Response to: Deeks et al. Briefing note for journalists on harm from continued rollout of the Innova Lateral Flow Test. 10 January 2021

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1. This document contains factual errors and makes several unsubstantiated allegations and assertions. Some of these allegations are extremely serious. The authors allege that the use of Lateral Flow Devices (LFD) is doing harm to children and young vulnerable adults. Clearly, this allegation, if true, is of the utmost importance. However, the authors provide no evidence to back this assertion.

2. The authors demonstrate persistent and continuing confusion between PCR tests that detect non-viable virus particles containing RNA fragments and LFD that detect substantive quantities of viral antigen shed from the nose or throat of an individual. LFDs have biological credibility to be a surrogate marker for infectiousness, as it requires a large amount of viral replication and budding from cells of the upper respiratory tract.

3. The authors treat PCR mathematically as a perfect gold standard of infectiousness when there is now substantial evidence that it is not. The authors appear unaware of the biology of Covid-19. The authors, as experts in the assessment of test performance in general, do not discuss the obvious challenge of how to assess a new type of test when no 'gold standard' exists, or the substantive differences in time-to-result and action-to-reaction that are critical for an effective public health intervention.

4. The authors give the impression of having prejudged the performance of LFDs. They appear to have made up their minds that LFDs are dangerous and of no value and therefore should never be used. They argue that UK LFDs stocks should be given to other countries without a diligent assessment of the opportunity costs.

5. The authors provide a selective review of the evidence only highlighting possible harms and overlooking the proven and potential benefits. They do not acknowledge that with increasing use of the test kits real-world performance and utility increases. Their complaint that the results of testing evaluations have not been published is at variance with their quoting, albeit selectively, the results from ongoing evaluations with which their professional bodies are involved and are represented by nominated experienced members.

6. The authors imply they are the key experts and should have been consulted by UK Government. Yet the Royal Statistical Society Covid-19 Taskforce is actively represented in the evaluations of the testing pilots, alongside experienced academic public health physicians and infectious diseases experts who are actively involved in a wide range of Covid-19 responses.

7. We acknowledge that, ideally, new technologies for population-wide interventions are assessed carefully with first small scale and then large-scale studies before they are introduced. In a pandemic setting, where time is of the essence, we believe that, after successful small-scale studies for technical validation, it is necessary to conduct largescale pragmatic studies realistically nested within complex, urgent public health interventions.

8. LFD are now widely used in the UK. More than 2 million kits have produced results in front-line operations and >27,000 SARS-CoV-2 infected individuals have been identified (figures up to 6th January 2021) who would otherwise not have been asked to self-isolate so quickly, if at all. The rapid self-isolation of many of these individuals will have broken chains of transmission of the virus in ways that could not be achieved with PCR tests. To conclude, the LFT is an additional risk reduction measure not a replacement for PCR as the authors imply.

We deal with the *comments* in turn: -

"No one questions the need for evidence-based approaches to Covid19 treatments and vaccines. Why then is this principle being ignored for programmes of testing and other disease control interventions?"

We reject the view that there is no evidence base underlying the roll out of LFD. There is a mass of evidence, of which the authors are aware. Recently a study from Boston, USA evaluating the use of the Abott BinaxNow antigen test has been posted (Pollock NR et al. https://doi.org/10.1101/2021.01.09.21249499) showing similar results. They have chosen to quote selectively and ignore the rest which is lax scientific practice.

"The government is widening roll out of the Innova Lateral Flow Device (LFD), and we understand that this may soon extend to home use by members of the public.

Here we outline the serious harm that this will cause."

We not only reject this assertion of harm but also raise the potential harm to public trust, and consequent lower uptake of risk-mitigation measures, that this irresponsible, non-evidence based assertion may cause.

"The Innova lateral flow test is not fit for many of the purposes being proposed by government.

Studies have shown that it misses the SARS-Cov-2 virus in a substantial proportion of people, particularly those without symptoms [1,2].

In the Liverpool pilot, the test missed infection in 60% of people, and of greatest concern missed it in 30% of those with very high viral loads who are at highest risk of spreading the virus to others [1]."

