

Reducing liver function tests for statin monitoring. An observational comparison in two East London Clinical Commissioning Groups (CCGs).

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Background

Statin monitoring is the single largest reason for liver function testing (LFT) in people without known liver disease, usually ordered as an array of up to seven different tests. Reduced testing using a single alanine transaminase test (ALT), would benefit patients at reduced cost.

Aim

To evaluate changes following an intervention to reduce the number and type of liver function tests ordered by general practitioners in people without liver disease.

Design & Setting

Cross-sectional time series in patients 30 years and over, comparing liver function testing by general practitioners in two east London Clinical Commissioning Groups (95 general practices with 650,000 patients).

Methods

The intervention, available in only one CCG, consisted of development and dissemination of local stakeholder guidance on liver function testing for people prescribed statins and from 1 April 2015, access to a single ALT rather than full LFT array. Data were extracted monthly for one year before and one year after intervention. For one quarter evidence of pre-existing liver disease was assessed.

Results

Of the total population, 18.3% were on statins and they accounted for 45.5% of total LFTs. In the population without liver disease, liver function tests were 3.6 times higher for those on statins compared to those not on statins.

Following intervention there was a significant reduction in the full LFT array per 1000 people on statins, from 70.3 (95% CI 67.1 to 73.6) in the pre-intervention year, to 58.1 (95% CI 55.2 to 61.1) in the post-intervention year ($p < 0.001$). The rate in the final quarter to March 2016 was 53.2 represented a reduction of 24.3% on the average pre-intervention rate. Although ALT use increased in people on statins in the intervention CCG, there was a reduction of 16.5% in total liver function tests (both full LFT and ALT).

Conclusion

Statins are the single largest reason for liver function testing. Guidance on testing combined with availability of a single ALT test, decreased full LFT array testing in people on statins by 24% and total

liver function testing by 16.5%. This reduction represented a substantial cost saving and improved patient benefit.

Key words

Liver function test. Primary care. Inappropriate testing. Quality improvement. Diagnostic testing. Statins.

How this fits in

- Statins do not cause hepatotoxicity and current liver function monitoring is often unnecessary and costly.
- Where testing is required a single ALT measurement is often sufficient (repeated once if on a high intensity statin). A single ALT test rather than the traditional full array of up to seven different liver function tests is sufficient for routine statin testing.
- Local guidance on testing and availability of a single ALT test, reduced ordering of full array LFTs by 24% in people on statins.

Background

Historically there have been concerns about possible hepatotoxicity of statins (HMG-CoA reductase inhibitors).¹ However, more than thirty years use has confirmed that statins do not cause liver disease.² Statins cause a mild and usually transient elevation of liver transaminases: typically less than three times the upper limit of normal with around 2% above that level.³⁻⁶ Statins are also likely to be beneficial in people with non-alcoholic fatty liver disease in whom cardiovascular disease is the commonest cause of death and statins are associated with reduced primary liver cancer.^{7,8} A UK health technology assessment confirmed ALT as one of the two most useful analytes for routine identification of liver disease.⁹

In 2012 the US Food and Drugs Administration changed product requirements for statins to recommend a single liver function test prior to starting statins and thereafter only if clinically indicated.^{10,11} Despite this reassurance, concern about raised transaminases has continued to act as one of the barriers to statin prescribing in the USA and a source of unnecessary liver function testing at high cost and potential patient harm from over-testing.^{2,12,13}

There are two issues with testing: one is the frequency of liver function tests for people on statins and the other is whether a full array of liver functions tests (LFTs) are routinely required. Frequency of monitoring was addressed in 2006 in the USA National Lipid Association's Statin Safety Task Force which recommended reduced liver function monitoring after starting a statin. A 2014 update by this Task Force confirmed that mild to modest elevations in liver enzymes were safe and did not cause liver disease.¹¹

In the UK the summary product characteristics (SPCs) for simvastatin 40mg, recommend testing before starting treatment and "... thereafter when clinically indicated". For simvastatin 80mg testing at 3 months and periodically for the first year was advised.¹⁴ For atorvastatin, the SPC simply advises testing before starting and "periodically thereafter".¹⁵ In 2015, NICE quality standards advised the measurement of ALT before starting a statin, with a repeat ALT after 3 months treatment only for high intensity statins (atorvastatin 20mg, 40mg and 80mg and simvastatin 80mg and rosuvastatin 10mg or more) and not again unless clinically indicated.¹⁶

