**Business Case**

**Administration:**

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| Project Name: | **Diagnosis and Management of Familial Hypercholesterolaemia – a Nurse-led Service in Leicester, Leicestershire and Rutland STP** |
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| Executive Lead: | **Tbc** |
| Clinical Lead: | **Tbc** |
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| Project lead/Operational Lead: | **Tbc** |

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| 1. Executive Summary |
| *Brief summary to include:*   * *Proposal* * *Recommended option* * *Benefits* * *Total costs* * *Savings (recurrent/non-recurrent)* |
| Familial Hypercholesterolaemia (FH) is a genetic condition where people have a high level of cholesterol in their blood that is caused by an inherited genetic defect and not by lifestyle. If undetected, people are at significantly increased risk of premature cardiovascular events and early mortality.  FH leads to a greater than 50% risk of coronary heart disease in men by the age of 50 years and 30% in women by the age of 60 years. However, early treatment with statins reduces the CHD risk and therefore reduces the financial burden of cardiovascular events on health and social care as well as reducing premature mortality.  **FH Services across the East Midlands do not currently meet:**   * **NICE Guideline CG71** * **NICE Quality Standards (QS41)** * **Department of Health - Best Practice Guidance CVD Outcomes Strategy (DH 2013)**   Over 12 months (between December 2017 and November 2018) across the LLR STP area there were **702** premature cardio vascular events recorded in males under the age of 55 and females under the age of 65. Many of these patients will have undiagnosed FH and therefore, many of these could be avoided by being diagnosed and treated appropriately.  FH in the UK population is estimated by Public Health England (PHE) and NHS England (NHSE) to be 1 in 250 and this assumption has been used in the business case. This means there are **4,461** people affected by FH in the LLR STP region. The NHS Long Term Plan[[1]](#footnote-1) estimates that only 7% of people are diagnosed with FH. In the East Midlands region it is suspected that only about 5% of these people are diagnosed which leaves **4,238** undiagnosed in LLR.  The NHS Long Term Plan sets a target to diagnose 25% of FH cases through genetic testing by 2023 which, for LLR is **1,115**. This means that LLR need to genetically diagnose an additional **892** people to meet the 25% target. This will require the development and implementation of an FH assessment and genetic testing programme across the LLR STP area. A nurse-led genetic testing service already covers the West Midlands region. Therefore the development of genetic testing services in the East Midlands would enable the new Midlands region to meet the NHS Long Term Plan target of diagnosing 25% of FH patients by 2023  The East Midlands Diabetes with Vascular Disease Clinical Network is proposing to support LLR STP by pump-priming the establishment of a nurse-led FH genetic testing service for 1 year to develop and implement a primary care-focused FH Services across LLR STP. This will address the detection and management of FH in people who are currently not diagnosed and will ensure that they and their relatives are offered and receive genetic testing for FH. This will help to reduce the burden on health and social care services by avoiding CVD events in the longer term and improving the quality of life for many people across the region.  Both the NHS Long Term Plan and NHS RightCare give primacy to preventing cardio vascular events: tackling FH as one of the causes of premature mortality and premature cardio vascular events is pivotal to achieving this.  **The NHS Long Term Plan** specifically sets out the need for expanding access to genetic testing for Familial Hypercholesterolaemia which will enable us to diagnose and treat those at genetic risk of sudden cardiac death. The document specifically identifies (pg. 62) the target of genetically diagnosing at least 25% of people with FH.  **The NHS RightCare Optimal Pathway** highlights FH as one of the 6 high risk cardiovascular disease conditions that are currently underdiagnosed and insufficiently managed despite a range of available interventions, and therefore FH represents a target for improvement and delivering cost efficiencies under RightCare. Cardiovascular disease has been identified by RightCare programme nationally as one of the key priorities for delivery in 2019  The preferred option is to develop Nurse-led FH services across the East Midlands. This option will benefit the LLR population by offering those identified at risk of FH the ability to be diagnosed locally, as close to where they live as possible, and receive treatment which will reduce premature death, reduce cardiovascular events and long term cardiovascular disease morbidity. This will also prevent families being trapped in a cycle of premature heart disease. It will reduce the incidence of, and therefore the cost of treatment and management of cardiovascular events. Funding provided to a ‘Lead commissioner’ on behalf of CCG’s in LLR STP should be used to establish a primary care focussed delivery model (as outlined in section 4) but with secondary care support for complex patients and paediatric patients.  The cost of implementing an FH service in each STP area is approximately **£68,000** to cover costs of the FH Nurses, consumables and IT (see appendix 1). It is proposed that the costs in year 1 (£71,000) are funded by the East Midlands Diabetes with Vascular Diseases Clinical Network. In year 2 onwards, the cost of the FH screening service would need to be funded by LLR STP. In years 2 onwards, costs of the service are approximately **£68,000**. However, it is calculated that the recurrent costs of the FH service in year 2 onwards would only be in the region of **£31,300** with £36,700 of the costs being off-set by avoiding unnecessary new and follow-up appointments at each hospital lipid clinic.  As part of this programme (and included in the year 1 costs), the Clinical Network is proposing to fund a clinical expert in year 1 only to provide support for the implementation of FH nurse led service across the region.  STPs will be expected to provide and fund dedicated programme management in year 1 to co-ordinate the implementation of the FH screening programme within the STP.  It is expected that sites will detect an additional 5% of FH patients in the first year thereby increasing overall genetic diagnosis to 10% in year 1. Years 2 and 3 are expected to incur similar costs with diagnosis rates increasing to 25% by the end of 2023.  Costs are avoided as more people with suspected FH are genetically detected and managed. This is due to the avoidance of cardiovascular events over time and these are outlined in Section 7 and Appendix 2. Appendix 2 shows the PHE Return on Investment tool overview for LLR STP.  It must also be borne in mind that the costs related to identification of patients of FH are non-recurring. Once all families have been screened for FH and diagnosed, there would be no recurrent costs incurred in screening the general population. FH is predictably inherited as an autosomal dominant condition and so only future offspring would need to be screened.  The weight of clinical evidence strongly supports the effectiveness of DNA index and cascade testing for individuals at risk of having the genetic disorder FH and will prevent families from being trapped in a cycle of premature heart disease. |
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| 1. Introduction/Background |
| *Provide some background information which will explain why this proposal has been developed* |
