June 2023

NHS AND CORONIAL SERVICE SUDDEN UNEXPECTED DEATH PROGRAMME EVALUATION

BRIGHTPURPOSE

British Heart Foundation

INTERIM REPORT

CONTENTS

GLOSSARY OF TERMS

First degree relative: a person's biological parent, sibling or child.

Index case: first individual in a family diagnosed with an inherited cardiac condition (ICC). In the context of this programme, the deceased person is often but, not always, the index case.

Signposting: this term is used when a letter is sent from a coronial service to the ICC service about a deceased index case. The letter will include the contact details of the first-degree living relative(s) to allow the ICC Coordinator to arrange an initial assessment.

EXECUTIVE SUMMARY

The NHS-C-SUD programme is a service improvement programme to ensure that families bereaved due to an inherited cardiac condition (ICC) have equitable and rapid access to the regional NHS ICC clinic. This facilitates clinical and, where appropriate, genetic assessment of the living first-degree relatives. The intended impact is to reduce further preventable and premature sudden deaths in the same family.

Rationale

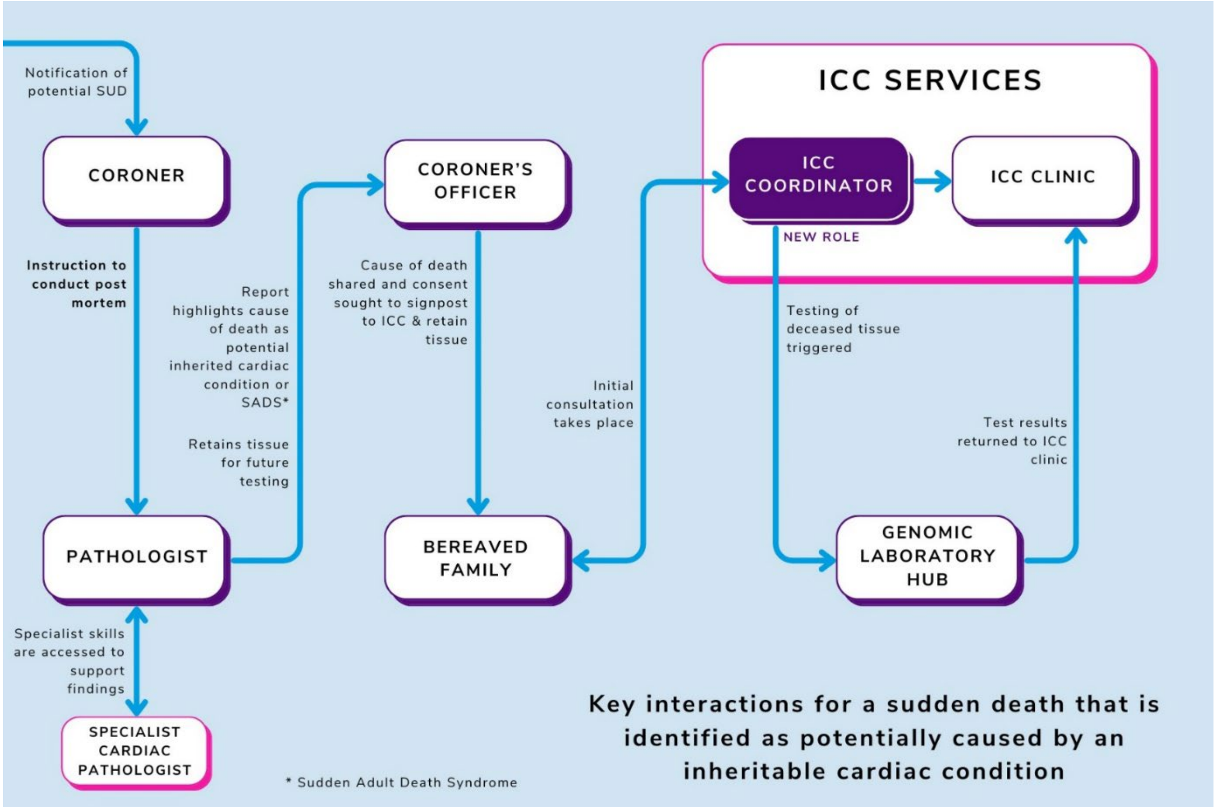
Cardiac pathology, post-mortem genetic testing and clinical family evaluation are the three primary components of the comprehensive personalised medical management of families who have suffered sudden unexpected deaths (SUD) and where an inherited cardiac condition is suspected to be the cause of death.

However, the delivery of appropriate patient pathways is highly variable across England and requires closer working between the NHS and the coronial service. The latter is governed by the Ministry of Justice and typically funded by local authorities and local police forces.

To address the variation in access to ICC services, a new national transformation project, the NHS and Coronial Sudden Unexpected Death Programme, was set up to improve the patient pathway for families following a sudden cardiac death. The programme focusses on the referral pathway between the coronial services and the ICC services.

The new pathway

The new pathway is shown overleaf:



Key interactions for a sudden death that is identified as potentially caused by an inheritable cardiac condition

It is being piloted in seven coronial jurisdictions in England. Each pilot site is located within one of the seven Genomic Medicine Service Alliance (GMSA) regions within NHS England.

The most significant changes introduced with the new pathway are a consistent approach to the following:

- The post mortem examination including examination of the heart by a specialist cardiac pathologist.
- Capturing consent from next of kin to retain tissue from the deceased index case (for DNA extraction), using a standard consent form within the coronial service
- Retention, labelling and storage of tissue (for DNA extraction) from the deceased index cases
- Families being signposted to the ICC services whereby the Coroner's Officer sends a letter, based on a standardised template, to the ICC service clinic
- Coordination of families signposted by the coronial services, through the appointment of an ICC Coordinator within existing ICC services

- Training of Coroners' Officers so that they can carry out the above tasks

The evaluation

The purpose of the evaluation is to determine whether the proposed pathway is effective and if so, to inform the delivery of the pathway at a national scale across all coronial services. This report presents the findings of the evaluation from the period May 2022 to June 2023, during which time 101 semi-structured interviews with key stakeholders were completed.

Progress to date with case identification

The pathway is working well in six of the seven pilot sites, with numbers of cases being signposted to the ICC services increasing in line with expectations.

To the end of May 2023:

60 index cases had been signposted to ICC services

249 family members were receiving support

137 family members were undergoing assessment

Key findings to date

The pathway is labour light for Coroners

The Senior Coroners participating in the programme have reported that the pathway is not creating an undue burden on their Officers, and the associated tasks have been easily incorporated into their workloads. Training is essential for the Coroners' Officers and requires 1.5hrs of dedicated time.

The ease with which the new pathway can be adopted has led several Senior Coroners outside of the pilot sites to voluntarily agree to implement the new pathway.

There is insufficient capacity among specialist cardiac pathology services

Implementation of the pathway is challenging if there is little or no access to a specialist cardiac pathologist within a region. This is the case in four of the seven pilot sites. The programme highlighted that there is very limited specialist cardiac pathology capacity in England.

For over a decade, the charity, Cardiac Risk in the Young, has funded the cardiac pathology service at St George's Hospital, London, which accepts referrals from all over the UK. The CRY funded service is supporting this programme by accepting referrals from regions where there is little or no specialist cardiac pathology available.

Toxicological testing can delay the post mortem

Another challenge identified is that the slow pace of processing toxicology samples has also been a bottleneck in the conclusion of the post mortem examination. The final post mortem examination report cannot be concluded without the toxicology results, and it can lead to delays of weeks, or in some cases – months, before the pathologist can determine the cause of death.

The ICC Coordinator role is vital

The role of the ICC Coordinator within existing ICC services is critical to the success of the pathway. The relationship between the local ICC Coordinator and the Coroners' Officers is particularly important and helps to ensure that appropriate cases are referred to the NHS. Without this role, it is likely that the pathway would fail, and families would be lost to follow-up.

The ICC Coordinator roles are being funded by the Genomics Unit at NHS England as part of a national GMSA transformation project for the duration of the pilot.

Good communication and teamwork between disciplines is essential

It is particularly important to establish effective working relationships between the Coroners' Officers and the ICC Coordinators. This helps to ensure that the index cases are identified and the families are supported appropriately.

Other factors critical to success of the pilot

- **Commitment and support** for the programme from all members of the multidisciplinary team involved in the pathway
- **Effective national leadership and support** from each of the partners
- **Effective programme management and support provided by BHF** convening stakeholders, facilitating problem solving and providing the infrastructure needed to deliver the programme

Challenges to national scale up

Several challenges were identified in the early set-up stage, most of which have been addressed and the lessons captured to inform national scaling up of the programme.

However, there remain some significant challenges remaining, to address before national adoption of the pathway could be achieved. These are listed below:

Funding for the ICC Coordinator role

The NHS Genomics Unit has funded the ICC Coordinator role in the 7 pilot sites until end of March 2024. Funding to sustain these posts beyond this date has not been identified. Funding needs to be secured to sustain the posts in the pilot sites at a minimum.

Ideally, funding will be secured for an ICC Coordinator role in additional existing ICC services to enable national scale up.

NHS England is overseeing the updating of the service specification entitled *Cardiology: Inherited Cardiac Conditions Service Specification*, which will outline the need for the ICC Coordinator role, but it will not be completed and implemented by March 2024.

Capacity within the pathology workforce

The current charitably-funded provision of specialist cardiac pathology is not sustainable in the long term, and needs to be addressed before a national scaling up of the NHS-C-SUD Programme can be achieved. NHS England is currently working with the Royal College of Pathologists to scope the feasibility of increasing the capacity within specialist cardiac pathology services.

Build the dataset

The collated dataset generated by the pilot sites will provide crucial evidence to support widespread adoption of the pathway. All partners should support continued data collection and finalise the adoption of a shared data repository.

Priorities for the remainder of the programme

We recommend that, for the remainder of the pilot period, the programme leadership focusses on:

- Supporting the ICC service leaders to secure funding for the seven ICC Coordinator roles as a matter of urgency, and exploring alternative funding sources if this is not feasible
- Influencing and supporting the updating of the new ICC service specification, to support the business case for the funding of the ICC Coordinator role
- Influencing the pathology workforce transformation programme to increase capacity in the specialist cardiac pathology workforce
- Planning for scaling up of the programme based on the lessons learned from the pilot

1. INTRODUCTION

The NHS-C-SUD programme is a service improvement programme that aims to ensure that families bereaved due to an inherited cardiac condition (ICC) have equitable and rapid access to an NHS ICC clinic and the associated clinical and genetic assessment. The intended impact is to reduce the risk of further preventable and premature sudden deaths in the same family.

A new pathway has been codeveloped by a multidisciplinary team (see page 10) and is being piloted in seven sites. The inclusion criteria include Sudden Unexpected Death (SUD) cases reported to HM Coroners, where a cardiac genetic cause is suspected, or where the death remains unexplained despite a full coronial and expert cardiac post mortem and toxicological testing. Deceased cases older than one year where resuscitation has failed, or there is no recovery despite an initially successful resuscitation, may also be included.

See appendix 1 for more information on the inclusion criteria.

1.1 Rationale for the programme

Cardiac pathology, post-mortem genetic testing and clinical family evaluation are the three primary components of the comprehensive personalised medical management of families who have suffered sudden unexpected deaths due to potentially genetic causes.

However, the delivery of appropriate patient pathways is highly inconsistent across England and requires closer working between the NHS and coronial services.