The second issue is the widespread use of a full array of up to seven different tests when clinicians request 'LFTs'. It is usually impossible to choose a single liver transaminase test on the electronic laboratory request forms which are currently used. Until recently, in two neighbouring CCGs in east London, Newham and Tower Hamlets served by the same hospital provider, the full array of up to seven different analytes was the only option. In 2014 a local consensus panel including hepatologists, general practitioners (GPs), prescribing advisors and laboratory staff, developed guidance for Tower

Hamlets CCG to promote the use of a single ALT test as sufficient to monitor statins, with a recommendation for a single ALT before starting but not again unless clinically indicated.^{17 18} The hospital laboratory provider enabled the ALT test to be ordered individually for these GPs in March 2015 and the guidance was disseminated to all GPs in Tower Hamlets in April 2015. Neither the guidance or single ALT option was available in Newham. Tower Hamlets was the designated 'intervention' CCG and Newham the 'control' CCG. The guidance was amended in October 2015 to include a single repeat test for people on high intensity statins to accord with the new NICE standards guidance.

The aim of this study was to estimate the extent to which liver function testing was associated with statin use rather than known liver disease and to compare changes in the rate and type of liver function tests in people taking statins in the intervention and control CCGs.

Methods

The study conformed to the STROBE and RECORD guidance on reporting observational studies.^{19 20} Data were taken from general practitioner electronic health records in 95 general practices serving a registered population of 650,000 patients in the inner east London CCGs of Tower Hamlets and Newham. All contributing practices used the same web-enabled record system (Egton Medical Information Services, EMIS) with agreed data entry templates ensuring consistent data entry and coding. All requests for these liver function tests were made by GPs and all results were obtained electronically. We did not include liver function tests ordered by hospital clinicians. All long-term statin prescriptions were electronically prescribed by GPs. Anonymised data were for the preceding month were extracted beginning 1st April 2014, with repeated extractions monthly until 1st April 2016, 24 months in total.

Anonymised data were obtained for all patients aged 30 or over, currently registered at the start of each month. Variables included statin prescription within 6 months prior to the search date, practice and CCG locality. A value and date were extracted for the ALT test. We assumed that where the dates for ALT and LFT were equal, the value for ALT was recorded as part of a full LFT array, rather than as a single analyte. A serum bilirubin test was used as a proxy indicator for LFT which designates a full array of seven different tests. Serum bilirubin values below 0.01 were excluded. For the last quarter prior to the intervention, ending March 2015, presence or absence of liver disease was collected as latest ever code of liver disease recorded. Counts of tests for both CCGs were combined for this quarter to investigate presence or absence of liver disease by statin prescription.

The intervention in Tower Hamlets CCG in March 2015, consisted of enabling ordering of a single ALT on electronic systems and dissemination of locally developed guidance on liver function testing to all GPs.¹⁸

The intervention aimed to achieve a reduction in the primary outcome, the rate of full array liver function tests in people on statins in the intervention CCG compared to the control CCG. Reduction in total liver function testing (both LFT and ALT) was a secondary outcome of interest.

Regression analysis was used to assess differences in monthly trend for LFT and ALT per 1000 for the intervention CCG before and after the intervention. Differences in average testing in each CCG before and after the intervention was assessed. All analyses were conducted using Stata version 12.1. The p-values were two sided with statistical significance set at 0.05.

Results

Table 1 and Figure 1 show the number of LFTs and rate/1000 by statin and liver disease status for Newham and Tower Hamlets combined, for the three months ending March 2015. Liver disease was recorded in 2% (8,961/353,001) of the population and LFTs in these people accounted for 5.1% of all LFTs. In those with liver disease 36.9% (3,304/8,961) were on statins and in those without liver disease 17.1% (58,981/344,040) were on statins.

18.3% of the total population were on statins and they accounted for 45.5% of total LFTs. Patients on statins were 3.6 times more likely have LFTs than those not on statins. Of all patients on statins 25.4% (15,793/62,285) had LFTs recorded in the quarter compared to 7.1% (20,747/290,716) not on statins.

Table 2 shows the numbers and rates/1000 population of the full LFT array and single ALT test for people on statins by CCG by month and Figure 2 illustrates this graphically.

In Tower Hamlets LFTs for people on statins decreased significantly from an average rate per 1000 of 70.3 (95% CI 67.1 to 73.6) in the pre-intervention year, to an average of 58.1 (95% CI 55.2 to 61.1) in the post-intervention year ($p < 0.001$). The rate per 1000 in the final quarter to March 2016 was 53.2 which represents a reduction of 24.3% on the average pre-intervention rate.