| Introduction In some people, a high cholesterol concentration in the blood is caused by an inherited genetic defect known as familial hypercholesterolaemia (FH). A raised cholesterol concentration in the blood is present from birth and may lead to early development of atherosclerotic disease such as coronary heart disease. The disease shows an autosomal dominant pattern of inheritance, being transmitted from generation to generation in such a way that siblings and children of a person with FH have a 50% risk of inheriting FH.  Most people with FH have inherited a defective gene from only one parent (heterozygous). Rarely, a person will inherit a genetic defect from both parents (homozygous).  The prevalence of heterozygous FH in the UK population is estimated by PHE and NHSE to be 1 in 250 and we have used this assumption in the business case. This means there are **4,461** people affected by FH in LLR STP  Figure 1 shows an estimate of the FH population in LLR STP and the East Midlands as a whole  Figure 1 Estimated FH Population (using 1 to 250)   |  |  | | --- | --- | | **STP name** | **Total Population  March 2017** | | LLR STP | 4,461 | | **EAST MIDLANDS** | **19,044** |   FH is largely genetically undiagnosed with articles suggesting 80-85%[[2]](#footnote-2) however, others suggest is could be less than 10% of predicted FH[[3]](#footnote-3) known, particularly in the <35 years group. The NHS Long Term Plan uses a figure of only 7% of people genetically diagnosed with FH through genetic testing.  PHE have estimated that only **5%** are genetically diagnosed in the East Midlands region which means that, in LLR, **4,238** people remain undiagnosed and at greater risk of premature cardiac events and/or premature death.  The elevated serum cholesterol concentration that characterises heterozygous FH leads to a greater than 50% risk of coronary heart disease in men by the age of 50 years and 30% in women by the age of 60 years. However, early treatment with statins reduces the CHD risk and therefore reduces the financial burden of premature cardiovascular events on health and social care as well as reducing premature mortality.  People with FH are at 300 times greater risk of developing CHD than the general population, and onset is typically severe and early. However traditional cardiovascular risk calculators do not necessarily highlight cases. Even if a young person is detected with a raised cholesterol (bearing in mind cholesterol is not routinely checked under the age of 50) current risk calculators such as QRISK2, used in primary care, will deem them very low risk for cardiovascular disease in the absence of other risk factors, such as hypertension/smoking status. For example, the estimated QRISK2 score of a 45-year-old male with total cholesterol of 8.0 mmol/l and no risk factors will only be 4% at 10 years when, in fact, his real cardiovascular risk if FH is confirmed is around 30-50% (10 times more than the standard calculation).  In 1999 the UK FH register reported that the standardised mortality ratio (SMR) for untreated FH patients between 20 and 59 years of age was 8.1 (equivalent approximately to a 23-year reduction in life expectancy).  A person with untreated FH is at much higher risk of a premature cardiovascular event (i.e. much earlier on in their life than someone who does not have FH). Figure 1[[4]](#footnote-4) shows that, if treated early on with high dose statin at age 18, their risk of disease burden reduces and, for a child with FH treated with low dose statin before the age of 10, they can go on to have the same life expectancy as the general population. However, those that are undiagnosed or untreated may experience a cardiovascular event by the age of 35 years  Figure 2 below shows the trajectory of the risk of having a CVD event. This is dependent on the point at which a person is diagnosed with FH and treated with statins.  Figure 2 Trajectory for risk of CVD event for people with FH    Access to FH services is variable across the East Midlands region as are diagnosis and treatment pathways. Within LLR STP, patients with suspected FH are usually referred by primary care to lipid clinics for assessment. Patients with probable/possible FH are treated as if they have FH and commenced on statin treatment by the lipid clinic. However, most patients with probable/possible FH do not receive genetic testing to confirm FH.  There is currently no programme to support cascade testing to identify people with FH in the LLR STP area.  Barriers to developing FH services up to now have included the cost of genetic testing as well as access to FH nurse resource. The costs of genetic testing for FH in Index and Cascade cases will be funded centrally by NHSE from April 2019 therefore this will no longer present a barrier. Aims of the programme The East Midlands FH Nurse-led programme aims to identify people across the East Midlands region that may carry the genetic disorder leading to FH and to identify any family members that may also carry the gene mutation. This will help to reduce cardiovascular events and premature mortality.  The programme also aims to ensure best value for money by using controlled targeted genetic testing so that it is used to confirm FH and facilitate the next process of cascade testing. Targeted genetic testing will further support family planning choices for people and will help with clinical management to reduce the incidence of cardiovascular events, particularly at a young age.  Genetic testing will not be used just to rule out FH in patients with high cholesterol who do not meet Simon Broome criteria.  The purpose of this business case is to set out a proposal for developing FH Nurse-led services across the LLR STP area which will improve access to standardised pathways for diagnosis and treatment across both primary and secondary care including access to genetic testing for index and cascade cases.  The NHS Long Term Plan sets a target to diagnose 25% of FH cases through genetic testing by 2023 which, for LLR STP is **1,115**. There are approximately 5% of FH patients identified with probable FH but only a small proportion of those have had a diagnosis confirmed by genetic testing. This cohort of probable FH patients will require genetic testing to confirm an FH diagnosis. In order to meet the NHSE target of 25% of genetically tested FH cases, an additional **892** people will need to be genetically diagnosed. This will require the development and implementation of an FH assessment and genetic testing programme including development of robust pathways and FH nurse resource.  It is proposed therefore that LLR STP will need to diagnose 10% of **233** people in year 1, an additional 20% in year 2, an additional 30% in year 3 and an additional 40% in year 4 (total 100% of the 25% target).  Using the assumptions from the NICE Resource impact report[[5]](#footnote-5) to calculate the numbers needed to treat, it is assumed that approx. 2,331 people will need to be identified and screened for FH in order to achieve genetic diagnosis of approximately 573 index cases and 381 cascade cases (40%) (see appendix 3 for detailed breakdown). For example, in LLR it is expected that there will be an existing cohort of approximately 350 patients and 150 new referrals annually to the lipid clinic. Assuming that 80% of the cohort already in the clinic and 80% of the new referrals are tested (n=400), with a detection rate of approximately 23 % - i.e. 92 index cases could be detected. In addition, cascade screening to detect approximately 2.2 cases per index (n=202), around 294 cases would be confirmed to have FH by the end of year one. This is close to 7% of the total expected prevalence for LLR in year 1. NICE Guidelines In 2008, NICE published a clinical guideline for the Identification and Management of FH (CG71). The guideline recommends identifying cases of FH, using cholesterol measurements and diagnostic criteria. This is to be followed by Index and (where necessary) cascade genetic testing of their families. Referral to a specialist service is recommended to initiate a referral for genetic testing, provide patient counselling and, where necessary support the process to initiate cascade testing. For children with FH, they should, with their parent(s), be offered specialist advice in a child-focused setting.  Since the original NICE Guideline, many statins have come off-patent and their costs are now much cheaper. In addition, genetic testing has advanced and costs of this have reduced as a result. NHS England has committed to fund the genetic testing for possible FH cases from April 2019 and therefore the cost of this is not to be borne by CCG’s. Models of Care There are currently three models of care for FH, both secondary care specialist led and primary care led, where primary care manages the majority of patients in the pathway with secondary care supporting those who need access to more specialist care.  **Secondary Care specialist-led model**  The majority of services for people with suspected FH in the East Midlands are led by secondary care where patients are managed and reviewed in consultant-led services, usually in lipids clinics. However, not all areas have well-established lipids clinics, and services for paediatric FH patients are also variable in their remit and delivery. Patients are clinically diagnosed with FH but most are not genetically diagnosed as they are not funded by CCG’s to provide this. There are no cascade genetic testing services in the East Midlands.  The lipid clinic incurs a new outpatient tariff cost and follow-up costs for each patient seen in the clinic. Information from a number of hospitals in the region estimates that approximately 2 to 3 new ‘possible/probable FH’ referrals are received each week into lipid services. Most of these new outpatient appointments could be avoided by patients first seeing the FH Nurse in a primary care setting. These numbers mirror those experienced in lipid clinics in the West Midlands where a nurse-led FH screening service is already in operation as identified in their FH Business case (page 8)[[6]](#footnote-6).  **Primary Care-led model**  There are no primary care-led FH models in the East Midlands.  The Medway model is an example of a primary care-focussed approach to clinical diagnosis and management of FH. It started in 2014 and has seen improvements in the numbers of people diagnosed and treated for FH, with the proportion of patients at risk and unscreened reducing by three-quarters,[[7]](#footnote-7) now enabling them to achieve an FH diagnosis rate of 1 in 300. Patients are clinically diagnosed with FH and primarily managed by the GP where cholesterol levels and other indicators (using an audit tool) suggest possible or probable FH. Patients with probable/possible FH are treated by primary care with statins as if they have confirmed FH diagnosis. However, none of these patients have received genetic testing to confirm FH diagnosis due to the cost barrier of FH genetic testing (the NHSE proposed funding of genetic testing will enable Medway to address this) and there is no formal cascade testing approach for children or other relatives.  The West Midlands model, funded for 2 years through the British Heart Foundation with CCG’s paying for the genetic testing, is an example of an FH nurse-led approach in primary care and patients are genetically tested via the Bristol Laboratory to establish a genetic diagnosis of FH. The FH nurses have access to a monthly MDT which includes a secondary care consultant/clinical lead to provide access to support and advice where appropriate for discussion of cases where the pathway is unclear.  **East Midlands Model**  The East Midlands would wish to progress with a primary care-focussed FH Nurse-led service similar to that of the West Midlands which would support people with suspected FH to access genetic testing where clinically appropriate. FH services will be able to refer directly to the laboratory for genetic testing without the need to go through secondary care lipidologists. However, pathways and protocols will need to be in place to ensure that appropriate referrals are made for genetic testing by primary and secondary care. In addition the East Midlands Clinical Network are in the process of clarifying whether, with training, referrals to the genetic laboratory could be made directly by GP’s in certain circumstances. |
|  |
| 1. Strategic Context |
| *Include how this proposal supports NHS wider strategy/organisational direction e.g.*   * *Strategic Transformation Plan* * *NHSE Strategic Objectives* * *National Strategy and Policy* * *Local Strategy and Policy* |
| NICE Guidance NICE Guidelines 2008 (updated 2017) recommends case finding of people who:   * Have a total cholesterol level greater than 7.5mmol/l and/or * Have a personal or family history of premature coronary heart disease (an event before   60 years in an index individual or first-degree relative).   * Or are younger than 30 years, with a total cholesterol concentration greater than 7.5 mmol/l   These individuals should have a clinical diagnosis based on the Simon Broome or Dutch Lipid Clinic Network diagnostic criteria in primary care and, where appropriate, offered a DNA test to confirm definite FH and to assist in further cascade testing of relatives.  NICE also recommends that children aged 0-10 years at risk of FH (because they have 1 or more affected parents) should be offered a DNA test by the age of 10 but definitely at the earliest opportunity thereafter given the benefits highlighted in figure 1.  The Department of Health outlined in its strategic outcomes in 2013[[8]](#footnote-8) a number of citations for FH diagnosis and management linked to the improvements required to identify individuals and families at very high risk of cardiovascular events, in particular those with inherited conditions such as FH. NICE Quality Standard In 2013, NICE developed the FH Quality Standard in support of the NHS Outcomes Framework 2013/14 for domains 1 (Preventing people from dying Prematurely), 2 (Enhancing quality of life for people with long-term conditions) and 4 (Ensuring people have a positive experience of care).  The quality standard for FH specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole FH care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to people with FH NHS Long Term Plan NHS England has identified cardiovascular disease prevention as a priority within the NHS Long Term Plan[[9]](#footnote-9) which was published in January 2019. Familial Hypercholesterolaemia is a priority within the long term plan with a target to diagnose 25% of FH patients by March 2023. NHSE are committed to expanding access to genetic testing for FH, and this will enable us to diagnose and treat people with FH.  NHS England has committed to covering the cost of the genetic testing for FH although this has been delayed (from October 2018 to April 2019).  Public Health England is also committed to support the implementation of preventative interventions of cardiovascular disease[[10]](#footnote-10) including how this links to the NHS Health Checks which include testing for cholesterol. RightCare – CVD Prevention The NHS RightCare Optimal Pathway[[11]](#footnote-11) highlighted FH as one of the 6 high risk cardiovascular disease conditions that are currently underdiagnosed and insufficiently managed despite a range of available interventions, and therefore FH represents a target for improvement and delivering cost efficiencies under RightCare.  Although there isn’t a specific RightCare pathway for FH, it is prominent in the Cardiovascular Disease Prevention: Risk Detection and Management in Primary Care pathway. Given the greatly increased risk of having a premature cardio vascular event or premature mortality for those with undiagnosed FH, the development of FH services across LLR STP would support the RightCare CVD prevention programmes. Cardiovascular disease has been identified by RightCare programme nationally as one of the key priorities for delivery in 2019. |
|  |
| 1. Case for Change |
| *State what needs to change supported by reasons and evidence where available e.g.*   * *Reference to information sources and what these indicate that this project will help address e.g. Better Care Better Value; JSNA; Network Recommendations; DH directive etc. – prevalence; opportunities etc.* * *National and local issues that the proposal aims to address* * *Stakeholders views - (include sources e.g. feedback from surveys)* * *Objectives and goals of project e.g. quality of patient care financial benefits; workforce etc.* * *Future needs of the population/health and care economy/service – horizon scanning including demographic change and within local and national strategic ambitions* * *Assumptions: state these – what we don’t yet know or have had to guess and based on what.* * *Proposed change e.g. overview of new service, new process* |
