

# Kent and Medway Pathology Network

Update for Kent Health Overview and Scrutiny Committee 11<sup>th</sup> May 2022

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## Summary

The report informs the Committee of the progress of the Kent and Medway Pathology Programme since the update in July 2020.

## 1 Strategic context

1. Around 70% of all diagnoses made in the NHS involve pathology. National demand for pathology is estimated to be around 1.2 billion tests per year with approximately 44% originating from primary care. Year on year increases are being observed by individual laboratories and across Kent and Medway approximately thirty-nine million tests are undertaken annually with continued growth. Activity growth stems from multiple causes; changes in demographic composition of the patient community cohort, for example, will impact pathology testing rates
2. The five strategic network objectives are;-
  - a. **Objective 1:** The delivery of a clinically and financially sustainable single pathology service based on a strong, viable service that is clinically led, standardised, innovative and creative.
  - b. **Objective 2:** Delivery of a high-quality diagnostic service for patients, hospital and general practitioners that meets their current and future needs.
  - c. **Objective 3:** Creating a workforce that feels valued, involved and owns the single pathology service as partners in the service; and it is a great place to work.
  - d. **Objective 4:** Transforming service models in the pathology service in Kent and Medway to deliver technological change, increased efficiency and meaningful roles for staff that maximises their potential and meets the needs of the client Trusts and Commissioners.
  - e. **Objective 5:** Managing the transition to the new service in a creative and competent manner.

## 2 Programme status as at last report

- 2.1 The outline business cases(OBCs) for LIMS and MES are enablers for the service change OBC. The order of deployment is LIMS followed by MES followed by service change. In reality, there are likely to be service changes in advance of the completion of LIMS and MES implementation. The whole programme timeline is 13 years with LIMS from year three, MES from year five and service change from year six/seven. The report to the Committee in July 2020 provided details of the progress of the outline business cases for the key enablers of the Network.
- 2.2 The OBCs have been approved by MTW Board, EKHUFT Strategic Investment Committee and MFT Finance Committee. The trusts managing North Kent Pathology Services (NKPS) have, since the gateway review in March, proposed a hybrid option – joining in the single LIMS and MSC but not at this time joining a single service with single management. They do not want their pathology services to go through more major change following the merger of their two trusts' pathology services at this time.
- 2.3 The feasibility of the NKPS hybrid model was considered by the pathology programme board on 7 July 2020. Five considerations were explored:1) Feasibility of single LIMS without a single management; 2) the content of the service change full business case and extent of the target operating model; 3)financial impact on all trusts and the system as a whole; 4) lessons learned from the NKPS merger; and 5) the requirements of NHSE/I. The paper concluded the hybrid model is possible but would be more complex and difficult to manage; would result in lower savings across the system and would need to demonstrate commitment for working towards a single service to meet NHSEI requirements. The Board requested an 'alliance agreement' be drawn up for approval at the next programme board.

## 3 Progress to April 2022

- 3.1 The UK and the wider world entered into a pandemic during 2020 and 2021. NHS Pathology services undertake many of the tests that provide the results to support individual case management and the Kent and Medway (South 8) Network performed exceptionally during that period. The network however, has been impeded by its poor connectivity across laboratories. The recent Richards Review, (Diagnostics Recovery & Renewal, October 2020), published during the pandemic, highlighted the importance of increased connectivity, stating:“*Digitisation and IT connectivity across the NHS is currently variable, but will be vital for diagnostic networks to work efficiently.*”
- 3.2 LIMS: The OBC was approved by NHSEI on 14<sup>th</sup> May 2021 with caveats which were all addressed in the full business case (FBC). The FBC was approved by NHSEI on 4<sup>th</sup> February 2022 and the contract signed with the provider Clinisys on 8<sup>th</sup> February 2022. EKHUFT hold the contract with Clinisys and the risks/rewards and liabilities of the contract are shared with the

other Network members via a legally binding collaboration agreement.

- 3.3 MES: Due to the pandemic NHSEI team had other priorities so delayed the review and approval of the OBC. Formal approval is still awaited. In the mean time the procurement documentation including specifications and procurement strategy is being developed. There are now to be nine lots tendered in three tranches.
- 3.4 Digital technology: The system received capital funding which enable the purchase of the TIE and archive solution for the LIMS in 2021/22. During 21/22 capital funding was received to acquire a GP and Community order Comms. System for pathology and radiology which will be implemented over the next 3 years.
- 3.5 Governance: Governance has been refreshed to strengthen the involvement and leadership of the programme. The pathology project group is now a pathology network clinical and operational committee (PNCOC) which includes service leads and not only holds the steering groups to account but is to focus on the operations and risks of the operations of the service.
- 3.6 NHSEI provided a maturity matrix against which the network self assessed itself. There are five status levels: Pre-emergent, Emerging, Developing, Maturing and Thriving. To enable assessment seven domains were to be assessed and this assessment resulted in an overall assessment of 'Emergent' for the Kent and Medway Pathology Network.

