



OUTLINE BUSINESS CASE

T13/T18 & NON-INVASIVE PRENATAL TESTING IMPLEMENTATION IN SCOTLAND

DOCUMENT CONTROL

Key Personnel

[Text redacted]

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Distribution

[Text redacted]

Glossary

The following terms appear throughout this document and its related attachments:

cffDNA	Cell free fetal DNA
CMO	Chief Medical Officers
ISD	Information Services Division
NES	National Education for Scotland
NHS	National Health Service
NIPT	Non-invasive Prenatal Testing
NNMS	National Network Management Service
NSD	National Specialist and Screening Services Directorate
NSS	National Services Scotland
NSSC	National Specialist Services Committee
PCF	Procurement Commissioning and Facilities
PHI	Public Health and Intelligence
SG	Scottish Government
SGHSCD	Scottish Government Health and Social Care Directorates
SGLC	Scottish Genetic Laboratory Consortium
SSC	Scottish Screening Committee
T13	Trisomy 13 (also known as Edwards syndrome)
T18	Trisomy 18 (also known as Patau syndrome)
UK NSC	United Kingdom National Screening Committee

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A. EXECUTIVE SUMMARY

This Business Case is in response to a request from the Scottish Government (SG) and the Scottish Screening Committee (SSC) to complete an Outline Business Case to advise Scottish Ministers of the options for NHSScotland to implement UK National Screening Committee (NSC) recommendations.

This document discusses the current position of Non-invasive Prenatal Testing (NIPT), Edwards syndrome testing and Patau syndrome testing in Scotland and evaluates the available scenarios to deliver them across NHS Scotland. As part of quantifying the cost and impact of any implementation, the method and supporting environment required are considered and confirmed as a part of the recommended scenario.

Non-invasive Prenatal Testing (NIPT) can identify pregnant women who are at higher chance of having a baby with certain genetic and chromosomal conditions. The test detects DNA fragments in a sample of blood taken from the mother and carries no risk of miscarriage. NIPT is not currently offered within NHS Scotland. In January 2016 the UK NSC recommended an evaluative implementation of NIPT as an additional test into the pregnancy screening programme.

Edwards' Syndrome (Trisomy 18) and Patau's syndrome (Trisomy 13) are rare but very serious conditions which affect a small number of babies every year. In June 2014 the UK NSC recommended that screening for both Edwards' and Patau's syndrome should be offered in the first trimester as an extension of the Down's syndrome screening programme.

The implementation of NIPT and T13/T18 testing is dependent on three key areas to ensure a successful delivery:

- **Agreeing optimal laboratory setup to minimise costs and ensure standards**
- **Training and support available to staff and associated supporting documentation**
- **Data capture and analysis in support of all implementation activity**

[Text redacted]

In order to deliver each of the above, a programme of work will be carried out and overseen by National Services Division and reporting via an Expansion of pregnancy screening Steering Group into the SSC.

[Text redacted]

B. THE STRATEGIC CASE

PURPOSE

The purpose of this business case is to define the cost of amending existing pregnancy screening pathways and testing processes to include Patau's syndrome (Trisomy 13) and Edwards' syndrome (Trisomy 18) testing as an extension of the first trimester Down's syndrome (Trisomy 21) screen and Non-invasive Prenatal Testing (NIPT) as a 2nd line screening option for Trisomies 13,18 and 21 across Scotland.

INTRODUCTION

1.1 PREGNANCY SCREENING PROGRAMME

The Pregnancy Screening Programme in Scotland identifies mothers and babies who may have rare but serious conditions. Most mothers and babies screened will not have any of the conditions but for the small numbers that do, the benefits of screening are significant. Early identification and treatment can improve their health and prevent severe disability or even death or offer reproductive choice.

There are two types of test offered within the programme:

- Screening tests, which are offered to everyone, and are intended to show whether there is a chance both mother and baby may have a condition.
- Diagnostic tests, which are further tests that may be carried out depending on the results of the screening test, to confirm what, if any, problem there may be.

At present, all pregnant women in Scotland are offered screening for Down's syndrome either in the first trimester (11⁺² -14⁺¹ weeks gestation) or second trimester (14⁺²-20⁺⁰ weeks gestation). If results indicate that the pregnancy is at a higher (more than a 1 in 150) chance of having a baby with Down's syndrome women are then offered follow-up diagnostic tests (amniocentesis or chorionic villus sampling). These diagnostic tests can confirm whether the baby will have Down's syndrome but they are invasive and carry a small (generally quoted as 1-2%) risk of miscarriage.

1.2 PATAU'S SYNDROME (TRISOMY 13) & EDWARDS' SYNDROME (TRISOMY 18)

Edwards' Syndrome (Trisomy 18) and Patau's syndrome (Trisomy 13) are rare but very serious conditions which affect a small number of babies every year. Like Down's syndrome they are caused by the baby having an extra copy of chromosome 13 or 18. Most babies will die before they are born or shortly after birth. Some babies may survive to adulthood but this is rare. If they survive it is difficult to say how serious the effects will be before the baby is born. However, all babies born with Edward's Syndrome and Patau's Syndrome will have a wide range of problems, which are usually extremely serious. These may include major brain abnormalities, heart problems, unusual head and facial features, growth problems, mobility and speech problems and problems with their kidneys.