| Patient Case Study The following is a real-life case.  A 39 year old man presented with severe crushing chest pain to A&E. He was sent straight to the cath lab. He had experienced an ST elevation myocardial infarction of the left anterior descending artery (STEMI of LAD) and multiple other coronary lesions. He developed post MI heart failure with an ejection fraction of less than 30%.  He had a cardiac resynchronization therapy device (CRT-D) fitted and now has a prognosis worse than most cancers.  He Lives with his wife and 2 young children but has no siblings (brothers/sisters). He is unable to return to work following cardiac rehab and gets breathless even on light exertion. He is now seen regularly in his local Heart Failure clinic and is being assessed for a heart transplant.  Prior to this he had no significant medical history. HOWEVER… his Father had a coronary artery bypass graft in his 50s. The case study was found to have “high” cholesterol at an earlier private health assessment and the GP started him on cholesterol lowering treatment (simvastatin 40mg). His most recent total cholesterol was 5.6mmol/L and he had a cardiovascular risk Qrisk2 of only 6%. He was not assessed for possible FH.  What could have been done differently:   * At registration with their GP a more detailed family history of early cardiovascular disease could have been taken. This would have identified he was at possible risk of FH. * Take an accurate lipid profile to include LDL, HDL and non-HDL cholesterol * Estimate what his lipid levels would be without starting treatment and identify an extreme lipid profile * Look for tendon xanthomas * Refer for genetic testing to confirm FH and initiate aggressive lipid lowering treatment * **Initiate cascade FH screening –** both children have 50% risk of inheriting FH   Many other people like this are presenting to health services across LLR STP. Not only do they present as emergency cases but they also then go on to utilise many other health and social care services as a result of undiagnosed and untreated FH. Overview FH is a genetic condition which affects approximately 1 in 250 people and creates a very high risk of cardiovascular events at an earlier age than the general population. Children of affected adults have a 50% chance of inheriting FH yet, if detected and treated early in their childhood, can lead a normal life with risk of CVD being no worse than that of the general population. However, there is no standardised approach to diagnosis and management and there is a lack of consistency for identifying those who require cascade testing.  Currently there is no standardised FH service across LLR STP.  **Currently, FH Services across LLR STP do not meet:**   * **NICE Guideline CG71 X** * **NICE Quality Standards (QS41) X** * **Department of Health - Best Practice Guidance CVD Outcomes Strategy (DH 2013) X**   Developing and delivering FH nurse-led services across LLR STP will:   * Improve quality outcomes for people with FH by reducing the risk of premature and avoidable cardiovascular events through improved detection, diagnosis and management. * Reduce burden and costs of Health and Social Care * Provide a proven cost-effective method of case finding for FH compared to general population screening and reduce/avoid costs to the health and social care system through index and cascade testing[[12]](#footnote-12)[[13]](#footnote-13)[[14]](#footnote-14) * Focus on care which helps to keep people as healthy as possible for as long as possible * Provide health promotion and health education for patients and their relatives on the significant risks of undiagnosed and/or untreated FH * Provide education and support for health care professionals in the diagnosis and management of FH in a primary care setting   The QALY of cascade testing for people with suspected FH is £2,676[[15]](#footnote-15), significantly below the threshold used by NICE (£20,000/QALY) for cost-effectiveness. By comparison, the QALY of a hip replacement is between £7,058 and £7,220 for patients under the age of 75[[16]](#footnote-16).  Successful earlier pilots conducted by the British Heart Foundation suggest that FH Nurse posts have a positive impact on the delivery of cascade testing and driving up of referrals but there needs to be clarity in the FH pathway and an understanding of the gaps in resources available in order to deliver a successful service. This includes access to lipidologists, access to genetic testing (funded by NHSE), protocols and resource for case finding, a pathway for referral from primary care and access to FH databases.  Based on Heart UK’s modelling from their 2012 publication *Saving lives, Saving Families* (figure 3) we can see that the opportunity to avoid **721** events over a person’s lifetime for every 1000 FH patients optimally treated and managed (versus no treatment) is significant. This is an opportunity to reduce or avoid emergency admissions and avoid associated costs of treatment for life-long cardiovascular disease, and importantly, reduce the impact on the person’s quality of life by reducing the risk of cardiovascular events across their lifetime.  Figure 3 - Number of lifetime events avoided (followed up from aged 30 to 85 years) for every 1000 FH patients optimally treated and managed vs. no treatment.  Based on the estimated FH population in LLR STP of circa 4,461 this could lead to an avoidance of **3,216** lifetime events if all 4,461 people were optimally treated. (figure 3 above)  Across the LLR STP footprint, between December 2017 and November 2018, **702** premature cardiovascular events were coded across LLR STP area in males under the age of 55 and females under the age of 65 for emergency admissions with primary diagnosis of Stroke, Angina, Myocardial Infarction, Coronary Heart Disease, Heart Failure (see figure 5). Many of these will have undiagnosed and untreated FH and many of these could be avoided with genetic diagnosis and appropriate treatment.  Figure 5 – Emergency Admissions between December 2017 and November 2018 (primary diagnosis)   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | MI | | CHD | | Angina | | Stroke | | HF | | | STP | Male <55yrs | Female  <65yrs | Male <55yrs | Female  <65yrs | Male <55yrs | Female  <65yrs | Male <55yrs | Female  <65yrs | Male <55yrs | Female  <65yrs | | LLR | **43** | **33** | **150** | **128** | **18** | **25** | **74** | **126** | **39** | **66** | | East Midlands Total | 255 | 234 | 749 | 815 | 120 | 143 | 429 | 582 | 202 | 311 |  Proposed Service Change – overview of new service A proposed DRAFT pathway is shown below (and available in larger print in appendix 4) and has been followed by the West Midlands FH service. This requires clinical sign off by STP’s within East Midlands. Using this pathway would allow for a consistent approach across primary care-focussed FH services.    It is proposed by the East Midlands Clinical Network that the LLR STP develops their FH service in line with the above pathway which is to follow a Care model where Primary Care undertakes the clinical diagnosis and referral for genetic testing via a primary care based specialist FH nurse-led service. This will be followed by the management of the majority of patients in the FH pathway by this service, supported by secondary care as outlined below.   1. Identification of potential/possible FH ‘Index’ cases   Primary Care will need to undertake an audit of patients on their primary care registers to identify people with Cholesterol >7.5 mmol/L and >9 mmol/L as follows:   * people younger than 30 years, with a total cholesterol concentration greater than 7.5 mmol/L and Triglycerides less than or equal to 5mmol/L and * people 30 years or older, with a total cholesterol concentration greater than 9.0 mmol/L and Triglycerides less than or equal to 5mmol/L   This includes patients who are currently untreated as well as those who are already receiving lipid-lowering treatment. Those that are already receiving treatment may fall below the threshold of Cholesterol >7.5 mmol/L therefore an audit tool such as the FAMCAT audit tool should be used to identify those who would exceed Cholesterol >7.5 mmol/L were they not on lipid-lowering treatment.  