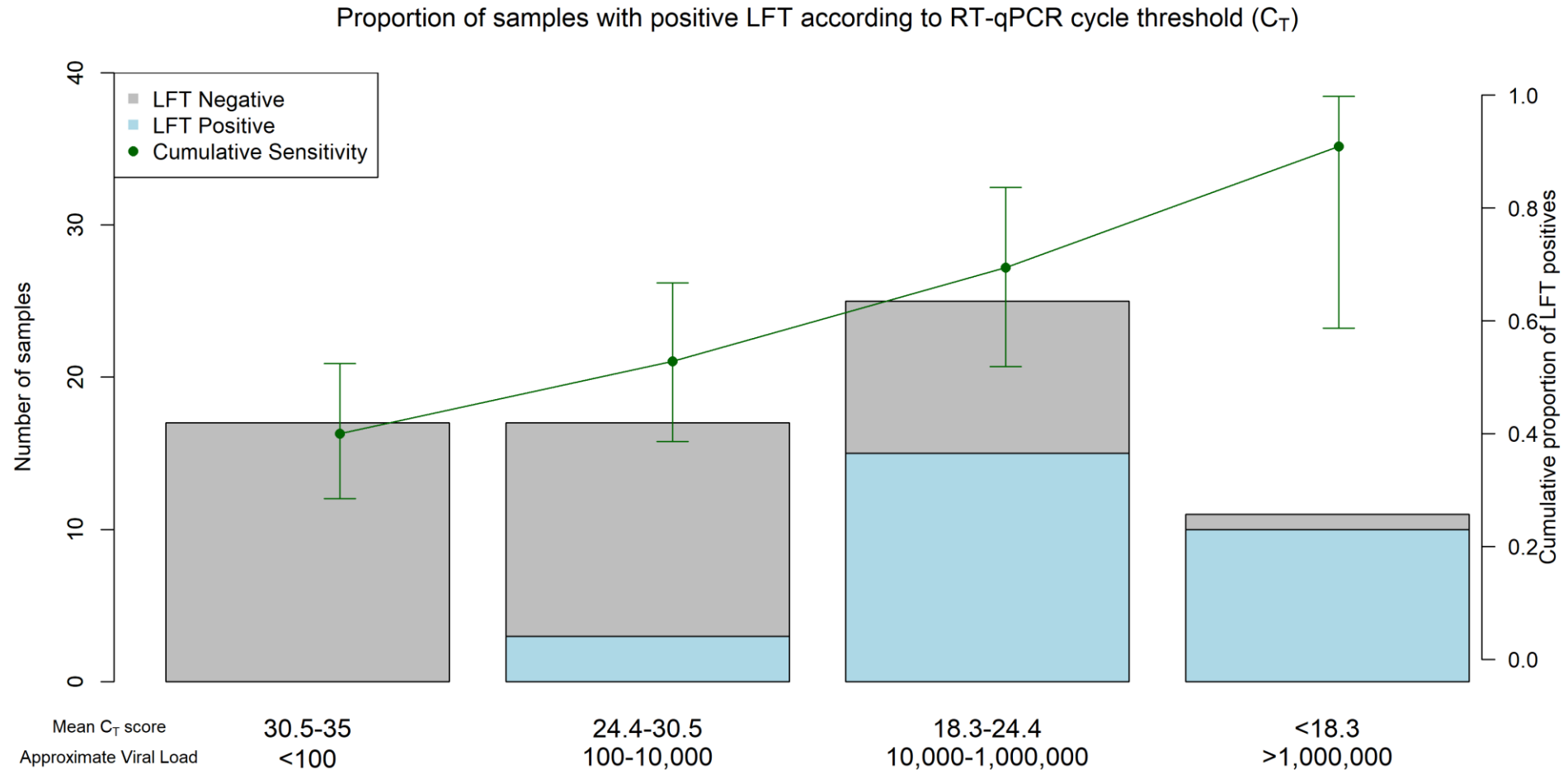
Positive predictive value = 90.3% (74.3% to 98.0%; 28/31)

Negative predictive value = 99.2% (99.0% to 99.5%; 5,431/5,473)