Therefore, the programme objectives are to:

- Establish consistent pathology referral practice for sudden unexplained deaths, including use of expert pathology
- Establish routine tissue retention for histopathology and DNA extraction in suitable sudden unexplained death cases
- Establish coronial and NHS communication pathways for referrals of families for genetic counselling and testing and clinical evaluation

- Establish mechanisms for standardised post-mortem genetic testing and reporting via NHS Genomic Laboratory Hubs (GLH) to support timely evaluation and cascade testing of families
- Develop and disseminate nationally applicable best practice pathways for NHS adoption employing a toolkit approach
- Ensure the engagement and input of patient and support groups with an interest in inherited cardiac disorders

1.2 Partners involved in the programme

The programme involved the following organisations:

- British Heart Foundation
- Cardiac Risk in the Young
- NHS England
- Office of the Chief Coroner for England and Wales
- Royal College of Pathologists

1.2.1 The multidisciplinary team

The following teams were involved in the design and delivery of the end-to-end pathway being tested:

- Senior Coroners, Coroners and Coroners' Officers
- Pathologists and Specialist Cardiac Pathologists
- Clinicians working within existing Inherited Cardiac Conditions (ICC) Clinics
- The newly appointed role of the ICC Coordinator in the ICC clinics
- NHS England's Genetic Medicine Service Alliances (GMSAs) and the associated Genomic Lab Hubs (GLHs)

There are different working practices within and between the specialist teams listed above. The multidisciplinary team needed to work collaboratively to review the current pathway and co-produce a new pathway to be tested including supporting documents such as the consent form for the retention of tissue (suitable for DNA extraction) of the deceased index case.

In the following sections, we introduce each of the teams. We discuss their roles in the programme, what worked well and the challenges they experienced in delivering the new pathway in Chapter 4.

Coronial services

There are a total of 76 coronial services across England. The role of the Chief Coroner includes providing support, leadership and guidance for Coroners in England and Wales. However, because Coroners are independent judicial office holders, like all judges the Chief Coroner is unable to comment on, review or otherwise intervene in the individual decisions of Coroners. Therefore, in addition to the liaising directly with the Office of the Chief Coroner, it was necessary for the programme team to liaise directly with each Senior Coroner taking part in the programme.

The role of a Coroner is to inquire into the cause and circumstances of death where this is not clear, for example a suspicious/unexplained death or the death of someone that has not been seen recently by a medical professional. A Coroner’s Officer assists in those enquiries.

Coroners’ Officers are typically funded and employed by the local authority. Their professional backgrounds include former police Officers and paralegals. There is considerable variation in how regional coronial service teams are set up. The Senior Coroners in each service taking part in the pilot cited limitations in capacity due to financial constraints.

The coronial service boundaries do not directly correlate with NHS local or regional boundaries.

Pathology and Specialist Cardiac Pathology services

Post mortem examinations are a standard component of a coronial investigation. Typically, the pathologists, commissioned by Coroners to carry out post mortem examinations work for the NHS in their substantive roles and, support the coronial services outside of their core NHS working hours.

Specialist cardiac pathologists have expertise in the examination of the heart, although it should be noted that the Royal College of Pathologists has not formalised a career pathway for this sub-speciality. Specialist cardiac pathology services are not provided in all parts of England. Table 6 on page 39 shows the availability in the regions taking part in this pilot.

As mentioned earlier, if a specialist cardiac pathologist is not available in a region, the local pathologist typically seeks advice and input from the specialist cardiac pathology centre at St George's University of London. This centre is funded by the charity Cardiac Risk in the Young (CRY). The local pathologist can also access a specialist cardiac pathology review through the UK Cardiac Pathology Network.

There are longstanding concerns about the pathology workforce which will impact on the programme being scaled up (see page 34 and 35).

Inherited Cardiac Conditions services

ICC Services are the existing specialist NHS services for the diagnosis, treatment and support of individuals and families with inherited cardiac (heart) conditions.

This programme focusses on the referral pathway for surviving relatives from the coronial service to the ICC service, as opposed to focussing on the processes within the ICC services for assessing the referred family members. However, as already mentioned, the programme includes establishing mechanisms for standardised post-mortem genetic testing and reporting via NHS Genomic Laboratory Hubs (GLH) to support timely evaluation and cascade testing of families. See page 45 for more information on this.

As part of the programme, an additional role, that of the ICC Coordinator, is being funded by NHS England in the seven pilot sites, to facilitate the setting up and testing of the new pathway.

In parallel, a revised service specification for ICC services is currently being drafted by the NHS England Cardiovascular Clinical Reference Group. While the updating of the service specification was not initiated because of this pilot, the data from the programme is being used to inform it. This includes outlining the need for the ICC Coordinator role in specialist services seeing families after a sudden unexpected death.

The service specification will not be completed by March 2024 when the current funding cycle from NHS England is due to end. This creates a risk for the sustainability of the seven centres included in the pilot.

Genomic Laboratory Hubs

The national genomic testing service is delivered through a network of seven Genomic Laboratory Hubs (GLHs), each responsible for coordinating services for a particular part of the country.

There are seven GLHs are listed below:

- Central and South Genomic Laboratory Hub led by Birmingham Women's and Children NHS Foundation Trust
- East Genomic Laboratory Hub led by Cambridge University Hospitals NHS Foundation Trust
- North East and Yorkshire Genomic Laboratory Hub led by The Newcastle upon Tyne Hospitals NHS Foundation Trust
- North West Genomic Laboratory Hub led by Manchester University NHS Foundation Trust
- North Thames Genomic Laboratory Hub led by Great Ormond Street Hospital for Children NHS Foundation Trust
- South-East Genomic Laboratory Hub led by Guy's and St Thomas' NHS Foundation Trust
- South-West Genomic Laboratory Hub led by North Bristol NHS Trust

Genomic Medicine Services Alliances

As part of the NHS Genomic Medicine Service (GMS) infrastructure, in December 2020, NHS England commissioned a network of seven NHS

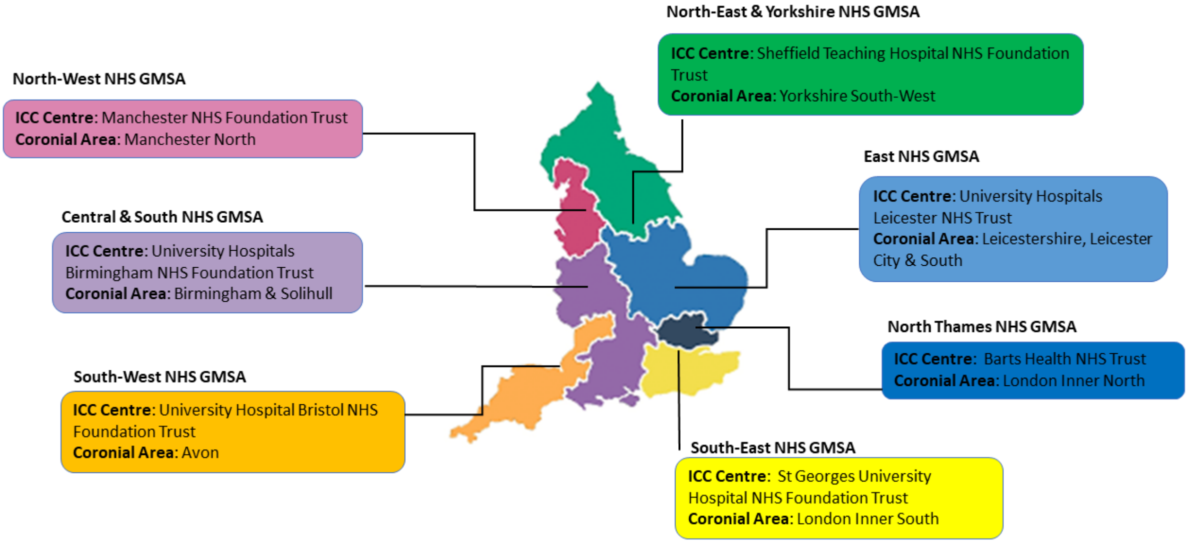
GMS Alliances (GMSAs) which map to the same geography as the laboratory hubs.

Each GMSA is a collective made up of NHS providers working in partnership to support the strategic systematic embedding of genomic medicine for a given population across providers within their geography. They support mainstreaming and equity of access to genomics in end-to-end clinical pathways and across clinical specialities. This is achieved through their multi professional clinical leadership and by delivering national and local transformation projects in priority areas.

The East and South-East GMSAs acted as the lead GMSAs for this programme.

1.3 Pilot sites

The programme is being piloted in 7 of the 76 coronial areas across England. As shown below, there is one live coronial site in each GMSA region. A named Senior Coroner is associated with each region. Each of the seven coronial area pilot sites is linked to an existing NHS ICC clinic.



North-East & Yorkshire NHS GMSA

ICC Centre: Sheffield Teaching Hospital NHS Foundation Trust
Coronial Area: Yorkshire South-West

North-West NHS GMSA

ICC Centre: Manchester NHS Foundation Trust
Coronial Area: Manchester North

East NHS GMSA

ICC Centre: University Hospitals Leicester NHS Trust
Coronial Area: Leicestershire, Leicester City & South

Central & South NHS GMSA

ICC Centre: University Hospitals Birmingham NHS Foundation Trust
Coronial Area: Birmingham & Solihull

North Thames NHS GMSA

ICC Centre: Barts Health NHS Trust
Coronial Area: London Inner North

South-West NHS GMSA

ICC Centre: University Hospital Bristol NHS Foundation Trust
Coronial Area: Avon

South-East NHS GMSA

ICC Centre: St Georges University Hospital NHS Foundation Trust
Coronial Area: London Inner South

1.4 The new pathway being tested in the pilot

The most significant changes introduced with the new pathway are a consistent approach to the following:

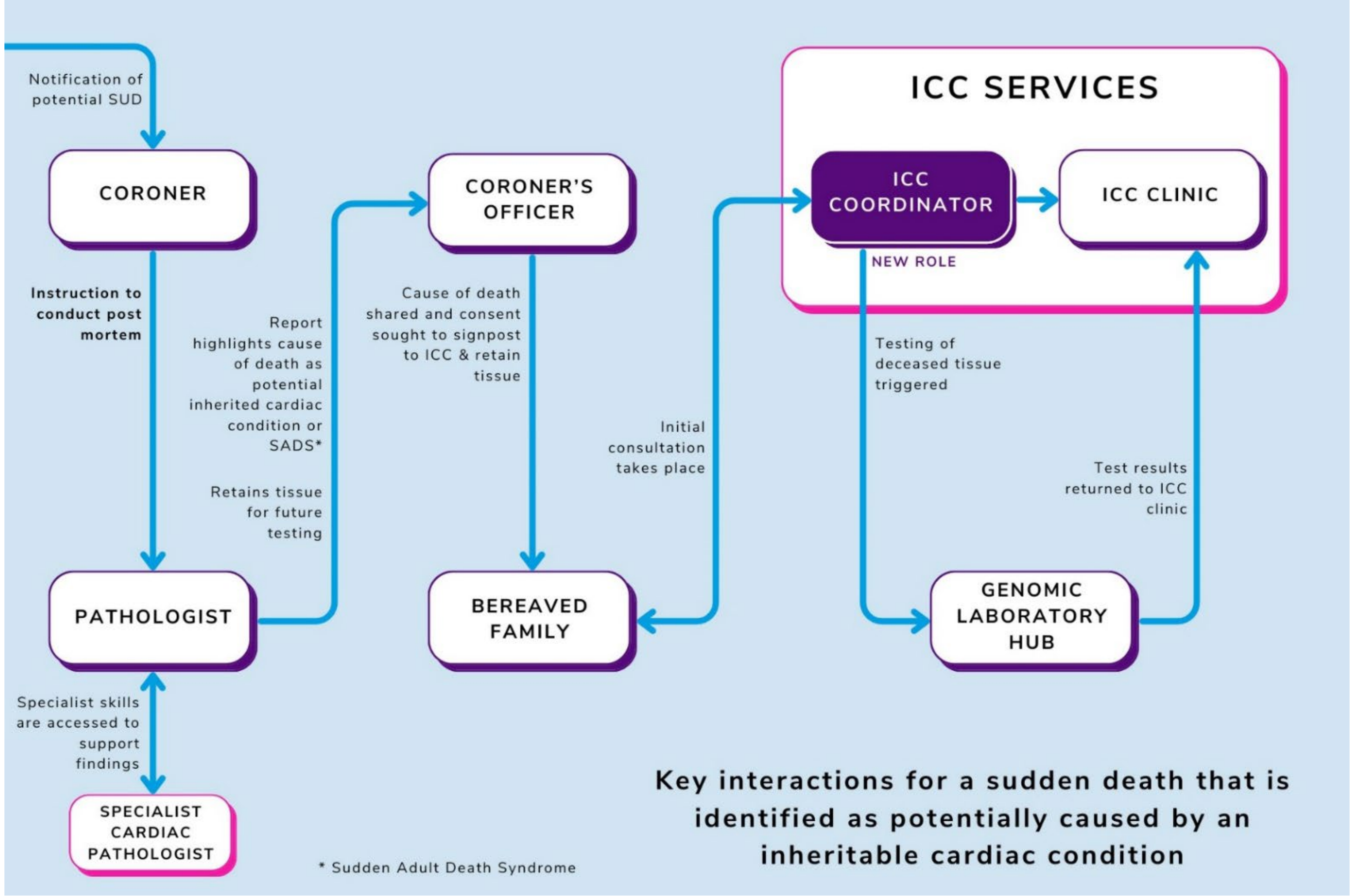
- The post mortem examination (see appendix 1) including examination of the heart where indicated by a specialist cardiac pathologist
- Capturing consent within the coronial service, using a standard consent form as shown in appendix 2, to retain tissue (including tissue suitable for DNA extraction) from the deceased index case
- Retention, labelling and storage of such tissues from the deceased index cases (see appendix 1)
- Signposting of families to the ICC services whereby the Coroner's Officer sends a letter to the ICC clinic with the family's contact details, based on a standardised template
- Coordination of families signposted by the coronial services through the appointment of an ICC Coordinator within existing ICC services
- Training of Coroners' Officers so that they can carry out the above tasks

In summary, the aim of the pathway being tested is to simplify and bring consistency to the process so that, in the event of a sudden unexpected death, the living relatives will be given equitable and prompt access to the specialist NHS service.