- Edwards' syndrome affects about 3:10,000 births
- Patau's syndrome affects about 2:10,000 births

Most babies with Patau or Edwards' syndrome will have the full form, where every cell in their body has three copies of chromosome 13 or 18, instead of two. About 5-10% of these babies will have the extra copy of chromosome 13 or 18 in only some of their body cells. This less severe form of the disease is known as mosaic trisomy 13 or 18. The severity of mosaic trisomy 18 depends on the type and number of cells that have the extra chromosome. Some babies may only be mildly affected, while some can be severely disabled. Around seven in every 10 babies born with mosaic

trisomy will live for at least a year and, in rare cases, babies with the condition may survive into early adulthood.

At present, no testing is currently offered for either Patau or Edwards syndrome within the NHS Scotland Pregnancy Screening Programmes.

1.3 NIPT

Non-invasive Prenatal Testing (NIPT) can identify pregnant women who are at higher chance of having a baby with certain genetic and chromosomal conditions, such as Down's syndrome (Trisomy 21), Edwards' syndrome (Trisomy 18) and Patau's syndrome (Trisomy 13).

The test detects DNA fragments in a sample of blood taken from the mother. Most of the DNA fragments are from the mother but some are from the unborn baby; these fragments are called cell free fetal DNA (cffDNA). cffDNA is detectable from around 7 weeks of pregnancy and the amount of detectable DNA is thought to rise as the pregnancy continues. The test carries no risk of miscarriage. NIPT is not currently offered within NHS Scotland.

NIPT for Down's syndrome screening has been available through the private sector as a primary screen since 2012, with costs ranging from £300-£600 per test.. The availability of NIPT in the private sector has led to inequalities in screening choices available to women in Scotland on the basis of ability to pay. Concerns about counselling inadequacies in relation to the test within the private sector have also increased the demand that it should be made available within the NHS as soon as possible.

1.4 DATA COLLECTION AND ANALYSIS

[Text redacted]

Across NHS England, data collection (using excel templates) is completed to allow data analysis and publications on pregnancy screening activity on a regular basis. No such activity is currently undertaken for pregnancy screening within NHS Scotland.

[Text redacted] the need to develop a national data collection strategy for pregnancy and newborn screening has been identified to facilitate service, operational and strategic planning across NHS Scotland in support of the implementation.

ORGANISATIONAL OVERVIEW

1.5 NATIONAL SPECIALIST AND SCREENING SERVICES DIRECTORATE

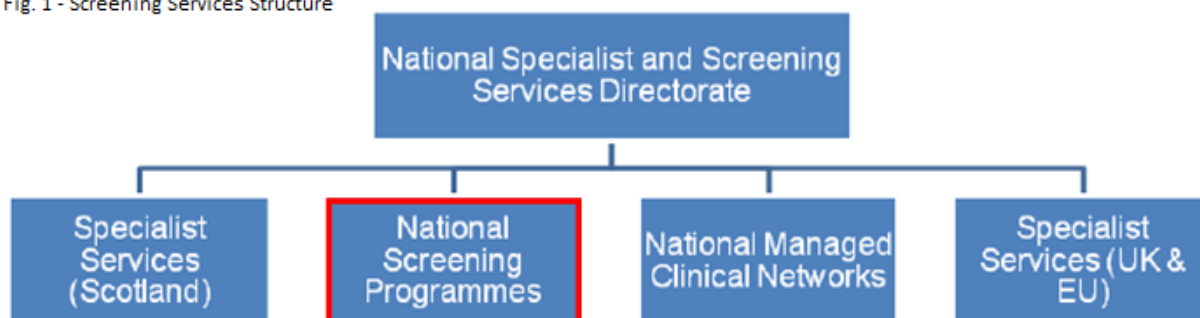
National Specialist and Screening Services Directorate (NSD) sits within the Procurement Commissioning and Facilities (PCF) Strategic Business Unit of NHS National Services Scotland.

Each year, NSD receives top-sliced, ring-fenced funding from the Scottish Government Health and Social Care Directorates (SGHSCD) to commission, co-ordinate and performance manage nationally designated specialist services and screening programmes. NSD seeks to be valued as a trusted partner within NHS Scotland that enables and supports transformation in the health and wellbeing of all the people of Scotland by ensuring the provision of high quality, effective, specialist health and screening services to meet the needs of the population of Scotland. In addition, National Managed Clinical and Diagnostic Networks are supported by NSD through the National Network Management Service (NNMS).

NSD develops service agreements with each nationally commissioned service which cover service specifications, quality standards and activity expectations. There are also regular meetings

between clinical and management personnel from NSD and the services to discuss quality, audit, clinical outcome and specific service issues.

Fig. 1 - Screening Services Structure



1.6 NATIONAL SCREENING PROGRAMMES

All national screening programmes sit within NSD. This includes:

- Abdominal Aortic Aneurysm Screening
- Bowel Screening
- Breast Screening
- Cervical Screening
- Diabetic Retinopathy Screening
- Newborn Blood Spot Screening
- Pregnancy Screening
- Universal Newborn Hearing Screening

Screening programmes are designed to identify apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests, and appropriate treatment to reduce their risk and/or any complications arising from the disease or condition or reproductive choice. Screening policy is set by the Scottish Government Health Directorates on the advice of the UK National Screening Committee (UK NSC) and other appropriate bodies. NSD helps to ensure consistent, effective, coordinated national screening programmes for the people of Scotland.

The pregnancy screening programme is supported by two laboratories. At present the NHS Lothian laboratory completes all 1st trimester screening programme analysis, and the 2nd trimester testing is delivered by an NHS England laboratory based in Bolton.

