Full Business Case for the Reconfiguration of Pathology Services

January 2014

East Kent Hospitals University NHS
NHS Foundation Trust

Maidstone and Tunbridge Wells NHS
NHS Trust

Kent Pathology Partnership – Key Messages

The Vision

'To create an efficient and innovative diagnostic service of the highest quality which delivers the best patient outcomes and is the first choice for clinical users, patients and staff against a background of an organisation which is competitive, commercially aware and market focussed.'

KPP is best for our patients because it will deliver:

- **Easier access to the service – right test, right place, right time.**
- **Less risk of duplication of testing.**
- **Higher service quality through standardised delivery.**

KPP is best clinically:

- **Through unified quality and operational management across its scope.**
- **Through single accreditation of its services with all regulatory bodies.**

KPP is best for our staff because it will:

- **Safeguard futures with more efficient delivery**
- **Provide opportunities – multi-disciplinary training, innovative technologies, flexible working.**

KPP is best for our customers because it will deliver:

- **Standardised service delivery across its scope.**
- **Improved access to services through 24/7 delivery.**
- **Expansion of service menu.**

KPP is best for the partnering Trusts because:

- **It provides resilience and future capability, safeguarding the current business base, and providing opportunities to expand.**
- **It delivers service efficiencies and improvements through integration and consolidation.**
- **It delivers significant financial savings generating a positive net cash flow of £20.7m (next 7y).**
- **To 'Do Nothing' is untenable.**

It is recognised and understood that KPP represents significant change. All proposed changes will only be implemented in a safe and clinically appropriate manner that upholds service quality. Equally all changes to staffing levels will be undertaken in a measured, phased way that, where possible, will utilize natural wastage.

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Glossary of abbreviations

ACB	Association for Clinical Biochemistry and Laboratory Medicine	KSS ASHN	Kent Surrey & Sussex Academic Health Science Network
AfC	Agenda for Change	LFE	Learning From Experience
ASPH	Ashford and St Peters Hospital	LIMS	Laboratory Information Management Systems
CCGs	Clinical Commissioning Groups	LiNK	Local Involvement Networks
CEO	Chief Executive Officer	MDM	Multi-Disciplinary Meeting
CIP	Cost Improvement Programme	MFT	Medway Foundation Trust
CLRN	Comprehensive Local Research Network	MH	Maidstone Hospital
COSHH	Control of Substances Hazardous to Health	MHRA	Medical Healthcare Regulatory Agency
CPA	Clinical Pathology Accreditation	MLS	Managed Laboratory Service
CQC	Care Quality Commission	MTW	Maidstone and Tunbridge Wells NHS Trust
CSL	Central Services Laboratory	NBV	Net Book Value
D&G	Dartford and Gravesham NHS Trust	NHS	National Health Service
DoH	Department for Health	NICE	National Institute of Clinical Excellence
EKHUFT	East Kent Hospitals University NHS Foundation Trust	NIHR	National Institute for Health Research
ESL	Essential Services Laboratory	NPV	Net Present Value
FBC	Full Business Case	OBC	Outline Business Case
FTFF	Foundation Trust Funding Facility	OCS	Order Communications Systems
GMC	General Medical Council	PbR	Payment by Results
HEE	Health Education England	pa	Per Annum
HPC	Health Professions Council	PAS	Patient Administration Systems
HPV	Human Papilloma Virus	POcT	Point of Care Testing
HTA	Human Tissue Authority	PPE	Post Project Evaluation
IBMS	Institute of Medical Laboratory Sciences	QEQM	Queen Elizabeth the Queen Mother's Hospital, Margate
ILS	Integrated Logistic Support	RcPath	Royal College of Pathologists
IM&T	Information Management & Technologies	RfPB	Research for Patient Benefit
IPP	Integrated Pathology Partnership	R&D	Research and Development
ISO	International Standards Organisation	SPS	South West Pathology Services
JV	Joint Venture	TDL	The Doctors Laboratory
KCH	Kent & Canterbury Hospital	TUPE	Transfer of Undertakings Protection of Employment
KMCS	Kent and Medway Commissioning Support	TWH	Tunbridge Wells Hospital
KMPN	Kent and Medway Pathology Network	UKAS	United Kingdom Accreditation Service
KPI	Key Performance Indicator	WTE	Whole Time Equivalent
KPP	Kent Pathology Partnership	WTE	Whole Time Equivalent

Glossary of terms

Agenda for Change	Agenda for Change (AfC) is the current National Health Service (NHS) grading and pay system for all NHS staff, with the exception of doctors, dentists and some senior managers.
Andrology	The branch of medicine concerned with diseases in men, especially of the reproductive organs.
Biochemistry	The science involving chemical analysis of body fluids to diagnose disease.
Blood Sciences	Merges aspects of Haematology, Biochemistry and Immunology.
Blood Transfusion	The laboratory process supporting the safe transfer of blood or blood-based products from one person into the circulatory system of another.
Cellular Pathology	The combined service of Histology and Cytology.
Central Services Laboratory	A Laboratory that will receive and manage all non-urgent work from the other network locations. This will include all direct access work, and hospital based work that does not fall within the less than 2 hours clinical need.
Clinical Commissioning Groups	These are the entities responsible for commissioning the majority of NHS funded Pathology services.
Commissioning Support Unit	Provide transformational and transactional support to CCGs and other NHS Departments.
Cytology	The examination of individual cells and small clusters of cells to diagnose and screen diseases.
Department of Health	Government department with responsibility for government policy for health and social care matters and for the NHS.
Essential Services Laboratory	A Laboratory that will manage all site-based acute Blood Sciences activity that demands a turn-around time of less than 2 hours. This will be limited to In-patient and A&E activity, unless clinical need dictates otherwise.
Financial appraisal	An assessment of the relative financial outcomes of the various options being considered.
Fixed asset impairments	The revenue charge incurred when a fixed asset is immediately fully depreciated as it has no further useful economic value.
Haematology	The study of blood, the blood-forming organs and blood diseases.
Haemophilia	A genetic disorder, usually inherited, of the mechanism of blood clotting.
Histology	The study of the microscopic anatomy of cells and tissues.
Immunology	The study of an organism's defence (immune) system, in both health and disease.
Kent and Medway Pathology Network	Consortium formed in 2005 comprising 5 Acute Trusts (one in Sussex and the rest in Kent). Disbanded as a result of PCTs being abolished.
Kent Pathology Partnership	Name of the proposed joint venture between EKHUFT and MTW to centralise Pathology services in Kent.
Microbiology	The study of pathogenic microorganisms such as bacteria, fungi, parasites and viruses.
Modernising Pathology Services	Document produced in 2004 outlining recommendations to modernise Pathology services.
Molecular Pathology	The study of molecular events that underlie the cause of disease.
Net Present Value	The discounted value of the stream of future financial benefits.
Pathology	The scientific study of the nature of disease and its causes, processes, development, and consequences.
PCT	NHS body responsible for commissioning primary, community and secondary health services from providers until April 2013.
Project Board	Board formed as the decision making group for the KPP Project.
Project Team	Team formed to support the KPP Board.
Stakeholder	Any person, group or body with an interest in the services.
Trusts	Provider Trusts.
Workforce Workstream Groups	Team formed to address specific areas of KPP project.

1. Executive Summary

1.1. Background

With the objective of modernising Pathology[1] services, Kent and Medway Pathology Network[2] (KMPN) consortium was established in 2005 comprising the four acute Trusts in Kent and one in Sussex.

In 2006 and 2008, Lord Carter of Coles produced independent reports commissioned by the Department of Health[3] (DoH) which recommended consolidation of Pathology departments, with focus on achieving improved quality together with significant increases in operational effectiveness and the identification of major financial savings.

Plans developed by KMPN to implement Carter's consolidation recommendation did not come to fruition despite both East Kent Hospitals University NHS Foundation Trust (EKHUFT) and Maidstone and Tunbridge Wells NHS Trust (MTW) support. Dartford and Medway NHS Trusts chose to decline the opportunity to join the Kent Pathology Partnership (KPP) initiative. As a result, the EKHUFT and MTW Trusts determined, in 2012, to work together in order to consider a joint venture. The vision for KPP was established in 2013 as follows: -

'To create an efficient and innovative diagnostic service of the highest quality which delivers the best patient outcomes and is the first choice for clinical users, patients and staff against a background of an organisation which is competitive, commercially aware and market focussed.'

KPP represents change. All proposed changes will only be implemented in a safe and clinically appropriate manner that upholds service quality. Equally all changes to staffing levels will be undertaken in a measured, phased way that, where possible, will utilize natural wastage.

1.2. Benefits of KPP

The KPP proposal will provide leadership and strengthen the service for future expectations i.e. future proofing diagnostic services therefore benefit patients, service users, staff and those involved in the partnership.

All proposed changes will only be implemented in a safe and clinically appropriate manner that upholds service quality.

[1] The scientific study of the nature of disease including its causes, processes, development and its consequences.
[2] Consortium formed in 2005 comprising 5 Acute Trusts (one in Sussex and the rest in Kent). Disbanded as a result of PCTs being abolished.
[3] Government department with responsibility for government policy for Health and Social Care matters for the NHS.

The KPP proposal therefore offers the following benefits:

For patients:

- Improved patient care implementation of full electronic requesting and reporting.
- Improved access to Pathology.
- Reduction in repeat tests through visibility of results across the scope of the service to all users.
- Reduction of inappropriate testing.
- Reduction in sample loss through electronic monitoring.
- Fewer transcription errors in patient details through electronic monitoring.
- Enhanced data quality through improved legibility of requests.
- Cleaner data bases through implementation of a single IM&T solution across the partnership network.
- Speedier and standardized results will allow more appropriate clinical decisions making and facilitate rapid discharge from an In Patient environment.
- More appropriate and timely clinical decision making in the emergency environment.
- Improved and standardised access to pathology specialists across the scope of KPP and subsequent advice on test/test and/or test/exam contraindication.
- The opportunity to repatriate specialist tests currently referred to outside pathology laboratories – improving turnaround times and clinical management of patients.
- Preparedness for changes in result access by 2015 when patients will be able to own personal diagnostic record and ask advice from other health care providers, rather than just the referring clinician.
- Equal and improved access to tests and results for clinicians wherever patients are within the KPP catchment area.
- GP access to inpatient results across the whole of MTW and EK.

Clinical benefits:

- Creation of a more robust R&D program.
- Expansion of specialist services.
- Enabling of test repatriation and the creation of local expertise for esoteric and complex analytical pathways.
- Service continuity – acute and primary care with unified records.
- True 7 day working across all diagnostic area.
- Improved access to laboratory and 24/7 results (e.g. GP out of hour service).
- Centralisation of quality assurance and governance processes with associated benefits to patients, referring clinicians and staff.
- Larger patient cohorts for any audit and / or QA review processes.
- Coordination of genetic expertise across disciplines to facilitate genotypic and genomic profiling of patients.
- Collaboration with CCG's to reduce 'over-testing' by some GP's – with robust data management processes to support this initiative.

- Better facilitation of involvement in clinical trials with subsequent direct benefits for patients.

For GP's and other clinicians:

- Increased frequency of and timelier sample collection from GP surgeries.
- Faster and more efficient specimen reception with resulting improved turnaround times.
- Electronic demand management processes to prevent unnecessary repeat testing.
- Speedier and standardised results allowing more effective decisions making across the scope of KPP.
- An on-line history of results ensuring that complete records are available to assist clinical decision making.
- A reduced requirement for enquiries and phone calls to laboratories from GP practices.
- A controlled and standardised test catalogue ensuring that best practice is followed.
- More relevant testing designed to improve quality.
- More robust electronic ordering and specimen tracking processes.

For Staff:

- Improved, equitable and standardised training opportunities.
- New opportunities for rotational training.
- Enhanced opportunities within the Research and Development environment.
- Larger sample numbers ensuring expertise and competence routine and specialist diagnostic areas.
- Experience in large complex pathology services - without having to work in London.
- Improved links with Universities.
- Continued benefits of employment within an NHS organisation (NHS pension Membership etc.).
- Standardised terms and conditions.

For the Trusts:

- Reduced risk of losing current customers to other potential (NHS and private) providers.
- Reduce costs with improved economies of scale and subsequent competitiveness.
- Continued and enhanced provision of an NHS led Pathology service.
- Improved financial performance within both the pay and non-pay operational areas of Pathology services.
- Improved quality and consistency through standardisation of processes and delivery of services.

- Enhanced business development opportunities through the development of effective services with a low cost base.
- Increased income opportunities with current customers, new services, local new business opportunities (e.g. Kent Institute of Medicine & Surgery), neighbouring Trusts etc,
- Improved access to Pathology services.
- Improved management of acute pathology provision to acute patients, with associated more efficient patient management pathways.
- Repatriation of esoteric tests, in line with measured business case benefits being demonstrated resulting in savings over current provision e.g. Repatriation and centralisation of Cytomegalovirus testing will result in savings of £16500 p.a. as well as avoidance of unnecessary treatment at £500 per patient. Repatriation and redesign of antifungal susceptibility testing will lead to net savings of £24500 p.a.

1.3. Overview of Rationale for the Initiative

One key outcome of both Lord Carter of Cole's reports on Pathology has been a substantial increase in equipment where Trusts have invested heavily to defend their market share, especially that of the direct access activity. This has resulted in over capacity and unit costs increasing.

With the emergence of the Clinical Commissioning Groups (CCG's), the focus on high quality and realistic cost has been paramount in that commissioners are no longer obliged to use local providers. They can tender services from any provider to obtain highest quality at lowest price.

Pathology service provision within both Trusts comprises direct access and acute workload activity. The direct access element generates significant income. This effectively subsidises the acute activity. The environment in which NHS Pathology currently finds itself makes it particularly vulnerable.

The risks of "doing nothing" i.e. keep the status quo are:

- Offer competitors the opportunity to bid and win the valuable Direct Access activity.
- In turn this would burden the Trusts with expensive and complex acute activity.
- A major reduction in activity would result in the need to reduce the size of Pathology accordingly.
- Loss of direct access revenue would destabilize the provision of Pathology acute services, and potentially prohibit expansion of these key services.
- Clinical risk may subsequently increase.

- This scenario would equate to substantial job losses with a high level of redundancy costs being borne by the Trusts as it is perceived that TUPE transfer of staff would not occur due to the mixed acute/direct access workloads of staff, as we cannot be sure that this will not if we lose business to another provider.
- This scenario would render the remaining acute activity unaffordable.
- A two system scenario would result in a loss of clinical interpretation
- There will be a loss of control of Pathology services
- Current training that staff sees as a right would disappear as they become unaffordable thus preventing career progression.
- Research and Development would be threatened.
- The well-established excellent reputation currently offered to all customers by of both Pathology services would be in jeopardy.
- There would be potentially reduced clinical management of primary care patients.
- The risks to Pathology could well impact on the future success of other non-pathology based acute services.
- To “Do Nothing” is untenable.

Whilst a relatively immature market, there are a number of private Pathology providers within the UK. Notable examples are The Doctors Laboratory (TDL) who have a number of contracts with NHS and private providers, Integrated Pathology Partnership (IPP) who supply services to Taunton & Somerset and Yeovil, and GSTS a partnership between SERCO and Guy’s and St Thomas’s who provide services to their own Trusts, Kings and Bedford hospitals. The imminent opening of the Kent Institute of Medicine and Surgery in Maidstone adds to the more local competitive threat.

Because of this significant threat to the future viability of both Trusts Pathology services, the “Do Nothing” Option cannot be considered as a strategic option.

The financial impact of loss of direct access revenues is highlighted in the table below.

1.4. Rationale for Joint Venture

A fundamental requirement for the venture is the establishment of a business operating model which can successfully compete with commercial and NHS providers of Pathology services in terms of price and quality.

In establishing this model, The Kent Pathology Partnership (KPP) will be strongly placed to retain its existing client base and expand its service offering into the wider Pathology market place. This will result in increased client contracts, and savings realised via economies of scale.

Retaining ownership of service provision will also allow control over future strategic changes in how clinical support services are delivered.

A joint venture with the appropriately resourced management structures which recognises the imperative for forward planning will facilitate a proactive approach to future configuration needs in terms of future technological, innovation and service developments.

In order to understand the advantages, risks and implications of a joint venture to the Trusts, the Trusts through the KPP Project Board enlisted the expertise of the legal experts DAC Beachcroft. Their advice indicated the appropriateness of the joint venture approach and described the associated implications. Full details of this legal advice are shown in Appendix Q pages 180-183.

1.5. Progress to Date

In January 2013, the KPP was initiated. A clinically led project structure was established comprising of a Project Board, Project Team[4] and seven workstream groups. In addition to achieving significant financial savings, the overall aims of the project were to establish a merged, high quality, robust and sustainable Pathology service which could thrive and grow within an evolving competitive market environment.

