

## **Carl Heneghan**

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**Subject:** concerns about the roll out of the lung cancer screening programme and the continued roll out of AF screening set out in the NHS Plan.

Dear Mr Stevens

We are writing to express our concerns about the roll out of the lung cancer screening programme and the continued roll out of AF screening set out in the NHS Plan.

Our concerns are deepened by the publication of the NAO report on the management of screening programmes last week. This report set out wide ranging concerns about the commissioning arrangements for cancer screening, particularly pertaining to uptake and IT systems. It is notable that in Ireland, in debating shortfalls in cervical screening, now intend to establish a Screening Committee similar in scope and design to the independent UK National Screening Committee. Yet we are concerned that UK National Screening Committee, ensuring patient safety and cost effectiveness, is actively being undermined by the NHS.

We illustrate our concerns with these two examples, lung cancer and AF.

### **Lung cancer**

We have significant and substantial objections to Lung Health Checks. We have set out eight concerns below.

1. **This is a screening programme.** A case by proponents is made that it is case finding and thus doesn't require NSC oversight. We have yet to see a coherent difference between "screening" and "case finding": scientifically there is simply no distinction. Lung Health Checks are unsystematic screening, and as such should be subject to a National Screening Committee recommendation. As you will know, the NSC have a position, which is that screening for lung cancer is not recommended. Undermining the UK NSC is highly risky for patient safety and cost effective decision making.
2. **There is concern that there is no benefit to all cause mortality.** NELSON concludes there IS a disease specific mortality advantage of screening vs no screening – ie screening changes the cause but not the time of death. We accept arguments about stage shift, although we are still awaiting for the final NELSON data. We are concerned that enthusiasm for screening exceeds a deliberative and independent effort to understand the benefits relative to the costs.
3. **Screening carries risk, our interpretation on the balance of risk and benefit is that there is NOT a case that the benefit outweighs the risk even in high risk populations.** The Canadians suggest that lung cancer screening means doctors use low dose CT to kill a high-risk person and disrupt 354 lives (through false positives) to benefit 3 people who will no longer die from lung cancer. This balance of benefit and risk, and, should the UK NSC approve it, would require to be explained to patients with Montgomery standard information. We are concerned that because there is no independent oversight of the lung screening already in progress, this standard along with independent audit will not be met. We consider this legally risky and ethically questionable.
4. **Screening seems unlikely to be cost effective within normal accepted thresholds.** See the NIHR analysis of a month ago. This concluded that the proposition to screen in a high-risk cohort almost certainly doesn't pass the threshold at £30k/QALY, and there is significant uncertainty as to whether screening would be cost-effective at £20k / QALY. Given the Claxton work, and the current financial climate, there is a ready case to be made we should be making decisions based

on a lower QALY threshold than £20k. Thus a proposition to screen for lung cancer is hard to square with the commitments for value for money in Chapter 6 of the Long Term Plan.

5. **The cost of implementing is likely to be substantial. It is unclear there is any transparent process for determining who bears the opportunity cost**
6. **Our understanding from GM is there is a significant workload implication** - as an example, nine new radiologists will be required in Manchester to process the follow-ups generated by screening. Is this the best use of scarce radiology capacity? What will the opportunity cost be and will symptomatic people have to wait longer as a consequence?
7. **Who ensures QA process is unclear.** If we agree it's a screening programme, then it will carry harms. It is unclear how the QA for the whole process will work. This concern is particularly acute given the NAO report.
8. **Who ensures full Montgomerie consent which ensures there is and shared decision making in this process.** The review of information for screening programmes in the UK in the late 90s emphasised the need for informed choice and shared decision making. We are concerned that this standard is not being carried forward. A recent set of articles in the Archives of Internal Medicine highlighted the parlous state of informed consent in lung cancer screening in the USA. There is no reason to think it will be any different in England

### Atrial Fibrillation

Secondly, we know that AF screening is being widely promoted and pushed heavily by AHSNs and CCGs, and . As you know these are sponsored by many of the companies whose products stand to benefit from increased detection of AF. AF screening is often framed as case finding which, it is suggested by proponents, somehow requires a lower standard of evidence - but this is an unsafe supposition.