The pathway being tested is shown overleaf. The main points of difference between the processes before this pilot and those being tested are summarised in Table 3 on page 25.

In addition to supporting the living relatives, the ICC Coordinators have played a key role in implementing the new pathway, developing relationships with the local Senior Coroners, the Coroners' Officers and the pathologists.

A simplified version of the new pathway is included below to illustrate the organisations/roles involved and the key transition points.



* Sudden Adult Death Syndrome

Key interactions for a sudden death that is identified as potentially caused by an inheritable cardiac condition

2. THE EVALUATION

The purpose of the evaluation is to inform a potential national scaling up of the pathway including:

- practical learning about what works well and doesn't work so well in implementing the pathway
- enablers and barriers to implementation
- critical success factors for national roll out
- potential challenges to national roll out

It has been designed based on the theory of change for the programme shown in Appendix 3.

The evaluation is divided into three phases, the first two of which have been completed and inform the findings of this report:

Discovery Phase (May – Sep 2022) – this involved engaging with key Programme stakeholders, both nationally and in each pilot site, to give us a clear understanding of how the Programme was working on the ground as well as gathering insights about stakeholders' aspirations for the Programme and experiences so far.

Review Phase (Mar – Jun 2023) – in this phase we revisited each pilot site to focus on the realities of implementation and the factors underpinning both progress and challenges. We also spoke to national stakeholders to get their perspective on progress.

Final Phase (Sep 23 – Feb 24) – this phase will have a more summative focus looking at the changes achieved and the aggregated learning from implementation across the whole pilot period. It will involve:

- a final round of fieldwork with each pilot site and national stakeholders
- interviews with families who have experienced the pathway
- economic assessment, using a cost consequences approach

2.1 Discovery and Review Phases

The table below summarises the number of semi-structured interviews completed in each of the pilot areas in each evaluation phase. In addition, we undertook semi-structured interviews with ten national stakeholders in each phase.

We have also attended the National Oversight Boards, Steering Group meetings, and regular drop-in meetings for ICC Coordinators and Coroner’s Officers.

Table 1 – Number of interviews conducted across pilot sites by profession/role

Role/Profession	Discovery phase	Review phase
ICC Lead/Consultant Cardiologist Consultant Paediatric Cardiologist	8	6
Pathologist/Histopathologist	5	6
ICC Coordinator/ICC Clinical Nurse Specialist/Genetics Counsellor	9	9
Consultant Clinical Geneticist/GMSA Lead/GLH Lead/Clinical Scientist	11	8
Coroner/Senior Coroner	4	4
Senior Coroner’s Officer/Coroner’s Officer	5	6
Total	42	39

Limitations

As can be seen from Table 1, we have not been able to engage Coroners and Coroner's Officers from every site during each phase. The evidence suggests that this is a capacity issue rather than a lack of engagement with the Programme. However, there are two pilot sites where we have not been able to speak with either Coroner or Coroner's Officers in either phase, which represents a gap in the data.

2.2 Final Phase of the evaluation

The final phase of the evaluation will include:

Interviews with stakeholders

A final round of semi-structured interviews with stakeholders in the each of the pilot sites, and national stakeholders to be conducted between November 2023 and February 2024.

Engagement with families

We have carefully planned our engagement with families that have accessed the pathway to be as unintrusive as possible, using those interviews only to answer those questions that cannot be evidenced form other data sources.

We have sought advice and guidance from St George's Ethics Committee, Cardiac Risk in the Young (CRY), ICC Coordinators and three bereaved families to design an approach which takes into consideration the traumatic nature of bereavement and complex grief experienced by families.

All families that have experienced the pathway and are at least one year post-bereavement[1] will be invited to participate. The ICC Coordinators will make the approach and gain verbal consent to introduce the

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[1] If a family's bereavement is more recent than one year, the ICC Coordinator can still invite them to participate in the evaluation if they express a particular desire to be involved.

evaluation team. The interview format will be online or by telephone, according to preference, and will last no longer than 30 minutes.

We are aiming for 56 interviews in total, ideally with representation from all pilot sites.

Economic assessment

Following discussions with programme stakeholders in July 2022, agreement was reached to adopt a cost consequences approach to the economic assessment. Cost consequences evaluations seek to understand and report the costs of delivering an intervention in monetary terms and express the different benefits of the intervention in their natural units, rather than ascribing proxy values to each. The evaluation's audience is then invited to make its own decision about whether the programme delivers value for money. The approach – which is widely used in evaluation – trades off a more quantitative approach to calculating benefits (for example, cost-benefit analysis) with a more cost-effective evaluation methodology that works well where an intervention's benefits may not easily be quantified.

While the focus of the assessment is on the coronial service, there may be opportunities to gather some additional evidence about the economic impact of the programme in other areas of the pathway such as healthcare settings.

3. OUTCOMES TO DATE

3.1 The pathway being tested is effective

The pathway is now operational in all seven pilot areas and all areas have at least one case on the pathway.

To the end of May 2023, **sixty cases had been signposted to ICC services** and as a result **249 family members were receiving support** from experts to help them come to terms with their grief and make informed decisions about their own health. Over half of these individuals (137) were already undergoing assessment at the time of the interim evaluation. The assessment of the living first degree relatives of the deceased index cases has the potential to reduce additional avoidable premature deaths from an inherited cardiac condition in these families.

Table 2 – Number of cases by pilot area

Site	Go live date	Cases signposted to ICC[2]	Family members identified	Family members assessed
Manchester (North West)	Feb 2022	8	40	23
Leicester (East)	Feb 2022	7	29	14
Birmingham (Central & South)	Feb 2022	11	43	43
South London (South East)	Aug 2022	13	43	9
Sheffield (NE & Yorks)	Feb 2022	5	19	3
Bristol (South West)	Mar 2022	15	71	41
North London (North Thames)	Feb 2023	1	4	4
Totals		**60**	**249**	**137**

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[2] Additional cases have been identified by the Coronial Service and may be signposted to the ICC once cause of death has been confirmed.

It should be noted that at the time of the interim evaluation, some sites had not yet completed the end-to-end assessment process of a living relative of a deceased index case, because this can take up to 12 months (includes clinical assessment, genetic counselling and genetic testing on both the deceased index case and the living relative).

3.2 Reduced stress for families

While the evaluation has yet to engage families who have recently been bereaved and are undergoing or waiting to undergo assessment as part of the new pathway, we have heard anecdotal evidence from families bereaved some years ago that suggests the new pathway will reduce stress and the risk of family members not undergoing appropriate assessment in an ICC service. One person we spoke to described asking their GP for a referral to ICC services (following a letter from the Coroner advising them to do so). After a brief clinical examination, the GP told the person that referral was not necessary. They had to insist upon a referral to ICC services, which revealed that the person was indeed at risk, as were their children. If the pathway that is being tested by the pilot existed at that time, the burden would not have been on the bereaved family member to request and ultimately argue for a referral to the specialist ICC service.

3.3 Increased awareness and early expansion

The programme has been presented to the majority of Senior Coroners and Local Authority colleagues at national conferences hosted by the Chief Coroner during March 2023. Coroners from other jurisdictions have volunteered to adopt the pathway. For example, the Manchester NHS Foundation Trust ICC service in the North-West has recently started taking referrals from the Coroners within the Liverpool and Blackburn area as part of planned expansion. The University Hospitals Leicester NHS Trust ICC service in the East region is also exploring options and developing opportunities in nearby jurisdictions.

There is recognition that early expansion needs to be controlled with all appropriate steps taken to ensure adherence to the model. This includes appropriate training provision for Coroners' Officers and raising awareness within the local pathology services.

The Programme has also been promoted at meetings of the Association for Inherited Cardiac Conditions, the British Cardiovascular Society Conference, the European Society of Cardiology, the Chief Coroners' Conference and the Senior Coroners and Local Authority Leads Conference.

4. HOW THE PATHWAY IS WORKING

All pilot sites have fully implemented the pathway and have at least one current case in the system. The last site to go live was North Thames in February 2023.

Overall, the pathway is working effectively, and the processes are being carried out in a consistent way. There are some minor local variations in process, which are listed on page 48.

The rest of this chapter considers each role contributing to the pathway outlining:

- the tasks/activities **specific to the sudden unexpected death pathway** they are accountable for
- what has changed in the management of these types of deaths since implementation of the pathway?
- what is working well and why?
- what has been challenging and how have the challenges been addressed?
- what are the implications of what has been learned for potential roll out?

Table 3 – Key points of difference pre and post new pathway

Point of difference	Existing pathway	The typical outcome of the existing pathway	New pathway	Intended outcome
Access to specialist cardiac pathology	There is variation in access to a specialist cardiac pathology examination. This leads to delays in determining the cause of death in the index case which adds to the family's stress.	Some cases of SUD due to an ICC are missed or misdiagnosed leaving first-degree relatives without appropriate clinical assessment. Hence there is a risk of further premature and avoidable deaths in the family.	Pathologists are supported with access to a specialist cardiac pathologist. There is greater awareness of the specialist cardiac service, funded by CRY, at St George's University of London.	There will be an increase in the number of deceased index cases identified. This will facilitate greater support for the first-degree relatives
Capture of consent from the living relatives to store tissue (DNA) of the deceased index case	The family needs to give consent for tissue (DNA) from the index case to be retained. This is not routinely obtained by Coroner's Officers in every case currently.	If consent is not obtained samples cannot be retained and therefore will not be available for genetic testing. If the genetic cause of death cannot be identified, , diagnoses may be missed and the diagnostic process limited to screening family members only.	The pathologist prompts the Coroner's Officer to seek written consent from the family.	Written consent is sought in every appropriate case and captured appropriately. This supports a more definitive cause of death through genetic testing at an appropriate time.