Discussions within the project groups led to ratification by the Project Board of the following:

- A name for the joint venture - “Kent Pathology Partnership” (KPP).
- Each Trust to share risk and reward
- The need for a contractual agreement between the Trusts for the joint venture based on the venture being a non-legal entity.
- One Trust to host KPP.
- Equal representation of both Trusts on the Management Board of KPP.

The Project Team identified a long list of options for the configuration of Pathology services. This was reduced to 3 options for detailed evaluation within an Outline Business Case (OBC).

The three options identified were:

> ***Option 4: -*** *A twin Central Services Laboratory[5] (CSL) approach, with a Microbiology, Molecular[6], Cytology[7] and Andrology CSL at Maidstone Hospital (MH); a Blood Sciences[8] and Histology CSL at William Harvey Hospital (WHH) and Essential Service laboratories (ESL) at each of the 5 acute hospital sites.*

[4] Team formed to support the KPP Board
[5] A Laboratory that will receive and manage all non-urgent work from the other network locations. This will include all direct access work, and hospital based work that does not fall within the less than 2 hours clinical need.
[6] The study of molecular events that underlie the cause of disease.
[7] The examination of individual cells and small clusters of cells to diagnose and screen diseases.
[8] Merges aspects of Haematology, Biochemistry and Immunology.

Option 5: - *A twin CSL model, with a Microbiology and Histology CSL at MH; a Blood Sciences, Molecular, Cytology and Andrology CSL at WHH and ESLs at all five acute sites. NB It should be noted that the ESL at WHH will be operationally integrated with the CSL.*

Option 6: - *An off-site CSL, with a single facility housing all CSL functionality and ESLs at each of the five acute sites.*

This more detailed evaluation included a financial appraisal[9] of each of the 3 options in comparison with a 'Do Nothing' option.

Central Services Laboratory is a Laboratory that will receive and manage all non-urgent work from the other network locations. This will include all direct access work, and hospital based work that does not fall within the less than 2 hours clinical need.

Essential Services Laboratory is a Laboratory that will manage all site-based acute Blood Sciences activity that demands a turn-around time of less than 2 hours. This will be limited to In-patient and A&E activity, unless clinical need dictates otherwise.

1.6. Key Project Drivers

There are a number of fundamental drivers identified for the joint venture which include:

- Improvement in patient outcomes and clinical quality by providing integrated Pathology services across Kent to a consistent high standard meeting regulatory and professional requirements.
- If the two Trust's Pathology Services continue to work in isolation from each other they will be unable to deliver the low prices expected by commissioners, and will risk losing work to other providers through potential open tendering process. The KPP collaboration will continue the work started by the Kent & Medway Pathology Network designed to deliver required efficiency savings through integration and rationalisation to achieve standardised, low cost, safe and effective Pathology services.
- The need to retain existing direct access income, a loss of which will seriously undermine the viability of Pathology Service Provision within both Trusts.
- Development of a new and more sustainable model for delivering Pathology services in Kent that reduces costs in order to improve competitiveness.
- The need to safeguard services from competitive threat e.g. the advent of the Kent Institute of Medicine & Surgery.
- Improvement capability to seek new markets in order to further reduce unit costs.
- The need to increase income from secured business growth e.g. with current customers, new business opportunities (e.g. Kent Institute of Medicine and Surgery), neighbouring Trusts and further afield,
- Continued delivery of an NHS run Pathology service within both Trusts, with enhanced training and career opportunities for staff.

[9] An assessment of the relative financial outcomes of various options being considered.

- Identification and implementation of the necessary transformation changes required to deliver sustainability and quality improvements through consolidation.
- Implementation of the required changes in a phased manner that has a minimum impact on service continuity.
- The need to recognise and learn from service failures in other Trusts. In the review of the activities at Kingsmill Hospital (Sherwood Forest Hospitals NHS Foundation Trust NHS Trust) it was shown that low-volume activity is associated with increased risk. The KPP objectives set out to address this by integrating services to manage analytical activity more effectively, providing quality improvements and a safer service.

1.7. Benchmarking- Cost Comparisons

A number of sources have been researched in order to understand the current Trusts Pathology delivery models and to assess the optimum structure for KPP going forward. These include:

- A review of Department of Health reference costs.
- An independent critical friend review of ESL staffing needs at QEQM Margate.
- Involvement and feedback from a management consultant heavily engaged in the post Lord Carter of Cole's review of pilot sites and associated costs.
- Collation of Freedom of Information (FOI) data received from >150 Trusts.
- Feedback as to ESL staffing requirements from a number of Pathology departments that have or will be undertaking similar service consolidation.

Extensive analysis of the Keele Benchmarking data received for 2012/13.Dialogue with current Managed Service providers to ensure that service delivery in the ESLs can be delivered effectively.

A benchmarking analysis of productivity and cost for EKHUFT and MTW is provided in Table B below. This analysis is based on detailed data from over 50 health organisations. The authors are Keele University who have provided annual NHS Pathology benchmarking reports for a number of years.

Table B - Comparison of EKHUFT and MTW Pathology Services

Current Trust Performance - based on Keele Data 2012/13											
		PRODUCTIVITY					COST				
		Bottom	Median		Top		Bottom	Median		Top	
		0-25%	25-50%	50-75%	75-100%		0-25%	25-50%	50-75%	75-100%	
Biochemistry	EKHUFT										
	MTW										
Haematology	EKHUFT										
	MTW										
Microbiology	EKHUFT										
	MTW										
Cell. Path.	EKHUFT										
	MTW										
KPP Performance - forecast based on Keele Methodology											
		PRODUCTIVITY					COST				
		Bottom	Median		Top		Bottom	Median		Top	
		0-25%	25-50%	50-75%	75-100%		0-25%	25-50%	50-75%	75-100%	
Biochemistry	KPP										
Haematology	KPP										
Microbiology	KPP										
Cell. Path.	KPP										

The benchmarking exercise reveals the need for KPP to materially increase productivity in order to be economically viable and competitive within the context of clinical appropriateness. Against this background, a staffing review has been undertaken of Blood Sciences involving external experts and utilising other industry sourced data. An analysis of the impact of the review is as follows:

- Any reduction is WTE numbers will be undertaken in a phased way from (as described in the Outline Business Case - OBC).
- ESL reduced from 5 to 4 with WHH ESL workload subsumed into WHH Central Services Laboratory (CSL).
- The need for a flexible work-force to give resilience to the ESL from CSL staffing resources.

These processes are described in **Section 7.3 Staffing Review** later in the document.

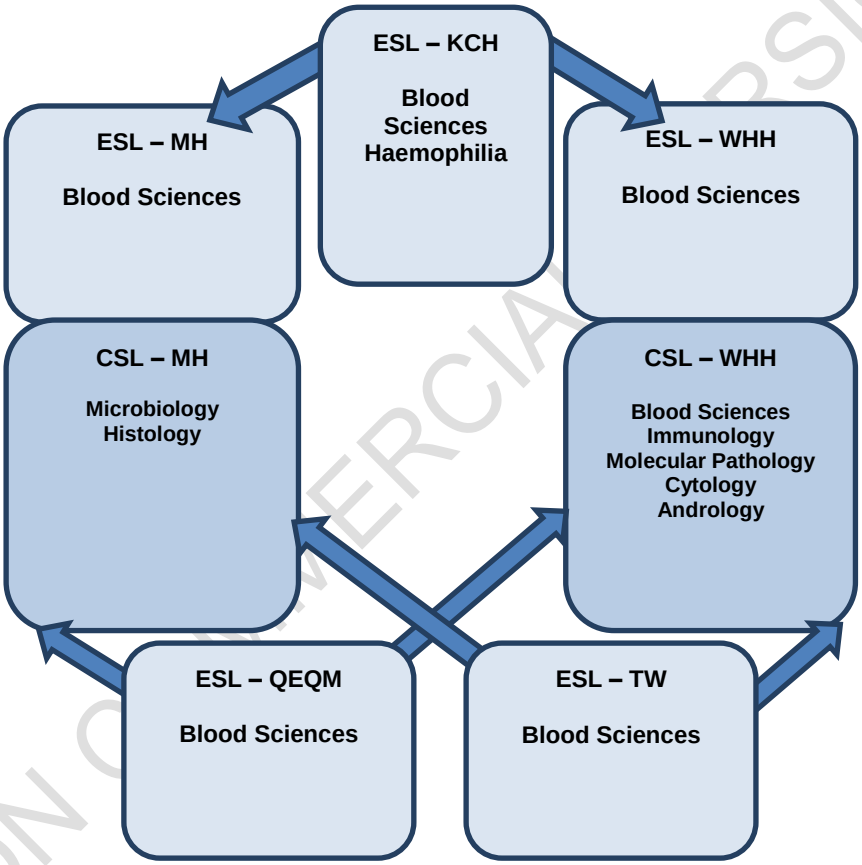
Further detail regarding the approach and findings of both the benchmarking and subsequent staffing levels challenge can be found in Section 7 and Appendix M of this Full Business Case (FBC).

1.8 The Preferred Option

The clinical and qualitative evaluation was linked into a financial appraisal assessed on the basis of the value of the net cashflow of each option to arrive at a Preferred Option - Option 5.

Option 5 – Preferred Option

Twin CSLs with a Blood Sciences, Molecular, Cytology and Andrology CSL at WHH; a Microbiology and Histology CSL at MH and ESLs at all five sites



Based on subsequent staffing reduction assessments, it is proposed that the Essential Services Laboratory[10] workload for the WHH is subsumed into the Central Services Laboratory to be based at WHH. There will be clear delineation of emergency and non-emergency work consistent with current arrangements.

This option will result in the following financial outcomes:

[10] A Laboratory that will manage all site-based acute Blood Sciences activity that demands a turn-around time of less than 2 hours. This will be limited to In-patient and A&E activity, unless clinical need dictates otherwise.

It should be noted that, as a non-cash movement, fixed asset impairments[11] are not included in the above.

The preferred option has the following key features over the seven years modelled:

- Generates a positive net cash flow
- Delivers on-going long term revenue
- Additional revenue costs during 2014/15 are largely due to a combination of potential redundancy and project implementation costs.
- Overall the integrated KPP service will, when on-going annual Cost Improvement Plans (CIPs), are added, reduce its cost base.

In order to achieve this, the following deliverables are essential:

- Estates reconfiguration work being completed to enable a phased movement of staff to their new locations over the period 1st February 2014 to 31st March 2015.
- A new merged MLS contract being in place by 1st April 2015.
- An integrated IM&T system being in place by 1st September 2014.
- Staff consultation commencing during February 2014 with a phased implementation being fully effective by 30th July 2015.

The key requirements for ensuring the successful implementation of the preferred option include:

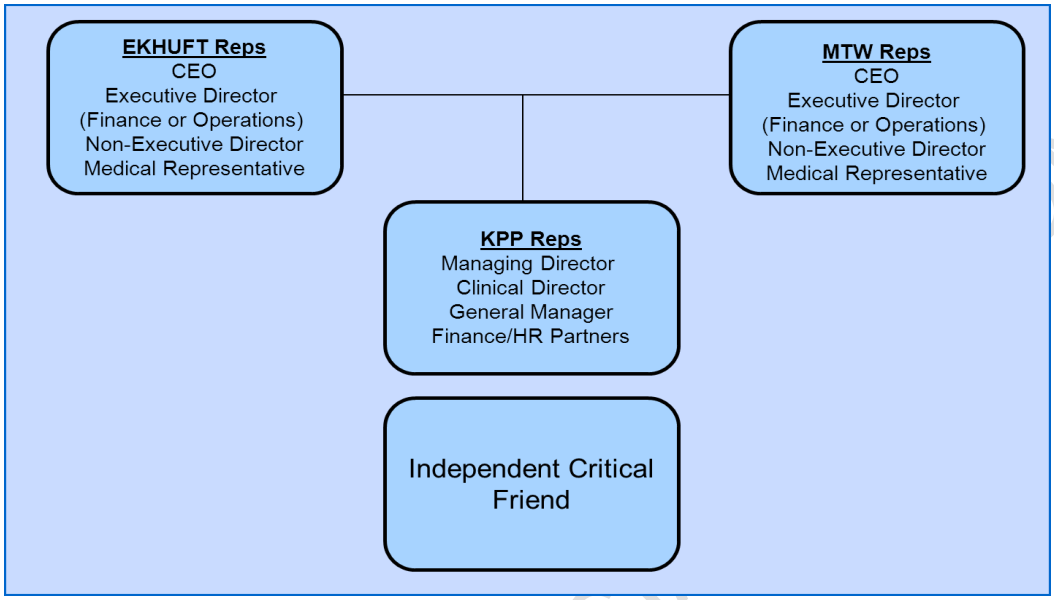
- Recruitment of a senior management team with the appropriate clinical and commercial expertise. Putting in place effective project planning and project management during the implementation process.
- Achievement of the key procurement milestones.
- Development of the commercial, financial and legal aspects of the Joint Venture.

[11] The revenue charge incurred when a fixed asset is immediately fully depreciated as it has no further useful economic value.

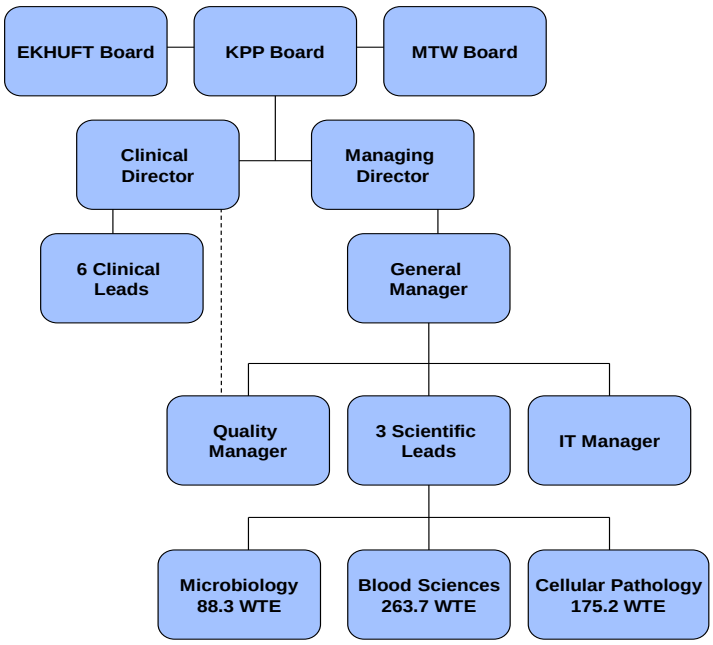
1.9 Governance

The proposed KPP Governance and Management structures are detailed in the Figures below

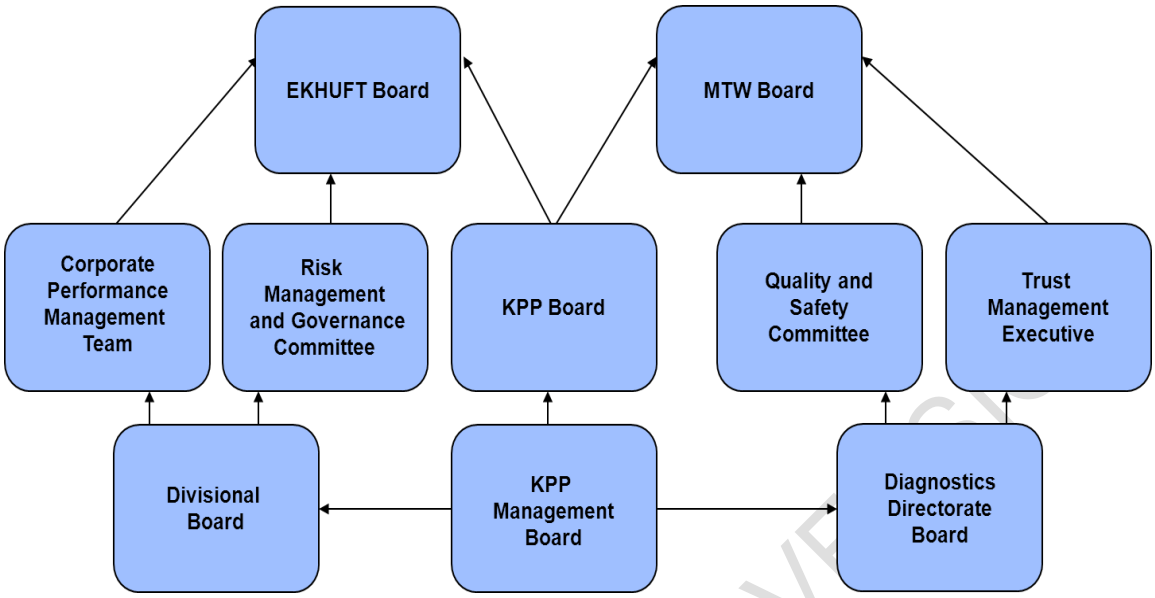
Figure 1 Proposed Structure of KPP Board



Proposed Management Structure of KPP



Proposed Governance Structure of KPP



Proposed Internal Governance Process

The host analysis was undertaken from information received from the Trust Finance department and after discussions at the KPP Board meeting. The analysis undertaken resulted in EKHUFT being the host Trust. KPP will therefore adopt the policies and procedures of that EKHUFT. Key components of this hosting arrangement will be:

- All staff having a common bespoke contract which is labelled as a KPP contract but clearly identifies the host employer as EKHUFT. This recognises that KPP staff will have rights and obligations whilst working on none host Trust property, this will also be regarded as part of the agreement between the two Trusts.
- Payslips referring to KPP but recognising the host organisation as the employer.
- Trust commitments outside KPP being accommodated through secondment arrangements where appropriate.
- The Chair of the KPP Board being the CEO of the non-contract-holding Trust.
- All staff from both Trusts having a simultaneous consultation regarding transfer to the new entity and TUPE arrangements.
- All staff working across both Trust sites being provided with ID badges for both Trusts.
- Car parking charges being paid according to the individuals main base, unless staff choose to park at their original base and use any transport provided to cross between Maidstone Hospital and William Harvey Hospital, when fees will be payable for the site at which they park.
- The contractual joint venture contract including a clause precluding either Trust from setting up a Pathology service outside the KPP with a financial penalty for breaching the terms of the contract.
- TUPE arrangements not to involve any non-Pathology staff at this time.
- All costs associated with this process to be shared in accordance with the joint venture agreement.