The current policy position of the NSC and NICE is that screening for AF is not recommended. The proposition to screen for AF fails NSC criteria on some criteria. We have seven concerns about NHSE pushing this:

1. **The current trials showing a benefit from treating AF are based on patients who were either symptomatic or who were found incidentally when being investigated or treated for another reason. This is a different population to that which is currently being screened. Because anticoagulation can cause harm, including death, we should be reasonably certain that treating a new population will result in an overall benefit. We do not currently have that information. Instead efforts should be made to enter patients into the large RCT on AF screening, n = 120,000, led by Prof Mant of Cambridge University which has been funded by the NIHR to determine cost-effectiveness.**
2. **The current management of AF is not optimised.** There may be bigger benefits by better managing the already identified population with AF. **Current screening has a relatively high false positive and false negative rate, leading to investigations which cost time and effort and incur opportunity costs.** A recent article [ref] concluded that screening low-risk adults would require 10,000 people screened to prevent one stroke, but 800 of those people would get a false +ve result. **Overall the benefit/risk ratio is not understood in the screened population. The 'healthy attender effect' means that patients at low risk are liable to be screened and prioritised against patients who do not attend, leading to widened health inequalities.**
3. **Cost-effectiveness of the screening programme as a whole is not proven.** The proposition will likely not *be* cost effective if using DOACs.
4. **This is further complicated by the increasingly widespread push to use new technology to screen,** often phone or watch based. AliveCor is one of these, as is the Apple watch. We know this is being pushed heavily by AHSNs and manufacturers. We are aware of a study that was presented to ESC Congress that found against the use of these types of technology in a screening

context. Apple watches have an over 80% false positive risk for AF. The resources to deal with this in the NHS have not been identified.

5. **These new tools lead to the screening on a mass scale :** Concerns are also being expressed that the easy availability of a tool will make screening easier- if an easy screening tool is available, individuals will be able to screen themselves on multiple occasions leading to more false positives - and in the healthiest and weathiest population who use more resources leaving less for people at higher risk of earlier death.
6. The impact on GP workload has not been established, but it will likely be significant
7. There is not QA of AF screening

Given that both of these examples are screening, there are many others, we have set out some recommendations for your consideration:

#### **Recommendations**

1 We strongly recommend that the NHS adopts the UK NSC position on screening. Thus the prominence given to these propositions in the Long Term Plan can only serve to harm the international credibility of the National Screening Committee.

2 We would encourage NHSE to make a clear policy statement setting out how to minimise the harm from rolling out screening without a positive NSC recommendation, in the absence of this local areas will get on with screening, and absence of a statement will be inferred as support given what is in the Long Term Plan.

3. Specifically, on AF, we would encourage NSHE to consider it's position re-screening esp with AliveCor / Watches and other new diagnostic technologies and make clear recommendations. We would also encourage some serious consideration given to how to increase enrolment to the NIHR funded trial on AF screening .

4. On lung cancer, we would encourage NHSE to establish how it will set up a QA programme around lung health checks and to state thresholds of abandoning the programme should the UK NSC continue to find against it.

5. Avoiding the scrutiny of the NSC by calling it a "health check" or "case finding" is bad for cost-effectiveness, and bad for equity and for the NHS as a whole.

#### **Conclusions**

Directors of Public Health have an assurance role to their local populations for the safe delivery of screening and GPs often spend considerable time and resource picking up the consequences of unevidenced screening. It would seem that there is a significant lack of focus on both performance management and Quality Assurance in the management of screening, both of which are core commissioning issues for which NHSE is responsible under Section 7a of the 2012 Act.

We remain concerned that this push to the screen is not evidence-based, is not informed by quality research evidence and risks wasting resources and harming patients. Most worryingly, it dispenses with the careful deliberations of the UK National Screening Committee, which was set up to try and avoid as much harmful screening as possible. By deliberately over riding this safety mechanism, the NHS is capable of creating avoidable and direct harm to patients. Further, the UK NSC has to ensure equity. If this screening works, then all should have access who may benefit. If it does not work, all should be protected from it. The current inequality is untenable.

It is worth remembering we have the UK NSC for a reason. Given our concerns set out here, it seems there is little regard to NSC positions as screening "creeps" into new areas. In our experience, few "understand" screening, and there is a significant misunderstanding about the differences between screening and case finding. Often, in our experience, people misconstrue screening, significantly underplay (or don't understand) the harms and overplay the benefits.

We find it disturbing there is a push for screening outside NSC recommendations, and seemingly against NSC advice.

Obviously we would be more than happy to discuss with your team(s)

Mr Greg Fell, Director of Public Health, Sheffield

Dr Margaret McCartney, GP and Honorary Fellow Centre for Evidence Based Medicine Oxford

Prof Carl Heneghan, Dept of Primary Care Health Sciences, Oxford University.