

**Board of Directors**  
**Thursday, 31 January 2019**

<b>Report Title:</b>	<b>Pathology Update</b>
<b>Executive/NED Lead:</b>	Neill Moloney – ESNEFT Managing Director and Executive Sponsor for Pathology Transformation
<b>Report author(s):</b>	Andy Higby – NEESPS Head of Improvement
<b>Previously considered by:</b>	QPS

Approval     
  Discussion     
  Information     
  Assurance

<b>Executive summary</b>  This paper provides members of the Trust Board with a high level briefing on the North East Essex & Suffolk Pathology Services (NEESPS)
<b>Action Required of the Board of Directors</b>  <ul style="list-style-type: none"> <li>Note the contents of the report</li> </ul>

<b>Link to Strategic Objectives (SO)</b>		<b>Please tick</b>
SO1	Improve quality and patient outcomes	<input checked="" type="checkbox"/>
SO2	Provide better value for money	<input type="checkbox"/>
SO3	Sustain and improve access to services that meet the needs of the population	<input checked="" type="checkbox"/>
SO4	Deliver a sustainable, skilled workforce	<input type="checkbox"/>

<b>Risk Implications for the Trust</b> <i>(including any clinical and financial consequences)</i>	Clinical – Patient Safety & Clinical Outcomes, the Trust must have a robust incident reporting and investigation process which is underpinned by risk identification and controls put in place
<b>Trust Risk Appetite</b>	Quality: The board will take minimal risks when it comes to patient safety, patient experience or clinical outcomes. Its tolerance for risk taking will be limited to decisions where the impact is low and the potential mitigations are strong

<b>Legal and regulatory implications</b> <i>(including links to CQC outcomes, Monitor, inspections, audits, etc)</i>	The failure to deliver key mitigations, may lead to regulatory action being placed upon the Trust by both CQC and Monitor, against its requirements for compliance with
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	<p>Monitor's Well Led Framework and Regulation 17: Good governance as identified within the Health and Social Care Act (Regulated Activities)</p> <p>Failure to assure incoming services that affect samples processing may lead to inability to secure or maintain ISO 15189 (2012) as awarded by UKAS</p>
<b>Financial Implications</b>	<p>The failure to provide safe care to patients may lead to potential financial consequences through the cost of increased controls, and subsequent externally driven impact, such as associated financial costs related to claims, complaints, incident investigations, contract queries and penalties. The cost is not possible to quantify due to the complexity of risk management required within an organisation of such diversity and complexity</p>
<b>Equality and Diversity</b>	N/A

## **NEESPS Briefing Trust Board – 31 January 2019**

### **1.0 Context and Background**

Pathology networks have been developed in response to the findings of reviews undertaken by Lord Carter of Coles, and their development was supported by NHS East of England Strategic Health Authority's (SHA) Strategic Projects Team's Pathology Transformation Project, which was itself initiated in May 2010. The continuing development of pathology networks is supported by NHSI.

The Pathology Partnership (TPP) developed a two-hub pathology network covering Addenbrookes, East & North Herts, Hinchingsbrooke, Ipswich, Colchester and West Suffolk Hospitals and GP practices in their associated CCG areas. This partnership was originally intended to also include Mid-Essex Hospital, but it withdrew shortly before TPP formed.

TPP was hosted by Cambridge University Hospitals NHS Foundation Trust (CUH), and operated as established in May 2014 as a response to the SHA's Pathology Transformation Project and the Carter reviews. The intention of the Pathology Transformation Project was to streamline the Anglian region's pathology services in order to realise cost savings of 20%, in line with the recommendations of the Carter Report (Review of NHS Pathology Services in England) published in 2006. TPP effectively dissolved at the end of April 2017, reportedly with significant debts.

TPP was replaced for Northeast East Essex CCG area including Colchester General Hospital, Ipswich & East Suffolk CCG area including Ipswich Hospital and West Suffolk CCG area including West Suffolk Hospital by the North East Essex & Suffolk Pathology Services (NEESPS) operating from May, 2017. Some supporting contracts (e.g. lab coats) continued to be provided across the former TPP area following the establishment of NEESPS.

The change from TPP to NEESPS was without a compliant transformation documentation /plan.

