



Via email only

Mr Andrew Bland
Chief Executive Officer
South East London Integrated Care Board

30 October 2024

Dear Andrew,

We are writing on behalf of south east London general practitioners to escalate ongoing and serious concerns about pathology services in SEL.

The concerns relate to patient safety, clinical and information governance, and operational effectiveness. We have attached our previous correspondence which you had responded to back in 2022. The correspondence demonstrates that these issues long pre-date the Cyber-attack on the provider and have reoccurred on repatriation of the service following temporary provision by alternative providers.

We have been raising these concerns through the designated escalation routes for years, working with the current provider and the trusts to address these, to no avail. We have also attempted to escalate the concerns outside of the provider and Trusts, but the escalation route has proven to be circular.

Safety concerns

The ongoing safety concerns:

1. Failure to state reference ranges
 - As you know, reference intervals can differ between labs for the same tests, for example depending on the instruments and reagents used to perform the test. Failure to provide reference ranges is unacceptable, introducing significant clinical risk on interpretation of the results. Absent ranges have over the past months included PSA, CRP, GGT so some cancer markers and we are aware of at least one consequent delayed referral for further cancer investigations.
 - Reference ranges for cholesterol/lipid profiles are now no longer provided. (25 September 2024 Bulletin) but lipid profiles are reported with interpretive comments to aid in the management of high-risk patients. This seems to not take into account the importance of primary prevention risk assessment and reduction in individuals who have not already been diagnosed as high risk or as having a primary condition.
 - Reference ranges containing a '<' (less than) and '>' (greater than) non-numerical character have not been showing up on electronic test results. We believe a fix is still not in place. This has resulted in GPs having additional work in that there is no retrospective solution. So, information for old tests has to be viewed via care history and investigations screens, and investigations views, as the full reference range cannot be seen in the workflow view.

2. Failure to highlight abnormal results
 - Please see above comment re providing references ranges in order for GPs to be alerted to results outside expected normal ranges.
 - There have been incidents where the red exclamation mark has been absent from reports, so GPs have not been alerted to potential abnormal results

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Chief Executive: Dr Michelle Drage



- A number of SEL practices had been trialling AI tools to support efficient automated filing of results that are returned within normal ranges. The removal of the highlight of abnormal results has prompted potential pause in these pilots and in some cases resulted in requirement for manual filing and review of results, therefore losing efficiency savings that had been previously realised.
- We have this week heard of a significant patient safety incident which occurred last week. A SEL Community provider outpatient team had failed to action a very high T4 / low TSH (thyroid function result) Bloods were taken week commencing 14 October by the provider. They reported this was because they did not receive a reference range.

3. 'UKAS blood results not accredited'

- GPs have been receiving results which include this statement. This is causing confusion and is not understood, it prompts queries re validity, reliability and safety of result provision.

4. Duplicate and delayed results

- This remains an issue for practices. We have been made aware of microbiology samples taken during 31 July and 25 September that were sent to the incorrect lab and bloods taken on a GP site between 29 Jul 2024 - 5 Aug 24 were sent to St Helier's.
- GPs will necessarily know which samples have been lost or delayed as a result. This clearly has both safety and workload implications.
- Practices are reporting frequent instances of partial results being received, with remaining results being received in a staggered way, resulting in requirement for repeated/duplicate review for a single set of results due to the fragmented approach in reporting.
- Practices have continued to receive bulk batches of results (up to 700 at a time) many of which when reviewed are found to be duplicate results. This causes significant additional work for practices.
- In rare instances practices have received duplicate results from the same sample offering different results – individual cases have been reported.
- We understand that some delays and outages in sending results to GPs have been due to EMIS/Keystone interface. EMIS, the provider of the Keystone system, has rewritten part of the software that connects to NHS Digital to send results.

We understand an update was implemented in early August. This does not appear to have solved all issues related to delays.

5. Reporting and recording incidents and concerns

- There are a number of problems with reporting as GPs have reporting fatigue. There is little confidence that issues reported are being collated, rectified and responded to which is impacting ability to ensure all issues are captured.
- There is confusion in reporting pathways as there are a variety of pathways via which practices are asked to raise concerns: SEL QAs pathways, Synnovis customer services team, tQuest support

team, Let's Talk inbox or via the ICB clinical lead for pathology and via the Synnovis Incident form which was set up following the cyber-attack.

- It is unclear where all reports are collated, recorded and actioned. The concern is that with a number of routes to report we have no idea of how many, repeated themes, issues or when and if they are being actioned and resolved. This is clearly unsafe with a variety of organisations being aware of concerns but no apparent collation of these to identify and act upon themes.

6. Significant Events

- Over the past 2 years there have been what we would term as 'significant incidents' where incidents have resulted in significant disruption to service provision so affecting patient care and GP professional safety. We have asked the provider to confirm their definition of what is regarded by them as a 'significant incident' but have not received clarity on this. We have also requested to have sight of the more detailed reports if/when these incidents have been investigated.