Liverpool QA study – Ct values

		RT-qPCR test (Average across three gene targets)								
RT-qPCR C _T (mean C _T)		<18.3	18.3-24.4	24.4-30.5	30.5-35		Void (30-35)	Void (>35)	Void (NA)	-ve
Approximate viral load (RNA copies/ml)		>10 ⁶	10 ⁴ -10 ⁶	10 ² – 10 ⁴	<10 ²					
LFT Site Results	Negative	1	10	14	17		5	8	328	5431
	Positive	10	15	3	0		0	0	2	3
	Void	0	4	0	0		0	0	0	18
Sensitivity (95% CI)		90.9 (58.7,99.8)	60.0 (38.7,78.9)	17.6 (3.8,43.4)	0.0 (0.0,19.5)					
Cumulative Sensitivity (95% CI)		90.9 (58.7,99.8)	69.4 (51.9,83.7)	52.8 (38.6,66.7)	40.0 (28.5,52.4)					

Liverpool QA study results by Ct values



QA study – data flow

- CIPHA data flow included all test results in the region
- Identified participants by matching LFT and PCR tests taken on the same day from the same person (based on Pseudo ID), at the asymptomatic testing sites taking part
- After initial calculations, we identified a few participants who had multiple pairs of tests (sometimes with differing results)
- Makes virtually no difference to specificity due to large numbers of negative tests, but could impact on sensitivity
- Results recalculated to only include one pair of results per person

QA study - reporting

- Preliminary results (not full data set) were reported to SAGE on 25th November 2020
- Calculated sensitivity at this stage was 49%
- Based on these preliminary results, the Liverpool Health Protection Board paused plans for LFT test-to-enable visitor access to care homes
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943187/S0925_Innova_Lateral_Flow_SARS-CoV-2_Antigen_test_accuracy.pdf

QA study - reporting

- MAST interim report published on University of Liverpool website in December 2020
- Full evaluation report on SMART pilot published June 2021
- BMJ paper accepted in June 2021

Performance of the Innova SARS-CoV-2 antigen rapid lateral flow test in the Liverpool asymptomatic testing pilot: population based cohort study

Marta García-Fiñana,¹ David M Hughes,¹ Christopher P Cheyne,¹ Girvan Burnside,¹ Mark Stockbridge,² Tom A Fowler,^{2,3} Veronica L Fowler,² Mark H Wilcox,⁴ Malcolm G Semple,^{5,6} Iain Buchan⁷

[thebmj](#) | *BMJ* 2021;374:n1637 | doi: 10.1136/bmj.n1637

QA study conclusions

- Overall conclusion was that LFT could be a valuable tool in combination with other health protection measures, in identifying people with higher viral loads who are not showing symptoms
- “Policy makers need to consider LFT utility in context sensitive ways, regarding population levels of infection, phases of epidemic curves, and the transmission risks and consequences in specific settings”
- Most response was focused on 40% sensitivity

QA study response



The screenshot shows the top navigation bar of the BMJ Opinion website. The logo 'thebmjopinion' is on the left, followed by 'Latest', 'Authors', and 'Topics' with dropdown arrows. To the right, the 'thebmj' logo is followed by a menu with 'covid-19', 'Research', 'Education', 'News & Views', 'Campaigns', and 'Jobs'. Below the navigation, a news article snippet is visible with the title 'Covid-19: government must urgently rethink lateral flow test roll out' and the date 'January 12, 2021'. To the right of this snippet, a 'News' section header is followed by another article title: 'Covid-19: Safety of lateral flow tests questioned after they are found to miss half of cases'. Below this title, the citation information is provided: 'BMJ 2020 ; 371 doi: <https://doi.org/10.1136/bmj.m4744> (Published 04 December 2020)' and 'Cite this as: BMJ 2020;371:m4744'.

The Telegraph

Mass coronavirus testing in Liverpool has missed half of positive cases, Government figures show

Results published this week from a pilot scheme show many people who had Covid-19 would wrongly believe they did not have the disease



Scientists in Liverpool mass Covid testing trial defend rapid tests

Professor says programme was very helpful, despite criticism about accuracy of lateral flow tests

Context

- Clearly needs to be put in context of what it's being used for – what are the risks associated with missing a case?
- Even with low Ct values likely to be most infectious, LFTs will miss some cases
- LFT did not detect cases with high Ct values
- “Sensitivity of 40%” not the right headline message – what is of interest is infectiousness not PCR positivity

Context

- Our results suggested that LFTs will not detect cases with high Ct values
- This is consistent with the results from a study of Birmingham students, which found 6 false negatives, all with Ct values of >29
- Only 2 positive LFTs were found from >8000 students, with a 10% sample being retested using PCR
- How infectious are these cases with high Ct values?