The FH Nurse will support the analysis of the data using the agreed clinical diagnostic criteria to exclude those with high cholesterol as a result of secondary factors not related to FH. The majority of people with clinically diagnosed FH will require genetic testing.  People will be identified for possible or probable FH using either the Simon Broome or Dutch Lipid Clinical Network diagnostic criteria and those who are clinically diagnosed with FH will be referred for genetic testing to confirm a genetic diagnosis of FH. Positive genetic diagnosis of an index case will then provide an opportunity for relatives to be invited to undertake genetic testing.   1. Referral for testing   Primary care-focussed FH Services will refer directly to the laboratory for genetic testing without the need to go through secondary care lipidologists. However, pathways and protocols would need to be in place to ensure that appropriate referrals are made. In addition the East Midlands Clinical Network are seeking clarification on whether, with training, referrals to the genetic laboratory could be made directly by GP’s in certain circumstances. If direct GP referral into genetic testing is allowed, it is proposed that patients with a cholesterol level of >9 mmol/L are referred directly to the genetic testing laboratory from primary care.  It is proposed that people whose cholesterol is >7.5 mmol/L but <9 mmol/L are referred to an FH nurse for assessment before referring to genetic testing.  The FH nurse should have access to lipidologist consultant support and advice where necessary to establish whether further assessment is required in cases where direct referral to genetic testing is unclear.   1. Management   It is proposed that the default pathway for management of patient treatment once genetic testing has been completed should be via primary care. Exceptions include patients who require secondary care management e.g. Children and young people who require access to paediatric services, adults who have complex management needs or where optimum management of cholesterol is not being achieved in primary care.  This process should see a reduction in unnecessary hospital outpatient appointments and therefore avoid costs for the CCG’s.  Following genetic testing, patients who are not genetically diagnosed as having FH but who have high cholesterol will be managed as appropriate in primary care or in a secondary care lipid clinic.   1. Cascade testing   As a result of a positive genetic diagnosis of FH in an ‘index case’, a process will be undertaken, led by the FH nurse to establish potential relatives of the index patient that are to be invited for cascade testing. This should include at least the first, second and, when possible, third-degree biological relatives. Consideration will need to be given as to how these people will be contacted and the process required for those that live outside of the LLR STP area.  Healthcare professionals should offer all children and young people diagnosed with or being investigated for a diagnosis of FH a referral to a specialist with expertise in FH in children and young people. This should be in an appropriate child /young person-focused setting.[[17]](#footnote-17)  It is proposed that FH nurses (1.0 WTE band 7 FH Nurse and 0.2 WTE administration support per STP serving a population in the region of 1 million) will support primary and secondary care colleagues to help patients through the process of diagnosis and cascade testing, including providing counselling and information for index cases and cascade relatives at risk of FH, and undertaking care planning and treatment reviews. The FH nurse will receive referrals from primary and secondary care and will undertake an assessment to clarify if the patient is appropriate for genetic testing. The FH nurse will be supported through the implementation phase in year 1 by a lead FH nurse (band 8a) who will also act as the programme manager across all the East Midlands STP implementation sites during the early development and implementation process. This post will be funded by East Midlands Clinical Network for one year.  It is proposed that funding for the FH nurse and the lead FH nurse/programme lead in year 1 is provided by East Midlands Clinical Network to support the development of FH services within each STP. LLR STP will be required to fund the FH Nurse post in subsequent years. Outcomes and Impact The outcomes and impact of the programme are to   * Increase the rate of genetic diagnosis of FH to at least 25% by 2023 * Reduce the risk of premature cardiovascular events for people diagnosed with FH * Reduce premature mortality as a result of CHD particularly those incurred in early age for people diagnosed with FH * Reduce emergency admissions for people diagnosed with FH * Ensure best value through appropriate genetic testing. |
|  |
| 1. Scope |
| *State what’s included in the proposal and if anything has been specifically excluded. Include any assumptions made.* |
| The proposal is to provide funding for a Primary Care-based FH nurse to work with Primary Care and Secondary Care colleagues linked to LLR STP. In Scope  * All patients (adult and paediatric) will be eligible to access the service if they have a clinical diagnosis of possible or probable FH (based on agreed clinical diagnostic criteria). * All relatives of index cases will be eligible to access the service for cascade testing where meet the clinical criteria AND they are registered with a GP who is within one of the 5 STP areas mentioned above.    Out of Scope  * Patients already genetically tested for FH (whether positive or negative) will not need to be genetically tested again. These patients will be clinically managed in line with NICE Guidance (cg71) * Cascade relatives who live outside of the LLR region will be directed to their local GP/FH service to access genetic testing services in their local area |
|  |
| 1. Benefits |
| *State the benefits of accepting this proposal which may include:*   * *Service improvements* * *Strategic fit with local & national objectives* * *Impacts on quality of services and patient experience and how these will be delivered/monitored* * *Financial costs or savings and how these will be delivered/monitored* * *Creating efficiencies or freeing up resources* * *Improving safety and preventing avoidable harm* * *Workforce improvements* |
| Benefits  * Reduce premature mortality rates for people with FH and prevent families being trapped in a cycle of premature heart disease. * Ensure that the STP is compliant with NICE Guidelines * Enable the STP to achieve the target set out in the NHS Long Term Plan to diagnose 25% of FH patients through genetic testing * Provide a standardised pathway for patients with possible or probable FH * Improve detection of FH Index and cascade cases ensuring patients have a confirmed diagnosis of FH through genetic testing. * Provide access to genetic testing for all eligible patients/relatives * Develop access to testing via primary care as well as secondary care * Improve diagnosis and management of FH in primary care by upskilling practitioners * Avoid longer term costs of cardiovascular events in FH patients through early detection, particularly paediatric FH * Reduce CVD risk over the longer term by identifying cases in childhood so that patients have the same life expectancy as that of the general population by preventing premature deaths and cardiovascular events and reducing the cost and activity associated with caring for the survivors of MIs, strokes, TIAs and angina. * Reduce costs of managing FH cases by transferring the care of some patients from secondary care to primary care with a potential to reduce outpatient appointments to lipid clinics for new FH patients who through this pathway will now be seen by the FH nurse in a primary care setting * Costs related to identification of patients of FH are non-recurring. Once all families have been identified, there would be no recurrent costs in screening the general population. FH is predictably inherited as an autosomal dominant condition and so only future offspring need to be screened. |
|  |
| 1. Options Appraisal |