Emerging
<p>Constituent pathology service within a network currently operate independently at trust level, but with engagement or leadership in place to take forward trust board signed network-wide understanding and development of a Network-wide plan.</p>

#### 4. Timeline

PROJECT	Milestone	Current scheduled Date
<b>MES (MSC)</b>		
	Activity validation	TBC
	Tranche 1 Tender launched	15/08/2022
	Tranche 2 Tender launched	27/09/2022
	Tranche 3 Tender launched	08/11/2022
	Tranche 1 Tender complete	20/03/2023
	Tranche 2 Tender complete	17/04/2023

PROJECT	Milestone	Current scheduled Date
	Tranche 3 Tender complete	15/05/2023
	FBC complete - pre check and challenge	19/06/2023
	Contract award (all contracts)	08/01/2024
<b>Service Change</b>		
	TOM developed	TBC
	Issue Strategic Case for review	TBC
	Issue Economic Case for review	TBC
	Issue Commercial Case for review	TBC
	Issue Financial Case for review	TBC
	Issue Management Case for review	TBC
	FBC complete	30/09/2027
<b>Governance</b>		
	MES (MSC) FBC approved by Programme Board	13/07/2023
	MSC FBC approved by Trust Boards	31/08/2023
	MSC FBC approved by NHSEI	21/12/2023
	SC FBC approved by Programme Board	15/09/2027
	Gateway review of SC FBC	30/09/2027
	SC FBC approved by Trust Boards	31/12/2027
	SC FBC approved by NHSEI	N/A
<b>Implementation</b>		
	Go live site 1 LIMS	01/11/2023
	Go live sites 2 LIMS	01/07/2024
	Go live sites 3 LIMS	01/01/2025
	LIMS Project Closed	31/05/2025
	Commence MES (MSC) – MTW	08/01/2024
	Complete MES (MSC) MTW	09/04/2025
	Commence MES (MSC) – EKHUFT	10/04/2025
	Complete MES (MSC) EKHUFT	17/07/2026
	Commence MES (MSC) – NKPS	20/07/2026
	Complete MES (MSC) NKPS	14/07/2027
	Commence service change	01/04/2028
	Programme Closed	30/10/2034

## 5. Risk management

5.1 A robust risk management process has been adopted by the programme with risks held at project and programme level. Risks post mitigation scoring higher than 12 are listed below;-

ID	Risk Description (There is a risk that...)	Mitigation Plan
MES-007	BECAUSE of the complex nature of the procurement, there is a RISK that bidders raise high numbers of clarification questions RESULTING IN delays to the schedule	<p>Check data validity before submitting to suppliers.</p> <p>Undertake detailed pre-market engagement sessions and specification development workshops and provide draft specs to suppliers for review.</p> <p>Challenge requests for clarification from suppliers where suppliers should be able to work out themselves or extrapolate from other information</p>
MES-010	BECAUSE of potential unavailability of sufficient or experienced Trust resources there is a RISK of insufficient resource being available RESULTING IN a delay to the project delivery or adverse impact on quality.	<p>Mitigation is dependent on reasons for resource shortage but might include:</p> <ul style="list-style-type: none"> <li>&gt; Liaise with Pathology GMs to release resources as required</li> <li>&gt; Employ fixed-term staff and/or contractors to either back-fill or work directly on the project</li> </ul>
MES-020	BECAUSE it may not be possible to tender for all lots simultaneously due to the potential impact on Pathology departments, there is a RISK that the overall procurement timeline may extend beyond current estimates. This may RESULT IN a delay in the MES implementation start and the potential for reduced cash-releasing savings	<p>Meet with MES Procurement lead and GMs to agree procurement and implementation strategy ASAP and agree with them steps to ensure the timeline will be unaffected.</p> <p>Model any changes to the plan against the savings.</p> <p>Deploy different individuals within the various Lots where possible.</p>
MES-021	BECAUSE of multiple variables, it may not be possible to implement the MES contract fully on a site-by-site basis and therefore there is a RISK that the overall implementation timeline may change beyond current estimates. This may RESULT IN the potential for incurred early termination fees for existing contracts and/or reduced cash-releasing savings.	<p>Meet with MES Procurement lead and GMs to agree procurement and implementation strategy ASAP and agree with them steps to ensure the timeline will be unaffected.</p> <p>Model any changes to the plan against the savings.</p> <p>Deploy different individuals within the various Lots where possible.</p>
MES-022	BECAUSE of the change in accounting regime to IFRS16 rules there is a RISK OF the new MES contract being treated as capital spend so charged against CDEL RESULTING IN additional approval required to support as a capital priority	<p>Ensure the system capital group consider these new items as part of their 5 year plan.</p> <p>Work with NHSEI capital and cash to understand how the impact of IFRS 16 is being managed centrally both for charge to capital and the total capital control limits.</p>
MES-027	BECAUSE there is now only one CCG for Kent and Medway, there is a RISK that all direct access activity for Pathology services could be commissioned from a single provider, outside of the existing Kent services. This may RESULT IN the unviability of the existing services in Kent and Medway.	<p>Via CCG rep on behalf of the K&amp;M CCGs (pre K&amp;M CCG merger) They have given assurance not to outsource the direct access work during the lifetime of the programme.</p> <p>Monitor the situation as the new ICS/ICB evolves</p>