Clinical governance within Pathology is well-established and will continue with a collaborative approach across the two Trusts. A suggested corporate governance arrangement for KPP will involve the continuation of the current KPP Board with an agreed and defined constitution.

All proposed changes will only be implemented in a safe and clinically appropriate manner that upholds service quality. Equally all changes to staffing levels will be undertaken in a measured, phased way that where possible, will utilize natural wastage and avoid compulsory redundancy. A system will be in place to monitor changes at all times through the transitional phase of the project, to be reviewed at KPP Board level.

The Managing Director will be the Accountable Officer for KPP, responsible to the KPP Board for the following:

- The quality of the service provided ensuring statutory compliance of all aspects of KPP.
- The financial performance of KPP delivering both the strategic and operational goals and objectives.

The Managing Director will be responsible to the KPP Board, and will report directly to the Chief Executive of EKHUFT as host Trust of KPP.

The Clinical Director will be responsible to the Managing Director but professionally accountable to the EKHUFT Medical Director.

The ambition is to achieve the staffing levels shown in this document which are based on benchmarking from comparator sites. Essential to this will be to ensure that there are appropriate numbers of staff with the required education, training and competencies to provide services that meet the needs and requirements of users, as demanded by the regulatory bodies. At every appropriate stage of the phased implementation, the staffing levels and skill mix will be reviewed by a quality impact assessment process to ensure clinical safety.

The risks arising from such significant service transformation are well understood. These are described in detail in Appendix H – Risk Management Plan along with the mitigation undertakings. These include risks associated with: -

- Potential HR issues; - staff leaving through dissatisfaction or staff unrest through the transition phase of KPP. Mitigated by effective staff engagement and support.
- Competition laws / regulations impacting on KPP implementation: - mitigated by adherence to Office of Fair Trading guidance and legal consultation with DAC Beachcroft.
- Delays to key enablers e.g. IM&T solutions, procurement of managed service contracts, estates works etc: - mitigated by robust procurement and project implementation management processes.

1.10 Other Relevant Full Business Case Information

1.10.1 A Sales and Marketing Plan

KPP success will be dependent on two key aspects.

a) Becoming competitive through reduced costs, increased productivity, and focusing on improved efficiency and effectiveness. This is essential and finite.

b) Seeking and winning new markets.

There is evidence emerging that opportunities for new business are increasing and could accelerate further.

Subject to effective implementation of KPP full business case the organisation will be ideally placed to exploit new opportunities.

To enable this business development need within KPP, a Sales and Marketing Plan has been developed and is available as a separate document to this business case.

Post KPP establishment, the need for cultural change throughout the organisation to acknowledge the increasing competitive environment is a key factor in ensuring sustainability and growth.

1.10.2 A Communication Plan

This is provided in Appendix N. The section identifies target audience, method of communication, risks & mitigation and outline activity.

1.11 Recommendations

The evolving competitive Pathology market introduces both opportunities and threats for both Trusts as identified in the market analysis and marketing strategy.

The aims for the project are the establishment of a merged, high quality, robust and sustainable Pathology service, incorporating appropriate commercial and public sector expertise, supported by systems and processes resulting in the creation of an organisation which can thrive and grow within an evolving competitive market environment.

The direct access income substantially supports the EBITDA position of both Trusts, and therefore heavily subsidises acute Pathology service costs.

Direct access income represents a large percentage of combined Trusts' Pathology revenues.

The potential loss of the direct access business would have a major adverse cost impact on Pathology service provision within the regional health economy.

It is against a background of the above, together with other imperatives identified within this FBC, that a 'Do Nothing' approach to Pathology service provision in EKHUFT and MTW is considered not to be an option.

We recommend to the EKHUFT and MTW Boards, the selection of Option 5 as the preferred option.

Option 5 is a twin CSL model, with a Microbiology and Histology CSL at MTW; A Blood Sciences, Molecular, Cytology and Andrology CSL combined with ESL facility at WHH, and ESLs on the other four acute sites, all to be implemented in a phased, safe and considered manner.

Implementation will be dependent on the introduction of a unified IT infrastructure.

1.12 Conclusion

KPP offers an opportunity to create a successful nationally renowned and respected NHS Pathology service that offers the best to its patients, clinicians and staff.

This will be achieved by both Trusts and especially the staff within Pathology working together as one to not only secure a competitive, focused and flexible NHS Pathology service, but to counter any external threat posed by another provider. Doing nothing is an untenable position.

All proposed changes will only be implemented in a safe and clinically appropriate manner that upholds service quality. Equally all changes to staffing levels will be undertaken in a measured, phased way that, where possible, will utilize natural wastage and minimise redundancy costs.

2 Introduction and Context

The modernisation of Pathology services has been driven by the Department of Health since 1999. Various initiatives have been launched since this time but the pace of change has been slow. Subsequently an independent review of NHS Pathology Services in England was undertaken by a team led by Lord Carter for the Department of Health.

The first phase of the review, published in 2006, identified the need to achieve significant efficiencies, benefits and savings from further reform of Pathology services.

In 2008, data collected from 12 pilot sites during the second phase of the review were used to produce recommendations for service reform. It was concluded that, with the appropriate investment in infrastructure, consolidation of Pathology services could be achieved with a reduction in costs linked to an improvement in quality, patient safety and efficiency.

Since the review standardisation and centralisation of local Pathology Services has happened at each of the partner Trusts over the last few years, and this has already resulted in the release of substantial savings and enhanced quality improvements.

However, if the two Trust's Pathology Services continue to work in isolation from each other they will be unable to maintain low prices to commissioners and will risk losing work to other providers through potential tendering process. Working together in this collaboration, the Trusts will continue the work undertaken by the Kent & Medway Pathology Clinical Specialty Groups based on evidence-based practice enabling the efficiency savings from integration and rationalisation to achieve low cost, safe and effective service provision.

The Chief Executive Officers of EKHUFT and MTW have therefore agreed to lead work to develop a Pathology Partnership for Kent.

The aim is to:

- Build on the enhanced capability and efficiency of the joint venture to identify marketing opportunities to increase income within and beyond Kent.
- Improve patient outcomes by providing integrated Pathology services across Kent to a consistent high standard meeting regulatory and professional requirements.
- Provide a new and more sustainable way of delivering Pathology services in Kent which will involve a step change improvement in quality combined with significant financial benefits.
- Integrate the laboratories and pool the Pathology staff of both Trusts to form a single joint venture. This will have a distinct name and brand (Kent Pathology Partnership) and a single, unified management structure.
- Maintain acute services provision through the creation of acute essential service laboratories with rationalisation and centralisation of all non-acute work as deemed to be clinically appropriate.
- Position KPP as a Biomedical Diagnostic Hub and thereby a key provider of molecular Pathology and genomic services for the future.

- Safeguard services from competitive threat e.g. Kent Institute of Medicine & Surgery, private sector providers etc.

It is also envisaged that the efficiencies arising from appropriate consolidation of laboratory processes will help meet efficiency savings and allow reinvestment to develop services as they continually evolve to meet clinical need.

This collaboration is unique in its approach as it is NHS-led and clinically driven. This is in contrast to mergers taking place in other parts of the UK which have resulted in high profile failures due to lack of appropriate investment and/or understanding of the critical role Pathology plays in the provision of high quality, safe and effective patient care across the entire health economy.

2.1. Demographics

EKHUFT is part of a local health economy servicing Kent and Medway. Based on the Kent County Council South East Plan Strategy-based (2010) Population Forecasts, which is the latest available to us, the east Kent population is approximately 720,500.

MTW serves a diverse population of around 500,000 people living in the south of west Kent and parts of north east Sussex. The Trust also provides complex cancer services to 1.8 million people living in Kent and Medway and north East Sussex.

2.2. Overview of Project Structure & Governance

The project to integrate and rationalise Pathology services across the two Trusts was initiated in October 2012. A Project Team consisting of the Clinical Director and General Manager from each Trust was established with the two Clinical Directors acting as joint leads for the project. The Project Team meets fortnightly with the two Clinical Leads reporting to the Project Board on a monthly basis.

The Project Board consists of the following:

- Chief Executives from each Trust.
- Finance Directors from each Trust.
- Divisional/Senior Manager from each Trust.
- Two Clinical Directors one from each Trust.
- Senior representative from Human Resources.

A staff communication brief is produced to provide updates on progress after each Project Board. Various work-streams such as Workforce, Governance, Finance, Logistics and Business Development have been formed (Appendix D). These report into the Project Team and have agreed Terms of References and objectives which feed into the milestones of the Project Plan.

In January 2013, a Project Management Office was established, including a Project Manager, pathology, financial and business expertise.

A key part of the process is the involvement of and discussion with the staff of both Pathology departments. When KPP was launched in October 2012, simultaneous

presentations and staff briefings were given to Pathology staff in both organisations. In November 2012, a letter was sent by the KPP Clinical Leads to the Chairs of the five Clinical Specialty Subgroups in the Kent & Medway Network. They were asked to convene a meeting of subgroup members in Kent to provide views on how service transformation could be effected to provide high quality, efficient, sustainable services whilst maintaining value for money.

The Clinical Leads/Heads of Service and Head BMS/Service Managers from each Trust were also invited to attend Discipline presentations to express the views of their colleagues on how the joint service could be provided. These were held in January 2013 with a half day dedicated to Blood Sciences (Clinical Biochemistry[12] and Haematology[13]) and a further half day dedicated to Cellular Pathology[14] and Microbiology[15]. In addition, the KPP Clinical Leads met separately with the Clinical Leads and Head BMSs for Immunology[16] and Haemophilia[17] services to obtain their views on the reconfiguration, even though the services they provide are already centralised. A further meeting was held with the Clinical Scientist leading the provision of Molecular Pathology Services at MTW. Two meetings have also been held between the Clinical Directors and the Consultant Cellular Pathologists.

2.3. Summary of Pathology Services

Pathology services lie at the heart of the health care services provided to patients. They are essential to the delivery of many of the national priorities and targets for the NHS. It is estimated that 70-80% of all health care decisions affecting diagnosis or treatment involve a Pathology investigation. This includes individual patient treatment decisions, and monitoring responses to treatments, which is often dependant on a range of Pathology-based tests and investigations.

In England the main disciplines in Pathology deliver in one year:

- Over 500 million Biochemistry
- Over 130 million Haematology tests
- Over 50 million Microbiology requests
- Over 13 million Histology slides and 4 million Cytology slides

Of these requests over a third (35-45%) arises from primary care. Demand across virtually all disciplines of Pathology has been rising at an average of 10 per cent per annum in recent years, with variations across the disciplines. Average demand is predicted to grow at the same pace in future. Overall, Pathology services cost the NHS an estimated £2.5 billion per annum, of which the single largest element is the workforce.

[12] The science involving chemical analysis of body fluids to diagnose disease.
[13] The study of blood, the blood-forming organs and blood diseases.
[14] The combined service of Histology and Cytology.
[15] The study of pathogenic microorganisms such as bacteria, fungi, parasites and viruses.
[16] The study of an organisms defence (immune) system, in both health and disease.
[17] A genetic disorder, usually inherited, of the mechanism of blood clotting.

2.4. Quality and Safety

The laboratory quality management systems are fundamental to assuring the quality and safety of Pathology processes. These systems have been accredited as effective by Clinical Pathology Accreditation (CPA) standards. There is a programme of transition to ISO (International Standards Organisation) 15189:2012 Medical laboratories - requirements for quality and competence standards. The laboratories' quality management systems also satisfy the requirements of the Blood Quality and Safety Regulations (for Blood Transfusion) and the Human Tissue Authority (for mortuary activity), as well as the relevant standards of the Care Quality Commission (CQC).

A quality management system comprises the organisation of a laboratory and the use of resources (premises, equipment, personnel, consumables) to undertake pre examination, examination and post examination processes. The quality management system and the examination processes are continually evaluated and quality assured to maintain, and where required improve, the quality management process and to ensure that the needs and requirements of users are met.

Evaluation of the quality management system comprises a number of processes, risk management, internal audit, assessment of user feedback and complaints, recording and resolving errors and incidents, external review (inspection/assessment), review of the results from participation in external quality assessment programmes and internal quality control of results.

Risk management includes risk assessments and Control of Substances Hazardous to Health (COSHH) assessments, to ensure patient and staff safety. All unmitigated risks are recorded on the risk register and monitored by the Pathology board. Each service has continuity plans to maintain service provision, as far as possible, in the event of the loss of equipment or essential facilities. There are action plans for each service to follow in the event of the declaration of a major incident requiring special arrangements. There is a procedure for reporting incidents and subsequent investigation, root cause analysis and implementing subsequent corrective and preventative actions.

There is a schedule of regular internal and external audit. Findings from these audits are raised as non-conformities. Status of compliance with the audit schedule is a quality indicator and is recorded on the Pathology dashboard.

Non-conformities identified from audit, error, incident or complaints are recorded, investigated and a root cause analysis conducted. Corrective and preventative actions are determined and implemented where appropriate. The learning from such events is shared with staff at governance meetings to ensure continual improvement.

Quality objectives set in the previous year are reviewed annually by laboratory management, which then sets new quality objectives for the following year. The progress of these objectives is monitored via action plans at regular management meetings. Quality indicators are determined from the quality plans and objectives set at the management review to monitor progress of quality improvements. These are monitored via the Pathology dashboard. More details of the quality standards that need to be achieved by Pathology are in Appendix E, the Clinical Quality Plan. This outlines the standards to be achieved by Pathology.

Key performance indicators are determined from service level agreements and contracts and are monitored via the Pathology dashboard. The Pathology dashboard is monitored monthly at Pathology Board meetings and at quality and departmental meetings. Further details of this monitoring process and current performance of the Trusts is shown in Appendix F, Clinical Review Data.

2.5 Clinical Governance

Clinical governance is well established across the Pathology services of both Trusts. Governance meetings are attended by all grades of staff with agenda sections tailored to different staff groups.

Clinical governance meetings review and discuss clinical issues relating to both individual cases and wider issues such as introduction of new testing pathways, new equipment, new NICE guidance and changes in the clinical service of the Trusts. In Cellular Pathology, Clinical Governance meetings are held for sub speciality groups and individual departments (Molecular, Cytology etc) as well as for the discipline as a whole. Cellular Pathology

Quality issues including external and internal quality assurance, KPIs, risk registers and incidents are also discussed at governance meetings. Some departments have separate quality governance meetings to ensure that these matters can be discussed fully.

Outcomes and outputs from the meetings in all departments are reported up through the departmental management meetings and to the Pathology Board. Incidents and risks are also reported through the Pathology Quality committee to the Pathology Board. Assurance is given to the Directorate/Divisional Boards with Serious Incidents discussed in details.

The proposed arrangements for Clinical Governance are described in more detail in 9.2 Clinical and Corporate Governance.