Point of difference	Existing pathway	The typical outcome of the existing pathway	New pathway	Intended outcome
Retention, storage and labelling of tissue (DNA) of the deceased index case.	There is some inconsistency in the samples taken, labelling and storage. For example, a sample of spleen, which is rich in DNA and recommended for this purpose, is not always taken.	The samples retained from the deceased may not be optimal for DNA extraction or may become degraded due to inappropriate storage. If DNA cannot be extracted successfully then genetic testing is compromised. If the genetic cause of death cannot be identified, diagnoses may be missed and the diagnostic process limited to screening family members only. Extraction of DNA from poor quality samples is more involved requiring multiple attempts and more lengthy processes. This adds cost to the pathway and delays at a very difficult time for the living relatives.	Appropriate samples are taken from the deceased in line with the protocol (see appendix 1) developed for this pathway. Samples are labelled and stored appropriately facilitating easy access when required. This speeds up the process for assessment in first-degree relatives.	The end-to-end process for tracking and assessing DNA samples from the deceased index case is more time and cost effective. Unnecessary delays are avoided, which facilitates more rapid assessment of the living relatives.

Point of difference	Existing pathway	The typical outcome of the existing pathway	New pathway	Intended outcome
Access to a specialist NHS ICC service	Living relatives are advised by the Coroner's Officer to speak to their GP about a referral to the local ICC clinic.	In some cases, the living relatives are referred and undergo appropriate assessment. However, this is inconsistent and in many cases the referral is not made and living relatives are not assessed appropriately. Families are left at risk of another premature and avoidable SUD occurring.	The family is signposted (i.e., a letter is sent by the Coroner's Officer to the ICC Coordinator) to the ICC service. Therefore, the burden of ensuring appropriate assessment is carried out is removed from the family.	The ICC Coordinator follows up with the first-degree relatives and begins the assessment process which includes mapping the family tree and identifying any relatives who may be at highest risk. When appropriate, genetic testing is carried out on the retained tissue from the deceased. If appropriate, genetic testing is carried out on first-degree assessed as being at risk. Treatment is provided where needed. The risk of another premature avoidable death in the same family is reduced.

4.1 Coroner's Officer

4.1.1 Key activities/tasks

The duties carried out by the Coroner's Officer as standard practice and those carried as part of the new pathway are outlined below in table 4.

Table 4 – Coroner's Officer duties with the new pathway

Standard practice	**New duties as part of the pathway being tested**
Notify the next of kin or nominated family contact that tissue has been retained on a temporary basis as part of the post mortem examination and obtain their wishes on what should happen to that tissue (returned to the family or disposed of appropriately) on completion of the examination. Provide the next of kin with the post mortem report. If the pathologist concludes that the cause of death is a suspected inherited heart condition: Explain in high level terms the need for the living relatives to be assessed in a specialist ICC clinic and advised to see the GP.	If the pathologist concludes that the cause of death is a suspected inherited heart condition: Explain in high level terms the cause of death and the need for the living relatives to be assessed in a specialist ICC clinic and made aware of the new pathway. Provide the living relatives with the information produced by the BHF and CRY to help them to understand this. Seek verbal consent to send a letter to the ICC service so that the living relatives can be followed up later (see Table 3 on page 25 for a variation to this where written consent is obtained.) This letter is referred to as 'signposting'. Seek written consent from the living relative to retain tissue(for future DNA extraction) of the deceased individual so that it can tested at a later date as part of the assessment in the ICC clinic.

4.1.2 What's worked well and why

A positive programme that saves lives

Overall, the Senior Coroners and their Officers have viewed the implementation of the pathway as an opportunity to help save lives. Therefore, the potential to hear about success stories has been identified as a motivator/positive part of participating.

> **"It's not often we can see the end result, that we get to see how important it has been."**
>
> Coroner's Officer

In the same way, signposting to the ICC clinic has been viewed as a positive addition to Coroner's Officers' interactions with the family of those who have lost a family member. They viewed the ability to signpost the family to the ICC service and the specialists who work there as an opportunity to reassure the family that, although they have just received the difficult news that someone else may be at risk, they would be supported in accessing the specialist NHS service.

> **"A really positive thing you can do for someone in a horrid time."**
>
> Coroner's Officer

Leadership

The leadership from the Chief Coroner and the two Senior Coroners in Birmingham and Solihull, as well as Leicestershire, Leicester City and South who acted as leads for the programme has been instrumental to its progress to date.

Commitment and support by each local Senior Coroner has also been imperative and has helped to increase the pace of adoption of the pathway. Buy-in from the Senior Coroner gives permission for existing processes to be adapted and for their Officers to attend the required training. Without this support, the pathway is unlikely to be implemented effectively.

In one pilot site, progress was slow until a new Senior Coroner in the area became involved and ensured there was engagement with the programme. This resulted in a steadier and more consistent flow of referrals.

Commitment from Coroner's Officers

At the operational level, the commitment and support from the Coroner's Officers has helped embed the new processes and ensure that the deceased index cases that meet the criteria are identified and managed in the line with the new pathway. Some sites have allocated responsibility for these cases to a single Coroner's Officer or to a small team of two/three Officers within the service. This assists with maintaining competence though it does jeopardise resilience, especially if only one or two Officers are involved.

Pathway integrates easily into existing processes

When introduced to the pathway, some Coroners were concerned about the potential additional pressure for a service that was already at capacity. However, whilst there is some additional minor work required to implement the pathway, including some mandatory training for Coroner's Officers, once embedded the pathway involves very little additional work. Coroner's Officers report that they would be speaking to the families anyway and the consenting and signposting steps in the pathway add minimal work: one extra letter and a slightly longer conversation.

Training

Training (1.5 hours) has been provided by clinicians with support from the BHF to all Coroner's Officers in the pilot areas as a prerequisite for going live. This has ensured they have the required skills, knowledge and confidence to engage with families under these specific circumstances and help in their decision-making process about whether to signpost the family to the ICC clinic. The relationship between the Coroners' Officers and the regional ICC Coordinators has also been essential in supporting the Coroners' Officers in managing these cases and in increasing their knowledge.

Where there has been turnover of staff, the ICC Coordinators have been able to provide training to new joiners.

4.1.3 Challenges

Capacity

While the new pathway has not generated significant work for the Senior Coroner and their teams, general capacity within the coronial service has been highlighted throughout the implementation of the pathway. The coronial service is experiencing increased pressure and workload following the Covid-19 pandemic, and they do not expect this to reduce in the foreseeable future. Additionally, some sites have experienced turnover of Coroner's Officers and vacancies. These have resulted in reduced capacity to engage with the pathway in some sites, even though the pathway does not generate significant new workload.

The ICC Coordinators have worked with coronial services to help maintain competency levels including top up training as and when required. A training resource, that can be tailored to local sites, has been produced by one of the ICC Coordinators and shared with others to use.

4.1.4 Implications for rollout

So far, the programme has been well-received, and those involved believe it is 'the right thing to do'. We recognise that those currently involved are early adopters and enthusiasts, and not all Coroners may be as enthusiastic to adopt the pathway – especially in the context of capacity issues that are expected to continue for some years yet. However, there has been interest shown from Coroners in areas adjacent to some of the pilot sites, and this is a positive indication that there is appetite for expansion.

To commit to change, albeit on a small scale, Senior Coroners will need to recognise the value of the pathway and that any additional workload is minimal and justified.

The evaluation needs to demonstrate both of these benefits, and these will then need to be communicated effectively to all jurisdictions. Whilst we know there is much interest in the pathway, support will inevitably vary. Consideration will need to be give on how to influence slow adopters.

4.2 Pathology services

4.2.1 Key Activities/Tasks

As part of the project set up, the pathologists in sites taking part in the pilot were briefed on the inclusion criteria (see Pathology Protocol in appendix 1).

Table 5 below outlines the differences between the standard pathway and the new pathway being tested.

Table 5 – Pathology services activities with the new pathway

Standard practice	New duties as part of the pathway being tested
The pathologist undertakes a general post mortem examination, taking tissue samples as required to determine the cause of death and notifying the Coroner of the samples taken. The family are notified by the Coroner's Officer and consent is obtained from the family on retention or disposal of the tissue at the conclusion of the investigation. The pathologist determines if a specialist cardiac pathologist is required and arranges this within their region or at the Cry funded centre at St George's Hospital, London. This happens inconsistently currently. On completion of the post mortem examination, the pathologist determines the cause of death and sends the postmortem report to the Coroner	If not already standard practice, a spleen sample should be taken on a "presumptive" basis from potential index cases for early storage to reduce sample degradation. If the post mortem examination indicates potential genetic cardiac cause of death specialist cardiac pathology is **routinely sought** If a potential genetic cardiac condition is identified as a cause of death, the pathologist alerts the Coroner's Officer of the need to: Obtain written consent from the living relatives to retain the tissue (suitable for DNA extraction) from the deceased index case To signpost the living relatives to the ICC service. If the Coroner's Officer confirms that written consent to retain tissue has been obtained the pathologist should follow the protocol as outlined in appendix 1 for the storage of tissue.

4.2.2 What's worked well and why?

The pathologists involved in the pilot have been committed to the programme, because they understand that more timely access to ICC services can help save lives. They are also committed to ensuring that all families are provided with a consistent and high level of care.

There are minimal changes to their practices, with no impact on the time required for these types of examinations.

The ICC Coordinators have liaised with pathologists to help embed the pathway in their region. Whilst there have been some existing relationships between the pathologists and the ICC services, the ICC Coordinators have worked hard to reach out to all pathologists in the region who are commissioned by the Coroner to carry out post mortem examinations. The ICC Coordinators have helped to implement some of the changes required, such as the protocol for sample storage and transport.

There is some variation in how cases are being investigated within individual pilot sites. In some regions, where the circumstances of death meet the criteria to indicate a potential inherited cardiac condition index case, the pathology team has nominated a small number of dedicated pathologists to carry out the post mortem examinations. This has helped with adherence to protocols. Where a wider pool and locum pathologists carry out the post mortem examinations, more effort has been required from the ICC Coordinator to ensure samples are consistently taken as per the protocol and sent to the designated lab. Posters have been produced as a resource to help prompt and remind pathologists of the protocol for this programme.

4.2.3 Challenges

Skills shortage

As mentioned earlier, there is a significant capacity challenge within the pathology workforce as the number of pathologists practising post mortem examinations is reducing due to the following factors:

- recent and forthcoming retirements of experienced pathologists
- fewer pathologists opting to undertake the invasive post mortem examination module of the training curriculum
- fewer pathologists willing to undertake post mortems, even if trained to do so

- high demand for histopathology staff within the NHS, given the multitude of conditions that rely on histological services for diagnosis

Whilst there are a small number of pathologists who are very committed to the pilot, the overall shortage of this skillset poses a risk for scaling up the adoption of the new pathway.

Changes in practice such as the increasing use of non-invasive technology, CT and MRI scans, in post mortem examinations may ease some of these issues in longer term by introducing efficiencies into the system and the pathologists' time. Non-invasive post mortem examinations (via CT & MRI) are carried out by radiographers who undertake the scan which is then examined and reported on by radiologists. Pathologists review the report in the context of their wider testing and examination. However, it should be noted that availability of this technology is currently limited to a small number of centres and not yet widespread. Furthermore, a non-invasive post mortem examination is not sufficient to determine the cause of death if the deceased case had an inherited cardiac condition.

Some stakeholders indicated to us that the new role of medical examiner also had some potential to ease capacity issues.

Funding coronial post mortem examinations

Post mortems carried out as part of coronial investigations are funded by the local authority on behalf of the local Coroner. However, as mentioned previously, pathologists are not dedicated to coronial services. Typically, pathologists who undertake coronial post mortem examinations work substantively for the NHS and carry out the post mortem examinations outside of their core NHS hours. Neither the coronial services nor the local authorities have influence over the number of pathologists available in their area and nor can they influence the national-level issues outlined in this report.

The standard fee for a coronial post mortem is £96.80. This fee was originally set in 2008 and adopted within the Coroners Allowances, Fees and Expenses Regulations 2013. It has not changed since. In some regions, Coroners are reporting challenges in commissioning pathologists willing to carry out the post mortem examinations.

A short-term solution employed by some areas has been to pay pathologists at an enhanced rate (£276.90) by classing it as a post mortem examination requiring a sub-specialist histopathologist. This is a payment that can be made at the Coroner's discretion for certain types of post mortem.

Work is underway within NHS England and the Royal College of Pathologists to address some of the workforce issues outlined in this report. There is also a Ministry of Justice review underway, investigating the capacity issues. These are areas of work which the programme team could seek to influence but it should be noted that these are issues are long-standing and complex to address.