| * *List each of the options available including ‘do nothing’.* * *Describe each of the options available* * *State any assumptions that have been made (where information is not available)* * *Set out process and approach taken to review options and select a preferred option (provide a ‘ranking’ of options if appropriate) e.g. SWOT, cost-benefits appraisal etc.*   *For each of the options stated ensure that you include the following:*  ***7.a Risk appraisal***   * *State risks involved and how those risks may be mitigated* * *Traffic light the risks if appropriate in line with risk register rankings to indicate likelihood of the risk and consequence*     ***7.b Financial appraisal***   * *The financial cost or benefit. Include the investment required and savings to be gained. Also briefly state how these have been calculated (include specific calculations if possible/feasible).* * *This should include stating where costs or savings are recurrent or non-recurrent.* * *Also include the financial year in which costs will be incurred or savings will be made.*     ***7.c Preferred option***   * *Summarise why this is the preferred option specifying factors that have been taken into account in arriving at the preference* |
| Risk Appraisal Figure 6 – Risk Log   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Factors that may negatively impact the project and when they do what is the plan of action?** | | | | | | **Description (what could go wrong?)** | **Likelihood** | **Consequence** | **Rating** | **Mitigation Action Plan** | | Funding not available for FH nurses | 1 | 3 | 3 | Pump priming funding for Year 1 agreed by NHSE | | FH Nurses not recruited | 3 | 3 | 9 | Early recruitment with support for recruitment process from Lead Nurse/Project Manager | | Training not available for FH Nurses and/or GP's | 1 | 3 | 3 | Courses for FH nurses are already available through Health Education England and HeartUK. Primary care upskilling is planned for 2019 | | STP’s/CCG's not willing to support roles after funding expires | 3 | 3 | 9 | Get agreement from providers/STP’s/CCG's prior to programme going live Discussion with STP’s/CCG's about opportunity for avoidable costs in the future as this is not about taking money out of the system. Develop robust ROI information to evidence benefits and avoidable costs in long term | | Secondary care don't agree to a change of pathway with primary care being the default for requesting genetic testing | 3 | 3 | 9 | Include secondary care clinicians in development of case and specifications Get early buy-in from secondary care | | Primary Care don't agree to the new pathway | 3 | 3 | 9 | Include primary care clinicians in development of business case and specifications Get early buy-in from primary care Establish clinical leadership/champion in primary care | | Inappropriate referrals to genetic testing | 3 | 2 | 6 | Ensure pathway information is clear Provide access to adequate training for primary care.  FH nurses to screen referrals from GP practices through use of diagnostic criteria  Ensure that risk stratification methodology is developed to ensure high conversion rate | | Paediatric FH services not locally available | 3 | 2 | 6 | agree protocols for referral to appropriate neighbouring service |  Financial Appraisal As identified in the case for change section above, ‘Cascade testing of relatives of those with suspected FH is highly cost effective. The current Europe-wide high levels of undiagnosed FH, and associated morbidity and mortality, mean adoption of cascade services should yield substantial quality of life and survival gains’[[18]](#footnote-18)  Modelling supports this view, however it is difficult to accurately predict the financial break-even point. There are a number of assumptions with some being highly sensitive to variation, e.g. a small change in the value of the yield of index cases from the screening process can have a large impact on the modelling whereas a variation in the cost or use of available medications has a minimal effect on the cash flow. Front-loading costs will be recovered, but yielding a positive cash flow may require greater than five years after commencing the project. Costs The cost of implementing an FH service in each STP area is approximately £71,000 in year 1 to cover costs of the FH Nurses, consumables, accommodation and IT (see appendix 1). It is proposed that the costs in year 1 are funded by the East Midlands Diabetes with Vascular Diseases Clinical Network.  Included in this, the East Midlands Diabetes with Vascular Diseases Clinical Network will engage and fund a Band 8a Clinical Expert/Lead FH Specialist Nurse to provide oversight for the development and implementation of the programme across the region. This will be on a part time basis.  LLR STP will be expected to identify and fund a project lead who will oversee implementation at a local level.  In years 2 onwards, costs of the service are approximately **£68,500** and will be funded by LLR STP However, it is calculated that the recurrent costs of the FH service in year 2 onwards would only be in the region of **£31,800** with £36,700 of the costs being off-set by avoiding unnecessary new and follow-up appointments at each hospital lipid clinic.  Costs related to identification of patients with FH are non-recurring i.e. once **all** families have been identified there would be no recurrent costs in screening the general population. FH is predictably inherited as an autosomal dominant condition and so only future offspring would need to be screened.  The Public Health England CVD return on investment tool[[19]](#footnote-19) has established a reduction in CVD events over time for each of the STP’s. This is based on improving the detection rate of FH over the next 3 years to 12% (year 1), 19% (year 2) and 25% (year 3) with a treatment rate of 86% receiving lipid-modification.  The LLR STP model shown in appendix 2 plots the number of avoided (or added) CVD conditions over time.  The FH services are aimed at reducing cardiovascular events in the FH population over a longer term. The modelling highlights the number of avoided long-term cardiovascular events over time which avoids health and social care costs compared to a ‘do nothing’ approach. Avoided costs In familial hypercholesterolaemia, the absolute risk of first onset of coronary heart disease is 11/10,000 person years in statin treated patients compared with 119/10,000 person years in untreated patients[[20]](#footnote-20). Given this, if we were able to treat all FH cases we would prevent 48 cases of CHD per year across LLR. (See table 7 below)  Table 7 – Number of cases of CHD avoided per year if FH programme fully implemented in LLR STP   |  |  | | --- | --- | | Total no of CHD cases preventable | | | Total Number of FH cases | 4,461 | | No of new CHD cases per year if all untreated (119/10,000) | 53 | | No of new CHD cases per year if all treated (11/10,000) | 5 | | Reduction in new CHD cases | **48** |   Each non-elective admission for Myocardial Infarction costs between £1,313 (HRG code EB10E 2018/19) and £4,676 (HRG code EB10A 2018/19). Using 48 avoided MI’s (Table 7) there are potential cost savings of between **£63,024** and **£224,448** based on this number of avoidable heart attacks as a result of CHD. This figure does not take into account additional savings for CCG’s for avoided elective primary PCI and prescribing costs.  Using the PHE CVD Modelling tool, figure 8 shows the costs **avoided** over 20 years by achieving a 25% diagnosis of FH. The model shows at year 5 a saving of £55,816, year 10 of £189,082 and year 20 of £6,800 across LLR. Further details can be found in the embedded documents for each STP in appendix 2.  Figure 8 – cumulative costs avoided by increasing detection and management of FH   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | STP | Year 1 | Year 3 | Year 5 | Year 10 | Year 15 | Year 20 | | Leicestershire | -313 | -22,953 | -55,816 | -189,082 | -119,704 | -6,800 | | **TOTAL (East Midlands)** | **-12,483** | **-129,236** | **-339,119** | **-1,152,102** | **-1,503,552** | **-1,781,625** |  Avoided appointment savings In addition, by delivering a primary care-focussed FH Nurse-led service, costs can be avoided by referring patients to the FH Nurse rather than the secondary care lipid clinic. On average there are 3 new referrals per week into lipid clinics which incur a ‘new patient referral’ tariff of £157 each plus additional follow-up outpatient appointment tariff of £79 (assume 2 per patient per year). Most of these costs could be avoided by genetic testing prior to seeing the consultant so that the consultant only sees those that require specialist intervention.  