2.6 Summary of Key Information and Statistics

Section 4 of this document details the Pathology services currently provided by the two Trusts including profiles of the customers, activity and finance.

It should be noted that the above values relate to actual or forecast outcomes as opposed to targets or budgets, i.e. the financial values shown relate to year end forecasts as opposed to budgets. This is in line with standard practice as it is against actual expenditure that savings must be achieved as opposed to merely reducing a budget. Similarly the workforce levels shown reflect the actual staffing input into the service at a specific snapshot. This will differ from establishment in terms of vacancies, extra and over time worked as well as bank and agency. Again to reflect reductions in staffing input into the service this methodology must be used as the reduction of budgets does not reflect a saving unless backed up by an actual real terms reduction.

The income relates only to that received directly from primary care and other customers. This includes both GP Direct Access and services provided to other NHS bodies, private healthcare providers, and other client organisations. It does not include any notional income transfer for the provision of Pathology services internally to support other hospital services as this information is not readily available.

It should be noted that the financials include a modest element of inter-trust activity i.e. the provision of services between the two partner Trusts. These have not been removed from the above figures because they are not judged to be material to the outcome of the business case.

3. Vision for the Future of Pathology in Kent

3.1. Trust Strategic Context

Both Trusts have recognised that major transformational service change is a contributory factor in the delivery of significant future financial efficiencies across the NHS. Pathology is no exception and the KPP process is designed to deliver the safest and most efficient ways to implement this. It is anticipated that in time such changes will contribute to the financial strategy alongside other programmes of work.

3.2. KPP Vision

The need for major transformation change has led to the creation of the KPP.

The following vision has been developed for KPP:

'To create an efficient and innovative diagnostic service of the highest quality which delivers the best patient outcomes and is the first choice for clinical users, patients and staff against a background of an organisation which is competitive, commercially aware and market focussed.'

3.3. Commissioner Views

In terms of volume of work, the significant majority of KPP's activity that is commissioned comes from General Practice via the CCGs using the expertise of the Kent & Medway Commissioning Support (KMCS) organisation which is hosted by the NHS Commissioning Board. This takes the form of either direct access work or Pathology activity undertaken as part of acute services undertaken by the Trust.

To date, the commissioners of the Trust services have been very supportive of the progress that KPP has made, and are advocates of its objectives. KMCS have in discussions made it very clear that should local Pathology services, including KPP, fail to deliver on the efficiencies demanded by its customers there is a real risk that alternative commissioning options could be explored through legitimate market testing processes.

Commissioners will also require improvements to patient services which can only be delivered by the planned transformational changes in Pathology as detailed in this business case.

It is evident from discussions with Commissioners that there are specific expectations of the KPP process. Commissioners are also looking forward to the improvements in the patient experience that will be facilitated by the introduction of an integrated east and west Kent wide service that incorporates wholly merged systems.

3.4. Other stakeholders

A detailed stakeholder[18] analysis is provided at Appendix G. The Stakeholder Analysis describes a complex network of those with a direct and indirect interest in Pathology services, including:

- The public – through LINk, Overview and Scrutiny Committees etc.
- Commissioners of Pathology services.
- Customers – other Trusts, Clinical Commissioning Groups (CCG), Private Sector etc.
- 'Other' Providers – Private Sector, other NHS Pathology Organisations etc.
- Suppliers – of equipment, consumables, IM&T etc.
- Pathology providers – the partner Trusts, cancer networks etc.
- Monitors of Pathology performance – Department of Health (DoH), Care Quality Commission (CQC), United Kingdom Accreditation Service (UKAS), Clinical Pathology Accreditation (CPA – now part of UKAS), Medicine Health and Regulatory Authority (MHRA), Human Tissue Act (HTA) etc.

[18] Any person, group or body with an interest in Pathology Services in Kent.

4. Current Service Description

4.1. Current Pathology Configuration

Pathology or laboratory medicine services play an important role in the delivery of modern evidence-based healthcare. The service is a key enabler for commissioning patient care pathways leading to better and more effective outcomes. Services can be accessed at various points in a patient's care pathway including screening for disease, diagnosis and monitoring of disease, as well as determining and optimising treatment.

Pathology services are provided in response to a request from a clinician who may be working in primary, secondary, tertiary care or the community. Services are also provided to private contractors (including Category 2) as well as clinical and research organisations. All Pathology testing undertaken is restricted to human subjects.

Pathology is a clinical, consultant-led service which has developed individual areas of specialism and expertise. Although many of its processes can be automated, providing efficient, timely and cost effective service delivery, it is heavily reliant on medical and scientific staff. They provide pre-analytical advice, scientific expertise and authorisation of reports often with a diagnostic opinion or interpretative advice. A key component of the service is the provision of expert knowledge to assist and optimise patient management.

Medical personnel have a direct role in patient care. Haematologists provide specialist advice on haematological disorders to their medical colleagues in primary and secondary care as well as direct management of patients with haematological malignancies. Chemical Pathologists manage patients with a variety of metabolic disorders and Microbiologists spend an increasing amount of time in ward-based activities as well as advising on control and management of infection.

All services actively participate in clinical governance and internal and external quality control processes. Performance is monitored by Key Performance Indicators (KPIs) recommended by the Royal College of Pathologists and local commissioners. Training is provided for Biomedical Scientists and Clinical Scientists. In addition Cellular Pathology and Haematology provide specialist training for junior doctors.

All specialties in both Trusts hold Clinical Pathology Accreditation.

The main Pathology specialities provided across Kent are:

Cellular Pathology (including Histology, Cytology, Andrology, Molecular Pathology and Mortuary services)

The Cellular Pathology services are led by 19 Consultant Histopathologists at MTW and 14 at East Kent. Both departments have a number of medical trainees of differing grades.

Each Trust provides Histology[19] services for its own patients. In addition, MTW provides services to Medway Foundation Trust (MFT) and Dartford and Gravesham NHS Trust (D&G). Services include diagnostic examination of biopsy, non-gynaecological Cytology and surgical specimens, attendance (on-site or via teleconferencing) at Multidisciplinary Meetings (MDM) at all five hospitals of the two Trusts, Medway Maritime, Darent Valley and Kings College Hospitals, providing second opinions on complex cases, referring and reporting on cases for molecular studies and providing specialist advice to clinicians.

The Cytology service is split between diagnostic and screening tests. MTW also provides the Cytology service for MFT and D&G. In addition MTW also provides the Human Papilloma Virus (HPV) service across Kent and Medway.

The Andrology Service for Kent and Medway is provided by EKUHFT.

Both Trusts currently provide molecular services. MTW have a molecular scientist in post. Molecular tests are performed to guide treatment, particularly choice of chemotherapy, in cancer patients. The repertoire of molecular tests is currently expanding as a result of new cancer drugs becoming available. HPV testing is part of the molecular service.

Mortuary services are provided by both Trusts with all hospital sites having body stores. The Coronial Post Mortem service for East Kent is provided by EKUHFT. MTW does not currently provide a Post Mortem service although this is expected to be reinstated at TWH on behalf of the West Kent Coroner from April 2014.

Clinical Biochemistry (including Immunology)

The Clinical Biochemistry Service is led by 2.5 WTE Consultant Clinical Scientists at East Kent and one Consultant in Clinical Biochemistry and Metabolic Medicine at MTW. In both Trusts the service is supported by non-consultant grade Clinical Scientists.

Both services have undergone rationalisation in recent years and non-urgent work is centralised on the William Harvey and Maidstone Hospital sites. Other sites all have satellite laboratories to provide an urgent service for the acute sites.

The diagnostic service provides a clinical advice service for clinicians in primary and secondary care, including out of hours, and in addition, the consultant at MTW provides a metabolic medicine out patient service and day case metabolic testing.

The Immunology Service for Kent and Medway is provided by EKUHFT on the WHH site. This service is led by 0.1 WTE Consultant Clinical Scientist who also leads the Immunology service for St Thomas's Hospital.

[19] The study of the microscopic anatomy of cells and tissues.

Haematology & Blood Transfusion

The Haematology and Blood Transfusion[20] service is led by 5 consultant haematologists at EKUHFT and 4 Consultant Haematologists at MTW. All have dedicated laboratory time detailed in their job plans. In addition, Haematology registrars rotating from Kings College Hospital are trained at both Trusts.

A similar rationalisation as for Clinical Biochemistry has taken place in Haematology, with non-urgent work centralised on the William Harvey and Maidstone Hospital sites and satellite laboratories sited at Canterbury, Margate and Tunbridge Wells.

The consultant-led clinical service is part of the Cancer Service in each Trust and provides in-patient and out-patient care for patients with a variety of haematological disorders.

Blood transfusion services are co-located with all of the Haematology laboratories and provide full transfusion services to the five acute hospital sites.

Each Trust has a Blood Transfusion Co-ordinator with responsibility for facilitating the delivery of a safe, auditable and timely transfusion service that meets local and national guidelines for good practice.

Haemophilia Service

A specialist Haemophilia and Thrombostasis laboratory is co-located on the Canterbury site with the tertiary Haemophilia service providing haemoglobinopathy screening and leucocyte immunophenotyping.

The Haemophilia service provides specialist out-patient care for patients across Kent and Medway and East Sussex.

Microbiology

Diagnostic Microbiology services are led by four Consultant Microbiologists at MTW and five at EKUHFT. The current service provided by both Trusts includes bacteriology, virology, parasitology and mycology. Further specialist virology is provided by EKHUFT to MTW. In addition, EKHUFT also perform environmental microbiology services.

The consultants are based at all 5 acute hospital sites partly on a rotational basis. The consultants provide 24 hour Microbiology advice to hospital and primary care colleagues.

The consultant microbiologists also provide daily ward rounds on all hospital sites, advising on antibiotic use and ensuring good antibiotic stewardship. The consultants lead on antibiotic stewardship within the Trusts including devising antimicrobial guidelines.

Infection prevention is a key part of the Consultant Microbiologist role and the consultants work closely with the infection prevention nursing teams. At each Trust the Director of Infection Prevention and Control is a Consultant Microbiologist who leads the infection prevention strategy and activity.

[20] The laboratory process supporting the safe transfer of blood or blood-based products from one person into the circulatory system of another.

The Wider Role of Pathology

The extended role of Pathology in providing accurate and effective treatment as well as appropriate follow up is demonstrated by other clinical services provided:

- Provision of specialist information and advice to professionals in primary and secondary care as well as public health.
- Mandatory surveillance of disease.
- Infection prevention and control.
- Participation in multidisciplinary team meetings.
- Provision of specialist advice both on ward rounds and over the telephone.
- Provision of guidance and advice, quality assurance and support for Point of Care Testing (PoCT).
- Specialist advice on Blood Transfusion.
- Specialist advice on Health and Safety in relation to Pathology.
- Specialist advice on Information Management and Technology as it applies to Pathology.
- Mortuary services, including Post Mortem examinations.
- Education and training for pathologists, undergraduate & postgraduate doctors and other healthcare professionals.
- Research and development, including involvement with clinical trials and evaluation of new technologies.
- Population / public health medicine.

To ensure quality and governance standards are maintained Pathology services are regularly assessed against standards set by Clinical Pathology Accreditation (CPA) (now incorporated into UKAS), the Medical Healthcare Regulatory Agency (MHRA) and the Human Tissue Authority (HTA). In addition the service is also required to meet standards set by organisations such as the Care Quality Commission (CQC) and the NHS Litigation Authority.

A quality matrix prepared by the KPP Quality and Governance work-stream summarises the standards to be achieved by KPP (Appendix E). The quality of the end-to-end services provided within Kent has been monitored by the Commissioner since 2011 as part of the Pathology Service Specification using Key Performance Indicators (KPIs) issued by the Royal College of Pathologists (RCPath) and KPIs set locally. Appendix F shows the monitoring information for the current year.

To meet the above requirements, staff working in various roles in Pathology require registration with various professional bodies such as GMC and HPC with on-going demonstration of knowledge and competence to meet the standards of their professional bodies such as the RCPath, Association for Clinical Biochemistry and Laboratory Medicine (ACB) and the Institute of Medical Laboratory Sciences (IBMS).

4.2. Customer Profile

As set out in the Stakeholder Analysis at Appendix G, the customers of the Pathology services include:

- Specialist Commissioning and, on behalf of Primary Care, Clinical Commissioning Groups.
- NHS Trusts.
- Other Customers including Non-NHS healthcare providers.

4.3. Activity Profile

Table E provides a summary of the current total activity delivered by both Trusts for the year 2012/13. For the purpose of this summary the Blood Sciences activity comprises the sum of Biochemistry, Haematology and Blood Transfusion activities. Cellular Pathology activity comprises Histology and Cytology activity.

4.4. Estate Profile

There are Pathology areas within each of the five acute sites:

- William Harvey Hospital, Ashford (WHH)
- Kent & Canterbury Hospital, Canterbury (KCH)
- Queen Elizabeth the Queen Mother's Hospital, Margate (QEQM)
- Maidstone Hospital, Maidstone (MH)
- Tunbridge Wells Hospital, Pembury (TWH)

The current space utilisation across the five sites within the scope of KPP is shown in Table F. For the purpose of this summary, the Blood Sciences areas comprise those areas occupied by Biochemistry, Haematology, Blood Transfusion and Haemophilia. Cellular Pathology comprises of the areas occupied by Histology and Cytology.

It should be noted that certain disciplines, predominantly Blood Sciences, have already undergone significant transformation in terms of delivery with subsequent material cost savings and reductions in staff numbers. Common and large scale automated systems have been introduced, enabling multi-disciplinary working, in large single areas of Pathology laboratories.

The current Pathology accommodation comprises:

William Harvey Hospital (WHH) – Ashford

- All of Pathology is co-located within a single Pathology suite in the main body of the hospital, and comprises of the following.
- Microbiology – a fit for purpose laboratory >20 years old.
- Cellular Pathology – a fit for purpose laboratory re-furbished in 2012 to accommodate a Trust related Pathology consolidation programme.

- Blood Sciences – a fit for purpose laboratory suite modernised and extended in 2005/06 to accommodate a Trust related Pathology consolidation programme incorporating highly automated equipment through a managed laboratory service (MLS) contract.
- A separate mortuary facility – including facilities for post mortems.

Kent & Canterbury Hospital (KCT) – Canterbury

- A multi-disciplinary Blood Sciences laboratory accommodated in the old part of the hospital.
- A specialist Haemophilia Laboratory separate from Blood Sciences and adjacent to the Haemophilia Centre.
- A separate mortuary facility used for body store only.

Queen Elizabeth the Queen Mothers Hospital (QEQM) – Margate

- Comprising of a two storey Pathology laboratory in the old part of the hospital:
- Within this sits a multi-disciplinary Blood Sciences laboratory currently fit for purpose.
- There is a relatively recent refurbished Microbiology laboratory. Due to continued consolidation of Pathology Services at EKHUFT, this area is no longer required.
- A separate mortuary facility including facilities for post mortems.

Maidstone Hospital (MH) - Maidstone

- A two storey Microbiology laboratory in a purpose built construction completed in 2006.
- A two storey Cellular Pathology laboratory, adjacent to Microbiology, in a purpose built construction completed in 2011.
- A two storey Blood Sciences laboratory, at the front of the hospital, and remote from the above. The current accommodation underwent refurbishment in 2011 and is fit for purpose.
- A separate mortuary facility, currently used as a body store only.

Tunbridge Wells Hospital (TWH) – Pembury

- The Blood Sciences laboratory occupying a purpose-designed area within the new PFI Tunbridge Wells Hospital.
- A separate mortuary facility currently, used as a body store only, with post-mortems scheduled to commence 1 April 2014.

There are no Pathology-specific, contracted-out, facilities management arrangements to support these laboratories, other than for the TWH laboratory, which is within the scope of that site's PFI contract. All other facilities and support arrangements fall within local hospital related provision.

Mortuary and / or body storage facilities are available on all five current sites as and when required.

4.5. Staffing Profile

A review of all staff that is currently deployed in Pathology services has been undertaken. This represents a 'snap shot' of staffing input as opposed to formal budgeted establishments.

4.6. IM&T Profile

EKHUFT and MTW have significantly different IM&T solutions that are required to manage the complex flow of data and information within and external to the Pathology laboratory environments. There is currently no inter-laboratory link between the two Trust Pathology services which continue to operate independently. This represents a significant barrier to any proposed integration of the two services.