UK NSC RECOMMENDATIONS

The UK National Screening Committee (UK NSC) advises ministers and the NHS in the four UK countries about all aspects of population screening and supports implementation of screening programmes.

The UK NSC is an independent committee that:

- advises Ministers and the NHS in the four UK countries about all aspects of screening including the case for introducing new population screening programmes and for continuing, modifying or withdrawing existing population programmes against a set of internationally recognised criteria
- supports implementation of screening programmes in the four countries including the development of high level standards and maintains oversight of the evidence relating to the balance of good and harm as well as the overall cost effectiveness of existing programmes
- works with partners to ensure it keeps abreast of scientific developments in screening, including screening trials, screening policy in other countries and emerging technologies

- is accountable to the four chief medical officers (CMOs), who agree work plans for the UK NSC on an annual basis

The Scottish Screening Committee (SSC) is established to consider the advice and recommendations of the UK NSC, and to take a view on how recommendations should be implemented in Scotland. The SSC then reports to Scottish ministers.

1.7 TRISOMY 13/ TRISOMY 18 RECOMMENDATIONS

In June 2014 the UK NSC recommended that screening for Edwards' syndrome (Trisomy 13) and Patau's syndrome (Trisomy 18) should be offered in the first trimester as an extension of the Down's syndrome screening programme; this was fully implemented in NHS England by March 2016. In NHS Scotland a decision to proceed awaited the setup of the SSC. Once established the SSC prioritised the change for consideration and progression.

1.8 NIPT RECOMMENDATIONS

In January 2016 the UK NSC recommended an evaluative implementation of NIPT as an additional test into the pregnancy screening programme. The evaluation aims to answer the specific questions raised by the UK NSC around behavioural choice, test accuracy for T18/T13, test failure rate and turnaround time for results to be processed by laboratories and returned to patients. It is proposed that the evaluation period will take a minimum of 3 years. This approach will enable continuous evaluation of the implementation ensuring that required changes can be made efficiently and effectively. If necessary the UK NSC would also be able to make a recommendation to cease use of NIPT as part of the screening pathway.

Whilst NIPT is considered to be more accurate than the current screening tests it is not diagnostic and if the result still shows the pregnancy to be at higher chance of being affected by the condition being screened for, then diagnostic testing should still be offered. The research commissioned by the UK NSC into the case for offering NIPT concluded that its introduction could result in the number of invasive tests in the UK falling from an estimated 7,900 to 1,400 each year and the number of miscarriages related to invasive tests would fall from around 46 to 3. The work done by the UK NSC also suggested that the reduced number of invasive tests would release sufficient funds to cover the costs for the new test making it cost neutral to the NHS once implemented.

NHS Wales is working towards a combined implementation of T13/T18 testing and NIPT in Spring 2018. NHS England is planning to introduce NIPT as an additional screening test from Autumn 2018.

The recommendation to proceed with NIPT has proved controversial with some individuals and groups including the Down's Syndrome Society expressing concerns regarding the ethics in the use of NIPT in the NHS as it could lead to an increase in the number of terminations following a diagnosis of Down's, Edwards' or Patau's syndrome. As such the Nuffield Council on Bioethics were commissioned to produce a report to consider the ethical, legal and regulatory implications of recent and potential future scientific developments in NIPT, with regard to its use in both NHS and private services. Their report¹ was published on 1st March 2017 and concluded that women and couples should be offered NIPT, but only within an environment that enables them to make autonomous, informed choices.

1.9 RATIONALE

The rationale behind the development of this business case is to ensure the screening service delivered across NHS Scotland aligns with UK NSC recommendations and patients in Scotland have access to screening opportunities reflected across the UK. Aligning with

¹ Non-invasive prenatal testing: ethical issues. Nuffield Council on Bioethics (2017)

the recommendations detailed above will ensure the service continues to provide a high quality service, improving the experience of patients nationally and ensuring clinical standards are maintained.

STRATEGIC DRIVERS

In addition to the above rationale, there are a number of strategic drivers that the proposed implementation directly aligns with.

2020 Vision - In 2011, the Scottish Government set out its strategic vision for achieving sustainable quality in the delivery of healthcare services across Scotland, in the face of the significant challenges of Scotland's public health record, changing demography and the economic environment.

The implementation proposed in this document directly relates to the Vision:

“Whatever the setting, care will be provided to the highest standards of quality and safety, with the person at the centre of all decisions”.

With the introduction of T13/T18 testing and NIPT, the number of patients being enabled to make informed choices will increase, and the delivery of NIPT as a non-invasive test will ensure the screening programme is delivered safely and to the highest quality standards.

Health and Social Care Delivery Plan – In December 2016, the Scottish Government published the Health and Social Care Delivery Plan with the aim of setting out the framework and actions needed to ensure that our health and social care services are fit to meet the challenges of our changing society.

Within that plan, the emphasis was placed on the “triple-aim”:

- we will improve the quality of care for people by targeting investment at improving services, which will be organised and delivered to provide the best, most effective support for all (**'better care'**);
- we will improve everyone's health and wellbeing by promoting and supporting healthier lives from the earliest years, reducing health inequalities and adopting an approach based on anticipation, prevention and self-management (**'better health'**); and
- we will increase the value from, and financial sustainability of, care by making the most effective use of the resources available to us and the most efficient and consistent delivery, ensuring that the balance of resource is spent where it achieves the most and focusing on prevention and early intervention (**'better value'**).