Ferguson J, Dunn S, Best A, Mirza J, Percival B, Mayhew M, Megram O, Ashford F, White T, Moles-Garcia E, Crawford L, Plant T, Bosworth A, Kidd M, Richter A, Deeks J, McNally A. Validation testing to determine the sensitivity of lateral flow testing for asymptomatic SARS-CoV-2 detection in low prevalence settings: Testing frequency and public health messaging is key. *PLoS Biol.* 2021 Apr 29;19(4):e3001216. doi: 10.1371/journal.pbio.3001216.

Wording is important

- From an NHS Test and Trace Schools and Colleges handbook, late 2020

Safe

These tests work - in validation studies conducted by Oxford University and Public Health England, they were shown to be as accurate in identifying a case as a PCR test (99.8% specificity). The tests have lower sensitivity but they are better at picking up cases when a person has higher viral load. Hence, the need to test frequently.

Not just accuracy

- Mass testing not all about accuracy
- Public trust, social and organisational factors to support uptake, contact tracing, adherence to quarantine
- Study on twice-weekly testing of care home staff showed 9% of staff with >75% adherence to the testing protocol
- Study on daily testing of key workers after positive test showed 93-97% compliance with testing regime



Tulloch JSP, Micocci M, Buckle P, Lawrenson K, Kierkegaard P, McLister A, Gordon AL, García-Fiñana M, Peddie S, Ashton M, Buchan I, Parvulescu P. Enhanced lateral flow testing strategies in care homes are associated with poor adherence and were insufficient to prevent COVID-19 outbreaks: results from a mixed methods implementation study. *Age Ageing*. 2021 Nov 10;50(6):1868-1875. doi: 10.1093/ageing/afab162.

Marsden L, Hughes DM, Corcoran R, Cheyne CP, Ashton M, Buchan I, Coffey E, García-Fiñana M. Daily testing of contacts of SARS-CoV-2 infected cases as an alternative to quarantine for key workers in Liverpool: a prospective cohort study. *Lancet eClinicalMedicine*, accepted

MAST/SMART programme uptake

RESEARCH PAPER | [VOLUME 6, 100107, JULY 01, 2021](#)