The authors are misinterpreting the results of the Liverpool pilot interim evaluation. The report clearly demonstrates that the results are consistent with those originally presented in the PHE/Oxford Technical Report after adjustment for the different distributions of viral loads. The authors confuse 'missed infection' with infectiousness. It is well known that PCR detects non-viable RNA fragments as well as viable virus, meaning that large proportions of PCR test positive individuals will not be infectious. The use of the lateral flow test is designed to detect live virus allowing identification of individuals who are infectious to others. The ideal test for infectiousness would be negative among many of the PCR positive individuals. The authors do not appear to be addressing the fundamental and important difference between 'infectiousness' and 'recent or current infection'.

The authors are concerned that the 'test missed 30%' of those with very high viral loads. This is not consistent with the report which shows that, even in a low/falling prevalence situation, the test missed 17.6% of individuals with Ct<20 and 33% where Ct<25 (Table 2) – the people likely to have higher viral loads and to comprise most of the infectious population. The authors are also investigating the change over time in sensitivity that may be seen as procedures bed-in after initial field deployment of the equipment – with indications of improved end-to-end sensitivity (Table 3).

"An erroneous test result may lead to people taking the wrong actions and putting themselves and others at risk of infection. This may increase and not reduce disease spread, illness and death."

Clearly test results that are not interpreted in the correct manner may lead to mis-informed actions. However, there is little or no evidence that 'erroneous' test results have led to people taking wrong actions whereas there is preliminary evidence of no harm. We are unaware of any evidence of a net increased risk of disease spread and death, after accounting for the lives saved by breaking chains of transmission. The authors have not attempted to quantify the risk, which they claim may result from use of the test and provide no documented evidence of its having already occurred. The allegation is an extremely serious one which is, however, unsupported by any evidence.

"The Government is misleading the public about the performance of the Innova test. The most favourable estimates from initial government studies have been selectively reported [3]."

This is a serious allegation, but again it is not substantiated by the authors. They provide no details and therefore it is difficult to respond to.

"final results from some studies have not been reported at all [4],"

The authors are complaining that data that has been made available to them has not been published in a peer-reviewed journal. The authors have been given further information on the report for the purposes of helping them prepare a Cochrane report. The authors are, quite

reasonably, relying on the report for much of the data that they are quoting in the document but they cannot at the same time assert they have no access to data. Indeed, the problem seems to be that they have not themselves either generated or published any peer reviewed data supporting their highly inflammatory suggestions.

"And schools and parents have been misinformed with letters and guidance stating that "they [Innova tests] were shown to be as accurate in identifying a case as a PCR test" [5] and "these tests are very accurate" [6]."

As lateral flow tests were proposed to be used in large numbers on asymptomatic individuals the first concern was that the test would not be specific. Namely, that there would be many false positives. Prof Deeks in the BMJ November 2020, emphasized the possible number of false positive results as a reason for not using the test. The use of the phrase 'accurate' was designed to deal with the possibility of false positives. In this setting the test was described as accurate in identifying a case as a PCR test. It is accepted that the phrase 'very accurate' is vague and might have been confusing. Overall, the performance of the test is sufficient for it to gain regulatory (MHRA) approval.

"People being tested have not been informed of the risks and implications of a false negative result. Without this information it is inevitable that people will be falsely reassured and behave in ways that will increase disease spread."

We agree with the authors that the risk of false reassurance should be mitigated, and the Liverpool pilot includes many such risk mitigation measures with individual and population level communications. Scientific communication to the public needs to convey the message that there no absolute test to identify non-infectious individuals. Even a perfect test cannot guarantee that individuals will not become infectious in subsequent days. This is an intrinsic property of the biology of Covid-19. Even a 'perfect' test for infectiousness could rapidly become out of date if the individual is incubating the infection or is about to contract it.

We strongly refute the allegation that we are unaware of the challenges in ruling out infectiousness in the context of high transmission. We similarly refute the allegation that people who are tested negative are not warned that they might still transmit the disease in the following days. The authors did not fact-check their allegations but could have done so at any time with the national or pilot evaluation teams.