Figure 3 shows LFT/1000 by month for people on statins in Tower Hamlets pre and post intervention and the fitted regression lines. Before the intervention there was a monthly increase of 0.76% in LFT/1000. After the intervention the rate of LFTs decreased by 0.74% every month. The two slopes differed significantly ($P = 0.016$, 95% Confidence Interval 0.31 to -2.68) and the test for difference

between the slope intercepts confirmed a significant reduction in LFT/1000 post-intervention (95% confidence interval -4.88 to -21.32, $P=0.003$).

In Newham, there was no significant decrease in LFTs in people on statins from an average of 96.3/1000 (95% CI 93.0 to 99.5) to 92.9/1000 (95% CI 89.8 to 96.1) post-intervention ($P=0.12$).

In Tower Hamlets the rate of total liver function testing (LFT+ALT) per 1000 reduced from an annual average pre-intervention of 78.2 (24769/316678) to 65.3 (18436/282377) post intervention, a reduction of 16.5% (12.9/78.21) ($P<0.001$)

In the study CCGs a full LFT was priced at £45.50 and a single ALT at £6.50. In Tower Hamlets there were 3300 fewer full LFTs in the post-intervention than the pre-intervention year which represents a saving on the cost of testing alone of £150,150, less 3033 single ALT tests costing £19,714 which represents a decreased cost of £130,189. In Newham CCG there was an increase of 185 in full LFTs and 114 single ALT at a total increased cost of £9158.

Discussion

This study is the first of its kind to evaluate the impact of statin use on liver function testing in routine UK practice. We describe the changes that occurred in one CCG when new guidance on liver function testing and a single ALT test were made accessible to general practitioners. Although people on statins represented 18.1% of the total population, they accounted for almost half, 45.5%, of total liver function tests undertaken.

By the end of the post-intervention year there was a 24.3% reduction in the full LFT array in people on statins in comparison to the year preceding the intervention. There was no significant decrease in Newham, the control CCG. There was also a significant reduction of 16.5% in total liver function tests (both LFT and ALT) in people on statins in Tower Hamlets.

Comparison with previous literature Liver function testing for statin use is recognised as a substantial contributor to treatment costs in the UK.²¹ In Finland, an analysis of cost-effectiveness of statins for primary prevention gave monitoring costs for patients taking statins for primary prevention as 147.90 Euros [£108.59] per annum, based on one additional doctor consultation, nurse consultation and blood test per year.²² Lilford et al. have reviewed liver function testing in the wider context of liver disease and also highlighted the cost implications of a reduced analyte panel.^{9 23}

Strengths and limitations

The data was collected from 95 practices across the two CCGs and electronic recording of both prescribing and investigations ensured almost complete recording of data. Our results are an accurate

reflection of changes in liver function testing by GPs in an entire local area, not just selected practices. However, we did not include liver function testing undertaken by hospital clinicians and our results may underestimate the potential gains from adopting a single ALT for routine statin monitoring. The CCGs studied are not representative of the UK as they serve populations who are exceptionally socially disadvantaged and ethnically diverse with high levels of cardiovascular disease, diabetes and high use of statins.²⁴ However, the rate of liver function testing by general practitioner is unlikely to differ systematically to that in other areas in the UK.

We were not able to directly ascribe all liver function testing in people on statins to the use of statins as testing occurs for other reasons including repeat testing due to abnormal test results. However, the 3.6-fold increase in testing in people on statins without liver disease represents substantial additional testing associated with statin use.

Implications for practice

The price charged by different hospital trusts for laboratory testing varies substantially. The price of the full LFT analyte panel was £45.50 in Tower Hamlets and Newham CCGs. In Tower Hamlets approximately 20,000 LFTs were performed by general practitioners each year for statin monitoring at a cost per annum of £910,000. The intervention reduced the cost of LFTs by £130,89 and in the control CCG it increased by £9158. Additional savings are likely as practices make more use of the ALT-only option.

It is beyond the scope of this paper to formally analyse the national costs of testing. However, the magnitude of these costs can be estimated, assuming a cost per full LFT array of £10, with 20,000 tests in people on statins per CCG in each of the 209 CCGs in England costing £42 million per annum; a reduction of 20% in testing would save £8.4 million per year, offset by increases in ALT testing. These costs take no account of the costs of clinical consultation time associated with testing or phlebotomy. Reductions in cost would be sensitive to pricing of LFTs.