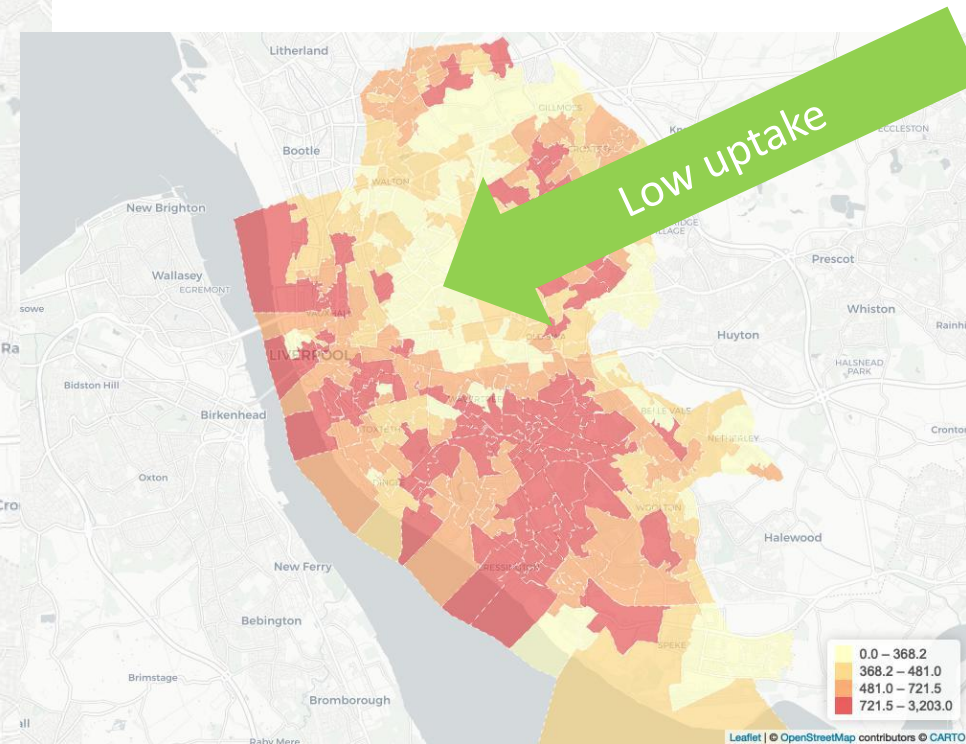
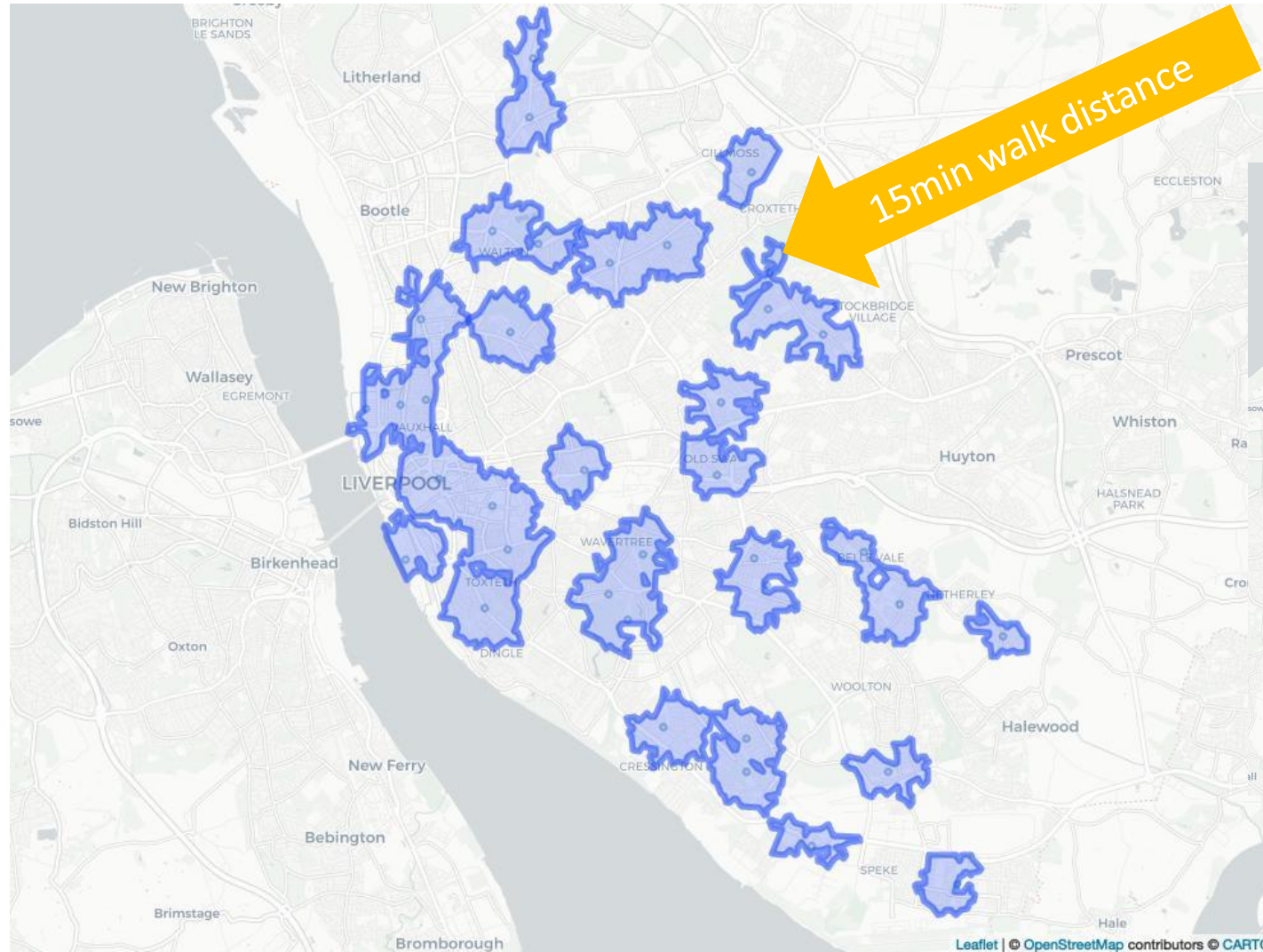
Evaluating social and spatial inequalities of large scale rapid lateral flow SARS-CoV-2 antigen testing in COVID-19 management: An observational study of Liverpool, UK (November 2020 to January 2021)

