



Public Health  
England

Protecting and improving the nation's health

## NHS Health Check content review form

Please read the guidance notes before completing this form. Please only complete the contact details and section 1 and return the form to the ESCAP secretariat at [nhshealthchecks.mailbox@phe.gov.uk](mailto:nhshealthchecks.mailbox@phe.gov.uk) by **31 March 2017**.

### Section 1

#### 1. Please tick the categories that apply to your proposal.

- ☐ It involves amending the eligible population.
- ☒ It involves amending an existing component of the risk assessment.
- ☐ It involves introducing a new component to the risk assessment.

#### 2. Please provide a short summary describing your proposed change [max 200 words]

At present the guidance on liver function testing in people who are started on statins is inconsistent with the evidence. For primary prevention using atorvastatin 20mg the SPC simply indicate that liver function should be assessed but how (ALT or other) and how frequently is unclear.

NICE guidance provides no evidence whatsoever to support the contention that ALT should be undertaken 3 times – at baseline, after three months and at 12 months. The American FDA and the lipid review panel have now twice reviewed all the evidence on this and conclude that statins do not cause liver disease (and may in fact be beneficial to those with NAFLD). They recommend a single ALT before starting a statin and not repeating this unless clinically indicated. The NICE quality standards say before starting and after 3 months but do not specify at 12 months or annually.

Clarification as to the evidence for ALT testing at all, and the evidence for repeat testing needs to be provided. There is both a major cost issue (LFTs are seven different analytes and GPs can often not order a single LFT) secondly 'abnormal' test results are frequent with anxiety and potential harm to patients from unnecessary investigation which will undoubtedly occur due to the scale of this testing. The bill from all this is costing more than the stains that are used!!

[Please be sure to clearly state what your change or addition is e.g. to introduce a lung function test]

To reduce liver function testing from primary prevention with atorvastatin 20mg to a single ALT before commencing a statin.

**3. Please state which strategic health priority in the NHS outcome framework or the public health outcome framework the proposed change supports**

[max 200 words]

I have explained why this is important.

[Please identify up to three priorities]

1. Patient benefit from reduced testing and false positives
2. Cost effectiveness of testing
3. Absolute cost of unnecessary testing to the NHS

**4. Please identify which of the programmes objectives the proposed change supports [please tick]**

- ☐ To promote and improve the early identification and management of the individual behavioural and physiological risk factors for vascular disease and the other conditions associated with those risk factors.
- ☒ To support individuals to effectively manage and reduce behavioural risks and associated conditions through information, behavioural and evidence based clinical interventions.
- ☐ To help reduce inequalities in the distribution and burden of behavioural risks, related conditions and multiple morbidities.
- ☐ To promote and support appropriate operational research and evaluation to optimise programme delivery and impact, nationally and locally.

**5. How will the proposed change support the(se) objective(s)?**

I have explained this.

**6. What is the evidence for the clinical effectiveness of the proposed change?**

“Reviewed data indicate or support the recommendation from US FDA that “all currently marketed statins appear to be associated with a very low risk of serious liver injury.” Asymptomatic and usually transient elevation of aminotransferases often observed affect the adequate use of these agents among those indicated.

Unprecedented fears regarding the hepatic adverse effects of statins among prescribers and patients can deny patients of the significant benefits of these agents. Alterations in liver enzymes often result in discontinuation/interruption of the statin therapy. Clinicians should not withhold statin therapy for patients whose transaminase elevations have no clinical relevance or are attributable to known stable chronic conditions. Evaluating other causes for alteration in LFTs should be made before establishing a causal relationship with a statin agent. Cardiovascular benefits of statins generally outweigh noncardiovascular harms including the hepatic adverse effects. Routine periodic monitoring of LFTs does not appear to detect or prevent serious liver injury in association with statins and hence may not be indicated.”

Jose J. **Statins and its hepatic effects: Newer data, implications, and changing recommendations**  
*J Pharm Bioallied Sci.* 2016 Jan-Mar; 8(1): 23–28.  
 doi: [10.4103/0975-7406.171699](https://doi.org/10.4103/0975-7406.171699)

I have referred to the extensive work of the National Lipid Association Task Force and FDA in the USA on this topic. In contrast, there is an almost complete lack of evidence for the NICE recommendations or NHS Check advice on ALT testing for primary prevention.

## 7. What is the evidence of cost effectiveness of the proposed change?

See above

McKenney JM, Davidson MH, Jacobson TA, Guyton JR. National Lipid Association Statin Safety Assessment Task Force. Final conclusions and recommendations of the National Lipid Association Statin Safety Assessment Task Force. *Am J Cardiol.* 2006;97:89C–94C

Jacobsen et al. NLA Task Force on Statin Safety - 2014 update. *Journal of Clinical Lipidology* (2014) 8, S1–S4

<https://www.fda.gov/drugs/drugsafety/ucm293101.htm>

There is no evidence of cost-effectiveness to support the current practice of universal testing. The FDA recommend ....

“The labels now recommend that liver enzyme tests should be performed before starting statin therapy and as clinically indicated thereafter. FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing serious liver injury.”

## 8. Please provide an outline of how this would change current practice

i.e. what would frontline professionals delivering the NHS Health Check need to do that isn't already a part of the programme?

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 ESCAP secretariat  
 Email: [nhshealthcheck.mailbox@phe.gov.uk](mailto:nhshealthcheck.mailbox@phe.gov.uk)

<b>9. If you are proposing a new component to the programme, please describe the effective treatment and management systems that are exist and are available.</b>
<b>10. Please state whether you feel the change will have a negative, neutral or positive impact on health inequalities and on the nine protected characteristic groups and why.</b> [please tick, <i>max 200 words</i> ]
<input type="checkbox"/> Negative <input type="checkbox"/> Neutral <input checked="" type="checkbox"/> Positive
<p>[Why...]</p> <p>This will reduce unnecessary testing in all adults in whom treatment is being actively considered.</p>
<b>11. Please name a local authority that has already adopted this proposed change to their delivery of the NHS Health Check programme.</b>
<p>Tower Hamlets has adopted this policy of restricted testing as recommended by the FDA and endorsed by prof Graham Foster hepatologist.</p>
<b>12. Please list any relevant references</b>

**For completion by the ESCAP secretariat**

<b>13. Proposal to be shared with ESCAP</b>
Yes.
<b>14. ESCAP feedback</b>
<p>Members agreed that recommending a single liver function test (ALT) before starting a statin and not repeating this unless clinically indicated went beyond the role of the NHS Health Check programme. However, the CVD prevention team will explore how information in the best practice guidance can be strengthened to reflect current NICE recommendations.</p>

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