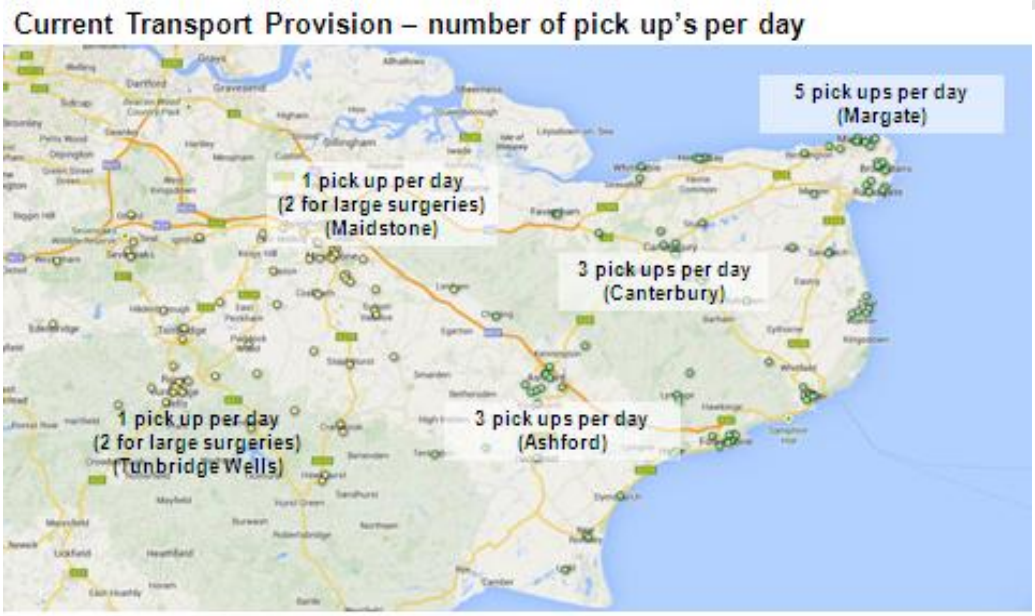
The principal components involved in data management across both organisations are:

- Laboratory Information Management Systems (LIMS) – laboratory based networks.
- Patient Administration Systems (PAS) – hospital based networks.
- Order Communications Systems (OCS) – GP surgery and hospital based networks.
- External interfaces – to clinical systems outside the laboratory environment.
- Integration engines – IM&T solutions (middleware) to enable information flow into the LIMS from external sources.

4.7. Logistics Profile

Both Trusts have discrete in-house local transport services with differing levels of service provision across both Trusts. With the advent of KPP and greater consolidation of Pathology functions on specific sites, this will need to be expanded to incorporate the movement of samples and other items between the sites of both Trusts. An allowance for this extra cost has been included in the financial projections.

EKHUFT currently offer more pick-ups than MTW introduced through previous consolidation planning. It is recognized that integration of the transport services provides future opportunity for improved operational capability as well as financial efficiencies.



4.8. Financial Profile

An analysis of each Trust financial forecast for 2013-14 has been undertaken. This forecast has been used as the basis for the comparison with the future cost of the options.

5. Strategic Case

5.1. The Project Objectives

The objectives ratified by the KPP Project Board are as follows:

- To improve patient outcomes by providing integrated Pathology services across Kent to a consistently high standard meeting all regulatory and professional requirements.
- To provide a new and more sustainable way of delivering Pathology services in Kent which will involve a step change in quality combined with significant financial benefits.
- To integrate the Pathology services of both Trusts to form a single joint venture entity.
- To provide efficiency savings to the benefit of both Trusts and commissioners of its services.
- To effect consolidation through the principles of delivering essential site-based acute activity and centralised provision of non-acute activity, using sound clinical principles.
- To develop the model with inbuilt capability and flexibility to expand and take advantage of marketing opportunities as they arise, without compromise to existing service provision.
- To position KPP as a Biomedical Diagnostic Hub and recognised provider of evolving specialist Molecular Pathology services.
- To develop robust and innovative logistics solution to underpin service delivery by the new joint venture and its clients, to include IM&T, transport, etc.
- To develop the service in a way that utilises innovation to deliver long term sustainability and growth.

It is considered that to remain as independent departments is NOT a viable option in relation to Pathology services provision – i.e. the 'Do Nothing'. This view is predicated on the following:

- The risks associated with the loss of existing direct access business which can be regarded as high margin low resource work.
- The limited potential which exists for savings/revenue generation where benefits from economies of scale potential through the joint venture are not realised and the ability to successfully bid for new business in an emerging competitive market place is not achieved.
- The potential for destabilisation of Pathology services to both Trusts through loss of revenues streams identified above.
- There is currently significant duplication of service delivery across the scope of KPP.
- There is significant over-capacity within the current delivery across the scope of KPP.

Other drivers for change include:

- A movement of diagnostic medicine from hospital to primary and community care. This can be delivered through controlled implementation of Point of Care Testing (PoCT).
- Changes in patients' expectations.
- Scientific, innovation and technological developments which offer possibilities in all applications of Pathology.

The preferred option enables all the criteria above to be satisfied. The process for the achievement of the criteria is set out in the Objectives Realisation Plan in Appendix I.

5.2. Future Operating Model

A fundamental approach to the KPP project is the enhancement of service provision through the development of a robust operational and business model.

In considering the model a comparison of KPP versus private sector provision, advantages and disadvantages are identified in Table K below.

A primary consideration relating to the change management process is the maintenance of, and continued improvement in, service quality with minimal risk during and after the transition period.

Against a background of the above a phased approach has been identified which facilitates delivery in key areas such as patient safety, quality, financial efficiencies and commercial readiness.

Seven key areas are identified and are being addressed within this phased implementation planning process. These are described in the following sections 5.2.1 to 5.2.7.

5.2.1 Staffing

- Establishment of a strong, single, cohesive management structure with the injection of commercial know- how.
- Increase in the client relationship support resource.
- Appropriate staffing in key areas effecting patient care outside of the laboratory, such as point of care and blood transfusion to ensure CPA/ UKAS and MHRA compliance.
- Management of the staff transition process to avoid destabilisation.
- Management of the transition to new structures ensuring at all times that there are appropriate numbers of staff with the required education, training and competence to provide a service that meets the needs of the users. This is a key requirement for the ongoing maintenance of mandatory regulatory standards – UKAS (CPA), ISO 15189, and MHRA etc.
- Monitoring of transitional change throughout, and progress being continuously reviewed with regulatory bodies to ensure compliance.
- Introduction of measures designed to improve the efficiency of the workforce such as:
    - Multidisciplinary working – especially across Blood Sciences.

- Review of establishment levels in specific area with a corresponding reduction in overtime / excess hours / agency working resulting in net savings.
- Mobility of workforce to facilitate absence cover and / or workload spikes.
- Introduction of fully integrated KPP solutions which enable test validation processes to be undertaken across all sites.
- Harmonisation of Agenda for Change (AfC[21]) grading.
- A comprehensive review of AfC banding to reflect future roles and responsibilities – a workforce fit for purpose based on current needs and new ways of working.
- Flexible working practices to include extended working day and 7 day rotas dependant on service needs.
- Consistency across KPP in respect of automated test ordering.

5.2.2 Quality Management

Currently each of the Trusts Pathology services has its own quality management system. The full detail of these processes is shown in 'Appendix E - Clinical Quality Plan – Standards To Be Achieved By Pathology'. In terms of ensuring the future success of KPP a process is in place, led by the Quality and Governance Workstream, to integrate and consolidate the two Quality Management systems in to a single managed process. As previously indicated a vital component of the Quality Management system is maintenance of mandatory accreditation with all appropriate regulatory bodies including CPA / UKAS (currently embracing ISO 15189), MHRA, HTA etc, These accreditation mandates will need to be managed through the transition phases of KPP and beyond in to the new integrated structure of the new organisation. In order to achieve this the following process will be followed, having been sense-checked with CPA / UKAS as one of the main regulatory bodies:

- Formally informing the appropriate authorities when the hosting organisation has assumed responsibility for service delivery as KPP.
- Ensuring that current accreditation cycles are understood (e.g. surveillance visits at 2y and main visits ay 4y in the case of CPA / UKAS).
- Until services change significantly as KPP, maintaining accreditation through current regulatory cycles.
- Formally notifying the appropriate regulatory body of any service change.
- Ensuring that, in the case of CPA / UKAS all services adopt the ISO 15189 standards to be used for all future main service assessments.
- Continuous dialogue with all regulatory authorities through the transition phase of KPP implementation.
- Implementing all recommendations made by the regulatory authorities to ensure continuous compliance.

[21] Agenda for Change (AfC) is the current National Health Service (NHS) grading and pay system for all NHS staff, with the exception of doctors, dentists and some senior managers.

In order to support this transition of quality management processes to KPP, the current RCPath registrar, Dr Rachael Lieberman, has been co-opted on to the Quality & Governance Workstream to ensure continuous monitoring of the process.

5.2.3 Managed Laboratory Service (MLS)

Currently each of the Trusts Pathology services has its own MLS contract with different suppliers, scope and terms & conditions. In order to enable effective and efficient integration, the operating model will need to consolidate to a single comprehensive MLS servicing all of the requirements of KPP. The key advantages of this strategy are described below.

- Procurement of a single KPP MLS contract with a single supplier, encompassing all disciplines and all current contracts. This is a critical enabler of:
    - Cross-site working through the introduction of standardised technologies, equipment and working practices.
    - Consistent test reporting criteria across the Kent health economy.
    - Transfer of risk to a single supplier, from a multitude of individual suppliers.
    - Standardised and cross-disciplinary training across the scope of KPP.
- Economies of scale through an MLS contract based on consolidating to one client procuring from a single contract provider.

Consideration must be given to the current contracts in place (MTW with Roche Diagnostics and EKHUFT with Abbott Diagnostics), in terms of contractual obligations, timeframes, and penalty clauses.

5.2.4 Information Management & Telecommunication Solutions

In order for the KPP to integrate the laboratories successfully, a single IM&T solution must be delivered to facilitate centralisation of services across the partnership to enable the benefits identified to be realised.

For the purposes of the FBC any income / expenditure requirements resulting from a successful bid have been excluded from financial data.

5.2.5 Estates Reconfiguration

Within each of the 3 options there are requirements to reconfigure estates provision to enable:

- Scope for increased workloads.
- Transfer of specialities to be based in single locations at the CSL(s).

- Creation of proposed structures involving 4 ESLs and 2 CSL(s).

5.2.6 Transport Arrangements

The proposed approach to Transport service provision is as follows:

By 1 April 2014

To develop a single transport agreement on a service level agreement basis which accommodates the scheduled movement of services during the implementation period and movement of samples by and other Pathology items between Trusts.

By 1 April 2015

To introduce an enhanced service which provides improved service to the Trusts and existing clients plus enhancing the service offering to new and prospective clients. This will include the requirement for real time tracking and tracing of samples.
The stated benefits from sample tracking include:

- Eliminating the risk of samples getting lost in transit.
- Avoiding samples being delivered to wrong destination.
- Avoiding need for patient re bleeding.
- Reducing transport costs.

(Source: City Sprint presentation at national Pathology event)

It is intended that the introduction of sample tracing and tracking will be achieved through a market testing process as incorporated within the detailed implementation plan produced as part of the FBC process. Sample integrity will be maintained through the introduction of centrifugation stations at ESLs where appropriate.

The primary objective of the integrated transport solution is shown below.

Current Transport Provision – number of pick up's per day

Future Transport Provision – number of pick up's per day

Centrifuge stations will be utilised at ESL's to secure sample integrity with integrated transport links between all sites

5.2.7 Communication Infrastructure, Website, Branding and Image

An effective KPP communication infrastructure (e.g. web site, signage, marketing literature, telecommunications etc.) is an important feature for an operation which aspires to favourable comparisons with both the NHS and commercial sector providers.

A comprehensive website is not only a powerful marketing aid but also provides a "shop window" for the organisation which will inevitably be reviewed by regulatory bodies, clients, prospective clients, the public, other interested individuals and organisations. Key elements of the site should include:

- Provision of Pathology services information.
- A facility for prospective clients to enquire about services.
- Client relationship management facilities.
- A customer feedback and complaints facility.
- Links to other appropriate NHS and non NHS sites.

The creation of the KPP entity will also necessitate signage appropriately situated within each location, as well as marketing literature and other materials expected of such a trading organisation. A discrete telecommunication network will also need to be established.

Branding and image create initial perceptions of organisations and it is recommended that the existing KPP logo is reviewed and updated prior to the formation of KPP.

5.3. Research and Development

Medical research is viewed as core business of the NHS. Increasing research activity is a central element of all relevant recent Government policy pertaining to the NHS and life sciences. Equally important is that patients want the NHS to be involved in research: 97% of the public believe that it's important for the NHS to support research into new treatments and 87% of those expressing a preference would rather be treated in a research-active hospital. Put simply, patients directly benefit from research and the NHS undertakes research activity to improve and deliver more efficient and effective treatments and outcomes for patients.

Without the support of KPP it would not be possible for the Trusts to undertake many of the extensive range of studies that are currently ongoing. Both MTW and EKHUFT actively recruit to NIHR 'Portfolio' studies, as well as running a number of studies led by local Chief Investigators.

Laboratory Medicine at EKHUFT currently supports ongoing studies/trials. This represents 50% of all active studies in the Trust. These tests are funded in a transparent manner either by the trial sponsor (whether industry or non-industry) or by the Research Networks. Similarly Pathology at MTW is actively involved in the support trials. Both Trusts have very close relationships between researchers & their teams including the Research and Development Departments. This frame work is pivotal as it allows efficient and timely feasibility assessment and approval for new research studies, in order to

deliver upon absolute, mandatory, nationally dictated timelines over and above the national target of 80%.

A number of EKHUFT's research-active clinicians undertake roles within Laboratory Medicine (e.g. clinical biochemistry, microbiology, haematology & haemophilia). As an example in early 2013 staff were successful in attracting funding from the prestigious NIHR HTA funding stream to support a 5-year multi-centre study of the biomarker cystatin-C as a prognostic marker in chronic kidney disease. The cystatin-C assay, absolutely central to this study, will be undertaken in EKHUFTs laboratories overseen by Chief Investigator, Dr Edmund Lamb. Teams led by Dr Lamb, Dr Chris Pocock (Haematology) and Prof Fritz Mühlschlegel (Microbiology) are highly active in recruiting to industry studies and/or undertaking and publishing original research, thereby contributing to the body of knowledge focussed upon improving health of the populations we serve. Notably, the recently appointed Co-clinical Director of the KSS LCRN, Dr Schofield, is a consultant in cellular pathology at MTW. The two departments are also part of the Kent Surrey & Sussex Academic Health Science Network (KSS AHSN) which integrates healthcare practice with industry and academia.

Specific examples of research activity undertaken in Laboratory Medicine at EKHUFT include:

Clinical Biochemistry

- Collaboration with the Kent Kidney Care Centre to understand and prevent chronic kidney disease.
- Investigation of novel markers of kidney function including NIHR Research for Patient Benefit (RfPB) funding.
- National Institute for Health Research (MIHR), Health Technology Assessment (HTA) funding as chief investigator for a multicentre study and participation as co-investigator in two further HTA studies.
- Exercise, markers of atherogenesis and heart disease.

The renal research group is recognised as a local priority group by the Kent & Medway CLRN.

Microbiology

- Genomic approaches for outbreak investigations.
- Managing fungal-medicated early voice prosthesis failure in total laryngectomy patients.
- Assessment of influenza virus morphology in clinical samples.
- Sepsis causing *Escherichia coli* isolates in East Kent.
- No effect of flavones in sensitising yeast to triazole antifungal agents.
- Molecular diagnostics and infection management of *Clostridium difficile* infection.

Specific examples of research activity undertaken in Pathology at MTW include:

Cellular Pathology

- Provision of Histopathology support for patients being recruited into Clinical Trials across Kent & Medway with support from CLRN as well as commercial

trial activity. A significant amount of support is also provided to centres such as the Royal Marsden and other centres outside of Kent & Medway.

Microbiology

- Participation in the multicentre OVIVA study for treatment of bone and joint infections.
- Genomic approaches for outbreak investigations.
- Molecular diagnostics and infection management of *Clostridium difficile* infection.
- Predictors of outcome of Clostridium difficile infection – an HPA specific R&D funded project.

Haematology

- Flow cytometry for monitoring chemotherapy in low grade B-cell disorders - with a staff member securing a PhD.

The integration of the two Pathology services into one unit will benefit R&D by increasing the size of the population available for research studies as well as strengthening research activity through diversity of expertise, scientific and clinical interest across the two organisations.

Failure to move KPP forward and the possibility of outsourcing pathology services to a 3rd party provider would threaten many aspects of successful research delivery at MTW or EKHUFT and would put back our mission to fully embed research in daily activities by a decade. In particular, such changes would impact on:

- the ability to deliver multi-centre NIHR Portfolio studies.
- the ability to deliver prestigious locally-led studies; the ability to provide timely approval for new NHS studies and ultimately the ability to benefit patients.