Reducing the total number of full liver function tests carried out in patients on statins is likely to yield both clinical benefits and resource savings. For patients, fewer blood tests will result in fewer false positive results, unnecessary testing and patient anxiety. Reducing the total number of liver function tests ordered, and increasing the proportion that are ALT-only, decreases the cost of testing through reduced laboratory costs and reduced use of phlebotomist and clinical staff time.^{13 25} Almost 20 years ago, simple changes in test ordering were shown to have a dramatic impact on use.²⁶ Enhanced feedback (publication of test requests per practice) and reminder messages may further improve the results. These each achieved a 10% reduction in laboratory test ordering in a study in of 85 GP practices in North-East Scotland.²⁷ There is much to suggest substantial overuse of a range of other common laboratory tests by both GPs and hospital clinicians than might be simply ameliorable with some systematic support.²⁸

Conclusion

Availability of an option to order a single ALT combined with guidance on testing in people on statins reduced full array LFT testing in the post-intervention year by 24% in people on statins. There was also a reduction of 16.5% in all liver function tests, both LFT and ALT, in people on statins in the intervention CCG. There was no significant change in testing in the control CCG.

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Ethics approval

All data was anonymised and managed according to the UK NHS information governance requirements. Ethical approval was not required for the use of anonymised data in this observational study.

Competing interests

None

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John Robson designed the study, Susanna Solaiman contributed to the local consensus statement and Kate Homer extracted and analysed the data. Saima Zubeda Khan, Abigail Davies, David McCoy and Sally Hull and all other authors contributed to the manuscript. Prof Graham Foster contributed to the original guidance. The general practitioners and their staff were responsible for entering the data on study subjects and Keith Prescott manager and the staff of the Clinical Effectiveness Group supported this process by providing standard data entry templates and support for web-based data extraction. The entire enterprise is contingent on local general practitioners who are able and willing to share their anonymised data for research and development purposes and the local laboratory staff and hospital who were willing to change their test ordering procedures.

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TABLES AND FIGURES

Table 1. Number of LFTs and rate per 1000 population by statin and liver disease status.

Both CCGs quarter ending March 2015

| | Statin | Population | LFT | LFT/1000 |
|------------------|--------|----------------|---------------|--------------|
| Liver Disease | No | 5,657 | 882 | 155.9 |
| | Yes | 3,304 | 965 | 292.1 |
| Total | | 8,961 | 1,847 | 206.1 |
| No Liver Disease | No | 285,059 | 19,865 | 69.7 |
| | Yes | 58,981 | 14,828 | 251.4 |
| Total | | 344,040 | 34,693 | 100.8 |

Table 2. Number and rate per 1000 population by month. LFT and single ALT for people on statins; pre and post intervention by CCG.