The implementation proposed in this document can be considered to fall under all 3 aims:

- Better Care – the expansion of the screening service to include the T13/T18 testing
- Better Health – informed choice to allow for better anticipation of the needs of newborns
- Better Value – the changes being delivered on a cost effective basis across the service

In addition to the above, the Scottish Government also has a duty to provide disabled people with high quality specialist health and social care and to tackle discrimination, exclusion and negative societal attitudes experienced by disabled people. Therefore any expansion of the existing

screening programme in Scotland will take the findings of the Nuffield Council Report on NIPT² into consideration.

OBJECTIVES

In line with both the rationale and the strategic drivers described above, the objectives targeted by the proposed amendment to the screening service are the following:

NHS Scotland Quality Ambitions	Objective This Proposal
Person Centred	Improve patient experience through less invasive testing
Safe	To ensure the programme maintains highly skilled staff to support the delivery of high quality patient service.
	To provide a high quality service to all women through maintaining all external and internal quality assurance
	To provide a high level of support and counselling to patients as an integral part of screening activity
Effective	To provide screening services that are clinically effective and sustainable over the long term

In order to meet each of the above objectives, the implementation aims to provide the following to the screening service or in supporting activities strengthening its delivery nationally:

- T13/T18 screening as a part of the first trimester screening service across Scotland
- NIPT as a 2nd line screening service across Scotland
- Comprehensive training and support to staff in support of implementation
- Quality training materials and documentation
- Agreed standards to which the laboratory process will adhere to
- Implementation plan for delivery of revised testing and screening services
- Data requirements to enable robust monitoring of new service delivery

The approach to delivering each of the above is described in more detail in sections 7/8 below.

REVISED PATIENT PATHWAY

The diagrams below illustrate the proposed pathway for patients throughout pregnancy screening following the successful implementation of both T13/18 testing and NIPT. The proposed changes from the current pathway are highlighted in red in Fig. 1 below. The proposed pathway allows for the patient to choose between testing for Patau/Edwards (T13/18) and/or Down's syndrome (T21). Where the initial screening indicates a higher risk the patient would then discuss options with their clinician and proceed to the next phase described in fig. 1.