6. Economic Case

The Project Team was charged with producing various options for reconfiguration and rationalisation of laboratory services. These options were developed following information provided by the Discipline Leads, as described above, taking into account previous experience and information on reconfiguration projects undertaken in other locations.

All the proposed options are based around the concept of ESLs and CSLs for the major disciplines. ESL's involve Blood Sciences only and will be provided at each of the five acute hospital sites within the KPP network' with the ESL at WHH subsumed into the CSL structure. Each laboratory will undertake all the site-based Biochemistry, Haematology and Transfusion activity that demands a turnaround time of less than two hours including urgent work from primary care as required. The ESLs will be complemented by either a single CSL accommodating all disciplines functionality, or twin CSLs, with disciplines being split over two hospital sites. A CSL receives and manages all non-urgent work that is not undertaken in the ESLs from primary and secondary care and the community.

Ten options were developed to make best use of the considerable investment in Pathology that has already taken place in Kent, as well as producing a laboratory configuration to provide the best service to users both now and in the future.

The ten options for service reconfiguration were shared with Pathology staff at all sites in May 2013 after approval by the Project Board. A list of advantages and disadvantages for each option has been created.

From the questions asked by staff and members of the Project Board it was apparent that it would not be possible to evaluate these 10 options properly on the Evaluation Day held on 6th June 2013. The 10 options were therefore reviewed by the Project Team with four options discounted prior to the Evaluation Day on grounds that they would not be supported by governance arrangements (Options 3a & 3b) or current estate investment (Options 4a & 5a).

The remaining six options were evaluated on 6th June 2013 by a number of representatives with links to Pathology. The representatives were as follows:

- Five representatives from each Trust – Pathology, finance, estates and non-Pathology clinical representation.
- A senior commissioning representative
- Two critical friends – external advisors to the KPP process, with experience of such projects
- An independent chairman for the day
- Two facilitators and administrative support – to present the options and prompt discussions
- GP representatives were invited but were unable to attend

The challenge for the fourteen multi-disciplinary representatives from different organisations was to arrive at consensus views assessing each of the six options against twenty-eight separate criteria, based on quality and financial measures.

This required and achieved widespread, proactive and balanced participation from all present.

During the evaluation, a short-list of three options emerged from the six, each to be measured against the "no change" configuration. The four models assessed were:

> ***"Do Nothing": -*** *With the two Trust Pathology services continue to operate in the same configuration as they currently function, a baseline comparator for the other three options.*
>
> ***Option 4: -*** *A twin CSL approach, with a Microbiology, Molecular, Cytology and Andrology CSL at Maidstone Hospital (MH); a Blood Sciences and Histology CSL at William Harvey Hospital (WHH) and ESLs at each of the 5 acute hospital sites.*
>
> ***Option 5: -*** *A twin CSL model, with a Microbiology and Histology CSL at MH; a Blood Sciences, Molecular, Cytology and Andrology CSL at WHH and ESLs at all five acute sites.*
>
> ***Option 6: -*** *An off-site CSL, with a single facility housing all CSL functionality and ESLs at each of the five acute sites.*

The evaluation process and the outcomes in terms of the short-listed options were presented to the June meeting of the KPP Project Board, chaired by the Trusts' Chief Executives, and received the approval of the Project Board to move to the next stage of the project.

At the joint Board meeting on 3 October 2013, it was agreed at the meeting to take the project to Full Business Case stage.

6.1. Impact of each of the options

"Do Nothing"

This option sustains the status quo i.e. the continuation of current Pathology services. This has significant risks and problems and these are highlighted below:

- Benchmarking data suggests that Blood Science is marginally competitive in East Kent but uncompetitive at MTW. This makes both vulnerable (especially MTW), to a loss of direct access (GP) business where commissioners market test the service and a private provider or other NHS provider seeks new markets at any cost to obtain increased market share.
- Pathology undertakes activity for GP's and for the acute.
- GP activity generates significant income for Pathology for both Trusts. This is seen as a means by which inpatient/acute activity is subsidised by this income stream.
- Commissioners (CCG's) are no longer obliged to use local providers.
- Commissioners have cost pressures and therefore are seeking new ways to reduce costs and improve efficiencies.
- The commissioners can tender services from any provider to obtain highest quality at lowest price.

- The loss of the GP work would result in a loss of the income (provided above) for Pathology.
- A considerable reduction in activity would follow and consequently a reduction in the size of Pathology services would be needed. This will equate to substantial job losses and consequent redundancy cost.
- It would also represent a large financial pressure for each Trust.
- It is notable that, within the 45% of total activity for a Pathology department that undertakes work for GP's, the variation of number of tests involved is small. Of the hundreds of tests available, 87% of all GP requests are made up of twenty routine tests. This makes GP work attractive to external providers, and if this service was lost to another provider it would present a significant risk to the financial stability of both Trusts.
- By having 'no change' the unit cost will make both Pathology services at each Trust uncompetitive.
- With this un-competitiveness new markets will not be found and exploited.

External NHS providers and especially private providers such as TDL, SERCO, and IPP are seeking to exploit vulnerable Pathology departments who operate with too many staff and have inefficient and ineffective ways of working. The top heavy staffing structures with a large number of senior staff, and expensive unit costs make this option unattractive and high risk.

A summary of the advantages and disadvantages of the 3 remaining options have been identified.

Figure 3 - Option 4

Twin CSLs with a Microbiology, Molecular, Cytology and Andrology CSL at MH; A Blood Sciences and Histology CSL at WHH and ESLs at all five sites

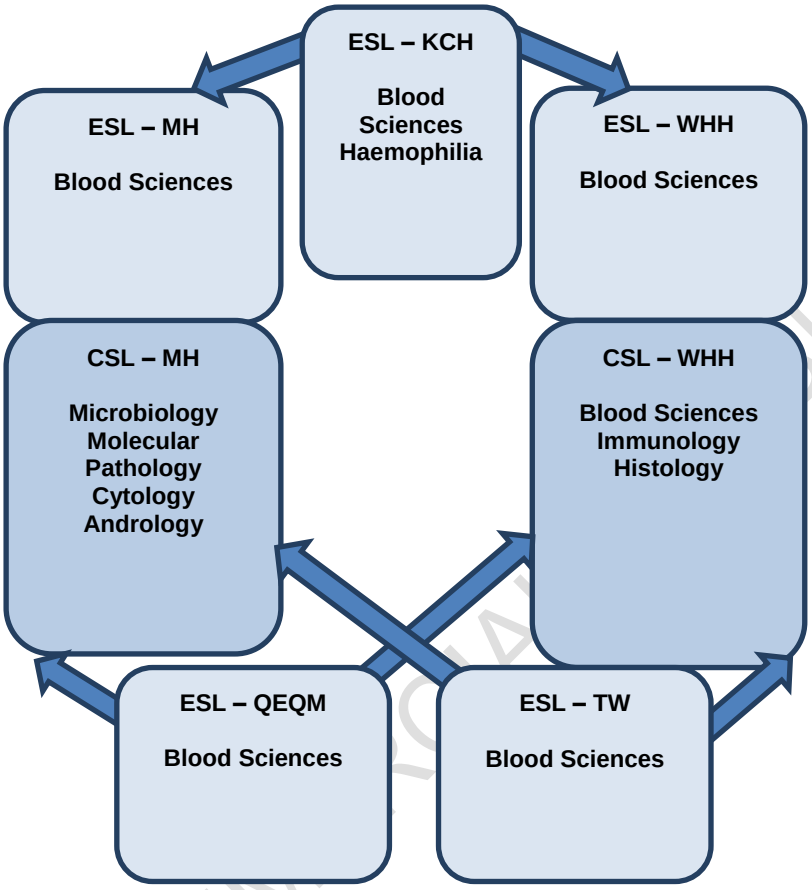
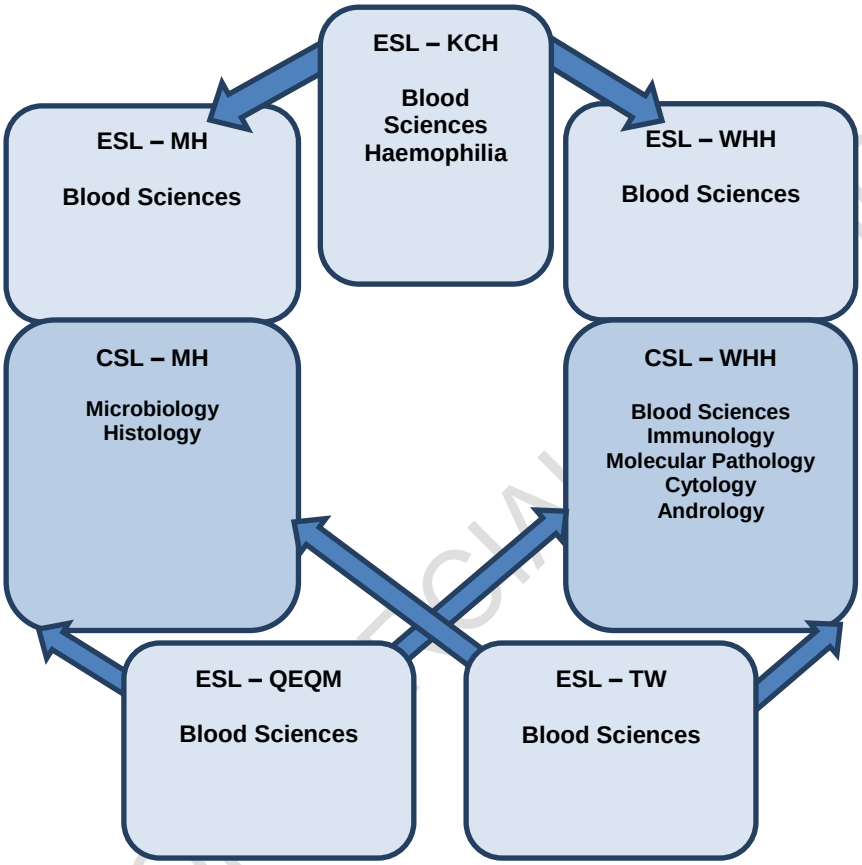


Figure 4 - Option 5 – PREFERRED OPTION

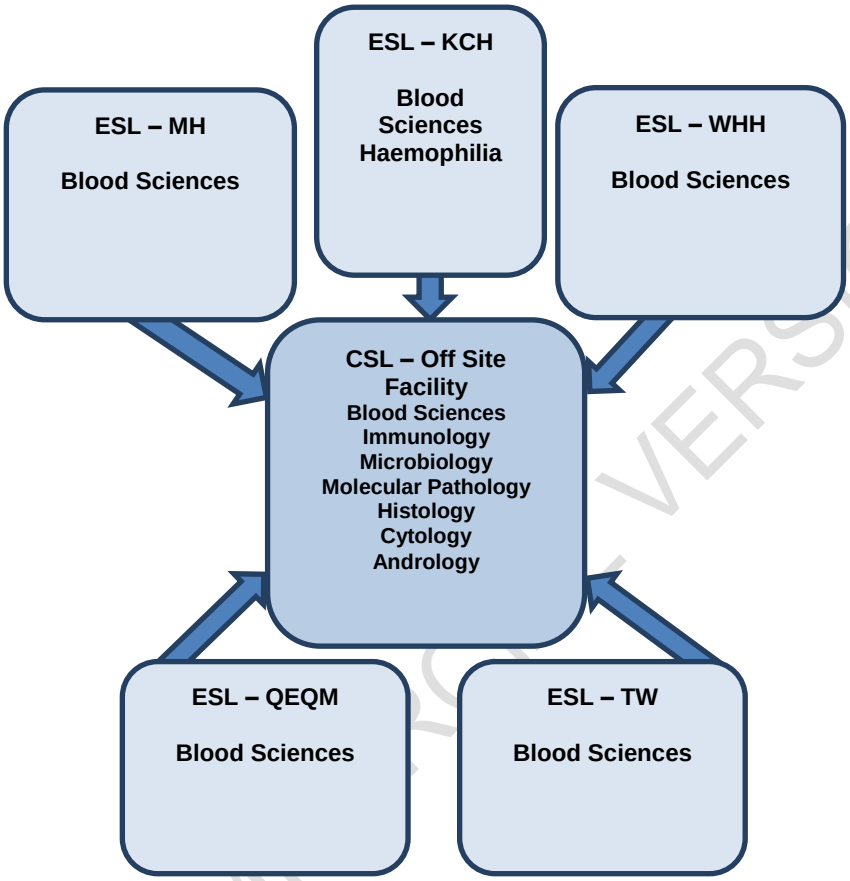
Twin CSLs with a Blood Sciences, Molecular, Cytology and Andrology CSL at WHH; a Microbiology and Histology CSL at MH and ESLs at all five sites



NOTE: OPTION 5 WAS SUBSEQUENTLY SELECTED AS THE PREFERRED OPTION

Figure 5 - Option 6

An Off-Site CSL, with a single facility housing all CSL functionality, and ESLs at all five sites



Following the evaluation day the three options selected were taken forward for financial appraisal. It had previously been assumed that the off-site facility, Option 6 would be a new build. A variant of this option has subsequently been added which assumes that a building shell would be rented and the facility then retro-fitted out. For clarity the original option has been renamed Option 6a and the new variant Option 6b.

In considering the economic case for the 3 remaining options and the one variant, a financial appraisal was undertaken in which the net cost of each option has been compared with a baseline represented by the Trusts' forecast net cost in 2013-14.

In order to bring both of these results together it was agreed at the initial project assessment day that the relative weighting of the qualitative and financial effects would be set as appropriate.

Option 6a, the offsite option, is preferred in qualitative terms. It has been assumed that the variant of this option, 6b, will score similarly based on the fact that it is merely the procurement of the physical estate that will differ.

Though Option 4 scored marginally better than Option 5 in this scoring, the difference was thought to be negligible by the evaluation team.

Option 5 is preferred in terms of the aggregated discounted financial savings generated. However, Option 5 only scored marginally preferably to Option 4.

Option 6a and the variant 6b do not generate net savings. Therefore the financial score for this option and variant have been set at zero.

This financial scoring has then been brought together with the earlier qualitative assessment to form a weighted overall score.

This demonstrated that the aggregate scoring methodology indicates that Option 5 is the preferred option. However this result is only marginally preferable to Option 4.

The scoring was assessed early in the project at an options appraisal meeting as described in Chapter 6. The differences seen between options 5 and 6 are based around the advantages of being on a single site for reconfiguration of staffing, enabling governance meetings between larger numbers of staff, linking all laboratory adjacencies and enabling least duplication of staff roles. These factors do not affect the quality of the service to patients and can be mitigated.

Option 5 was assessed as enabling an equal delivery of care to primary care patients and the best delivery of care to secondary care patients. These factors are felt to outweigh the lower scoring factors and support the choice of Option 5 as the preferred option.

7. Financial Case

7.1 Overview

The four options identified were financially modelled and then ranked using a NPV methodology as part of the OBC Option Appraisal process. This served to compare the discounted cashflow changes generated by each option over a seven year period.

Using this methodology, Option 5 ranked the highest because it delivered the largest discounted change in net cashflow.

Following the OBC Option Appraisal process further and more detailed analysis has been undertaken. This work as focused on the benchmarking and revision of staffing levels. This extensive work has generated significantly higher savings than were reported during the OBC stage. The ranking of the options remains unchanged because the amendments will have had the same effect each option.

The preferred option, (Option 5) has the following key features:

- Generates a positive net cashflow
- Achieves a cash payback during quarter 4
- Delivers long term saving.

- Initial increased revenue is largely due to potential redundancy and project implementation costs.

7.2 Benchmarking

The detailed analysis and review between the OBC and FBC was based on benchmarking and subsequent challenge to staffing levels. Details of the data collated for analysis and to inform the changes is identified in Appendix M.

The benchmarking has been carried out using a variety of information sources:

- **DoH Reference Costs** data from 2011/12 – collated from >150 Trusts across all Pathology disciplines. The full information is shown in Appendix M and shows a highly significant variation in reference costs across all Pathology disciplines, making analysis inconclusive. The information does however indicate at a high level that the KPP concept is correct and will drive reference costs down when fully implemented.
- **Freedom of Information** requests to >150 Trusts across England. Though resulting in receipt of a great amount of information, it is evident that much of the more useful information has been withheld as “commercially sensitive”. Remaining information shared to date may be useful as potential future reference material only.
- **Keele Benchmarking 2012/13** – A detailed benchmarking analysis of productivity and cost for EKHUFT and MTW has enabled KPP to be modelled

across the disciplines. This analysis is based on detailed data from over 50 health organisations in the United Kingdom. The authors and collators of the data are the Keele University Benchmarking Scheme, who have provided annual NHS Pathology benchmarking reports for a number of years. An analysis of the Keele data was undertaken.