ID	Risk Description (There is a risk that...)	Mitigation Plan
MES-030	BECAUSE the MES Framework provider is refreshing its framework documentation set and is not using DACB for legal advice, there is a RISK that additional time than estimated will be required for DACB lawyers to review and propose changes to the contract to suit the Network's needs. This may RESULT IN a slippage in the procurement phase plan, which until further information is available, is indeterminable.	Until information becomes available from the framework team on their plan re the availability of revised documents and the extent of any changes, meaningful mitigating actions cannot be determined.
LIMS-46	BECAUSE all of the legacy LIMS in use across K&M, provided by the same vendor, DXC, are all based on old technology; with the vendor's depleted and decreasing knowledge base there is a RISK that effective support for all of the legacy LIMS could be significantly reduced over the next few years. This could RESULT IN increased risk to patient safety, through increasing delays in resolving technical issues.	<ol style="list-style-type: none"> <li>1) Extend support agreements with the supplier in advance to ensure support will be provided.</li> <li>2) Monitor deviations from agreed service level KPIs for issue resolution times.</li> <li>3) Proactively log any identified instances of potential degradation in the vendor's knowledge base and raise with the account manager.</li> <li>4) Fully support the implementation of the single shared LIMS once approved.</li> <li>5) Ensure that the risk is consistently included as high-rated risk in Trust risk registers</li> </ol>
LIMS-48	BECAUSE categorical assurance regarding full VAT recoverability cannot be provided there is a RISK that HMRC may challenge the assumption that VAT is recoverable RESULTING in additional costs of up to £2.3m over the life of the contract (12 years and 11 months) if none of the VAT is recoverable.	Continue to identify information that enhances the case for recovering VAT including working with other Networks (e.g. South 6) who have also recently encountered the same risk/issue.
LIMS-51	BECAUSE the Target Operating Model (TOM) appears to be remaining unchanged, there is a RISK this will RESULT in reduced funding for the LIMS project from savings generated.	MN to raise the risk alongside the unchanged TOM to the programme Board and SRO's. NW to review the financial profiling of the project with AF, and closely manage spend.
LIMS-52	BECAUSE the MES project is behind schedule, there is a RISK this will RESULT in a later flow of money to fund the LIMS project.	CS to review the MES plan to deliver early savings wherever possible. NW to review the financial profiling of the project with AF, and closely manage spend.
LIMS-57	BECAUSE the CliniSys product Winpath Enterprise does not have a web viewer there is a RISK that external users can't view path results, RESULTING in more phone calls to the labs and frustrated service users	gap analysis to be done
LIMS-61	BECAUSE it has because apparent that KAMPA has been deployed but the data within it not validated, there is a RISK that KAMPA cannot provide the historical database with usable data that is required to support the LIMS replacement project, RESULTING in additional work to provide historical data to meet the service requirements	

ID	Risk Description (There is a risk that...)	Mitigation Plan
LIMS-66	BECAUSE POCT is out of scope for the CliniSys and there is a POCT project elsewhere within the programmes, there is a RISK that opportunities for harmonisation with the LIMS could be missed and integration within the implementation timeframe not scoped as part of the current plan, RESULTING IN late change control and unnecessary cost.	HA to Contact Jon Edwards-Moss to create a Workshop to clarify if POCT is in or out of scope, and if in scope how it should be planned.

## 6. Engagement and consultation -

- 6.1 A regular newsletter is sent directly to all colleagues and has included an anonymous feedback survey to temperature check how colleagues are feeling about the progress of the programme. Pathology colleagues and union representatives have been encouraged to join the sub-groups to ensure staff concerns and suggestions are fed into the change process.
- 6.2 The patient and public engagement assurance group has been temporarily suspended. The group included representatives from Healthwatch; patient groups representing those with medical conditions requiring regular pathology input; STP patient representatives; foundation trust governor; point of care coordinators from pathology; and members of the project team. The purpose of the group is:
- the engagement of key public and patient stakeholders in understanding the goal, methods and outcome of the OBC
  - the use of the group as a sounding board for input into the project
  - awareness of the progress of the project
  - internal communication to their organisations
  - equality impact assessment of options on groups and individuals.

This group will be reviewed and possibly reinstated once there is capacity within the programme following the return to normal from Covid-19.

## 7. Recommendations

The Committee is asked to note the progress of the Kent and Medway Pathology Network Programme.