² Non-invasive prenatal testing: ethical issues, Nuffield Council on Bioethics

Fig. 2 - Revised patient pathway following implementation

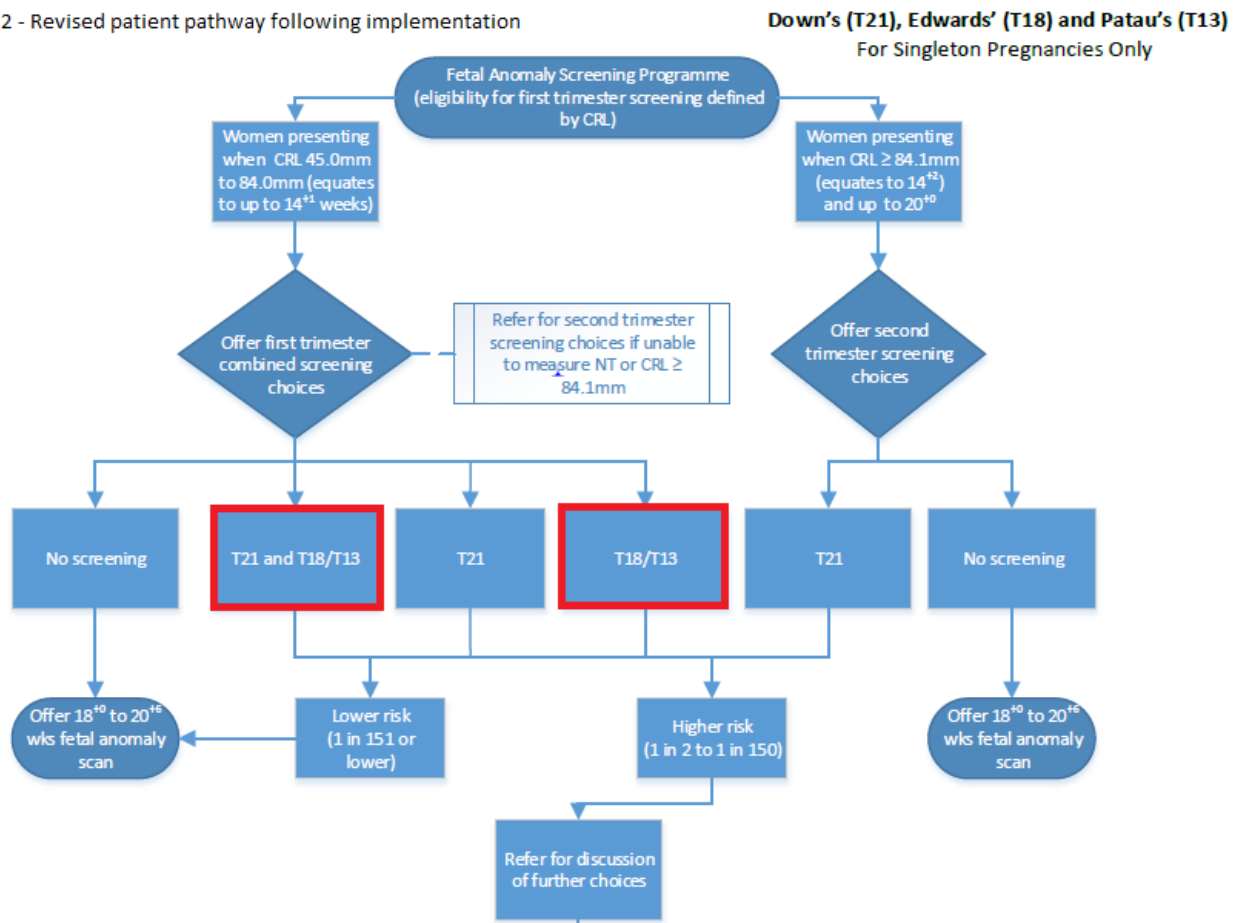
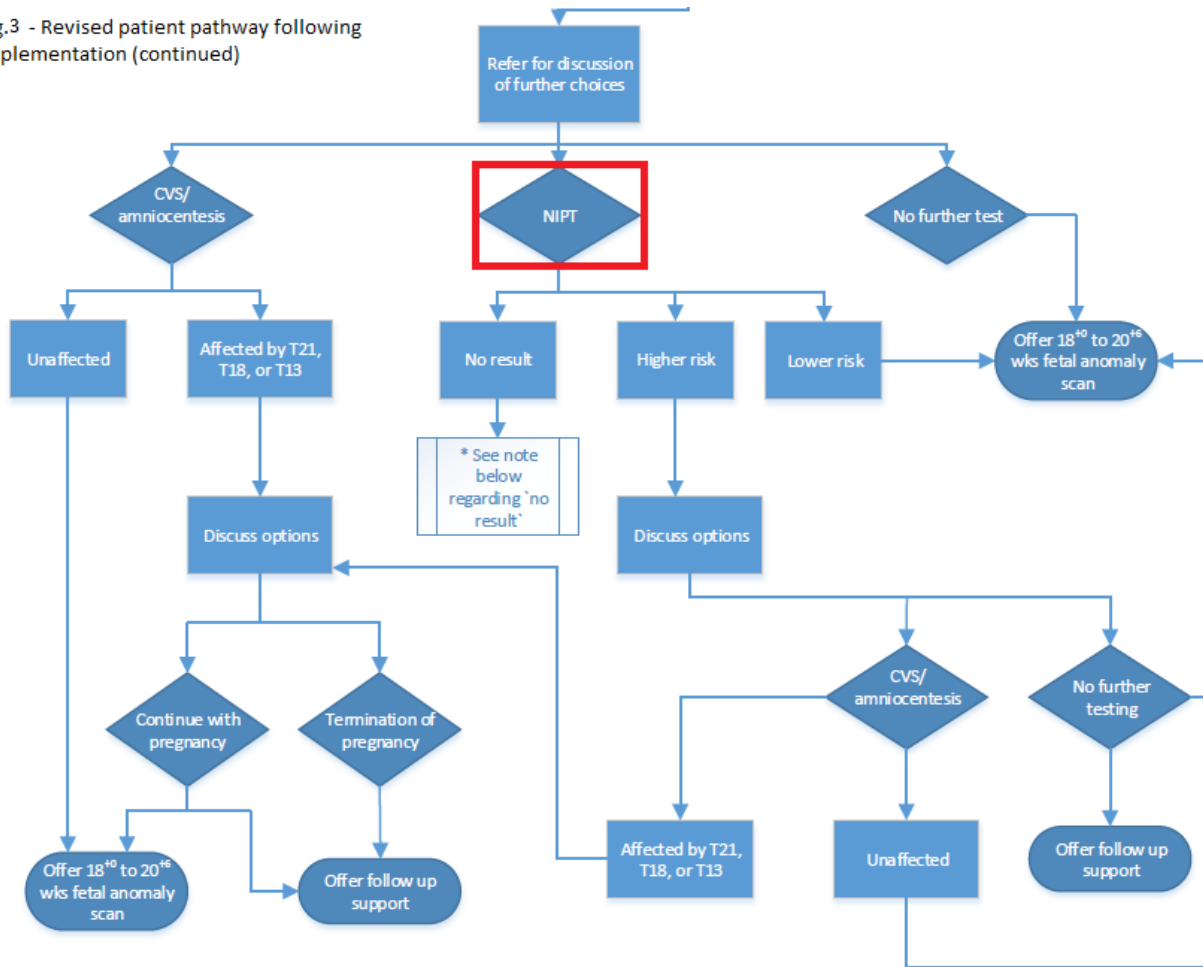


Fig. 2 below continues the pathway from the initial screening above and highlights the pathway for the newly available NIPT. At present within NHS Scotland, patients are asked to choose between the invasive tests or no further testing. The introduction of NIPT at this stage in the process is anticipated to attract a majority of patients through the non-invasive testing route, and later in the process where a diagnosis of a condition is required, the invasive testing option is then re-introduced.

The lack of NIPT within NHS Scotland's current screening service has led to a number of patients accessing NIPT through the private sector.

Fig.3 - Revised patient pathway following implementation (continued)



* In cases where 'no result' obtained from initial NIPT, offer of one further NIPT, CVS/amniocentesis or no further testing to be made. Please return to relevant points in the pathway. In cases where 'no result' obtained a second time, follow 'Higher risk' NIPT result.

In order to deliver the service described in the figure above, a range of changes will be required and these are covered in detail in section 8 below.

SCOPE, DEPENDENCIES, ASSUMPTIONS AND CONSTRAINTS

1.10 SCOPE

The scope of the proposed implementation is defined below:

All NHS Scotland Boards to offer T13/T18 testing

The expansion of the screening service provides the following choices for women undergoing first trimester screening:

- to choose not to have screening or
- to choose screening for T21 and T18 / T13
- to choose screening for T21 only
- to choose screening for T18 / T13 only.