It is evident that whilst the performance of the individual Trust Pathology service is acceptable in most disciplines, there is a clear need for KPP to deliver its services in the top 75-100% in terms of productivity and cost, and the service model will be designed to reflect that in order to facilitate future commercial success.

7.3 Staffing Review

In acknowledging the need to improve productivity and price cost a review was undertaken in respect of staffing levels proposed in the OBC.

In addition to the Keele data, advice was sought from 2 external expert consultants.

Provided below are relevant details regarding advice given and extracts from their written communications.

External Consultant, Critical Friend 1 - Experience Profile

Instrumental in forming and implementing a joint venture between three acute hospital Foundation Trusts which formed in April 2012. In addition, he was a member of the panel advising an area Pathology Network on their plans for consolidation and also worked with a London Hospital to advise them on their efficiency and preparation for integration into one of the London networks.

Extracts from Report

"If the Kent Pathology Partnership is keen to ensure that it is resistant to any future threats from other providers (both private & public sector), then it needs to ensure that it embraces a staffing model which is efficient, effective and fit for purpose."

"The draft shift system operates with the following number of staff for this site:"

"Assuming KPP implements this staffing model, the organisation will then be well placed to bid for new Pathology contracts which appear regularly, either through OJEU or through other means."

"The recommendations I have made in this report are entirely consistent with what other progressive services have done/are in the process of doing across the country. The proposed staffing model presented here is very similar to the one which has been in operation at a hospital I was involved in for the last 22 months without incident."

External Advice 2 - Experience Profile

Led the Collinson Grant Healthcare team in its work for Lord Carter's Independent Review of NHS Pathology in England, and subsequently led many teams working in Pathology for the Department of Health, Strategic Health Authorities, Pathology Networks and individual Acute Trusts. Projects often involved forming a view about options for the consolidation of Pathology Services and the savings associated, and included the re-profiling and re-balancing of the Pathology workforce, including the workforce profile of an appropriate ESL.

Extracts from communications to KPP

Communication 1 -"Local managers, clinical leads, and teams of staff charged with proposing the 'consolidated workforce of the future' usually agreed that a figure of around 25 'whole-time-equivalents (wte)', assuming an existing multi-disciplinary 'Blood Science' workforce, was considered adequate for an ESL for a 'normal' Acute hospital. I am aware of a Trust in the North-West of England that claims to operate an ESL for a general hospital with a staff of 17 wte (14 miles by good roads from the teaching hospital in the same Trust), albeit no team I have worked with has ever proposed such a number"

Communication 2 "You asked for my opinion about an appropriate number of staff for a European Working Time Directive compliant 'ESL' for urgent tests that would combine all 'urgent Pathology work' from a typical Acute site, as well as being responsible for the matching and issuing of Blood products at all times. I am not aware of any NHS organisation that has designed (as opposed to maintained a service that has emerged organically) an ESL with more than 27 WTE) – and that included allowances for elements of IT support, training, attendance at meetings during 'office hours', directorate meetings et cetera. So assuming that your proposed ESL is to be staffed by competent, multi-disciplinary (Chemistry and Haematology) personnel, your estimate of around 25 wte is in line with my experience of workforce designs created by local managers, clinical leads, and staff".

Essential Service Laboratory – Benchmarking Summary

Evidence has been collected from other NHS Trusts that have shared the WTE staff numbers within their ESL's. This has led to this business case recommending a controlled transition in each of the stand-alone ESLs. It is considered that each of these ESLs will be assessed in terms of the local requirements of the individual acute hospital sites.

The proposed change will only be implemented in a safe and clinically appropriate manner that upholds service quality. Equally all changes to staffing levels will be undertaken in a measured, phased way that, where possible, will utilize natural wastage.

7.4. Difference in Approach to OBC

There are two main differences between the figures presented in the FBC and those in the OBC.

- Further development of the savings to be generated.
- Inclusion of additional detail resulting from review of OBC and the insertion of information required for an FBC.

Revisions to Savings

The OBC identified a number of items that required further investigation and evaluation at the FBC stage. These included staffing levels, potential redundancy, MLS contract, IM&T and timescales.

It has been demonstrated that whilst the overall level of savings has increased, a significant deficit is generated in 2014/15. This is largely due to the re-phasing of savings and the increase in the redundancy costs modelled.

Additional Factors

The OBC analysed factors that were likely to lead to a differentiation between the various options being considered and certain financial considerations that would affect all options were excluded. This has been continued for the FBC however, for completeness, further financial projections have been provided that incorporate the following additional items:

- Activity growth
- PbR Tariff deflation
- General Inflation
- Annual CIPs

It should be noted that no additional CIPs have been assumed for 2014/15 and 2015/16 given the significant level of savings identified by the KPP transformation.

More details of these are given in points 7.14 below.

7.5. Basis of Financial Projections

The Financial Case has been developed within a financial appraisal model wherein the significant impacts in costs and income that would occur over time have been assessed and then aggregated to the existing baseline income and costs.

The financial impact of the move to KPP has been assessed over a seven year period. This time period has been selected as it is in line with the typical term of an MLS contract. The impact on the baseline has been assessed for each of the areas which significant financial impacts are expected.

7.6. Key Assumptions & Modelling Inputs

The assumptions which have been made when modeling the options are detailed in Appendix J “Modeling Assumptions”.

The key assumptions used and other inputs are outlined in the following sections.

7.7 Staffing Impact

Representatives of each of the main Pathology disciplines from both Trusts produced staffing proposals to support the future operating model.

The future salary cost of the staffing proposals was compared with the annual salary cost of the current staffing, as at June 2013, to identify the changes to the on-going costs of each option. The future operating model envisages the deployment of an extended working day and aspires to 7 day working if clinically required and financially affordable across KPP. This data informed the production of OBC staffing levels.

The staffing levels produced in the OBC were challenged for the following reasons:

- A subsequent benchmarking exercise which revealed a need for material improvements in productivity and cost per test in order to be competitive.
- Various review processes on OBC savings levels which raised concerns regarding the benefits of adopting the KPP route as opposed to other alternatives.

External expert advice on staffing levels was sought and further intelligence was gathered on other Pathology providers staffing levels. An analysis of data is provided in Appendix M.

The exercise identified additional reductions in staffing need for the ESLs and the opportunity to subsume the WHH ESL into the CSL with the ESL workload absorbed in part by the CSL staffing resources.

Once fully implemented, the changes above will result in on-going savings per annum for the preferred option.

The move to revised staffing structures will be undertaken in a phased manner with full recognition of clinical appropriateness. Throughout this transition process there will be a sense-check against all quality processes to ensure on-going compliance with the requirements of mandatory and desired regulatory standards – CPA, ISO, MHRA etc.

The net effect on substantive staffing by discipline is shown in the following table.

All changes to staffing levels will be undertaken in a measured, phased way that, where possible, will utilize natural wastage. However the likelihood of redundancy has been considered. An assessment has been made based on grade changes across each discipline. Where it is possible, redundancies will be avoided by implementing vacancy freezes and redeployment processes.

The ambition is to achieve the staffing levels shown in this document which are based on benchmarking from comparator sites. However, at every stage of the phased implementation the staffing levels and skill mix will be reviewed by a quality impact assessment process to ensure clinical safety.

A number of staff not selected for redundancy will be entitled to both salary protection and excess mileage and a provision has been allocated in this respect.

7.8 Consultant Medical Provision

The priority of the KPP quality is to improve the quality of pathology services to our patients and users. With this in mind, the consultant medical staff will continue to be a key element of the service, supported by increasingly efficient laboratory services and adapting to the changes in methods of working designed to enable improved turnaround times. The current and future provision of consultant medical staff is as follows:

Blood Sciences

Blood sciences services currently provided includes clinical biochemistry, haematology, immunology and haemophilia

There is currently one consultant in clinical biochemistry and metabolic medicine at MTW who works across the two sites and two consultant clinical scientists in biochemistry at EKHUFT, based primarily at William Harvey and Kent and Canterbury Hospitals. In each Trust the consultants are support by small teams of clinical scientists. The MTW consultant provides a clinical outpatient service in metabolic medicine in addition to the clinical biochemistry service provided in both Trusts which includes interpretation of laboratory results, clinical advice to clinicians and an out of hours clinical advice service for both hospital and primary care physicians.

Following the restructuring, the biochemistry consultants will continue to be responsible for laboratory results for their current base Trusts and surrounding CCGs and this will be facilitated by a robust IT system. This mirrors the current system in each Trust where laboratory results from one laboratory may be viewed and authorised from another Trust site. There will be increased resilience of the service due to the greater number of consultants and cross cover for the out-of-hours service. All consultants will continue to be involved in the audit and governance of the service and a single clinical lead will be appointed, responsible to the KPP Clinical Director

Currently the immunology service is relatively small and supported by a visiting consultant 2 days per month. With the restructuring of services within KPP, the

immunology laboratory activity will increase and it is the aspiration of KPP to enter discussions with the acute Trusts and CCG's to explore the development of a clinical immunology service, including out-patient clinics, for Kent. At present, patients travel to London for immunology out-patient services. Developing this service would necessitate a WTE consultant immunologist post which would also provide enhanced support for the laboratory. This in turn would enable some specialist tests, currently sent to other laboratories for processing, to be repatriated.

The consultant haematologists in both Trusts are part of the oncology directorate (MTW) or division (EKHUFT). There are four consultants at MTW and five at EKHUFT. The consultants provide a full clinical haematology service and in addition, each consultant has two job planned sessions devoted to laboratory work. This provides diagnostic, clinical advisory, audit and governance support to the laboratories. Currently there is a lead haematologist for each Trust laboratory service. At MTW they also lead the clinical service, whilst at EKHUFT there is a separate lead for the clinical service. Following reorganisation a single laboratory lead will be appointed, responsible to the KPP clinical director for the governance and clinical laboratory KPIs. Clinical service leads will also be in place in both Trusts, reporting to the Cancer Services Clinical Director.

Following reorganisation, there will be a single CSL processing all non-urgent work. The majority of new haematological malignancy diagnoses are currently made on GP specimens and a system will be developed to enable the consultant haematologists to review blood slides from patients within their current catchment areas. Initially, the slides will be transported between sites but as new technologies are developed and confidence in them is increased, these will be used to allow remote viewing of slides. Consultants may also have job-planned sessions in the CSL as appropriate.

The consultant in haemophilia and thrombostasis is based at Kent and Canterbury Hospital, where the specialist laboratory is co-located with the haemophilia centre. It is unlikely that any change to this laboratory service will be made other than improvements to quality and efficiency by employing Lean processes and centralising low volume molecular tests into the central molecular laboratory.

Cellular Pathology

There are currently 19 consultant cellular pathologists based at Maidstone Hospital and 14 based at William Harvey Hospital. There are also a number of specialist trainees on Deanery rotation based at each site.

The consultants provide laboratory and diagnostic expertise and support multi-disciplinary meetings (MDMs) on all five hospital sites together with those at Darent Valley Hospital and Medway Maritime Hospital. A proportion of this service is provided using video-links rather than on-site attendance. They also provide a frozen section service for rapid intraoperative diagnosis on the Maidstone and William Harvey sites.

Following the reorganisation of the service, the consultants will remain on their current sites and continue to provide the diagnostic service and MDM support as they do now. Histology and cytology processing will be centralised and this will necessitate the transport of slides between sites. A robust transport system will be developed to

facilitate this. As new technologies develop it is anticipated that remote viewing of slides will eventually become available for cellular pathology although this is likely to be 5-10 years in the future before systems are robust enough for routine use. The frozen section services will continue to be available. Enhancements to the service will include an increased resilience provided by cross-Trust support, larger sub-specialist teams providing increased second opinion and professional support and the potential for using new technologies to provide an increased level of support to MDMs.

All consultants will continue to be involved in the audit and clinical governance of the laboratory outputs. There will be a single clinical lead, to whom the sub-specialty leads will report and who will be responsible to the KPP Clinical Director for the governance and clinical KPIs of the combined department.

Microbiology

There are currently four consultant microbiologists at MTW and five at EKHUFT. All five hospitals have on-site consultant provision. The consultant microbiologists provide laboratory and diagnostic expertise and support the clinical service with clinical advice, ward rounds and attendance at MDMs. They also provide a seven day service for clinical authorisation of laboratory results and an out-of-hours clinical advice service for acute and primary care physicians. The Directors of Infection Prevention and Control in both Trusts are consultant microbiologists and they, together with their consultant colleagues provide a key role in the provision of the infection prevention service and contribute to the national surveillance of infectious disease. The infection control nursing teams will remain with their current Trusts and will not be part of the KPP TUPE.

At each Trust there is currently a single microbiology laboratory (Maidstone and William Harvey Hospitals) and the consultants are accustomed to working at a site remote from the laboratory with rotational working and time spent at the laboratory site. This works well currently and is expected to continue to be successful following the centralisation of the laboratory onto one site. Due to the high volume of out-of-hours workload it is expected that two separate services will be maintained to ensure quality of care for patients. A single clinical lead will be appointed, responsible to the Clinical Director for clinical audit, governance and KPIs.

7.9 MLS Impact

Estimates of the future cost of MLS were obtained from each of the two current providers of managed services based on the description of the future operating model.

The most robust of the submissions has been used to assess the impact upon the future cost of each option as compared with the figure received for the ‘No Change’ option. Therefore the savings shown are as compared with the estimate received for a new MLS contract based on the existing reconfiguration. This methodology generates an annual saving.

The use of a MLS provider delivers significant direct tax advantages in that VAT is fully recoverable on the costs incorporated’ into a MLS contract which would not be the case

of the majority of these items should they be purchased directly. Whilst the Trusts are not aware of any government plans to amend this arrangement, any decision to do so would increase the costs of KPP significantly. However this would also be the case should the constituent Trusts continue with their current arrangement i.e. individual discrete MLS agreements.

As moving to one contract across KPP will require early termination of contract, a penalty is likely to arise. Based on a review of contractual documentation a penalty would be due. However given the competitive nature of the market it has been assumed that this would be negated during procurement negotiations should the existing supplier be successful and that, to be competitive, other bidders would have to do likewise. Therefore, no value has been included within the financials for any such penalty.

7.10 IM&T Impact

An estimate of the future cost of integrating the Trusts' two laboratory information systems has been provided by the current provider. This has been assumed to involve the expansion of one of the existing systems to cover the whole of KPP. The additional cost of integrating the two systems has been included.

Both constituent Trusts of the proposed KPP are currently bidding for direct DoH funding from Pathology IM&T development under the "Safer Hospital, safer wards" scheme. As the outcome of this is unclear no effects of this are included in this FBC.

7.11 Capital and Estates Impact

Architects were commissioned to design building reconfiguration solutions for each of the preferred option. A summary of this capital investment has been undertaken.

The capital costs identified relate solely to refurbishment at the William Harvey and Maidstone sites.

An initial assessment of the impairments likely to arise due to the above changes to the estate has been included. This has taken the form of an outline review of the fixed asset register to identify specific Pathology fixtures, fittings and equipment that are likely to become redundant. Additionally it has been assumed that the 'architect fees' and 'non-build works' element of the offsite facility costs will be impaired when the new facility comes into use and is re-valued.

The impact upon the costs of maintaining the estate has been assessed as being minimal as the scale of the physical estate remains largely unchanged.

7.12 Implementation

Costs for the implementation of the staffing changes, IM&T integration and MLS changes are outlined above. Given the challenging but achievable project timeline, significant additional costs have been modelled for the project management and related professional advisors.

7.13 On-Going Savings

As outlined above, the implementation of KPP will generate significant on-going savings.

7.14 Cost of Change

As outlined above there are significant costs of change to achieve each of the above options.

7.15 Overall Revenue Impact

The overall net revenue effect of the move to KPP has been undertaken.

This does not incorporate inflation, tariff deflation, CIPs, etc. in that only items directly arising from the move to KPP are identified.

7.16 Cashflows

The in-year cash flows associated with the preferred option have been undertaken.

7.17 Full Financial Projections

As stated above the financials resulting from the move to KPP are best understood in terms of the changes forecast to arise when compared with the 'do nothing' option. However, for completeness, additionally full financial projections have been included in the FBC. For these purposes additional items which have been considered include:

- Activity growth
- PbR Tariff deflation
- General Inflation
- Annual CIPs

More details of these are given below.

7.18 Inflationary Changes

In line with Monitor guidance a general level of inflation rate has been assumed for 2014/15. This has been assumed to continue until 2017/18. Thereafter inflation has been assumed to fall for the remainder of the modeled period.