Information Governance concerns following the cyber attack

Following the cyber-attack, there are further concerns about information governance, data security (specifically the safety of the linkages to the confidential GP record). Despite repatriation, GPs have not received adequate assurance that data security and IG risks have been addressed, and that the connections between the pathology services provider's systems and the medical record do not:

- I) compromise the ability of GPs to maintain patient safety and
- II) compromise the practices' ability to discharge their responsibilities as data controllers.

GPs have been informed that the cyber-attack on the pathology services provider was not due to weakness in the provider's information governance nor failure to implement adequate mitigations to avert such an attack. However, trust is low because this provider has a history of failing to respond adequately to safety concerns and failure to take pro-active action to address risks and issues. We are advised that the cyber-attack formal investigation report is still pending, and many questions remain unanswered.

There are clearly considerable failings in the clinical governance (and possibly information governance) within the Pathology Services provider and failures in the contract performance monitoring and management. There also appear to be failings in the lines of accountability.

Contract management, management of conflicts of interest and lines of accountability

We have attempted to escalate the unaddressed concerns, but all escalation routes have brought us full circle back to the Trusts.

This is our understanding:

- The Pathology Services provider is Synnovis. This is a partnership between Synlab (51%) and GSST and Kings Trusts (49%) This contract is worth £2.25bn and this is a 15-year contract with no break clause.
- The previous provider, Viapath, (established 2009/2010) was a partnership owned one third by Serco and one third each by King's and GSTT. Records at Companies House confirm that Serco left Viapath in May 2020, leaving GSST and Kings as temporary equal shareholders.

At a GSTT Board meeting on 28 Oct 2020 it was mentioned in the CEO's report that Synlab was to be a 'new strategic joint venture partner' with GSTT and KCH. On 1 April 2021 Synlab officially formed a new pathology partnership with Guy's and St Thomas', and King's College Hospital NHS Foundation Trusts 'Viapath'.

- On 29 September 2022 Viapath Analytics LLP changed its name to Synnovis Analytics following a re-brand and relaunch of the ongoing partnership. This is relevant because the safety concerns extend back to provision by Viapath.
- SEL ICB commissions SEL's GP direct access pathology service from GSTT and KCH and this forms part of the overall contracts with both Trusts.
- The Trust have subcontracted their contract for provision for Pathology Services – historically to Viapath and now to Synnovis
- The contract is overseen and managed by a Pathology Business Unit (PBU) which is led by a Managing Director, employed by the Trusts, who utilises and manages a single team across the Trusts.
- The PBU manager is employed to, amongst other duties, 'represent the Trusts' interests in the negotiation of contract amendments with the pathology supplier'.
- The PBU managing director also ensures the smooth delivery of the transformation of pathology, the aims of which include delivering material savings for Trusts, and a risk and gain share royalty.*

We do not know the following elements which could provide some comfort to GPs about safety:

- What performance and safety metrics are included within the head contract and subcontract?
- How these are monitored and where they are reported?
- The process by which the subcontract was awarded?
- How conflicts of interest in managing the contract are addressed?

SEL ICB have informed us:

- Any questions related to GSTT and KCH contractual arrangements with Synnovis including the nature of the Joint Venture are raised directly with the Trusts.
- The ICB commissions SEL's GP direct access pathology service from GSTT and KCH, this forms part of their overall contracts with both Trusts.
- The monitoring and management of the contract is as set out in the national standard contract with a specific focus on GP Direct Access pathology as part of this contract monitoring and management process. It is through this route that the Trusts are held to account for the performance of their commissioned services.

NHSE have directed us back to the PBU, informing us that:

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- SEL ICB oversees delivery of the pathology services commissioned and contracted from Synnovis through a Pathology Business Unit which has an independently appointed Managing Director and team who work in partnership with Synnovis to ensure the contact terms and service conditions are met.
- The business unit is formally established and manages the contractual relationship on behalf of the partners; however, the contract serves wider organisations and therefore the Business Unit ensures receivers of services are engaged to ensure services are delivered to the standards commissioned.

Due to the longevity and severity of the concerns raised we are seeking **urgent clarity from the ICB** specifically in relation to the concerns about quality and safety, how conflicts of interest are managed, what the lines of accountability are (and to whom) and what are the further means of escalation either within the local system or beyond. We ask for this so that general practices and their patients can be assured that:

- i) The clinical governance concerns that are placing patients at risk will be rapidly and successfully resolved,
- ii) Assurance is gained about information governance and data security and
- iii) Concerns about wider governance issues relating to Synnovis are allayed

Please could we request that you prioritise an early response to these points and provide confirmation by Wednesday 6 November 2024.

Yours sincerely

Dr Simon Parton
Chair, Lewisham LMC

Dr Penelope Jarrett
Dr Alexandra Armstrong
Dr Gerard McHale
Chair and Vice Chairs, Lambeth LMC

Dr Tuan Tran
Dr Nayan Patel
Chair and Vice Chair, Greenwich LMC

Dr Sush Bhandra
Chair, Bexley LMC

Dr Ami Kanabar
Chair, Southwark LMC

Dr Ruth Tinson
Dr Hannah Josty
Chair and Vice Chair, Bromley

*Source – PBU Managing Director Job Description