Turnaround times for toxicology

Toxicology testing is a key component in establishing the cause of death. The turnaround time for toxicology testing is lengthy, averaging six to twelve weeks. This results in delays in determining the cause of death and finalising the post mortem examination report. There is regional variation in how toxicology services are commissioned with a mix of NHS and commercial laboratories in use.

Transporting samples to labs

The process for transporting samples of the deceased index case from the mortuary to the relevant regional GLH has been an unexpected cause of delays in the pathway. Some areas have access to pathology and testing under the same roof whilst others must transfer them to their local GLH elsewhere.

In some areas there have been logistical challenges transporting samples to the GLHs as existing contracts did not include the samples associated with the pilot. The funding responsibility for transporting samples from the mortuary to the GLH is also unclear in some regions.

GLHs recommend that the tissue is extracted from the spleen of the deceased. This has required a change in practice within some mortuaries. GLHs recommend that the spleen tissue samples are stored as fresh tissue or frozen (at -80 degrees). However, some mortuaries do not have suitable freezers in which case rapid transportation is required. In some of these cases, tissue is being preserved using a specific storage medium. This storage medium is not readily available to mortuaries, and there is not yet an accredited process in place for processing samples preserved using this medium. Trials are underway to explore the feasibility of creating an accredited process.

The ICC Coordinators and GLH staff have used workarounds to resolve some of these issues including 'piggy backing' onto other sample transport services.

Whilst local workarounds and goodwill are enabling the pathway to work in the short-term, formalisation of supply of suitable mediums for tissue storage will need to be addressed before the pathway can be adopted nationally.

New arrangements for extraction of DNA from spleen tissue

Previously when the heart of the deceased index case was transported to St George's hospital for specialist cardiac pathology examination, the spleen sample was transported with it so that DNA could be extracted for future access. A revised protocol was agreed for use in the new pathway, whereby the spleen sample was to be transported to the local GLH for DNA extraction. However, this change is not being adopted within every mortuary taking part in the pilot.

This has the potential to cause delays in determining the cause of death as samples need to be retrieved from St George's and returned to the relevant GLH before DNA can be extracted for genetic testing.

Posters for display in the mortuaries have been used to raise awareness of the new protocol for pathology staff as a way of addressing these issues. This is particularly pertinent when where locum pathologists are carrying out the post mortem examination.

Risk of cases being missed

In some pilot sites, the pathologist workforce that performs post mortem examinations is relatively small and consistent, whilst in others the workforce is larger and more transient with heavy reliance on locums. The latter group is harder to engage in the programme, as they are not closely connected to the pathway and may only perform post mortems periodically for the local Coroner. This presents the risk that the pathologists are unaware of the pathway and therefore do not request a specialist cardiac pathology examination where there might be a genetic cardiac cause, and/or highlight cases for inclusion in the pathway.

Furthermore, pathologists have different levels of skill in identifying cases that should be referred into the pathway, or recognising where a specialist cardiac pathology assessment is warranted. Locum and freelance pathologists do not necessarily have a local peer group to discuss cases with, unlike those working in smaller teams which facilitate more collegiate working practices.

4.2.4 Implications for roll out

The workforce and capacity challenges outlined above pre-date this programme. Anecdotal evidence suggests that this programme has helped highlight them. The challenges need to be addressed centrally within NHSE and the Royal College of Pathologists.

The process challenges can be proactively addressed during scaling up of the programme. This includes ensuring that protocols for collecting, storing and transporting tissue samples are formalised and communicated in the early stages of rollout so that practice can be changed, and the logistics and contracts can be put in place.

4.3 Specialist cardiac pathology services

4.3.1 Key activities/tasks

A small number of pathologists in the UK have specialist expertise in cardiac pathology. As mentioned earlier, this role is not formally designated by the Royal College of Pathologists. Three pilot sites have a local specialist cardiac pathologist in their region as shown in table 6 below.

The specialist cardiac pathologist examines the heart of the deceased index case in line with Royal College of Pathologists guidelines and includes microscopic examination. The findings are reported back to the referring pathologist for inclusion in their final post mortem report.

Table 6 – Availability of specialist cardiac pathology services

✓ **Specialist cardiac pathologist available in this region**	✗ **No specialist cardiac pathologist available in this region**
Sheffield Birmingham South-East London	Manchester Leicester North-East London Bristol

As mentioned previously, the CRY-funded specialist cardiac pathology centre at St George's accepts referrals from anywhere in the UK. CRY agreed to support the testing of the new pathway and funded the costs of referrals from the centres that did not have specialist cardiac pathology available within their region.

There has been no change to the provision of specialist cardiac pathology because of the new pathway but there has been an increase in awareness of the need for it in those centres taking part in the pilot. It has led to an increase in cases being referred to all specialist cardiac pathologists taking part in the pilot.

However, the intention is that all pathologists should routinely send the heart of the deceased for specialist examination in sudden unexpected death cases where an ICC is suspected as the cause of death.

4.3.2 What’s worked well and why

The pathway for transporting a heart of the deceased to a specialist cardiac pathologist was well-established before the pilot started. Consequently, any process challenges had already been resolved, and pilot implementation could focus on encouraging routine use of the service for cases with a suspected cardiac cause.

4.3.3 Challenges

Capacity

Pathologists are not typically employed within the NHS as specialist cardiac pathologists and the caseload is not of the scale to warrant it being a full-time dedicated role.

However, the pathologist working within the CRY funded service is employed as a specialist cardiac pathologist and combines the role with academic research.

The lack of a speciality career pathway poses a risk about future capacity:

- Demand: scaling up adoption of the pathway nationwide will increase demand for specialist cardiac pathology but the current capacity levels will be insufficient to cope with it.
- Succession: several specialist cardiac pathologists are approaching retirement, and only a small number of pathologists are in training to develop this specialist expertise
- Role recognition: unless a clear specialist career pathway is in place, it will be difficult to attract trainees to the specialty

The new ICC service specification, which is currently being drafted within NHS England, will set out the requirement for specialist cardiac pathology and the anticipated demand. We understand from our interviews that the prospect of an exclusively cardiac-focused specialist career pathway is unlikely and would need to have a combined focus (for example on cardiac and lung pathology) to be a viable option. The appendix in the ICC Service Specification and evidence from the evaluation will be important tools to influence decisions about pathology workforce transformation, to ensure that this pathway is factored into the design assumptions.

Dependence on charitable funding and goodwill

As mentioned previously, the charity CRY funds a specialist cardiac centre at St George's Hospital, London and accepts national referrals. In the absence of a formally recognised NHS service, this service is used by four of the sites taking part in the programme and other sites that are not adopting the new pathway yet. This contribution is highly valued, not only in ensuring there is a service available for regions without this specialist skillset, but also in developing the knowledge base on sudden unexpected death and examination of the heart of the deceased cases.

The workload has increased for each of the specialist cardiac pathologists in each of the three centres involved in the pathway, and they have carried out this additional workload over and above their workplans. They are doing so because of their commitment to the affected families and a desire to do the right thing. The reliance on this goodwill poses a risk, especially as pathologists retire, as their successors may not be willing or able to carry out this additional workload.

As specialist cardiac pathology is vital to this pathway and in the prevention of avoidable premature deaths, these capacity challenges need to be addressed in particular before the pathway can be adopted nationally.

4.3.4 Implications for roll out

As with the general pathology services, the challenges described above need to be addressed within NHSE and the Royal College of Pathologists.

The dependency on a charity-funded specialist cardiac pathology service is unlikely to be sustainable in the longer term, and is unlikely to be sufficient to manage the demand associated with a national adoption of the pathway.

4.4 Inherited Cardiac Conditions service

4.4.1 Key activities/tasks

NHS ICC services provide clinical assessment and where appropriate, genetic testing for individuals and families affected by inherited heart conditions.

Each of the ICC services taking part in the pilot were pre-existing services. Additional funding was provided by NHS England to each service testing the new pathway, for a part-time ICC Coordinator post to manage the cases signposted by the coronial service. This role includes liaising with the local coronial and pathology services and supporting the family members who agree to be signposted to the ICC service. The ICC Coordinator carries out the initial triaging of family members which includes mapping the family tree and taking a medical history from each member of the family taking part in the assessment.

4.4.2 What's worked well and why

The ICC Coordinators taking part in the pilot demonstrated that they are highly skilled and experienced professionals, who are committed to implementing the pathway and delivering a better and more consistent service to families suffering the trauma of sudden unexplained cardiac deaths.

They have worked effectively individually, showing great tenacity and creativity to embed the pathway and to find workarounds when things are not working well.

They have also worked collaboratively as a team across the wider programme, utilising opportunities for networking and sharing learning facilitated by the programme management structure.

4.4.3 Challenges

Embedding the role of the ICC Coordinator

The role of the ICC Coordinator is new. The findings of the interim evaluation indicate that this role is integral to the successful implementation of the new pathway.

In the light of this, the need for the role is included in the ICC Service specification currently in development within NHS England. Long term funding for the role is not guaranteed and hence there will be a potential funding gap from the period the pilot programme ends in March 2024 to the time the ICC service specification is completed and commissioned.

Therefore the ICC Coordinators are developing business cases for local continuation funding with the support of the core Programme Team.

If funding for the ICC Coordinator role is not secured for beyond April 2024, the existing ICC services are unlikely to be able to continue accepting referrals from the local Coroners. This is a significant risk.

Capacity within ICC clinics

As mentioned earlier, the ICC Services pre-date this pilot. Their existing clinical caseload is significant and includes families where the index case is living. They are now accepting the cases signposted from the Coroners.

Each patient being seen in an ICC service undergoes clinical assessment led by a consultant cardiologist and supported by a wider clinical team. As the new pathway has increased the clinical workload, some ICC services have had to set up additional clinic sessions. The additional clinics are not in the clinician’s job plan, and therefore there is a dependency upon on clinicians’ goodwill to manage additional appointments.

It also raises ethical and equity issues of ‘fast-tracking’ some families whilst others wait to be seen, sometimes more than a year.

While the number of families signposted from the Coroners is relatively low, reliance on goodwill for service delivery poses a risk for long term sustainability. When clinicians retire or move location, their successors may not be willing to undertake work not specified in their job plan.

The ICC service specification which is under development will need to reflect the actual workload required to deliver an equitable ICC service for all relevant patient groups.

All of the above, reinforces the point that the ICC Coordinator role is vital if the new pathway is to be sustained.

Requirement for GP referrals

In some of the pilot site regions, families are experiencing a delay in accessing the service because the signposting letter from the Coroner is not accepted by the local commissioners as a formal referral, as it has originated from an organisation external to the NHS. Therefore, the ICC Coordinator needs to write to the GP(s) of the living relative(s) to secure a formal referral and to ensure relevant payment follows. This is bureaucratic and time consuming as it often requires more than one contact with the GP to secure the formal referral.

The ICC Coordinators do their best in these situations to support the families and pre-emptively book appointments while waiting for the formal referral letter.

4.4.4 Implications for national adoption of the pathway

The pathway being tested in this programme needs to be part of the new ICC service specification so that it is part of the service commitment and clinicians’ job plan.

The role of the ICC Coordinator needs to be integrated into the service.

It will be challenging for ICC services that have not been part of the pilot to adopt the new pathway without having an ICC Coordinator role funded.

4.5 Genomic Laboratory Hubs

4.5.1 Key activities/tasks

The Genomic Laboratory Hubs (GLHs) receive the tissue sample taken during the post mortem examination, after consent to retain the tissue sample has been confirmed. This should be a small piece of spleen.

DNA is extracted and held by the lab until a request for testing is received from the ICC Coordinator.

Once requested, testing takes place using the R138 code which is a panel test for known inherited cardiac conditions. The results are reported to the ICC Coordinator.

If the results from the decedent indicate testing of family members is appropriate and if they consent, samples are taken and submitted by the ICC service. These are tested and the report returned to the ICC service.