The authors assert that it is 'inevitable' that people will be falsely reassured and behave in ways that will increase disease spread. The authors do not provide any evidence of this and, indeed, seem to disregard the evidence presented in the Liverpool Report (p26-27) which showed that many people were concerned about the accuracy of the test. The report showed that most respondents behaved in a responsible manner following a negative test. The authors do not comment on these findings.

"We have already been informed of confirmed outbreaks caused because a person with symptoms has relied on a falsely negative LFD result and has attended work, thereby spreading infection to others within NHS settings [7]."

Reference 7 refers to a Personal Communication. The authors have been complaining that some of the data on LFDs have only been published in a technical report. It is therefore surprising that the authors are relying on unattributable and unsubstantiated reports which are too vague to allow comment. This falls well short of their own declared standards of evidence.

"The administration of the test is also diverting precious staff time and energy at a time when delivery of vaccinations must take priority."

We are surprised by this statement. There is no evidence whatsoever that administration of LFD is diverting resources from the vaccine programme. Indeed, within the NHS, the test is carried out by staff at home in their own time and is successfully preventing disease by the detection of asymptomatic carriers. Given that levels of COVID in health workers is the single biggest challenge for the NHS and that at home LFD testing of health workers has been enthusiastically adopted across the NHS the evidence points toward these providing headroom for the NHS to do its job. Moreover, the substantial critical mass effect of LFT administration on improving wider public health measures in Liverpool is explained in the interim evaluation report.

"At least £1 billion has been spent procuring LFDs so far, and it could be very much more, depending on how contracts are classified."

The relevance of this comment is unclear. We assume that the authors mean that LFD's are not value for money. We disagree. The UK is not alone in these as other countries are adopting LFDs in large numbers.

"Further roll out of community testing, and on-request home use, if implemented, will escalate harm especially if people with symptoms choose the convenience of an LFD in preference to attending for PCR testing."

The authors, again, provide no evidence for this assertion. The UK has established substantial capacity for PCR, prioritising these tests for hospitalised patients, care home staff and for any individuals with symptoms. However, PCR processing has a slow turn-round time, as samples need to be transported to laboratories and processed and this may hinder the timely identification of clusters of cases.

"We urgently call upon the government and its advisors to;
− Stop further rollout of rapid asymptomatic testing using the Innova LFD including its use in care homes, schools, communities and self-testing by untrained people at home.

The main reason to roll out LFD testing is to identify infectious individuals who would otherwise not be tested. To date
− Publish full documentation relating to emergency MHRA approval of the Innova LFD for self-testing (23 December), for which the DHSC was regarded as the legal manufacturer.
− Publish full reports for all studies and models of Innova testing commissioned by the DHSC.

Most of these are in the public domain already. It is unclear what extra information the authors expect to get.

− Revise DHSC information materials so that the extremely poor sensitivity of the Innova LFD for community and self-use among those without symptoms be made explicit."

The authors are again confusing the concept of sensitivity against PCR, rather than the sensitivity to detect infectiousness. As already discussed, they are choosing to use the worst case scenarios as the standard result and are disregarding the experience from Liverpool that the performance of the test improves with experience.

"Immediately review, by appropriate experts, the aims, outcomes (including unintended harms), and costs of using the Innova LFD for keyworkers, schoolchildren, University students, and Care Home visitors."

The authors imply that they are the only experts in the field. Although Prof Deeks is an expert in the statistical evaluation of diagnostic tests and has completed some Cochrane reviews on Covid-19 tests, we are surprised that he considers himself an expert in Covid-19 or public health activity. LFDs are currently being assessed by many different organizations and eminent scientists. National evaluation meetings are currently taking place three times per week involving over a hundred experts in the science underpinning LFDs and in the front-line public health contexts in which they implemented. The authors are not actively involved in the breadth and depth of activities needed to evaluate LFD uses properly.

"Instigate a national scheme to strengthen the intervention that follows a positive test result, so that cases and contacts are adequately supported to self-isolate, with provision of free hotel accommodation and income support for those in need."

We agree that inadequate support to isolate is a barrier to LFD uptake, as it is to PCR uptake. LFDs are currently identifying large numbers of SARS-CoV-2 infected individuals and the Liverpool pilot has reported the importance of support to isolate.

"*LFDs can be useful if they pick up people who are: a) symptomless,*
b) actively infectious,
c) would have spread the infection had they not been tested and
d) change their behaviour and so do not transmit because of learning the test result.