All NHS Scotland Boards to offer NIPT as a 2nd line screening service

The UK NSC recommend that NIPT should be offered to pregnant women whose chance of having a baby with Down's, Edwards' or Patau's syndrome is greater than 1 in 150 as an alternative to the currently available invasive tests.

Change to the patient screening pathway

As shown in figures 2 and 3 in section 7 above, the patient pathway will change to reflect the availability of T13/T18 testing and NIPT following the initial screen.

The environment for delivery of NIPT to ensure all patients are able to make autonomous, informed choices and are fully supported

The Nuffield Council on Bioethics² were commissioned to produce a report to consider the ethical, legal and regulatory implications of recent and potential future scientific developments in NIPT, with regard to its use in both NHS and private services. Their report was published on 1st March 2017. The Report concluded that women and couples should be offered NIPT, but only within an environment that enables them to make autonomous, informed choices.

Given the above, the introduction of NIPT across NHS Scotland will be accompanied by high quality education and training for all NHS healthcare professionals involved in prenatal screening to facilitate accurate, balanced and non-directive information for women and couples about NIPT and the conditions for which it tests.

In addition a range of supporting documentation and leaflets will be developed for sharing with patients.

All completed NIPT & T13/T18 tests to be processed and analysed via recommended laboratory process in line with UK standards

This includes but is not limited to the turnaround time of results from receipt of sample in the laboratory, meeting throughput requirements, adherence to data standards and reporting requirements and participation in national external quality assurance and national audit.

In order to deliver the above, the implementation will be dependent on three key areas to ensure a successful delivery:

- **Agreeing optimal laboratory setup to minimise costs and ensure standards can be met**
- **Training and support available to staff and associated supporting documentation**
- **Data capture and analysis in support of all implementation activity**

1.11 OUT OF SCOPE

The potential introduction of NIPT as a primary screen is considered out of scope. The UK NSC recommendation acknowledged the potential for NIPT to replace the current screening tests in the future. It concluded, however, that at the time of the initial study, it would not be cost-effective and the number of inconclusive tests would mean that more women would be offered invasive testing than the current screening models.

Analysis and reporting will be confined to the common fetal aneuploidies. The identification of other conditions and fetal sex are considered out of scope.

The oversight and standards expected from NIPT delivery in the private sector is considered out of scope for the implementation.

1.12 DEPENDENCIES

The realisation of the preferred scenario detailed in this business case is dependent on:

- The approval of this business case by Scottish Screening Committee (SSC) in November 2017
- Subsequently ministerial approval to proceed to implementation
- The identification of necessary funding to allow implementation activity to proceed in early 2018
- The additional resources required to support implementation being recruited in a timely manner
- The release of NHS Board resources to attend training and support implementation

1.13 ASSUMPTIONS

There are a number of assumptions underpinning the preferred scenario for implementation as outlined in this business case:

- Any successful implementation will be completed in line with the recommendations within the Nuffield report i.e. only within an environment that enables patients to make autonomous, informed choices.
- The evaluative rollout of NIPT endorsed by UK NSC will continue after the initial 3-year period
- Staff across NHS Scotland will fully engage with the proposed changes and cascade training/knowledge where possible
- NHS National Education for Scotland (NES) have the capability to provide the necessary training services in line with timescales
- NHS National Services Scotland Information Services Division (ISD) have the capability to provide the necessary data analytical services in line with timescales
- Laboratories within NHS Scotland are able to adapt to deliver NIPT analysis in line with UK standards and cost expectations, or an alternative NHS laboratory is sources that can provide this service to the standard required.

1.14 CONSTRAINTS

The realisation of the preferred scenario outlined in this business case is associated with the following constraints:

- Availability of resource at board level to support implementation activities

STRATEGIC RISKS

Risk	Approach to mitigation
There is a risk that as the implementation is considered “evaluative” by UK NSC, it could be stopped	Acceptance. Continue to monitor NIPT implementation across UK and UK NSC approach to evaluation.
There is a risk that the implementation will impact several NHS Scotland budgets	Reduction. Ensure necessary budget holders are engaged prior to implementation to ensure necessary controls are in place to manage impact.
There is a risk that the implementation of NIPT will be negatively received given a perception of it normalising a path to terminations	Avoidance. Ensure that the approach to implementation closely aligns to the recommendations of the Nuffield Council Report. Engagement with wide group of stakeholders to ensure buy-in across all levels is appropriate and approach being taken minimises potential risk. Communications group to be setup to address concerns and communicate with stakeholders and patients directly.

BENEFITS CRITERIA

The following criteria have been identified in conjunction with stakeholders from across Scotland and capture the key anticipated benefits of the introduction of the preferred scenario.

Stakeholder	Benefits
Patient	<ul style="list-style-type: none"> Reduced number of invasive tests Reduced number of invasive test related miscarriage A more sensitive and specific screening pathway with less unaffected pregnancies being given a higher chance result reducing patient anxiety. Better support available throughout the screening journey Improved supporting documentation for the screening journey
NHS Boards	<ul style="list-style-type: none"> Improved clinical effectiveness – reduction in invasive testing Reduced laboratory costs from reduction in invasive testing Staff resource released from reduction in invasive testing Improved support mechanisms available to patients throughout screening journey Improved training approach and materials for staff

The benefits management and assessment will be taken forward by the identified Programme team during and following the implementation of the preferred solution.