This does not represent any significant change to the lab processes though it has resulted in a more consistent submission of preferred sample types from the decedent for DNA extraction and testing in some pilot areas.

Plans to introduce parallel whole genome sequence (WGS) testing as part of the pilot are underway. WGS testing is carried out for other conditions so processes are in place, but this is an addition for the pilot phase. Implementation of WGS will be a significant change in the pathway for these conditions.

4.5.2 What’s worked well and why

The GLHs, whilst relatively new, represent a consolidation and enhancement of existing laboratory provision. Provision is regional, making it easily accessible to all the pilot sites. In some instances, the hubs are located in the hospitals in which post mortems are conducted and/or ICC services are being provided. Where this is the case, the transport of samples is straightforward and lines of communication are good.

The labs are fully engaged with the pilot programme. Staff we spoke to could see the benefits for families. It fits with their existing processes and the number of additional cases coming through the system is small. The panel test is an automated process so there is little impact on workload.

One lab did report that the change in sampling protocols had enabled the lab to save time and improve outcomes. Previously some pathologists were submitting tissue samples fixed in paraffin. It takes about a day to perform DNA extraction and the success rate is only about 50%. In addition, because the paraffin extraction is so resource heavy, staff must find a big enough window in their work schedule to do it. This can result in delays of up to a month. Now they are receiving spleen samples this process takes an hour for multiple samples to be processed. Success rates are also much higher.

4.5.3 Challenges

Turnaround times

The programme has challenged labs to shorten the turnaround time, to accelerate the pathway. Labs have prioritised cases when known, but have reported that it is not always clear when a case is a pilot case or not.

There has also been a little discomfort around this practice as it pushes other cases back. Given the small numbers this has not been a major issue, but could pose difficulties as demand increases through roll out.

The labs are working towards shortening their turnaround times to 42 working days from March 2024, subject to support being put in place to facilitate this.

Still a growing workforce

The labs are under pressure as there is a high and increasing demand for their services as many areas of medicine seek to improve diagnostic process through genetic testing. Technology continues to evolve rapidly.

As a relatively new area of medicine the workforce is still growing, and labs reported that recruiting sufficient qualified genetic scientists is a challenge. Labs are taking on more training responsibilities to increase capacity but given the level of education and training required workforce shortages are likely to continue for some years to come.

Whole genome sequencing (WGS) testing

The proposed introduction of WGS testing for the pathway is causing some concern. This is partly due to a lack of clarity about what is happening and when. The WGS test has been added to the National Genomic Test Directory with the creation of an R code specifically for the pilot programme so it is available for use.

There has been some discussion about samples that have already been analysed using R138, being batched and run through the WGS pipeline retrospectively. There are concerns that this will have a detrimental effect on the workflow of labs.

We understand a decision has now been made to run the WGS in parallel with the panel test. It was unclear to some when we spoke to them if there would be attempts to apply WGS testing retrospectively.

4.5.4 Implications for roll out

Labs are under pressure as the demand for their services increases while the workforce is still growing. This pressure will potentially feel greater as the labs work towards halving their turnaround times. There is little the programme can do to ease this pressure except ensure sampling protocols are adhered to, so that labs have the best quality samples possible to work with.

The turnaround time for WGS is longer than panel testing currently, and there will be a greater mismatch if the new turnaround times are achieved. The time from submission of the sample to return of genomic sequencing data is six weeks, with a minimum of a further six weeks needed for reporting.

If the reporting of results requires both the panel test results and the WGS test results, the pathway will not benefit from the shortened turnaround times for routine panel testing. The introduction of WGS could therefore be counterproductive.

4.6 Minor variations in the new pathway

The new pathway being tested is shown on page 16. There are some minor local variations within the pathway illustrated below:

Consent for signposting into the ICC service

One site has implemented written consent for signposting to the ICC service.

Consent for tissue retention

One site has adapted existing documentation relating to consent for retention of tissue rather than using the form provided through the programme.

Access to specialist cardiac pathology

Some pilot areas have a local pathologist with the required specialist skills, whilst others access specialist cardiology provided by St George's, funded by Cardiac Risk in the Young (CRY).

GP Referral into the ICC service

One ICC service is unable to accept signposting from the Coroner only and still requires a GP referral before making contact with the family, which the ICC Coordinator has to trigger. This is a local commissioning protocol.

5. ADDITIONAL ISSUES

In this chapter, we summarise additional issues that have emerged to-date.

5.1 Pathway level issues

Stress caused to families by delays in the pathway

Every stage of the pathway has the potential for delays, resulting from capacity challenges in different parts of the system. While each delay can be relatively short when considered in isolation, when taken together they can add up long delays. These can add to family members' distress, and there is the risk of further cardiac events in the family while they are waiting. The main points of delay are:

- Toxicology testing turnaround times, which have a knock-on effect on final post mortem reporting and confirmation of cause of death
- Clinical cardiology testing (such as ECG, Echocardiogram, Exercise Testing) waiting times, which is a key component of the diagnostic process for family members
- Genetic testing turnround times, which is a key component of the diagnostic process for family members

Logistical management of retained tissue

The end-to-end processes for the logistical management of retained tissue has yet to be finalised and routinely adopted in each region. This leads to issues such as retained tissue samples being sent with the heart to the CRY pathology service when the new pathway process is for DNA to be extracted and stored in the local GLH. In some instances, the transportation of samples to the correct destination has been delayed due to a lack of clarity on the source of funding for the transportation costs.

Assumptions based on familiarity

In some regions, there was a pre-existing relationship in place between the ICC service and the local Coroner. This offered advantages, in that it was easier to bring about change and implement the new pathway. However, we noted that this familiarity sometimes led to assumptions about continuing to do things as they had been done before, rather than taking the time to scrutinise and adapt working practices to align with the new pathway. This led to a continuation of habitual working practices, which sometimes diverged from the nationally agreed pathway. For example, signposting to the ICC Service before the final post mortem is concluded or whilst still waiting for toxicology results.

By contrast, in sites where the relationships were being established for the first time, the teams had to agree in detail each stage in the pathway and clarify roles, responsibilities and process.

Fragility at transition points

Transition points between organisations/services are still relatively new, with relationships and working practices still developing. This is especially the case between the Coroner's office and the ICC Coordinator, and we have seen instances where staff absence, turnover and workload pressures have hindered smooth communication and signposting. This is partly a function of time, and experience tells us the connections will probably strengthen as time goes on. In the meantime, some sites have implemented practices that mitigate the risk. For example, nominating two or three Coroner's Officers to be liaison contacts with the ICC Coordinator, concentrating expertise and the relationship across a smaller group.

Case identification and the possibility of 'missed' cases

In some pilot sites, the pathologist workforce that performs post mortems is relatively small and consistent, whilst in others the workforce is larger and more transient with heavy reliance on locums. The latter group is harder to engage in the programme, as they are not closely connected to the pathway and may only perform post mortems periodically for the local Coroner. This presents the risk that the pathologists are unaware of the pathway and therefore not requesting a specialist cardiac pathology examination where there might be a genetic cardiac cause, and/or not highlighting cases for inclusion in the pathway.

Furthermore, pathologists have different levels of skill in identifying cases that should be referred into the pathway, or recognising where a specialist cardiac pathology assessment is warranted. Locum and freelance pathologists do not necessarily have a local peer group to discuss cases with either, unlike those working in smaller teams which facilitate more collegiate working practices.

Premature signposting

Some families have been signposted to the ICC clinic based on initial post mortem results, where the pathologist had a strong suspicion that the cause of death was a genetic cardiac condition. In a very small number of cases, when the post mortem was finalised the cause of death was not a genetic cardiac condition after all, and ICC clinic support was withdrawn as no longer appropriate.

The early signposting was done to minimise the waiting time before family members received support, but ultimately risked causing additional distress when the support was withdrawn.

We understand that early signposting is still happening on some occasions, but that ICC Coordinators are cautious about how much they proceed before final post mortem report confirms cause of death. In one site, the pathway has been clarified to ensure signposting does not take place until final cause of death is known.

5.2 Programme level issues

Absence of collated data set

As yet, data from each site has not been collated into a central repository. While a SharePoint platform for collecting data has been set up at St George’s Hospital, the information governance process delays remain unresolved for four ICC services. Those four sites are sharing their anonymised aggregated data with the programme separately, which requires additional data management tasks to merge into the collated dataset. Whilst this is currently small scale and therefore manageable, as time goes on the quantity of data will increase and the data management tasks will become more onerous.

Funding continuity

Programme funding will end in March 2024, which is before the new *Cardiology: Inherited Cardiac Conditions Service Specification*, which it is hoped will incorporate the pathway, will be completed. This therefore leaves a potential gap in service provision including the absence of the ICC Coordinator role, unless alternative funding can be found. ICC services involved in the pilot are developing business cases for the ICC Coordinator role, but it is not yet clear whether these will be successful. This could impact on the capacity of the programme to roll out if no additional resource can be identified.

Introduction of Whole Genome Sequencing testing

The planned introduction of Whole Genome Sequencing (WGS) testing is being met with some ambivalence from stakeholders.

Some clinicians are concerned that the testing will not have any clinical benefit as it is using a virtual panel, and therefore may give the same results as the R138 test. Clinicians have stated that normal clinical practice would be to complete panel testing and, if that did not provide an answer, consider WGS as a means of exploring the genome more extensively looking for other (unknown) variants.

Some Coordinators are comfortable with the requirements of the additional consent required and feel that this can be incorporated into the routine consultation appointments. Others are concerned about the complexity and time it might take and whether there will be a requirement to obtain consent retrospectively for cases already on the pathway.

Some genomic labs were concerned about the additional work required, especially if a virtual panel was not applied and a full analysis would be required as this is an additional process.

Stakeholders, in general, seemed least well sighted on what exactly was involved and when the WGS testing would be starting. The funding of WGS for inheritable cardiac conditions was not clear.

We understand that WGS for the pilot has been entered into the National Genomic Test Directory for the purposes of this programme. We further understand that a decision has been made to proceed with WGS testing in parallel with panel testing as samples become available.

Lack of clarity around purpose and process could cause some unnecessary challenges in the pathway and a possible distraction from important tasks and activities required to deliver roll out. Some clear communication around the introduction of WGS testing would be helpful.

Ad hoc roll out to other coronial jurisdictions

The programme is attracting interest from other coronial jurisdictions, and some are keen to be included in their local pilot as soon as possible. Some pilots have capacity and appetite to facilitate this, but roll out to other local coronial jurisdictions needs to retain fidelity to all the pathway protocols, to ensure that it complies with the same quality and patient safety standards as the core pilot.

Implementation capacity for roll out

The ICC Coordinators have played two distinct roles in the programme:

- facilitating set-up and implementation
- delivery once the pathway is established

If the pathway is to be rolled out to other coronial jurisdictions, there will be a continued short to medium term requirement for implementation capacity in the ICC Coordinator role.

Consideration needs to be given to how this capacity is found, should roll-out proceed, given the current funding uncertainty

6. KEY FINDINGS AND LEARNING

The key findings from the evaluation to date are listed below:

1. The pathway is working effectively in six of the seven pilot sites.
2. Implementation of the pathway is labour light for the coronial service.
3. There is insufficient capacity amongst pathology and specialist cardiac pathology services.
4. The role of ICC Coordinator is vital for both service delivery and implementation.
5. Good communication and teamwork between the different disciplines in the pathway is essential
6. Toxicological testing can delay the final post mortem result.

A summary of the key learning points is provided below:

1. Coroners' Officers are the gateway to the pathway so it is essential that they are supported and trained appropriately.
2. Relationship building is essential and takes time, capacity and effort.
3. Familiarity can lead to continuation of habitual working practices, rather than aligning with the new pathway. For example, continuing to signpost to the ICC Coordinator before the final post mortem is concluded, rather than waiting for the final post mortem result. It is important to review and revise existing practices to ensure fidelity to the new pathway.
4. Attention to detail is critical, to ensure all elements of the pathway are adhered to; clear protocols and standard operating procedures can help achieve this.
5. Limiting the number of personnel performing a specific role, such as designating pathologists within a region to carry out the post mortem examinations for cases that meet the criteria, helps with adherence to the pathway, but if there are too few this reduces resilience.