7.19 Tariff Changes

In line with Monitor guidance a level of general tariff deflation has been assumed for 2014/15. It should be noted that, whilst the 'headline rate' of reduction has been shared, the guidance states that of this relates to specific additional funding for litigation and related compensation costs.

This has been assumed to continue until 2017/18. Thereafter this has been assumed to fall for the remainder of the modeled period.

7.20 Cost Improvement Programme

Monitor guidance has outlined that the level of CIPs will be required for 2014/15. However, based on large scale transformation and resulting cost reductions, no further savings due to the KKP integration have been assumed for the years 2014/15 and 2015/16.

Thereafter the level of on-going CIPs required has been set so as to balance the differential between assumed cost inflation and income tariff deflation

It is assumed that the existing baseline costs will be removed from the service over the six years once the core savings are in place.

7.21 Activity Changes

In the base case model a generic activity increase in direct access work has been included. This extra volume is assumed to arise simply due to demographic, technological and medical practice changes i.e. no movement into new markets or increased market share in existing markets has been assumed.

Such additional activity will generate additional costs. These have been modeled on a marginal cost basis. This has been calculated by identifying the marginal element of each category of KPP expenditure and then forming a weighted average.

7.22 Full Financial Projections

Summary financial projections have been undertaken.. These include activity, inflation, CIPs etc.

It should be noted that only income and costs directly attributable to the KPP are shown above. In particular capital costs and internal Trust overhead recharges are not included.

As identified above the net cost to the two KPP partner Trusts will reduce over time, once Direct Access and other external income is included. This is largely driven by savings/CIPs being significantly in excess of the effects of cost inflation and tariff deflation. However the level of savings / CIPs assumed should be seen as challenging.

7.23 Other Scenarios / Risks

To better understand the financial forecasts and to evaluate the effects of possible future events a number of alternative scenarios have been modelled. These have been treated as entirely discrete exercises and no attempt has been made to include mitigations to rectify any adverse effects (with the exception on automatic marginal cost effects).

- Scenario 1: Due to a competitive local market the KPP is required to reduce the tariff for its Direct Access work in excess of general tariff deflation.
- Scenario 2: More competitive pressures from local CCGs force KPP to reduce its tariffs sufficiently so as to pass the savings generated to customers. This requires a tariff reduction, over and above that included for the national tariff.
- Scenario 3: A competitive local market results in KPP loosing its direct access work each year.
- Scenario 4: Tendering by local CCGs leads of Pathology direct access work being lost.
- Scenario 5: As scenario 4 with a continuing decline modelled by the remainder of direct access work being lost during 2016/17.
- Scenario 6: The project is delayed by 1 year.

When considering these, it should be recognised that the financial model used operates largely on a marginal cost approach. Therefore, when considering 'extreme' scenarios such as 5 above, the possibility of a more 'stepped' costing pattern would need to be considered if further refinement to this approach was required.

7.24 KPP Financial Operating Model

As outlined above, KPP will operate as a joint venture between the two Trusts. A proportion is to be applied to the share of the savings and costs generated by the project.

However the flow of income, expenditure and cash between KPP and its partners will not reflect this on an operational basis. Therefore one of the parties will be required to make a payment to the other to 'balance' back the split.

The above methodology will be used to generate a quarterly income and expenditure account with the elements paid by each partner shown. This is then compared with the current costs paid by each partner adjusted. An example of how this mechanism will work is shown in the table below.

Clear rules will be developed to clearly define what costs can be recharged to KPP by the constituent Trusts.

7.25 Future Sustainability

Both Trusts have experienced a significant annual increase in the demand for Pathology Services and whilst technological developments are likely to facilitate improvements in future efficiency, it is believed that these upward demand trends will continue.

The increases in demand, coupled with the growing requirements of the regulatory bodies, are resulting in resources pressures in both Trusts.

Should the two Trust Pathology departments remain separate, there would be, in addition to the proposed staffing above, an estimated cost equivalent to 1 Band 8a and Band 7 staff to meet the regulatory requirements. This is one example of how the establishment of KPP will provide future sustainability at a lower cost than that which would otherwise be incurred by the Trusts working separately.

A further additional post identified within costings is that of a Consultant Immunologist This post is necessary for laboratory CPA and UKAS compliance and will also enable the repatriation of laboratory work and out-patient activity currently outsourced to a London Trust. This repatriation will bring an increase in the revenues to KPP and to the two Trusts. For the purpose of this OBC, no additional revenues have been factored into the projections.

8 Commercial Case

8.1. Work-Streams Involving a Procured Solution

There are three major elements of the reconfigured Pathology services, critical to the achievement of the KPP Project Objectives, which will require a procured solution to be implemented in a timely and effective fashion:

- Reconfiguration and, where necessary, refurbishment of the Pathology estate
- Implementation of a single comprehensive MLS contract
- Integration of the two Laboratory Information Management systems

Other critical, but less major, success factors include the implementation of revised transport arrangements and development of KPP branding and image, web presence and internal communications infrastructure.

8.2. General Approach

The approach to be adopted for the procurement of services for KPP will reflect the extant procurement strategy of EKHUFT as the host Trust; thereby ensuring that KPP makes appropriate use of the expertise available, follows the required methodology and works within the appropriate governance arrangements.

When developing the specification and contracts for the services to be procured, consideration will be given to maximum risk transfer in order to deliver the best value for money for KPP and the Trusts.

8.3. Procurement Timelines

The Implementation Plan has been developed that shows the actions required for the successful implementation of the preferred option.

As an interim measure it is intended to migrate to one of the existing LIMs system for KPP. This is necessary to enable staffing savings identified within the FBC. Evaluation by the IM&T work stream group recommends migration to the CSC Apex system currently used by EKHUFT

9. Management Case

9.1. Management Arrangements

A number of arrangements need to be in place to ensure the successful implementation of the preferred option. These include:

- Clinical and corporate governance structures
- Project management arrangements and plans
- Risk Management arrangements and plans
- Objective realisation management and plans
- Post project evaluation arrangements and plans

9.2. Clinical and Corporate Governance

KPP will take the form of a 'contractual joint venture - non legal entity' (JV) with one Trust hosting. The agreement will provide a risk and reward arrangement. The JV legal structure was agreed following legal advice provided and the risk / reward split was determined following an evaluation process based on financial criteria.

Within the arrangement, each Trust will retain ownership of assets and contracts for supply of services. . Following the establishment of KPP, no material agreement will be entered into without the explicit approval of both Trusts. The Legal Advice summary has been acquired. is proposed that KPP will adopt the policies and procedures of EKHUFT as the host Trust as appropriate to the nature of the services provided.

Clinical governance within Pathology is well-established and will continue with a collaborative approach across the two Trusts. A suggested corporate governance arrangement for KPP is illustrated below. The KPP Governing Board could include the following:

- Chief Executive from each Trust
- Executive Director from each Trust
- Non-executive Director from each Trust
- Medical representative from each Trust
- Independent member (possibly one of our critical friends to provide expert challenge)
- KPP Managing Director
- KPP Clinical Director

Figure 6 Proposed KPP Governance Structure

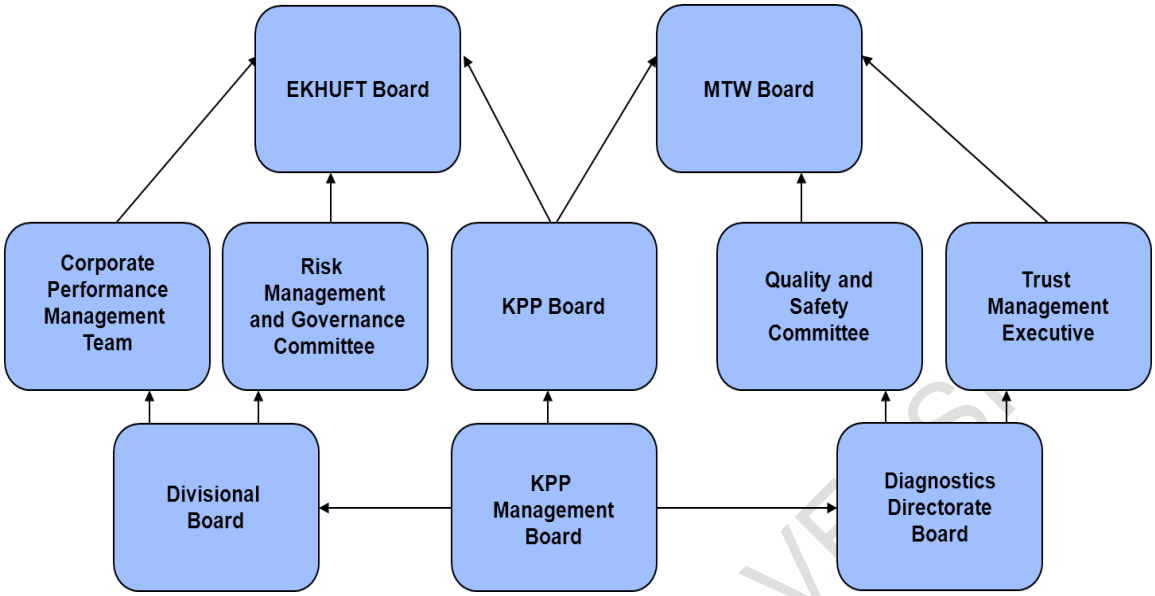


Figure 7 Internal Governance

9.3. Project Management

A project management approach has been in place since the project was initiated in January 2013.

This approach has included the establishment of a Project Management Office and has involved the convening of work groups for each of the main work-streams. The work-stream groups report to a Project Team, which is chaired by the Clinical Leads, this in turn reports to the KPP Project Board under the joint Chair of the Trust Chief Executives.

The Project Management Office has produced a Project Initiation Document and detailed Project Plan. These have been approved by the Project Team and Project Board and are used as the basis for on-going management.

With the approval of the FBC, the project with move to a transition and implementation phase. The outline project plan is provided in Appendix L and a detailed plan is available separately.

9.4. Risk Management Arrangements

A risk register has been developed for the project. The register has been updated to reflect the specific risks to the project associated with implementation of the preferred option. Risk mitigation and management actions have been identified for each of the risks and responsibilities and timelines assigned for their implementation.

The Risk register has been created.

9.5. Objectives Realisation Plan

The project plan for the implementation of the preferred option will include work-streams and tasks that enable optimum performance against the Project Objectives.

The Objectives Realisation Plan is included at Appendix I.

9.6. Post Project Evaluation

Post Project Evaluations (PPE).

A PPE is a major evaluation carried out after a project has been running for a suitable period of time). PPEs are usually performed directly after a project has achieved a significant milestone, such as passing from one phase in the project cycle to another or when a project has been terminated or completed.

It is recommended a small multi-disciplined team drawn from the project be established to conduct a formal PPE.

The evaluation team will consult the appropriate staff on performance, timescales and the actual in-service costs of the equipment in question.

The evaluation team will end the evaluation by presenting to the Project Board and discussing the findings to agree how they will be presented in the Evaluation Report.

The evaluation team will produce an action plan with nominated officers for those activities which require further attention.

10. Sales and Marketing Plan

10.1. Background

East Kent Hospitals University NHS Foundation Trust (EKHUFT) and Maidstone and Tunbridge Wells NHS Trust (MTW) have experience in winning external business. The continuing success of KPP offers an opportunity for expanding into new areas of business thus future proofing existing and acquired services.

A key objective of KPP is to transition from current provision of high quality reasonably cost effective pathology services to significantly more effective and efficient services through economies of scale and business development. However it is recognised that the delivery of pathology services in England is a developing and evolving area. To ensure that KPP achieves its aspirations and is able to successfully compete within the market a detailed review of sales and marketing and the injection of experienced specialists is required. Internal systems and process needs to be considered.

10.2. Market Analysis

Evidence from other recent pathology procurements indicate that an increasing number of new business opportunities exist for KPP including Clinical Commissioning Groups, other Providers Trusts, Private Hospitals, Specialist Send Aways and other public and private sector organisations.

Whilst NHS Pathology can be regarded as a relatively immature market there are a number of NHS partnerships, public /private sector partnerships and commercial organisations operating within the sector.

Some represent short term risk to existing KPP client business owing to a combination of geographical footprint and commercial ambition. The advent of the Maidstone based Kent Institute of Medicine and Surgery adds to the more localised competitive threat.

It is also reasonable to assume that neighbouring Trusts would wish to protect and increase their market share and as a consequence are a potential threat to KPPs ambitions. This is evidenced by a recent advert for Project Management resource to support their shared aims for pathology service provision.

The total NHS pathology market is £2.5 billion with a further estimated minimum £1.0 billion market in other public and private sector industries.

10.3. Marketing Strategy

As previously identified, there are a number of NHS and NHS/ Private sectors partnerships operating within NHS Pathology and in the early years of KPP there is a

need to ensure that bids are approached from a flexible perspective seeking to differentiate KPP from its competitors with attractive offerings which are compelling.

KPP also needs to consider ways within which it can quickly become a market influencer as opposed to being solely reactive to bid opportunities.

KPP should position itself as a major influence in the market including, a communication strategy, review of website and importance of effective branding together with client initiatives designed to promote commercial edge.

10.4. Target Revenues

Target profit margins based on low expectation, expected and best case have been considered. The wide variation in results reflects the risks surrounding the importance of successful FBC implementation, effectiveness of sales force, KPP embracing commercial know how and other sector market developments.

10.5. Sales Strategy

The sales strategy exists.

10.6. Pricing

A pricing strategy has been considered.

11. Recommendation

The evolving competitive Pathology market introduces both opportunities and threats for both Trusts as identified in the market analysis and marketing strategy.

The aims for the project are the establishment a merged, high quality, robust and sustainable Pathology service, incorporating appropriate commercial and public sector expertise, supported by systems and processes resulting in the creation of an organisation which can thrive and grow within an evolving competitive market environment.

The direct access income substantially supports the EBITDA position of both Trusts, and therefore heavily subsidises acute Pathology service costs.

Direct access income represents a large percentage of combined Trusts' Pathology revenues. There is a Commissioner expectation of future price harmonisation and reduction to be evidenced in the 2014/15 financial year. The potential loss of the direct access business would have a major adverse cost impact on Pathology service provision within the regional health economy.

It is against a background of the above, together with other imperatives identified within this FBC, that a 'Do Nothing' approach to Pathology service provision in EKHUFT and MTW is considered untenable.

We recommend to the EKHUFT and MTW Boards, the selection of Option 5 as the preferred option.

Option 5 is a twin CSL model, with a Microbiology and Histology CSL at MTW; A Blood Sciences, Molecular, Cytology and Andrology CSL at WHH, and ESL's on the acute sites, all to be implemented in a phased, safe and considered manner.

This Option provides the following:

- Generates a positive net cash flow.
- Delivers on-going long term revenue savings.

12. Conclusion

Various initiatives throughout Pathology services in the UK, focused on Lord Carter's recommendations, have either been implemented, are in the process of implementation, or are in the planning stage.

Whilst the evolving Pathology market presents opportunities there are also threats, as evidenced by the recent loss of Chlamydia testing contracts by both Trusts.

Direct Access revenues represent a significant proportion of the external income received by the Trusts' Pathology services. Whilst there are positive views being expressed by Commissioners regarding the Pathology services provided, there are also clear expectations that the different prices currently being charged by the Trusts will be harmonised and that prices will be reduced. Commissioners are looking for evidence that this price harmonisation.

The loss of direct access business would have a fundamental effect on the financial performance of both Trusts.

If KPP is established as a single-entity with the appropriate business and commercial capability, it will be well-placed to exploit the opportunities that exist in the evolving market.

It is against a background of the above, together with other imperatives identified within this FBC, that the 'Do Nothing' approach to Pathology service provision in EKHUFT and MTW is considered not to be a sustainable, economic and strategic option.

The financial analysis shown within this document clearly illustrates that neither of the variants of Option 6 considered is financially viable. Whilst Options 4 and 5 rank very similarly both in terms of the quality assessment and the financials, Option 5 generates a higher overall score using the assessment methodology set out in the Economic Case.

Appendices

A. Options and Option Appraisal
B. Options – Long List Advantages and Disadvantages
C. Financial Appraisal
D. Project Structure
E. Clinical Quality Plan
F. Clinical Review Data
G. Stakeholder Analysis
H. Risk Management Plan
I. Objectives Realisation Plan
J. Assumptions
K. Project Initiation Document
L. Implementation Plan
M. Benchmarking Analysis
N. Communications plan
O. Host Trust Recommendation
P. Financial Appraisal – OBC
Q. Legal Advice

APPENDICES HAVE BEEN REMOVED DUE TO COMMERCIAL SENSITIVITIES