CRITICAL SUCCESS FACTORS (CSFs)

This business case outlines the preferred scenario for delivering the T13/18 and NIPT into the screening service. The achievement of the service objectives will be gauged against a number of Critical Success Factors pertinent to the change to the service offering:

Nationally available with standards - Provision across NHS Scotland is to an agreed set of standards and in line with NHS England and NHS Wales service levels. The service is consistent across NHS Scotland with delivery mechanisms taking account of local differences and expertise.

Well informed – The development and introduction of data capture is completed to ensure monitoring and reporting on the service offering is of a high-standard.

Highly visible – The data captured and used to ensure quality standards are met and regular reports will be published to provide access to data previously unseen.

Provided by qualified specialists - The pregnancy screening service has access to a range of qualified specialists, and they will be supported and developed as necessary to complete revised screening approach and provide appropriate support and advice to patients.

Prompt and rapid - The screening service provides timely response times to ensure patients receive feedback from all testing results in a timely manner and delays are minimised throughout the screening journey.

C. THE ECONOMIC CASE

PURPOSE

The usual process for developing a business base within the public sector is to undertake an Initial Agreement (IA), Outline Business Case and then proceed to a Full Business Case. For this document a mandate was provided by Scottish Government to proceed with an Outline Business Case in order to achieve a timely evaluation of the preferred scenario. As a result the focus of the Economic Case is to compare the preferred approach to implementation to the “Do Nothing’ scenario’, and to provide assurance that proceeding with implementation represents value for money.

BUSINESS OPTIONS

As highlighted in section 8.2 above, the successful implementation of T13/T18 testing and NIPT is dependent on 3 primary activities:

- Agreeing optimal laboratory setup to minimise costs and ensure standards
- Training and support available to staff and associated supporting documentation
- Data capture and analysis in support of all implementation activity

Each of the above was considered in the context of current activity around the screening programme, and in-line with current responsibilities across NHS Scotland.

[Text redacted]

1.15 DATA CAPTURE AND ANALYSIS

In Scotland as a part of NHS National Services Scotland, Information Services Division (ISD) provides health information, health intelligence, statistical services and advice that support the NHS in progressing quality improvement in health and care and facilitates robust planning and decision making.

[Text redacted]

1.16 TRAINING AND SUPPORT

At present NHS National Education for Scotland (NES) are responsible for supporting NHS services in Scotland by developing and delivering education and training for those who work in NHS Scotland. Given their remit, it was identified that the optimal approach to the training and support of staff for the implementation would best be delivered by NES drawing on their experience and knowledge to best shape the delivery and approach to cascading across Scotland.

[Text redacted]

1.17 LABORATORY SETUP

[Text redacted]

SHORTLIST

1. Do nothing option

Given the intention of this document to quantify the delivery of NIPT, this was not considered but would reflect the Status-Quo for operational activity around the screening programme.

2. Preferred Scenario:

The preferred scenario is the provision of this service, delivered by a programme of work to complete implementation with the optimal approach to staff training/education, data capture/analysis and laboratory setup and processing. Each of the 3 approaches identified are described in detail in this section. The programme as a whole will be managed by a Programme team described in more detail in section F below.

2.1 Training and Education

In order for the implementation to be successful nationally, a comprehensive training and education package is necessary to inform and support staff prior to the introduction of any proposed changes. The approach for training will be to provide a range of options for delivery and guidance documents to allow staff the opportunity to engage with the programme and upskill as necessary in advance of the planned implementation. **[Text redacted]**

[Text redacted]

2.2 Data Capture and analysis

[Text redacted]

The costs provided above are for an initial implementation to focus specifically on capturing the data required to understand and evaluate the implementation of NIPT and T13/18 testing nationally. The setup and establishing of this data capture will allow for the future expansion of the data collected to include the pregnancy/newborn screening programmes as a whole. As a part of the initial implementation, ISD recommend that the data being targeted for collection be reviewed every 6-months until considered finalised and comprehensive. This approach will help to ensure the data work is fit for purpose, and the key findings of all data capture are addressed appropriately.

2.3 NIPT Genetics Laboratory approach

[Text redacted]

2.5 Programme Management Resource

In order to deliver the preferred scenario as described above, there is a need to identify additional programme management resource to lead on the implementation. NSD have identified the need for an additional Project Manager and Project Support Officer to complete all activities related to implementation over an 18 month period.

[Text redacted]

The detail of the approach to programme management to be utilised it described in section F below.

Summary of preferred scenario

The table below shows a summary of the costs described for each of the key activities above:

[Text redacted]

D. THE COMMERCIAL CASE

PURPOSE

The purpose of the Commercial Case is to outline the proposed commercial arrangements and implications for the implementation. This business case relates to an expansion of the existing screening service so there are limited procurement implications that would be applicable to this section.

LABORATORY TENDER PROCESS

[Text redacted]

E. THE FINANCIAL CASE

PURPOSE

The purpose of this section is to outline the funding arrangements of the implementation and ongoing pregnancy screening service necessary for the implementation of the recommended scenario.

FUNDING ARRANGEMENTS

[Text redacted]

F. THE MANAGEMENT CASE

PURPOSE

The purpose of the Management Case is to set out the arrangements that should be put in place to implement the recommended scenario.

The proposed programme approach and associated governance structure is described to enable the implementation and to monitor and support the work going forward. The proposed solution will be co-ordinated by a programme team within NSD and implemented by teams from across NHS Scotland.