NEESPS is jointly 'owned' by ESNEFT and West Suffolk NHS Foundation Trust (WSFT) and directly provides: Blood Transfusion, Clinical Biochemistry Haematology, and Cellular Pathology. Microbiology is provided under sub-contract by Public Health England (PHE).

### **2.0 Legacy position from TPP**

NEESPS inherited a number of significant difficulties from its predecessor network:

- Insufficient headcount in all technical disciplines
- A derelict Quality Management System (QMS) with different systems operating on different sites
- The 'hollowing out of TPP' very considerably reduced the quality and training functions resulting in poor regulatory compliance and large gaps in activity to support the ongoing accreditation of labs
- A Laboratory Information Management System (LIMS) that hadn't been rolled out to all labs and was not validated (a regulatory requirement for Blood Transformation to demonstrate that no patient harm has been caused through the supply of blood and/or blood products)
- Analytical instrumentation and other equipment without a rolling schedule of contract update (most instrumental is procured on a 'reagent rental' of 'cost per reportable' basis) or replacement programme for that equipment purchased from capital funds (mainly in Cellular Pathology).

### 3.0 Regulatory scrutiny and Accreditation

Incomplete LIMS validation and insufficient supporting quality work in Blood Transfusion during TPP has led to a very high level of regulatory scrutiny from the Medicines and Healthcare products Regulatory Agency (MHRA) of the Hospital Blood Bank (Blood Transfusion lab) at West Suffolk Hospital. This has included escalation within MHRA to the Inspection Action Group (IAG, and the consideration of issuing a cease and desist notice.

There has been a routine inspection of the Hospital Blood Bank at Colchester Hospital. Findings were made and monthly progress reporting is underway. No escalation to IAG has been made. MHRA inspections at West Suffolk and Colchester hospitals have both identified resourcing as a key issue underpinning the ability of the respective Hospital Blood Banks to

Pathology services are accredited against the International Standard for Medical Laboratories – ISO 15189. The accrediting body is the United Kingdom Accreditation Service (UKAS). There is no overarching requirement to operate an accredited laboratory; as long as users are aware. However accreditation is a contractual requirement for NHSE-funded screening work and an expectation from NHSI. Laboratories without accreditation are unable to run training programmes for staff to satisfy the requirements of the Institute of Bio-Medical Scientists (IBMS). NEESPS training is coordinated through the accredited labs at Ipswich. The current accreditation situation is summarised below:

<b>Laboratories at West Suffolk Hospital, Bury St Edmunds</b>	
Blood Transfusion	No accreditation
Clinical Biochemistry	No accreditation
Haematology	No accreditation
Cellular pathology	UKAS accreditation voluntarily suspended
Microbiology	No accreditation

<b>Laboratories at Colchester General, Colchester</b>	
Blood Transfusion	No accreditation
Clinical Biochemistry	No accreditation
Haematology	No accreditation
Cellular pathology	No accreditation
Microbiology	No accreditation

<b>Laboratories at Ipswich Hospital, Ipswich</b>	
Blood Transfusion	Accredited by UKAS
Clinical Biochemistry	Accredited by UKAS
Haematology	Accredited by UKAS
Cellular pathology	Accredited by UKAS
Microbiology	No accreditation

### 4.0 NEESPS main programmes of work

The deficits inherited from TPP form the backbone of a programme of improvement workstreams. These are overseen by the NEESPS Transformation Delivery Group – chaired by the Director of Operations and includes representation from WSFT as standing members.

The workstreams, and their progress are summarised immediately below:

Workforce	Progressing through business cases to Divisional Management Team
Regulatory Compliance & Accreditation	Project charter signed off. Project Initiation Documents in development

Quality Management System	Project Charter reviewed, awaiting approval.
Laboratory Management System	Project Charter scheduled for review 25.01.2019
Equipment	Project Charter scheduled for review 25.01.2019
Microbiology	Project Charter competed.