[Mark A. Green](#)   • [Marta García-Fiñana](#) • [Ben Barr](#) • [Girvan Burnside](#) • [Christopher P. Cheyne](#) • [David Hughes](#) • [Matthew Ashton](#) • [Sally Sheard](#) • [Iain E. Buchan](#) • [Show less](#)

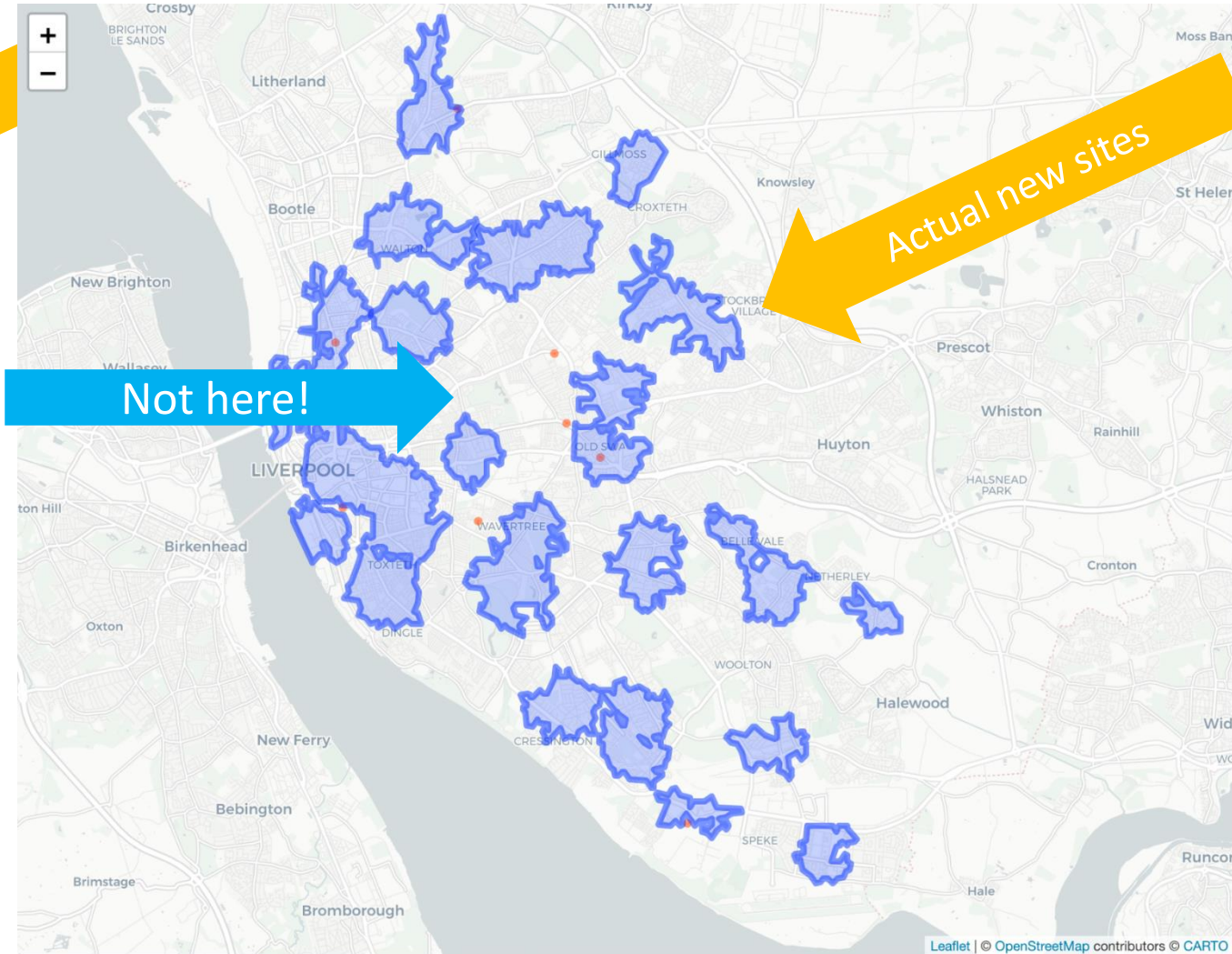
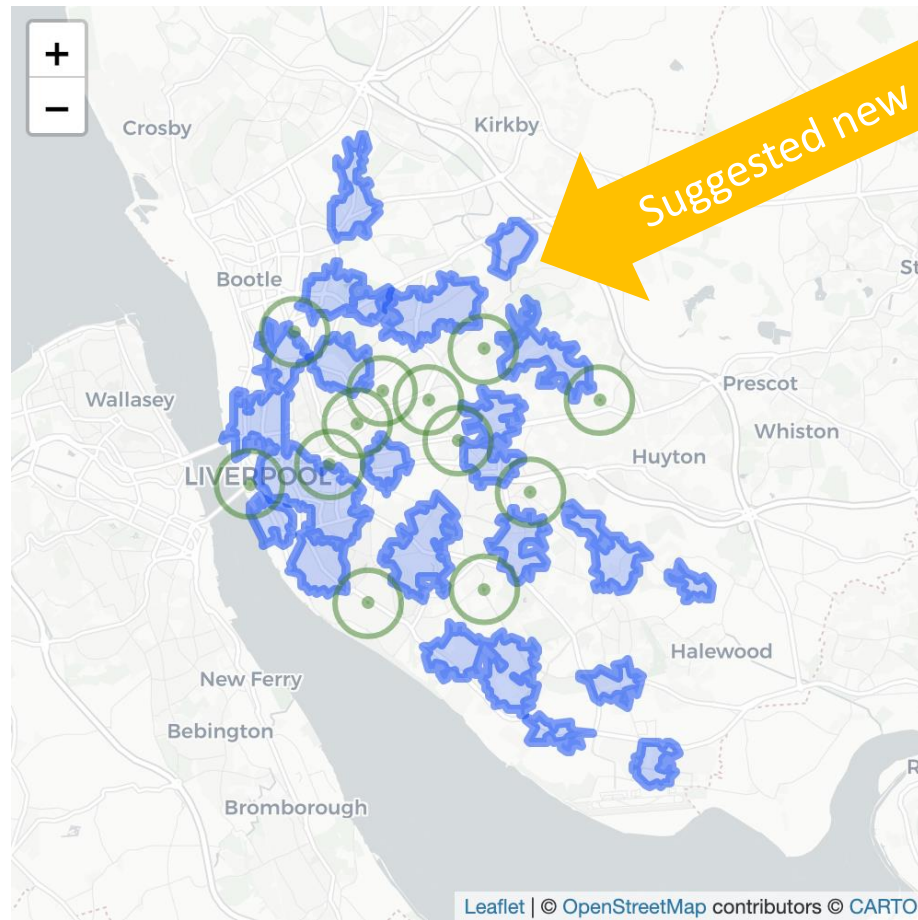
THE LANCET *Regional Health*
Europe