| | Tower Hamlets | | | | | Newham | | | | |
|--------------------------|---------------|---------------|-----------|--------------|-----------|------------|---------------|-----------|------------|-----------|
| | Population | LFT | LFT /1000 | ALT alone | ALT /1000 | Population | LFT | LFT /1000 | ALT alone | ALT /1000 |
| Pre-intervention | | | | | | | | | | |
| Apr 14 | 25,588 | 1,600 | 62.53 | 5 | 0.20 | 34,529 | 3,029 | 87.72 | 8 | 0.23 |
| May 14 | 25,602 | 1,874 | 73.20 | 2 | 0.08 | 34,524 | 3,573 | 103.49 | 11 | 0.32 |
| Jun 14 | 25,645 | 1,934 | 75.41 | 4 | 0.16 | 34,602 | 3,664 | 105.89 | 14 | 0.40 |
| Jul 14 | 25,632 | 1,636 | 63.83 | 1 | 0.04 | 34,649 | 3,006 | 86.76 | 12 | 0.35 |
| Aug 14 | 25,623 | 1,671 | 65.21 | 2 | 0.08 | 34,717 | 3,268 | 94.13 | 16 | 0.46 |
| Sep 14 | 25,604 | 1,849 | 72.22 | 3 | 0.12 | 34,806 | 3,827 | 109.95 | 23 | 0.66 |
| Oct 14 | 25,628 | 1,827 | 71.29 | 1 | 0.04 | 34,835 | 3,798 | 109.03 | 16 | 0.46 |
| Nov 14 | 25,686 | 1,699 | 66.14 | 8 | 0.31 | 35,019 | 3,220 | 91.95 | 13 | 0.37 |
| Dec 14 | 25,727 | 1,617 | 62.85 | 3 | 0.12 | 35,316 | 2,949 | 83.50 | 13 | 0.37 |
| Jan 15 | 25,768 | 1,945 | 75.48 | 6 | 0.23 | 35,525 | 3,502 | 98.58 | 18 | 0.51 |
| Feb 15 | 25,874 | 1,876 | 72.51 | 0 | 0.00 | 35,795 | 3,180 | 88.84 | 7 | 0.20 |
| Mar 15 | 26,102 | 2,169 | 83.10 | 4 | 0.15 | 36,115 | 3,453 | 95.61 | 14 | 0.39 |
| Total | | 21,697 | | 39 | | | 40,469 | | 165 | |
| Post-intervention | | | | | | | | | | |
| Apr 15 | 26,082 | 1,688 | 64.72 | 88 | 3.37 | 36,008 | 3,393 | 94.23 | 12 | 0.33 |
| May 15 | 26,105 | 1,528 | 58.53 | 174 | 6.67 | 36,021 | 3,407 | 94.58 | 16 | 0.44 |
| Jun 15 | 26,191 | 1,690 | 64.53 | 258 | 9.85 | 36,015 | 3,664 | 101.74 | 23 | 0.64 |
| Jul 15 | 26,241 | 1,524 | 58.08 | 209 | 7.96 | 36,212 | 3,365 | 92.92 | 17 | 0.47 |
| Aug 15 | 26,279 | 1,462 | 55.63 | 216 | 8.22 | 36,268 | 3,082 | 84.98 | 9 | 0.25 |
| Sep 15 | 26,629 | 1,529 | 57.42 | 315 | 11.83 | 36,280 | 3,601 | 99.26 | 24 | 0.66 |
| Oct 15 | 26,330 | 1,623 | 61.64 | 282 | 10.71 | 36,403 | 3,855 | 105.90 | 21 | 0.58 |
| Nov 15 | 26,442 | 1,532 | 57.94 | 283 | 10.70 | 36,568 | 3,294 | 90.08 | 16 | 0.44 |
| Dec 15 | 26,473 | 1,340 | 50.62 | 271 | 10.24 | 36,730 | 2,997 | 81.60 | 30 | 0.82 |
| Jan 16 | 26,528 | 1,516 | 57.15 | 310 | 11.69 | 36,792 | 3,376 | 91.76 | 34 | 0.92 |
| Feb 16 | 26,641 | 1,543 | 57.92 | 362 | 13.59 | 37,005 | 3,250 | 87.83 | 48 | 1.30 |
| Mar 16 | 26,737 | 1,422 | 53.18 | 304 | 11.37 | 37,204 | 3,370 | 90.58 | 29 | 0.78 |
| Total | | 18,397 | | 3,072 | | | 40,654 | | 279 | |

FIGURES

Figure 1. LFT/1000 by liver disease and statin status. Combined CCGs, quarter ending March 2015