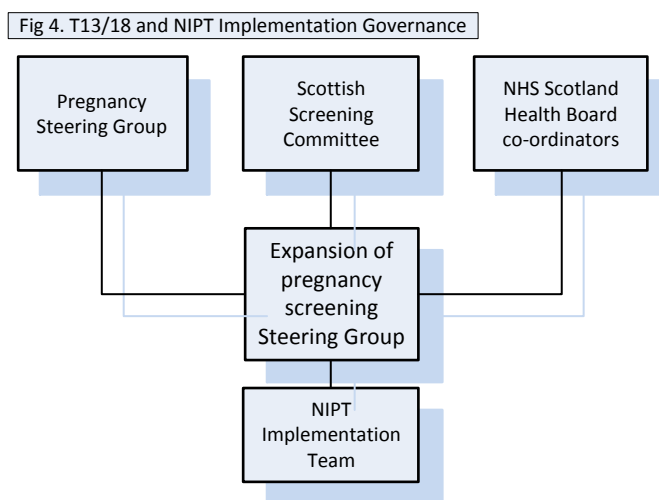
The recommended scenario envisages an expansion of the current service offering for the pregnancy screening programme but not require an increase in staffing levels to deliver the new service. As such the responsibility for the ongoing management of the service will continue as present.

PROJECT MANAGEMENT

The recommended scenario will be implemented in line with the PRINCE 2 methodologies and other best practices as used by NHS NSS. Regardless of the methodology used, the project will work to meet the expectations of stakeholders.

GOVERNANCE, ROLES AND RESPONSIBILITIES

The proposed governance arrangements in support of the implementation are set out in Fig. 4 below:



Implementation will be carried out by an implementation team residing within NSD. The team will be made up of the following resources, and will be in place for the duration of the implementation to co-ordinate and oversee the completion of all proposed activities.

- Senior Programme Manager – Existing resource within NSD
- Project Manager – 1.0 WTE
- Project Support Officer – 1.0 WTE

For aspects of quality assurance and governance, an Expansion of pregnancy screening Steering Group will be established to oversee the implementation drawing on a range of stakeholders from across NHS Scotland. The Steering Group will also report to the Scottish Government and to the Scottish Screening Committee to ensure stakeholders remain apprised of progress.

In addition, a communications and education group will be setup alongside the Steering Group to lead on the communications with all stakeholders and develop and refine the supporting materials required to successful complete the implementation.

The roles and responsibilities already assumed by organisations and individuals providing the pregnancy screening service will remain as is.

IMPLEMENTATION PLAN

A high level implementation plan for the recommended scenario is displayed in Fig 5 below. The timelines displayed should be considered indicative at this stage. The true timeline for implementation of the recommended scenario will be planned in detail as part of the initiation work of the implementation team once resources have been identified. It is anticipated that the work of the implementation would take between 12 and 18 months to complete.

RISK MANAGEMENT

Risks associated with implementing the recommended scenario will be directly managed by the Implementation team and escalated to the Steering Group as necessary.

Risks identified at a local level following implementation will fall under existing risk management processes at Board level.

Fig. 5 - Timeline and Implementation Plan

	2017/18			2018/19											
	Q4			Q1			Q2			Q3			Q4		
	Ja n	Fe b	Ma r	Ap r	May	Ju n	Ju l	Au g	Sep t	Oc t	Nov	De c	Jan	Fe b	Ma r
Implementation Team established	■	■	■												
Data requirements and templates confirmed			■	■	■	■									
Initial data capture completed						■	■								
Review of data and approach completed								■	■	■					
Communications group established			■	■											
Supporting documentation drafted and distributed				■	■	■	■	■	■	■	■	■			
Creation of training modules/materials				■	■	■	■	■	■	■	■	■			
Training delivery to key staff													■	■	■
Cascade of training locally begins									■	■	■	■			
Laboratory Tender process				■	■	■	■	■	■	■	■				
Laboratory setup completed											■		■	■	
Go-Live															■



POST PROJECT/CHANGE EVALUATION

This section aims to provide reassurance that a thorough and robust post-project evaluation will be undertaken by the Implementation team. The purpose of the post-project evaluation is twofold:

- Improve project appraisal at all stages of the project
- Appraise whether the project has delivered its anticipated improvements and benefits, post implementation review

The Programme will be considering the effectiveness of the project and the interlinked implementation of the recommended scenario to determine whether the original objectives have been achieved. The team will be identifying particular aspects of the project which have affected the benefits either positively or negatively, from which recommendations for future projects will then be derived.

Through analysis of the data within the ISD data capture proposal, benefits realisation can be monitored. At the end of the evaluative stage of implementation, consideration needs to be given to ongoing evaluation from at least six months after implementation and annually thereafter. The purpose of the evaluation is to reflect the Scottish position as a part of the UK evaluative roll-out and ensure agreed standards are met and benefits realised. The evaluative period will operate until confirmation from NSC on the best approach for business as usual moving forward.

The post-project evaluation process will bring to the fore the lessons learned for the future which will be fed into future decision making.

G. RECOMMENDATIONS

[Text redacted]

APPROVALS

Bid submitted by:		Date:
Bid approved by:		
Divisional Finance:		Date:
Corporate Finance:		Date:
Divisional Director / Head of Service:		Date:
HR (for Staffing impact only):		Date:
HIT (for IM&T bids only):		Date:
Chief Executive:		Date:

Appendix 1 – Business Case for the Delivery of Non-Invasive Prenatal Testing (NIPT) for NHS Scotland: On Behalf of the Scottish Genetic Laboratory Consortium

[Text redacted]