### 5.0 Clinical Leadership and Executive support

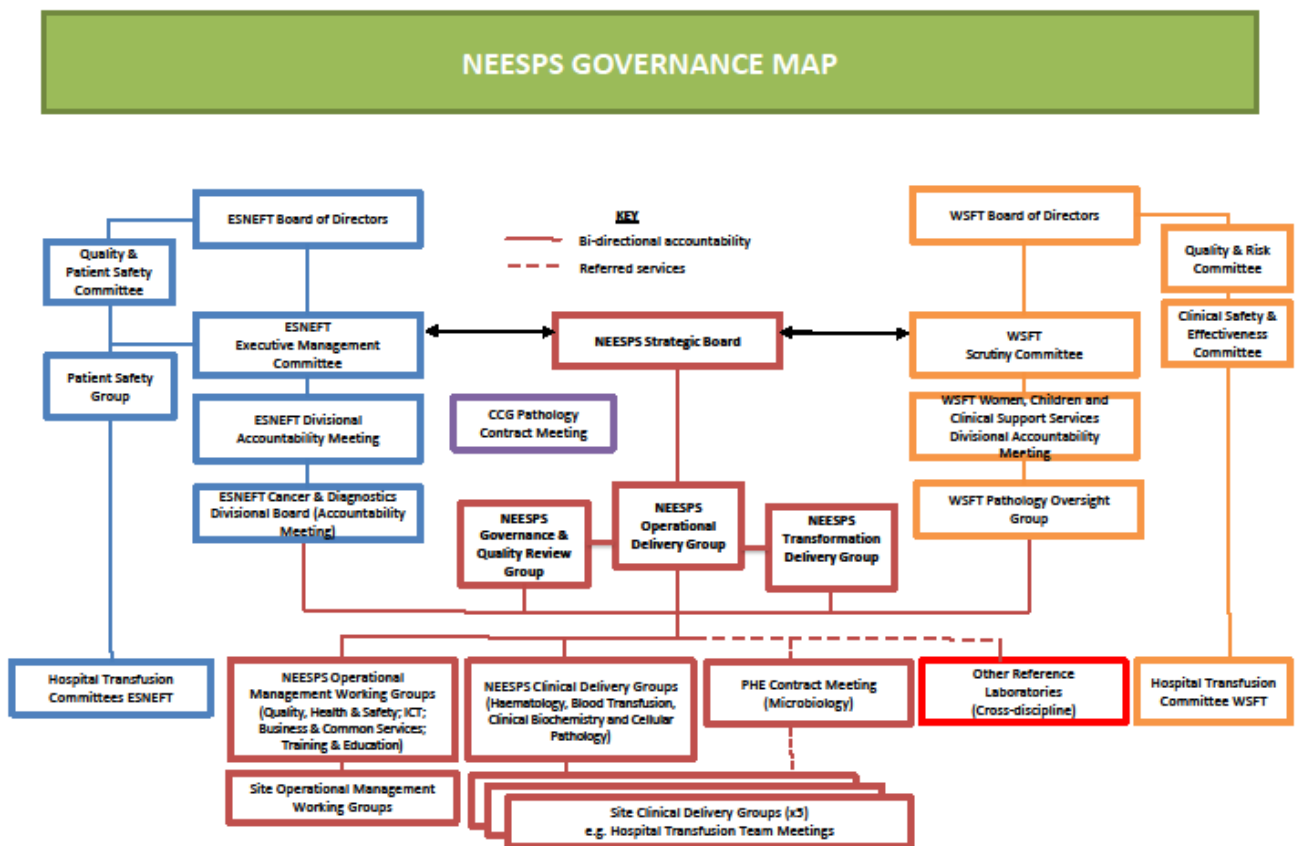
NEESPS as a Clinically-led service benefits from

- A Pathologist as ESNEFT Divisional Director, Cancer & Diagnostics
- ESNEFT Clinical Director for Pathology
- WSFT Clinical Lead for Pathology
- Specialty Leads for Biochemistry, Haematology (including Blood Transfusion), Cellular Pathology and Microbiology
- Medical Director oversight for MHRA scrutiny by-site

Additionally, NEESPS has the ESNEFT Managing Director as Executive Sponsor, supporting a broad exec engagement from both owners. Governance arrangements are being strengthened and this includes the Transformation Delivery Group mentioned above, as is support for change management.

### 6.0 Governance including risk management

The governance map for NEESPS is:



NEESPS risks are reported to the Strategic Board as well as through the normal divisional channels.