However, *in practice, only a subset of people testing positive are actively infectious and would have transmitted the virus, and only a subset change their behaviour as a result of a positive test."*

The authors imply that they do not recommend any method of identifying individuals, as infectious, because they may not be actively infectious and in any case may not transmit the virus and may not change their behaviour. We agree that not all infectious individuals will go on to transmit the virus and that not all individuals change their behaviour after a positive test. However, we consider, together with WHO and most other countries, that use of tests to identify infectious individuals is a key factor in reducing the transmission of Covid-19. The

appropriate comparator is a world with no testing in this population. The comparative impact on transmission should be made clear by anyone proffering expert opinion on this topic.

Furthermore, the authors appear to be confusing the results of PCR tests (where we agree that only a subset of people testing positive are actively infectious) with the results of LFD tests which are designed to detect actively infectious individuals. We know of no evidence showing that individuals with a positive LFD are not infectious while there is ample evidence that a positive PCR test will in many individuals not be associated with the presence of infectious particles.

"Also, a positive LFD result only leads to automatic notification to NHS Test and Trace if there is confirmatory PCR, yet many localities have adopted a pragmatic approach of acting solely on the positive LFD result [8]. This means that unless local staff perform a 'workaround' to make notification happen there is no automatic support to self isolate for those who test positive and no tracing of contacts."

Learning from the Liverpool pilot, a better system of notification and follow-up of individuals with positive LFD tests is being adopted. As expected in a pandemic, such services evolve quickly.

***"LFDs will do harm** if negative results:*
***a) lead people to decide not to get a PCR test when they have symptoms**; all screening tests lead to some people ignoring symptoms when they have a negative test result. There are already confirmed examples of this occurring with LFDs, and of outbreaks occurring as a result [7]."*

The authors provide no evidence that this occurs. We agree that there are important theoretical risks of symptomatic and pauci-symptomatic users accessing asymptomatic test facilities, and of negative test results reducing Covid-safe behaviours, which is why pilots have put communications in place to mitigate this risk and are actively monitoring behaviours. Currently, PCR testing is unavailable for many people and the availability of LFD expands access to testing. Reference 7 provides no information, and the authors appear to be relying on an anecdote to support their argument.

***"b) are used in ways that lead to increased exposure to risk of transmission**; the Government is directly endorsing testing strategies which use negative tests to enable individuals to undertake certain activities; for example, policies on visiting care homes [9], and for pupils remaining in classes despite known exposure to an infectious case [5]. Even individuals with high risk of being contagious may get a false negative result [1]. Such policies will increase not decrease spread of Covid."*

As discussed above, the authors are misquoting the results of the Liverpool study. Current studies of classrooms suggest that the use of LFDs reduces the risk of transmission as they are diagnosing likely infectious individuals who would otherwise remain undetected and in class. The authors imply that they know the results of new policies following negative tests before they are adopted. Their assertion that such policies will 'increase not decrease the spread of Covid' is an assertion which appears to be unsupported by any reasoned argument or any data. For example, the use of LFDs on asymptomatic individuals who would otherwise

not be detected has already led to the detection of >27,000 infectious individuals (figures up to 6th January 2021) who were able to self-isolate. The authors are disregarding this positive benefit. Modelling has suggested that serial testing is a safe way to manage contacts (who without LFDs would have remained undetected) and current studies are being undertaken to assess this in the field. We are surprised that the authors are only considering the harm of the tests without considering the benefits.

"c) lead to false expectations of LFD tests and the public 'voting with their feet' with resultant riskier behaviour*; Government publicity over recent months has emphasised the potential for tests in symptomless people to enable visits to vulnerable loved ones, safe travel home for Christmas, participation in sporting events, weddings etc. We are aware of examples of people without symptoms using LFDs (through community testing or obtained from NHS staff who have spare tests), as a means of seeking reassurance from a negative test before visiting others, going to parties etc. This is leading to people putting themselves and others at risk, and is increasing opportunities for transmission."*

The authors are using rumours and anecdotes to make unsubstantiated assertions. This is not an acceptable standard for scientific knowledge exchange. It is known that mis-information causes harm to the public health through undermining confidence in public health messages and reducing uptake of vaccines and non-pharmacological interventions that reduce risk of infection.