- Uptake was lower in areas of high deprivation, areas further from test sites and areas containing populations less confident in using internet technologies

Test site accessibility



Recommendations for new site locations







MAST/SMART programme results

- Between 6 November 2020 and 30 April 2021, 283,338 (57%) Liverpool residents took an LFT
- Of these, 47% had more than one test (27% of residents)
- In the same period 152,609 were tested by PCR
- 6300 individuals declaring no symptoms tested positive by LFT (case positivity 2.1%)
- 22,567 individuals declaring symptoms tested positive by PCR (case positivity 14.8%)
- https://www.liverpool.ac.uk/media/livacuk/research/Mass_testing_evaluation.pdf

Impact on hospitalisation

The impact of community asymptomatic rapid antigen testing on COVID-19 hospital admissions: a synthetic control study

 Xingna Zhang,  Ben Barr,  Mark Green, David Hughes, Matthew Ashton, Dimitrios Charalampopoulos, Marta García-Fiñana,  Iain Buchan

doi: <https://doi.org/10.1101/2022.04.19.22274050>

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

- Estimated 43% reduction in hospitalisations in Liverpool compared to control areas for the initial period of intensive military-led testing
- Estimated 25% reduction over the whole pilot period
- National data on hospitalisations took almost a year to obtain, compared to near-real time local data from CIPHA

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