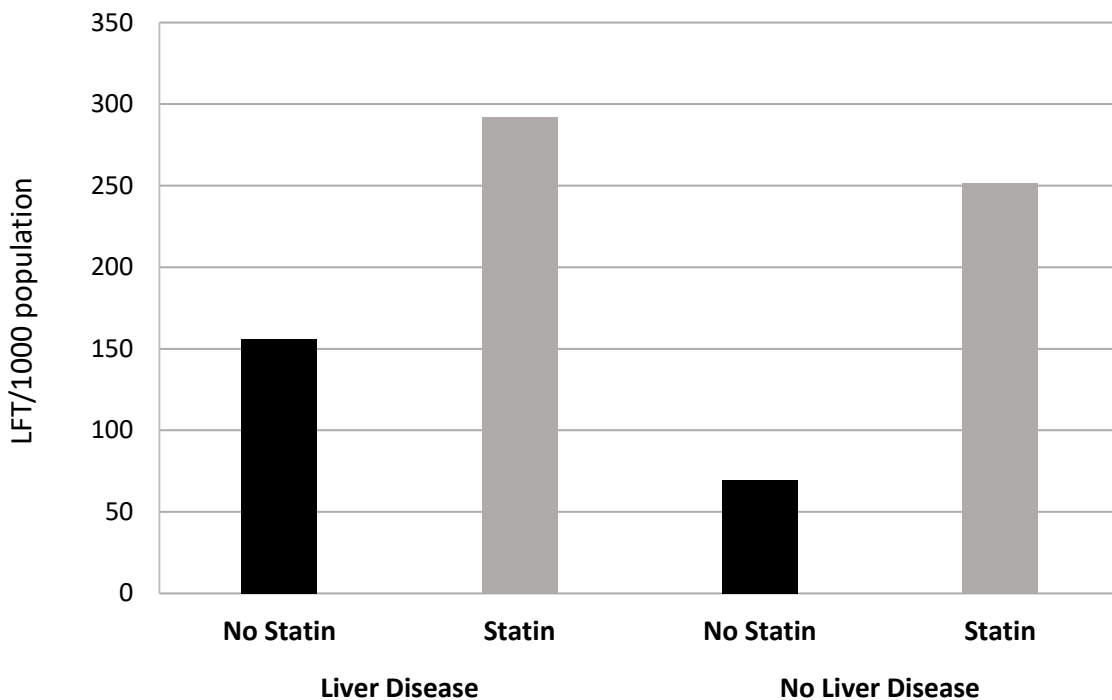


Figure 2: LFT/1000 and ALT/1000 by month for people on statins in Tower Hamlets and Newham

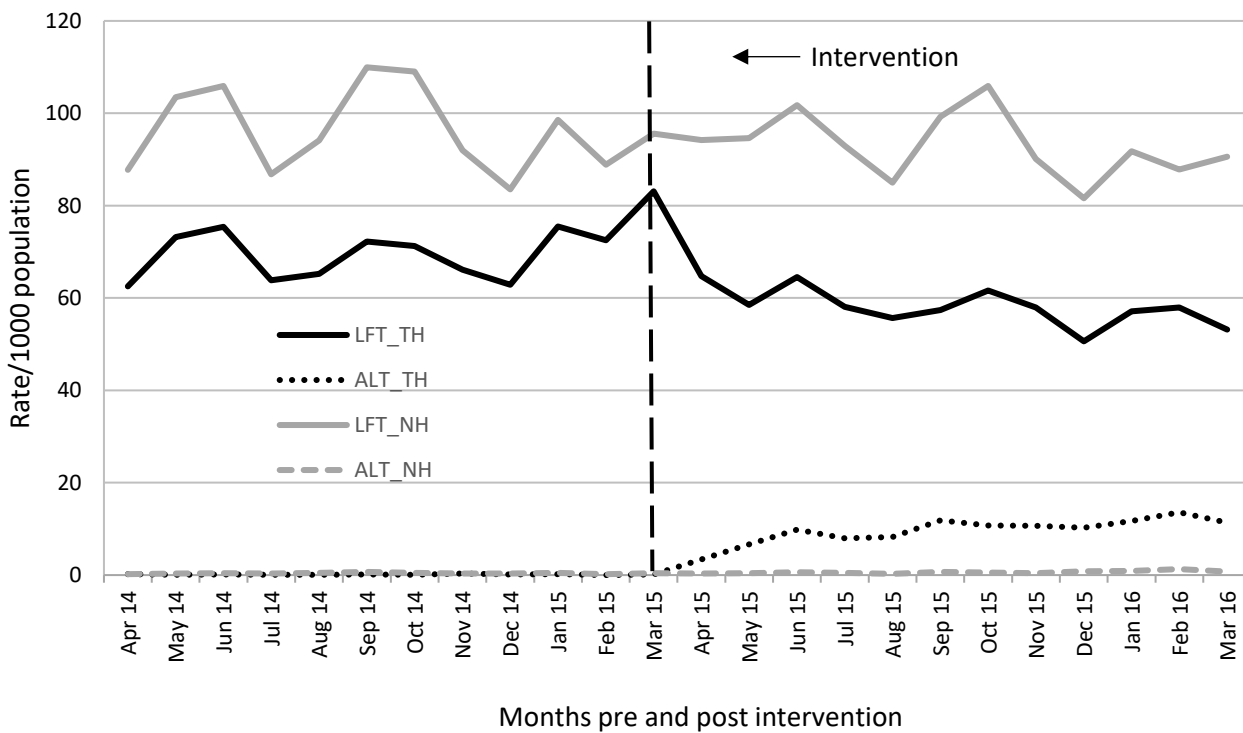


Figure 3. Fitted values for liver function testing by month in Tower Hamlets

LFT/1000 for patients on statins pre and post intervention