"There are additional harms of ineffective and repeat testing:
d) Harmful diversion of resources*; for any testing programme the cost of the test is a tiny fraction of the full programme delivery cost. Staff in schools, universities, care homes, and local public health teams are struggling with immense pressures. The added burden of delivering LFD testing is jeopardising delivery of education, care of residents, and the critically important vaccination programme."*

The authors appear to be trivializing complex issues. We interpret this allegation to imply that the UK is forcing institutions to adopt LFD. The use of LFDs is not compulsory. It is a further tool that local public health teams and organisations may adopt if they wish to. Further, as shown in the Liverpool pilot, localised implementation is important for optimising outcomes. Different options for delivering test kits, (self)swabbing and uploading results may fit different circumstances to ease pressures and maximise benefits. The ability to self-test at home is proving very popular with NHS hospital staff, all of whom have been offered testing kits.

"e) Direct trauma to young and vulnerable people; *repeated performance of nose and throat swabs on children and young people especially those with learning difficulties, sensory impairment, mental health problems, or a history of trauma or abuse, will be damaging both emotionally and physically. For a testing programme of uncertain value this harm is unjustified."*

This is a very serious allegation. The authors provide no evidence to support it. If such evidence exists, we urge the authors immediately to provide evidence to the relevant authorities so that immediate remedial actions can be taken to avoid future harm to children

and vulnerable adults. As with all tests, use is voluntary and should only be undertaken with appropriate assent or consent to proceed from the individual.

The authors appear to be confusing the relatively unpleasant nasopharyngeal swab technique with the gentler anterior nares approach recommended for large-scale LFD testing and used successfully in the Liverpool pilot. We are unaware that the process of voluntary testing is damaging to children and young people. We encourage different agencies to be clear and consistent in the guidance they give about appropriate swabbing techniques.

"How has the Government gone about evaluating the test?
DHSC originally commissioned evaluations done by PHE at Porton Down working with the University of Oxford. A brief preliminary report was made available at the beginning of November [4]. Two months later no full report has yet been released. The report described performance in test-and-trace settings where the test was done in people with symptoms, and with the test run by laboratory scientists, experienced research nurses or staff at a test-and-trace centre. The detection rates in these three different groups of test performers respectively were 79% (95% CI 73% to 85%), 73% (64% to 85%) and 58% (52% to 63%). This shows how experience made a difference to accuracy. DHSC press releases report on a 77% detection rate [3], combining the first two (experienced) groups and ignoring the third (test-and-trace staff)."

The summary of data confirms that much data has already been made available.

"At a select committee hearing the Secretary of State for Health appeared uninformed of the performance figures when test-and trace staff took the tests [9].
We are surprised that the authors are using a single performance of the Secretary of State at a select committee as evidence of the knowledge available to the Department of Health, and their willingness to criticise Ministers belies that their objection is as much founded on their interpretation of the science as a fundamental objection to policy decisions that excluded their involvement.

"The report also described a study in an Armed Forces setting but gave no results [4]."

The only purpose of the Armed Forces data was to give results on the incident of false positives and of kit failures. We agree that this should be clarified.

"Mass screening in people without symptoms in Liverpool resulted in 40% (29% to 52%) detected (PCR being taken as the gold standard) and 70% of those with high viral loads."

The authors use PCR as a gold standard without justification. As discussed above, PCR is a poor test of infectiousness and therefore should not be used as a gold standard. Their confusion is understandable as the authors are not experts in Covid-19.

"In students in Birmingham 3% (1% to 16%) were detected) [1,2]."

The authors quote a study in Birmingham that ran PCR tests on a 10% sample of LFD negative individuals. Taking the Ct values into account and considering inferred viral loads among this population, the effective sensitivity is consistent with that found in Liverpool. We

are surprised that the authors make no attempt to discuss the important contexts of prevalence and the purpose of testing, which is to identify and isolate infectious individuals and not to detect those who are PCR positive.

"Whether a test will do more good than harm can only be assessed in properly designed studies undertaken in the setting and for the people where it will be applied."

