Briefing Note for journalists on harm from continued rollout of the Innova Lateral Flow test. 10 January 2021

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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? 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.

Why the Innova test if not fit for purpose

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]. 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.

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], final results from some studies have not been reported at all [4], 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]. 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 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]. The administration of the test is also diverting precious staff time and energy at a time when delivery of vaccinations must take priority. At least £1 billion has been spent procuring LFDs so far, and it could be very much more, depending on how contracts are classified 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.

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.
- 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.
- 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.
- 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.
- 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.

FURTHER BACKGROUND FOR JOURNALISTS

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. 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.

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].
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.

c) lead to false expectations of LFD tests and the public 'voting with their feet' with resultant riskier behavior; 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.

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.
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.

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). 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]. The report also described a study in an Armed Forces setting but gave no results [4]. 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. In students in Birmingham 3% (1% to 16%) were detected) [1,2].

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. 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.

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.

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'. In the context of inadvertently causing potentially fatal infection in others, these arguments are dangerous. 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].

We call on the government to implement the recommendations above…

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