6. Opportunities to share learning and problem solve collectively have been highly valued and productive.
7. The end-to-end logistical processes need attention when establishing the pathway, e.g. storage and transportation of samples; the accountability and funding for these vital tasks needs to be agreed early.
8. Regional leadership at each part of the pathway is important, as is operational commitment.
9. As other coronial jurisdictions join the programme, either now or as the programme is scaled up, it is essential that they maintain fidelity to the pathway; this will require thorough onboarding and training, to ensure a full understanding of and commitment to what the pathway involves.

7. CONCLUSIONS

The pathway is effective in improving access to ICC services for bereaved families. On receipt of a signposting letter from the Coroner's Officer, the ICC Coordinator now has the responsibility for the initial assessment of the first-degree living relative(s). Previously, the family had to arrange a referral through their GPs, with varying degrees of success. By acting as a single point of contact and coordination for the family, the ICC Coordinators help to reduce their stress at a time of significant trauma and identify relatives at risk of sudden unexpected death.

Several factors have been critical to the success of the pilot to date:

- **Commitment and support for the programme** from all members of the multidisciplinary team involved in the pathway
- **National leadership and support** from each of the partners
- **Effective communication, problem solving and sharing** across a multidisciplinary and multi-organisational team in each pilot site, and in regions where this has been particularly strong the pilot has progressed at pace
- **The ICC Coordinator role**, both in set-up and ongoing delivery
- **Effective programme management and support provided by BHF** convening stakeholders, facilitating problem solving and providing the infrastructure needed to deliver the programme

However, some logistical challenges remain both nationally (capacity within the pathologist and specialist cardiac pathologist services, and funding for the ICC Coordinators) and regionally (e.g. efficient processes for transport and storage of retained tissue).

As with any new patient pathway, there is still a level of fragility, and this is particularly so at the transition points between teams and services. We expect the links between teams to strengthen over time.

Two years is a relatively short timescale to implement a new pathway, prove that it works and build a case for sustainability and national adoption. As the programme enters its final nine months, there are issues that need to be addressed if the pathway is to be adopted nationally.

7.1 Strategic priorities for the next nine months

We have identified three strategic priorities that need support and focus from the programme's leadership, to facilitate the success of roll out beyond the pilot period.

Completion and commissioning of the new ICC service specification

Some members of the programme Steering Group and National Oversight Board are involved in developing the new ICC service specification. The evidence from the evaluation supports the argument for the inclusion of the ICC Coordinator role and specialist cardiac pathology services in the specification.

The new service specification will not be finalised or commissioned before the end of the programme period, which poses a risk to continuity of service and a potential delay to national roll out. There is also no guarantee that the new service specification will be commissioned in the submitted format.

The programme's leadership should consider how it can influence the pace at which the specification can be completed and signed-off, to minimise this risk.

Influence pathology workforce transformation

While the need to address the capacity issues within the pathology and specialist cardiac pathology services is beyond the control of the programme, there are opportunities for influencing them. Specifically, pathologists taking part in the programme have an opportunity to highlight the issues which directly affect the pathway, by engaging with NHS England and the Pathology National Transformation Team as well as the Royal College of Pathologists.

Funding continuity

As funding for the ICC Coordinator roles comes to an end in March 2024, there is likely to be a funding gap between the end of the pilot and the launch of the new ICC service specification. This poses a risk to continuity of service during the intervening period and needs to be addressed urgently.

ICC services are being encouraged to develop business cases to continue beyond the pilot period, but success is not guaranteed. The programme's leadership could play an important role in exploring continuity funding to bridge the funding gap, thereby maintaining momentum for roll out.

Build the dataset

The collated dataset generated by the pilot sites will provide crucial evidence to support widespread adoption of the pathway. All partners should support continued data collection and finalise the adoption of a shared data repository. As the dataset grows, it will become increasingly problematic to collate data held at individual sites without early sharing of data and therefore a resolution to the data sharing issues needs to be accelerated.

7.2 Key decision point

As the programme approaches the end of its funded period, the National Oversight Board must make a realistic assessment of the benefits and risks of going forward with national adoption of the pathway. The success of the pathway is well evidenced, but it can only be adopted nationally when the major issues outlined in this interim report are addressed.

The effort required to implement the pathway across the remaining 69 jurisdictions will be significant, and if capacity issues along the entire pathway remain, the potential for failure will increase. The pace and timing of any national scaling needs to be carefully considered in the coming months.

If the decision is made to proceed with national adoption of the pathway, a clear framework that incorporates the lessons learned from the pilot needs to be created. It is not clear which organisation will take overall responsibility for coordinating national adoption of the pathway so this needs to be agreed.

7.3 Next steps for the evaluation

The final evaluation phase will take place between November 2023 and February 2024, and the analysis will include an economic assessment (using cost consequence analysis).

Between July and December 2023, the ICC Coordinators will work with Brightpurpose to invite bereaved family members to participate in semi-structured evaluation interviews about their experiences. The approach and focus for the interview programme were supported by the St George's Ethics Committee and signed off by the programme steering group and national oversight board. The ICC Coordinators are supportive of the approach.

The draft final evaluation report will be produced by May 2024.

APPENDIX 1 – PATHOLOGY PROTOCOL

British Heart Foundation

NHS England and NHS Improvement

Pathology Protocol

NHS and Coronial Sudden Unexpected Death (NHS-C-SUD) Programme

VERSION 1.6

Background to the project
Cardiac pathology, post-mortem genetic testing and clinical familial evaluation are the three primary components of the comprehensive personalised medical management of families who have suffered sudden unexpected deaths (SUD) due to potential genetic cardiac causes. The aim is to test the optimum pathway that identify a cause of death and diagnose and treat relatives who are also potentially at risk of a genetic cardiac condition. The delivery of appropriate patient pathways is, however, highly heterogeneous across the nation and requires close working between the NHS and coronial services. There is an opportunity now with the implementation of Genomic Laboratory Hubs and the Genetic Medicine Service Alliances across England to explore the systematic introduction of post-mortem genetic testing for SUD.

Introduction to this paper
This protocol has been developed in the context of the NHS and Coronial Sudden Unexpected Death project, set up in 2021, to standardise the end-to-end process carried out by the pathologist within each region taking part in the project.

Standardising this process should improve the experience for bereaved families, manage costs and optimise the potential to assess the surviving immediate relatives. It is assumed that the post-mortem examination will be completed in line with the Royal College of Pathologists Guidelines on Autopsy Practice: Sudden death with likely cardiac pathology

The protocol has been developed based on the following assumptions about access to specialist pathology within the 7 regions:

Table 2.0

There is not a specialist cardiac pathologist within this region	There is a specialist cardiac pathologist within this region
Manchester	Sheffield
Leicester	Birmingham
North-East London	South-East London
Bristol	

The charity CRY has kindly agreed to continue to support those services without access to specialist cardiac pathology within their region. Therefore, the CRY funded centre will accept what is anticipated to be a modest increase in referrals from the North-East London, Manchester, Leicester and Bristol pilot sites. This is an interim arrangement which will be in place during the pilot lifecycle.

Regions that have access to a local specialist pathologist should continue as they do now.
NHSE&I is currently working with the Royal College of Pathologists to address a longer-term solution.

We anticipate that each senior Coroner will deal with no more than 3-4 cases per month that will meet the inclusion criteria.

<u>Case inclusion criteria for this project</u>
All sudden unexpected death cases, aged 1-60 years, reported to HM Coroners in the participating sites will be included provided a cardiac genetic cause is suspected. Deaths occurring that remain unexplained despite a full coronial and expert cardiac post- mortem examination and toxicological testing (Sudden Arrhythmic Death Syndrome) will also be included. Decedents older than one year where resuscitation has failed or there is no recovery despite an initially successful resuscitation may also be included.
The pathologist will retain cardiac tissue blocks and tissue suitable for DNA extraction and flag up the case to the Coroner's Officer following autopsy of a sudden death case where the following findings are present:

- Unascertained cause of death*:
- Morphologically normal heart. Sudden arrhythmic/adult death syndrome (SADS)
- Equivocal/uncertain/borderline findings

- A dilated, thin walled, hypertrophied, scarred or fatty heart with normal or unobstructed coronary arteries:
- Hypertrophic cardiomyopathy (HCM)
- Dilated cardiomyopathy (DCM)
- Arrhythmogenic cardiomyopathy (ACM)/arrhythmogenic right ventricular cardiomyopathy
- Unexplained cardiac hypertrophy
- Unexplained cardiac scarring/ fibrosis
- Severe mitral valve prolapse with myxomatous degenerative valvular disease (<40 years**)
- Thoracic aortic aneurysm +/- dissection/rupture (<40 years**)
- Others – i.e. idiopathic calcification of infancy, possible metabolic/storage cardiomyopathy

* Toxicology will be required and will only likely be available at a later stage.
** If there is additional family history of sudden death or similar heart disease then older cases may be included.

NB cases where a non-cardiac cause of death was indicated (e.g. trauma) but a genetic heart disease has been identified incidentally will be included.

Alignment with the Child Death Review process
This project is aligned with the Child Death Review process for unexplained deaths in children. Alongside the review process, the case will be referred to the Coroner and the coronial pathologist will take forward the initial post-mortem examination. The pathologist will specifically address potential paediatric causes of sudden unexpected death such as inborn errors of metabolism. If the result of the post-mortem examination indicates that the cause of death is likely to be a genetic cardiac condition or unexplained, the case will be included in the pilot. In other words, the Coroner's office should signpost the parents of the child to the local clinic for inherited heart conditions and ensure retention of tissue.

Of course, if the post-mortem examination indicates a cause of death that is unrelated to inherited heart disease, the case should not be included in this pilot.

Managing the process within each region

5.1 Allocation of cases to the pathologists and specialist cardiac pathologists within each region

The Coroner should continue to allocate the case to the local pathologist through the existing allocation process/system (no change to existing process required). Some Coroners may choose to allocate cases automatically to the local specialist cardiac pathologist where the circumstances of death or the deceased's history indicates from the outset that a genetic cause of death is highly likely. If so, click here to read the criteria that would indicate a genetic cardiac cause of death prior to the post-mortem examination being carried out.

If the pathologist carrying out the initial post-mortem examination is satisfied based on their initial examination that the cause of death is a genetic cardiac condition, there is no need for further specialist examination unless that pathologist believes it would be of benefit. However, if the pathologist concludes that a specialist cardiac post-mortem examination is required, the case should be referred to the cardiac pathologist providing a service for that region (see table 2.0 on page 2) as quickly as possible.

If the case is being referred to the CRY funded specialist pathologist centre at St George's, more information on that process can be found in appendix A. Tissue suitable for DNA extraction should be stored locally and not sent to the CRY funded centre at St George's for the lifetime of the pilot. The post-mortem examination should be carried out in accordance with relevant guidelines (see Royal College of Pathologists Guidelines on Autopsy Practice: Sudden death with likely cardiac pathology)

Ideally the heart should be returned to the family within 2 weeks of the death to allow the funeral to take place (depending on local testing reporting timelines and family arrangements).

5.2 Reporting findings

Following completion of specialist pathology examination, the report detailing the findings should be provided to the coronial service investigating the death.

In cases where a genetic cardiac cause is the suspected cause of death, the specialist pathologist should highlight this at the front of the report and indicate the need for family and genetic investigation. This will act as a prompt for Coroner's Officer to advise the family of the need for specialist follow up in an ICC service and for tissue to be retained to support the assessment of the family.

Suggested wording: In view of the above diagnosis and negative toxicology, I would advise that the immediate blood family are screened by a cardiologist at an inherited cardiac condition centre. Retention of tissue suitable for DNA extraction and future genetic testing is strongly recommended (if not already given).