The authors appear to be suggesting that they are the only individuals able to conduct 'properly designed studies' and are implying that the studies on LFDs conducted in Liverpool and in many other settings are not properly conducted. The authors have not provided any criticism of the Liverpool study nor have they proposed a practical 'properly designed study'.

"DHSC are now using mathematical models to predict the performance of tests in different groups and strategies rather than getting real world evaluations of how the strategies will work [10]. Models are limited by the assumptions that they make both about test performance, and the way in which the test results impact on human behavior. A model published this week completely ignored the possibility that false negatives would lead to harm, so it is inevitable that modelling will fail to provide appropriate evidence and will mislead Government decision making [10]. It is exceptionally difficult to fully anticipate how people will behave when misled about the meaning of a test result, thus any prediction from a model is unlikely to be correct."

The authors are entitled to criticise the models that have been published. However, the authors, are, of course, using their own implicit models when they assume that false negatives would lead to harm because of the behavioural response to a negative test. As already discussed, the size of this possible harm, and particularly in relation to benefits, is not clear and the authors are simply stating that such harm should be considered. As already stated, the Liverpool study did not find much harmful behaviour following a negative test. Similar studies are being carried out elsewhere with similar reassuring results.

"What's the evidence for the accuracy of repeated tests?
Models are being used to predict how repeated testing will perform [10]. These models assume that test errors occur at random, just like an unlucky roll of a dice. Rolling a dice a second, third or fourth time will by chance almost certainly lead to better luck. However, this is not how testing behaves, as infected individuals who get a false negative test result do so for a reason, such as having lower viral levels, or difficulties in swabbing. These factors will recur with their second and subsequent swabs, without increasing their chances of a true positive rather than a false negative result. These assumptions all lead to overestimation of potential benefits of testing and underestimation of potential harms. The scientists on SAGE who are doing the modelling for the Government are undoubtedly the best in their field. However, they are experts in modelling infectious spread, not in the evaluation of diagnostic tests or mass testing. The UK has many individuals with appropriate expertise, none of whom have been involved in these evaluations and decisions."

Repeated tests reduce the errors arising from random mistakes in the use of the kit. Also, serial testing mitigates against the risk that the individual with a low viral load is in the incubation period of the illness and that the infection will become apparent over the

following days. The authors provide no evidence that individuals with a low viral load are particularly infectious.

We agree that difficulty with swabbing will affect the result of any test (PCR or LFD) as is well known. The use of swabbing the anterior nares, which is easy to access and not unpleasant, is designed to reduce this risk.

We agree that the scientists on SAGE are the best in the field. Although we understand that the authors are not members of SAGE, we do not accept that SAGE has not got access to other experts in the evaluation of diagnostic tests and mass testing.

"Why is the Government pushing the rollout of the Innova Lateral Flow Test in the face of such controversy?
Hundreds of millions of Innova Lateral Flow Testing kits were purchased before it was known how well they would perform when used in people without symptoms and when administered by less than expert hands. These tests are now sitting in warehouses around the UK. We have frequently been told 'we have to use them' or 'as long as we find some otherwise unknown cases, that will make the whole exercise worthwhile'. " The authors provide no evidence for this assertion.

"In the context of inadvertently causing potentially fatal infection in others, these arguments are dangerous. "
This is yet another serious and unsubstantiated allegation that the use of LFD will lead to more deaths rather than save lives.

"Perhaps one use for the warehoused testing kits would be to donate them to a country that does not have PCR capacity and can use the tests according to the manufacturer's instructions [11]."

These comments are facile. The statement that the tests should be used 'according to the manufacture's instructions' implies that there is no plausible use for the test outside of that intended by the manufacturer. It is not unusual for tests to be used outside the manufacturer's instructions especially if there is an understanding of the test performance in the context it is being deployed in.

There may be a helpful academic argument here, but we do not recognise it yet as this letter is full of bold allegations supported by neither observation data nor experimental work in the field. Criticising lack of data when no apparent effort has been made to look at that available is a threat to public health. These authors should know better.

A more positive contribution would be to help develop a measure of testing utility that incorporates time to appropriate action/isolation, taking background prevalence and point in the epidemic curve into consideration.