If each hospital lipid service sees, on average 3 new suspected FH patients per week (n=156/year/STP), based on the West Midlands modelling it is assumed that 80% of those will need a genetic test (n=124) with a conversion rate of genetically confirmed FH being 23% (based on West Midlands data) (n=32).  Therefore, based on the assumption that each FH service would only need to refer on average 32 patients to the lipid consultant for a ‘new patient’ referral, this would save at least £19,468 per year in avoided new outpatient appointments**.** In addition, theWest Midlands FH service estimates that 70% of patient follow-up care could be seen in the FH nurse-led service. Assuming that each patient has 2 follow-up appointments per year, this would save an additional 218 follow-up appointments (saving £17,254 per year) – **a total saving** of approximately **£36,772 per year per lipid clinic** based on new patients. There will be additional follow-up savings from patients already on the consultant case load who are being seen in follow-up clinics.  Hospitals report that lipid clinics are at saturation point with difficulty in coping with additional referrals and therefore utilising FH Nurses would improve this situation as well as reducing waiting times for those that need the specialist support from secondary care consultants. Options for consideration There are two options:   1. **Do nothing**   This option will **miss the opportunity** to implement a programme that will:   * Prevent premature deaths * Prevent premature cardiovascular events. * Avoid the cost and activity associated with caring for the survivors of MIs, strokes, TIAs and angina.   This option will continue to see the rise of premature death and premature cardiovascular events due to undiagnosed FH  In addition, LLR STP would not meet the NHS Long Term Plan target of diagnosing 25% of FH patients and will continue to be non-compliant with NICE guidance.   1. **Develop FH services across LLR STP**   This option will **benefit** the LLR population by   * Offering those identified at risk of FH a genetic diagnosis which will lead to cascade testing of relatives, in particular, children of index cases * Patients with FH receiving appropriate treatment which will reduce the risk of premature death, reduce premature cardiovascular events and long term CVD morbidity. * Preventing families being trapped in a cycle of premature heart disease. * Providing families with the information they need to make informed choices about conception * Reducing the incidence of, and therefore the cost of treatment and management of cardiovascular events.   Funding provided to CCG’s/STP’s should be used to establish a care model which has its focus in primary care (as outlined in section 4) but with secondary care support for complex and paediatric patients.  **OPTION 2 is the preferred option.** |
|  |
| 1. Commercial/Other Considerations |
| *State other considerations which need to be taken into account e.g.*   * *Funding sources* * *Competition and Procurement considerations* * *Any decommissioning/recommissioning implications* * *Commercial approach i.e. procurement programme/route to market, contracting approach etc.* * *Engagement and consultation with patients and stakeholders* * *Potential impact on local workforce* |
| Funding sources There are no commercial funding sources. Funding for year 1 will be supported through the East Midlands Clinical Network. The sum of up to **£71,000** will be provided to LLR STP to develop their FH services.  There is potential for CCG’s to secure additional funding from pharmaceutical companies to support ongoing delivery of an FH Nurse-led service in primary care if required in the future but this will be for LLR STP to initiate. Competition and Procurement considerations Consideration needs to be given to the use of information/audit tools for running audits and collating data to support detection of people with suspected FH who may require genetic testing. CCG’s use a variety of tools e.g. ECLIPSE, PRIMIS. Each programme of work will need to establish what current system is available and whether it is sufficient to support the FH service or whether an additional system needs to be commissioned. Any decommissioning/recommissioning implications There are no decommissioning implications however there is potential to reduce initial outpatient appointments to lipid clinics for new FH patients who through this pathway will now be initially seen by the FH nurse in primary care. CCG’s may wish to monitor this in year 1 to estimate potential recurrent savings in secondary care services. There is the potential for an increase in referral of complex FH patients to lipid clinics for management review but this could be balanced out by implementing virtual outpatient clinics for patient follow-up rather than face to face appointments. Engagement and consultation with patients and stakeholders A plan of communications will be undertaken with patients and stakeholders to highlight the new service and the impact this will have on the care of people with FH.  Engagement will be required at the outset with both primary and secondary care to establish a robust end to end pathway for FH in the LLR STP area and more widely across the East Midlands region. Whilst it is expected that a standard pathway would be established across the East Midlands region, there are likely to be areas of variation as a result of resource availability e.g. access to paediatric FH specialists. LLR STP/CCG’s should be supported to undertake a mapping exercise of current FH services and resource to establish a baseline and analysis of the gaps in provision. Potential impact on local workforce Resource for year one to develop and deliver the FH service will be supported by the East Midlands Clinical Network through funding of FH nurses and administration support to manage the initial volume of patients detected. Beyond this, LLR STP will be required to support the sustainability of the FH service across both primary and secondary care through the CCG’s usual contracting and commissioning processes.  Courses for FH nurses are already available through Health Education England and HeartUK. Primary care upskilling is planned for 2019. |
|  |
| 1. Management Arrangements |
| *Describe how the proposal will be implemented*   * *Explain how the benefits/success will be measured* * *Provide a project governance overview* * *State the project management approach and actions required to deliver outcomes* * *What are / is the resource or expertise required (internal and external)?* * *Project hand-off to business-as-usual e.g. ongoing contact management of service* * *Include a high level project plan with timescales and key milestones* |
| Measuring Success LLR STP will be supported financially to establish an FH service and KPI’s will be used to measure success.  KPI’s will include:   * Number of people genetically diagnosed with FH, both index and cascade cases * Conversion rate of people sent for genetic detection versus positive genetic diagnosis * Increase in rate of detection * Reduction in number of MI’s in males under 55 years old and females under 65 years old  Governance Overall project governance will be through the East Midlands Clinical Network FH steering group. This group will include key members from the Clinical Network (Clinical Director and Clinical Leads, Head of Network and Senior Quality Improvement Manager, FH Nurse Specialist). The steering group will support LLR STP to develop and implement the FH service through key personnel i.e. Lead Commissioner, primary care and secondary care clinicians and the FH Nurse.  The STP/lead CCG commissioner will be expected to set up an FH Delivery Group which will report to the FH steering group. The local project delivery group will work within a project management framework.  Expertise on implementation will be sought from BHF and Heart UK. The Clinical Network also proposes to commission clinical expertise from the West Midlands FH lead nurse who will support initial service implementation and provide oversight to the programme.  Once embedded within the timeframe of the programme, the STP/CCG FH services will be contracted through the usual CCG commissioning and contracting process. Milestones  |  |  | | --- | --- | | **Key Milestones:** | **Time Frame** | | Agree funding from NHSE | January 2019 | | Agree programme sites | January 2019 | | Agree FH pathway | January/February 2019 | | Recruit FH Nurses | March/April 2019 | | Train HCP’s | March/April 2019 | | Implement programme | April 2019 | |