5.3 Capturing consent to retention of tissue after the Coroner's purposes are complete.
Consent for retention of tissue after the Coroner's purposes are complete should be captured in accordance with the Human Tissue Act and using the agreed standardisation consent forms developed for this project (Histology Tissue Retention Consent Form)
Consent should be captured by the Coroner's Officer.
The Coroner's Officer will be supported to do this as outlined in section 5.6
The Coroner's Officer should inform the pathologist and/or specialist pathologist whether consent has been captured to retain the tissue so that it can be either stored or disposed of appropriately.

5.4 Retention of tissue
Provided consent has been captured to retain tissue after the Coroner's purposes are complete, the following samples should be retained depending on the availability of suitable -80 degrees Centigrade freezers at the mortuary:

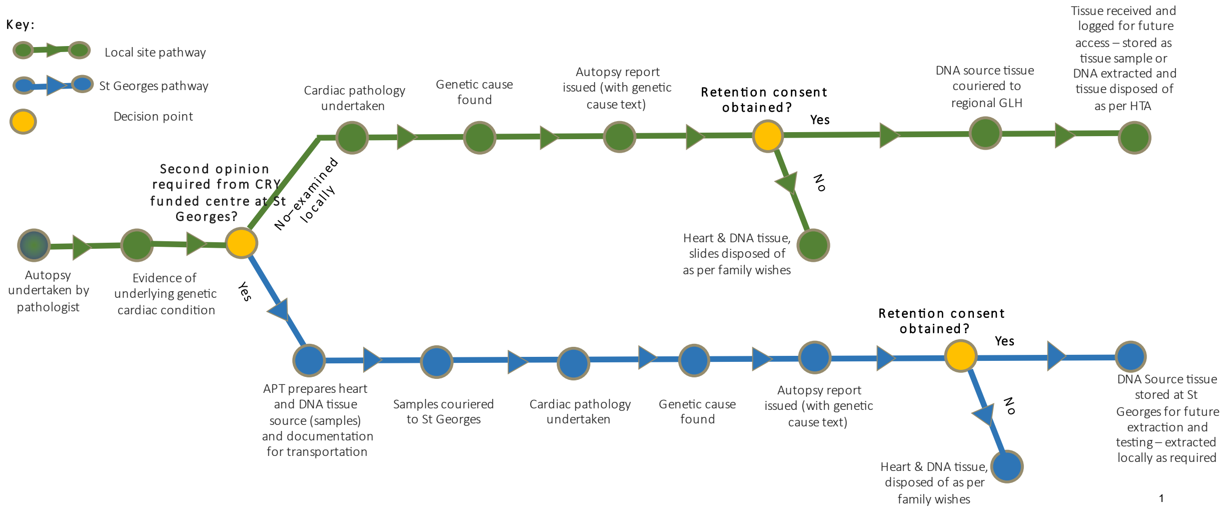
Cardiac blocks (FFPE at room temperature)
Tissue for DNA extraction
Blood (frozen)
1 cubic centimetre of Spleen or liver (taken at time of initial autopsy frozen or placed in RNA Later solution at room temperature)

Where no mortuary freezer is accessible, RNA Later solution is the recommended storage medium. Tissue should be taken and added to this solution at the point of initial autopsy to maximise tissue quality for DNA extraction

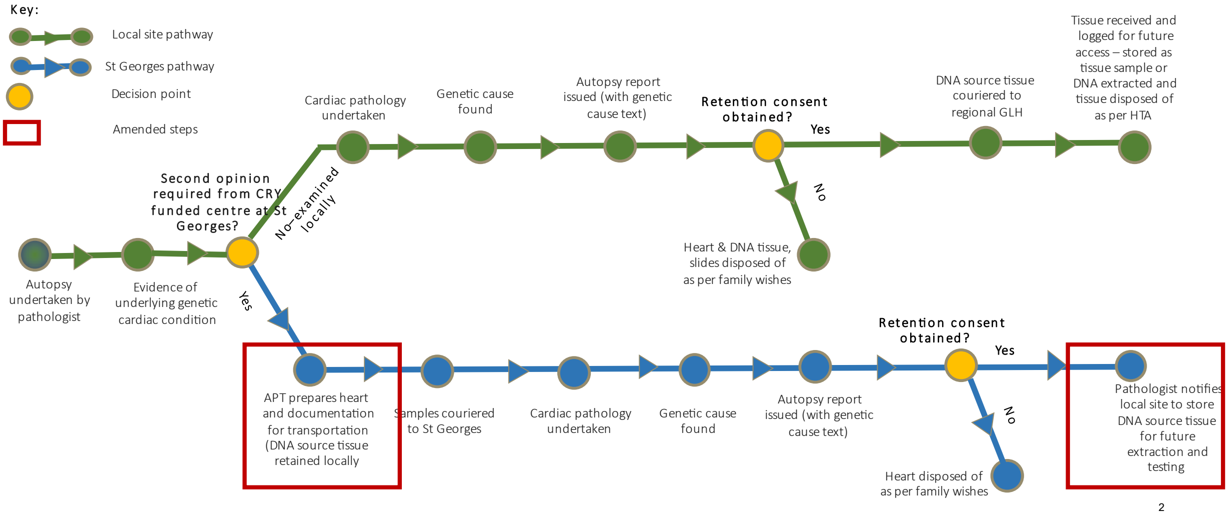
5.5 Storage of Tissue
Where cardiac pathology has been undertaken locally or sent to the CRY funded centre at St George's, locally stored tissue suitable for DNA extraction should be transported to the regional Genomic Laboratory Hub (GLH) for processing and storage according to existing developed practice. Each regional pathologist should liaise with their local GLH to finalise arrangements for transport of the tissue and storage arrangements thereafter or either that tissue or the extracted DNA.
Where cardiac pathology has been undertaken at the CRY Funded centre at St George's and examination indicates a genetic cardiac cause of death,

the CRY pathologist will advise that locally held tissue suitable for DNA extraction should be processed for storage as outlined in 5.5(a), above. The arrangements for each region should be shared with the Coroners' Officers (See diagrams below. The first diagram outlines pathways prior to the pilot programme. The second diagram outlines the pathway during the programme lifetime. Ideally, the location should be notified to the relevant ICC Coordinator during the signposting with consent process

Cardiac Pathology exemplar – Existing pathway



Cardiac Pathology exemplar – Pilot programme pathway



5.6 Training and support for the Coroner's Officer

Coroners' Officers within each area taking part in the project should undergo the training arranged by the British Heart Foundation to ensure they understand the end-to-end process and have the appropriate level of knowledge to support the families at this early stage of the pathway. They should also be aware of the support information offered by charities such as Cardiac Risk in the Young (CRY) so they can signpost the families to them. See the leaflet on 'Supporting families following a sudden unexpected death'

Appendix A: CRY Specialist Cardiac Pathology, Macroscopic and Microscopic Guidance Criteria:

Pathology	Macroscopic Criteria	Microscopic Criteria
Hypertrophic cardiomyopathy	Increase in heart weight (above 550 in male and 450 in female) Right ventricular wall thickness >5mm or left >15 mm . Atrial dilatation. Can be normal macroscopically. Absence of coronary artery disease.	Left ventricular myocyte disarray* (>20% of myocardial disarray in at least 2 cardiac sections) and myocyte hypertrophy with or without interstitial or replacement fibrosis and thick walled blood vessels.
Arrhythmogenic cardiomyopathy	Normal or increased heart weight . Right or left ventricular thinning, fatty replacement, fibrosis on the epicardial surface. Can be normal macroscopically. Absence of coronary artery disease.	Fibrosis admixed with fatty infiltration of the myocardium originating from the epicardial surface (>20% in at least 2 cardiac sections).
Dilated cardiomyopathy	Increase in heart weight with dilated left ventricle (>40mm chamber diameter) and thin compact wall (<10mm). Mural thrombi in ventricles Dilated atria	Widespread diffuse interstitial or replacement fibrosis (>20% in at least 2 cardiac sections) in the left ventricle with atrophic myocytes.

	with thrombi in appendages. Absence of coronary artery disease.	
Idiopathic left ventricular hypertrophy	Increase in heart weight . Left ventricular wall thickness >15 mm . No hypertension diabetes ,obesity or coronary artery disease	Myocyte hypertrophy with or without replacement or interstitial fibrosis. Absence of myocyte disarray.
Obesity Cardiomyopathy	Increase in heart weight . Left ventricular wall thickness >15 mm . No hypertension diabetes or coronary artery disease	Myocyte hypertrophy with or without replacement or interstitial fibrosis. Absence of myocyte disarray.
Hypertensive heart disease	Increase in heart weight . Left ventricular wall thickness >15 mm. History of hypertension. No coronary artery disease	Myocyte hypertrophy with fine interstitial fibrosis in subendocardium. Absence of myocyte disarray.
Myocarditis	Normal or dilated ventricles with variegated appearance. Fibrinous pericarditis. Can be normal macroscopically	Inflammation (>20% in at least 2 cardiac sections) with associated myocyte necrosis.
Coronary atherosclerosis	Atherosclerosis with luminal narrowing >75% or lumen less than 1mm or inability to insert 2mm probe. Infarction or scarring in myocardium. Normal myocardium Rupture with haemopericardium.	Acute or chronic infarction in right or left ventricle. May be no infarction .

	Thrombosis in coronary artery.	
Anomalous coronary artery	Anomalous origin of the coronary artery in the incorrect sinus with interarterial course or pulmonary artery origin .	May have acute or chronic infarction in the right or left ventricle.
Mitral valve prolapse	Prolapse of mitral valve above the atrioventricular junction with ballooning between cords in one or both leaflets. Diffuse thickening of leaflets. Mitral Annular dilatation Cordal thinning and /or rupture.	Myxoid degeneration with expansion in spongiosa of leaflets and destruction of fibrosa layer. May be subendocardial fibrosis in posterobasal left ventricle.
Aortic stenosis	Significant valve stenosis demonstrated by inability to insert a finger through the annulus. Calcified valve and/or bicuspid valve. Increase in heart weight[‡] and left ventricular wall thickness >15mm.	Myocyte hypertrophy and/or interstitial or replacement fibrosis throughout left ventricle.

APPENDIX 2 – CONSENT

RETENTION AND DISPOSAL OF TISSUE CONSENT FORM

Adult and older children
Name of Deceased
Coroner's Ref. No.
Date of Death
Date of Post-mortem

To be completed by the Coroner's Investigator / Officer dealing with the death
Name of Family Representative:
Relationship to the Deceased:

I have discussed the options available in relation to the method of disposal of the tissue taken for histology at post-mortem, and detailed on this form, with the above. All samples will be retained until the conclusion of the Coroner's investigation.

The above named person has confirmed that the tissue must be:

• Retained further, for use for clinical testing, medical research or other purposes in accordance with the Human Tissue Act 2004.	
• Disposed of in a respectful and legal manner in accordance with the Human Tissue Act 2004.	
• Returned to relatives via their Funeral Director to deal with lawfully in accordance with their wishes.	

(Name and address of Funeral Director)

I have advised that a letter confirming this decision will be sent to the above named person giving them a period of 14 days to contact me if they wish to change their decision.

Print name:
Designation:
Date

DISPOSAL OF TISSUE MUST BE IN ACCORDANCE WITH THE EXPRESSED WISHES OF THE FAMILY REPRESENTATIVE

APPENDIX 3 – THEORY OF CHANGE DIAGRAM

There is a consistent pathway, well understood and adopted by all partners

- Focused on supporting families to make an informed decision about tissue retention and referral to specialist support

Staff understand the pathway and their role in it

- Their part in the pathway
- Who they hand over to and how
- How their part in the pathway contributes to the overall family outcome

Staff are able to perform their part in the pathway

- Skills
- Confidence
- Capacity
- Relationships with their key contacts in the multidisciplinary team
- Supporting resources

Families get the support and info they need to make the decisions that are right for them

- Supportive discussions with skilled professionals
- Information materials that meet their needs
- Sensitivity to their individual needs as a family
- Proceeding at their pace

More surviving families will receive assessment and care in an ICC clinic

More families will consent to tissue retention

More families will consent to testing

Preventable deaths will be reduced

BRIGHTPURPOSE

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