|  |
| 1. Equality Impact Assessment |
| Design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and advances equal opportunities for all. This project has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. (Please detail below?) |
| **All/general:** Any issue that cuts across a number of protected characteristics   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Communication | This service can offer a number of positive outcomes | None anticipated | Important to ensure that patients are given all of the information that they need and can easily understand the benefits of this service. |   **Age:** Where a person is at risk of unfair treatment because of their age group   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | This service is for people of any age with possible or probable FH. However, there are limited specialist resources for children with FH | This service is for any age group. There are no upper or lower age ranges | Adults can be supported in both primary and secondary care. Children will be supported through Paediatric FH specialists in secondary care however these are limited and may not be available in every acute hospital | Specialist Paediatric Services can be accessed on a ‘hub’ basis in secondary care |   **Disability and health and wellbeing:** All forms of disability recognised under the Equality Act 2010 including sensory impairment, mental health, learning disabilities, mobility related conditions, conditions such as heart disease, diabetes and asthma. This also covers any impact on health and wellbeing.   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Compliance with attendance at OPA’s | Reducing the number of OPA’s in secondary care by increasing support in primary care could improve access | None anticipated | Develop clear patient information, link in with carers (including clinical support e.g. CPN) where consented to support attendance and access. | | People with complex conditions or cholesterol that cannot be managed in primary care | Specialist service for complex needs available via specialists in secondary care | Will not be cared for in primary care so may have less choice of where they can be seen | Dual care approach will include opportunity for step up/step down between primary and secondary care dependent on clinical need |   **Gender Reassignment:** this related to a person (or persons) who is proposing to undergo, are undergoing or have undergone a process (or part of a process) for the purpose of reassigning their sex, by changing physiological or other attributes of sex from that which was assigned to them at birth.   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Marriage and Civil Partnership:** people who have or share the common characteristics of being married or of being a civil partner can be described as being in marriage or civil partnership.   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Pregnancy and Maternity:** relates to women who are pregnant or within their allocated maternity period; up to 26 weeks after birth   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Race:** All ethnic groups including Asian, Black, East Asian and white minority ethnic groups, including Eastern Europeans and Gypsy and Travellers   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Compliance with OPA visits | There will be more choice of local community clinical venues to access this service and will reduce number of OPA’s overall in hospitals. | It is crucial that patients identified as being genetically diagnosed with FH attend genetic counselling to establish the need for cascade testing which may be challenging for people who are transient. Robust communication needs to be considered.  The BAME population may require access to interpretation and translation to support compliance | Develop clear patient information on the importance of compliance, including access to translation. Also information on how to access patient transport services for eligible patients. |   **Religion/belief:** all faiths including Christianity, Islam, Judaism, Hinduism, Buddhism, Sikhism and non-religious beliefs such as Humanism   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Sex (Gender):** referring to being a man or a woman   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Sexual Orientation:** including heterosexual, gay, lesbian and bisexual people   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Non anticipated | Non anticipated | Non anticipated | Non anticipated |   **Socio-Economic Status:** This can include people on low incomes, as well as issues around rural and urban deprivation- You may wish to include this, although it is beyond the scope of the Equality Act 2010.   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Travel to clinic appointments | There will be more choice of local community clinical venues as well as the existing clinics at acute hospitals if required which could reduce travel costs and time to appointments. | Non anticipated | Non anticipated |   **Good Relations:** This is where a decision or a change to services may risk creating tension between community groups in a local area, or had the potential to improve relations between groups   |  |  |  |  | | --- | --- | --- | --- | | **Issue/option** | **Positive Impact or benefits** | **Negative impact or risks** | **Action Required** | | Raising awareness of FH | Having local OPA clinics in the community can be used to raise the profile of FH | Non anticipated | Non anticipated | |

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| 1. Appendices |
| Please use this space to add any appendices |

# Appendix 1 – cost appraisal

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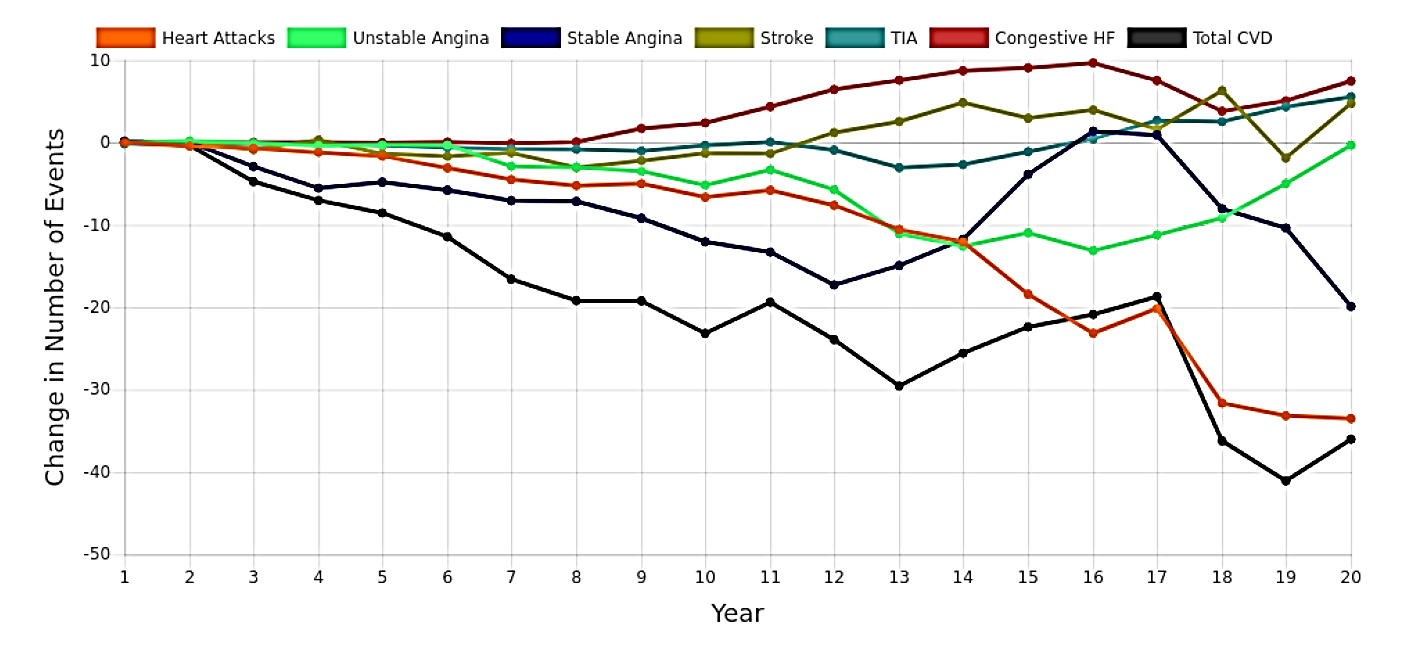
# Appendix 2 – Cumulative CVD events avoided over time

(Taken from the PHE Return on investment online toolkit.)

The PDF below and the chart shows the cumulative CVD events avoided by LLR STP by achieving a 25% diagnosis of FH in the next 3 years.

**Leicester, Leicestershire and Rutland STP**





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| --- | --- |
| Appendix 3 – Estimated FH population - 1 in 250 |  |
| Using assumed FH prevalence population and 5% already diagnosed rate | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |  |  |  |  |  |
| **STP name** | **Total Population  March 2017** | People identified by database search without a current diagnosis of FH | **Additional 20% undiagnosed FH patients to be diagnosed by March 2023** | Uptake of clinical assessment among people identified by database search (55%) | People with a positive clinical diagnosis for FH are referred for DNA testing (63%) | People who have the diagnosis confirmed by DNA testing (39%) | Average number of relatives per person diagnosed with FH (222%) | Uptake of DNA testing among relatives of people with a confirmed diagnosis of FH (60%) | Relatives who have a diagnosis confirmed by DNA testing (50%) | **Total DNA diagnosis** |
| LEICESTER, LEICESTERSHIRE AND RUTLAND STP | 4,461 | 4,238 | **892** | 2,331 | 1,468 | **573** | 1,271 | 763 | **381** | **954** |
| **EAST MIDLANDS** | **19,044** | **18,092** | **3809** | 9,950 | 6,269 | **2,445** | 5,428 | 3,257 | **1,628** | **4,073** |

# Appendix 4 – FH Pathway



1. The NHS Long Term Plan 2019 [www.longtermplan.nhs.uk](http://www.longtermplan.nhs.uk) [↑](#footnote-ref-1)
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