South East London Integrated Care System

NHS South East London

19th November 2024

Via email only
Chairs and Vice Chairs South East London LMCs

Dear Colleagues

Thank you for your letter of 30 October 2024. The letter is detailed and covers a range of complex issues, which we have sought to answer in our response. It might however be beneficial to meet to talk through some of the issues raised jointly with Synnovis and Trust Pathology Business Unit (PBU) colleagues to explore the points raised in further detail, rather than seeking to manage them through continued correspondence. I am also aware that many of the issues raised have been subject to previous discussion and correspondence with the LMC and that GP colleagues are part of various groups and forums where pathology is a regular agenda item.

Safety concerns

Taking each area in turn:

Failure to state reference ranges - all Synnovis results are reported with reference ranges if clinically appropriate. There was an issue with EMIS Web where, in certain circumstances, reference ranges were not displayed. This was reported to EMIS who have investigated and corrected the fault.

Failure to highlight abnormal results - Synnovis and the PBU have fed back that they have had this issue reported to them on two occasions. The first was in relation to a lipid profile where a normal range for cholesterol is no longer reported, in accordance with clinical guidelines. Specific details on the second are awaited to allow for an investigation. It may be there are more instances that have not been reported, in which case it would be good to have details of these, to enable the scale of the issue to be understood and to support effective investigation. I would encourage GPs to use the Quality Alert process to ensure issues are captured and passed to Synnovis for action with PBU oversight.

UKAS blood test not accredited explanation - Testing undertaken in the new Synnovis hub laboratory is temporarily unaccredited while UKAS undertakes the checks and assurances required to confirm that hub arrangements are operating in accordance with ISO15189. Our understanding is that this is normal when services transfer to a new setting and the reaccreditation process, which takes several months, is well underway. In the meantime, all existing Synnovis quality processes, such as rigorous in-house verification testing, internal quality control and quality assurance for all tests carried out at the hub, are being maintained to ensure that results are accurate and reliable following transfer to the hub. All hub service users have been informed and the UKAS status of the laboratory processing samples is typically indicated on test result reports.

Duplicate and delayed results - There were two events during the period that mutual pathology aid was in action that caused delays to results. The first related to microbiology results processed at Pathology First and an issue with sending results to GPs that had not been registered with Pathology First prior to the incident. Assurance was provided that any results falling outside of critical limits were phoned through to requesting clinicians as per the

standard operating procedure. The second event was in relation to the blood samples being sent to South West London. This was investigated and determined to have been a sample sorting / triaging process issue.

All samples were processed, no requests were cancelled, and all affected GPs were notified, noting that as these two events occurred during the period of mutual aid provision, extraordinary processes were being followed.

Practices have been reporting concerns of partial microbiology results being released causing additional work and duplication. There is a clinical argument for doing this so positive results can be acted upon as promptly as possible. A paper was presented to the Primary Care Digital Collaboration Group for discussion on this issue.

We recognise that duplicate results caused by IT system interfacing remains an issue and this is being investigated by Synnovis IT, Trust IT and EMIS colleagues.

In rare instances practices have received duplicate results apparently from the same sample offering different results. One possible cause appears to be re-using a photocopy of the same request form for a new sample. As a result, communications were circulated to primary care colleagues requesting tQuest forms are not re-used. Another example was raised by Clifton Rise (CS0381938) – on this occasion there were two different request forms and it appears the patient had two sets of bloods taken on the same day.
As above these areas of detail might warrant further discussion with Synnovis and PBU colleagues which we would be happy to facilitate if helpful.

We have continued to reiterate the need for GPs to use the potential harms review process to record any individual issues using the form on SELnet Information on the Synnovis cyber attack .

Reporting and recording incidents and concerns - incidents and concerns can be reported direct to Synnovis or via the ICB depending on the nature of the issue and concern, as summarised below.

Synnovis Customer Services (CS) - are the first point of contact for clinical queries, chasing results, requesting off catalogue tests as well as requesting an additional test be added. They are also able to respond to courier and consumable queries. All are recorded within the CS system and reviewed/ trended on a monthly basis. If a practice requires a case to be escalated due to time taken for resolution, or if unhappy with a response provided, they can reply to the last email received by Synnovis Customer Service regarding the case and request an escalation, with the reason for the escalation provided. This will then trigger the internal escalation process within Synnovis and be assigned to the appropriate manager for resolution.

Synnovis tQuest support team - who can address any new user requests, amending or removing users, reporting downtime for tQuest and Keystone as well as coding or access issues. These are recorded on the tQuest ServiceNow reporting system.

Let's Talk inbox - which was set up to respond to any queries relating to transformation projects, such as migrating to the hub and test catalogue harmonisation queries. This email address should be used for transformation queries only, not for chasing results or sending patient identifiable data.

ICB Quality Alerts - for clinical safety concerns and incidents. Primary care colleagues should be directed to use this pathway for issues of patient safety or clinical risk. For escalation of urgent safety concerns, GPs are also able to contact Dr Cheryl Leung or Sarah Cottingham. The ICB follows up on Quality Alerts and patient safety and clinical risk issues and they are

further reviewed as part of Contract Management Board meetings and where appropriate via the ICB's quality surveillance and harms review processes. Synnovis follow a documented process to investigate and respond to quality alerts. Responses are sent to the ICB, copying in the practice who raised the alert, via the trust quality team.

Significant incidents - EPRR frameworks determine incident responses, and significant incidents are subject to appropriate governance. The Synnovis cyber-attack was declared a Level 3 critical incident with coordinated management through national and regional teams. As part of standard practice harms review processes have and are being undertaken plus After Action Reviews. These will be taken through ICB governance to ensure we are applying any learning and to ensure full visibility of any resulting harm.

Information Governance concerns following the cyber-attack - The Synnovis IT system is currently being restored and has been and will be subject to a variety of changes as part of this process. This work is being supported by external industry experts. In addition, you are correct to say the incident investigation is still on-going, and this work must be concluded before further comments can be made regarding cyber security concerns.
In addition, Synnovis have provided further granular information on work undertaken to date, which is set out below:

For security reasons, and especially given the recent incident, we do not comment on the specifics of our IT systems or security protocols, however, we can confirm several of the steps taken to further secure our infrastructure and implement operational mitigations for partners of Synnovis here in the UK. These have included but are not limited to:

- *Working with a taskforce of IT experts from Synnovis and the NHS, together with third-party advisers*
- *Implementing a completely new cloud infrastructure environment, using CIS Benchmark standards*
- *Enhancing governance policies and procedures across all platforms (including resetting all service platform passwords and expiring MFA tokens)*
- *Compliance with NCSC infrastructure requirements and security principles*
- *External penetration testing.*

At a Group level, SYNLAB works to constantly improves security measures and emergency processes as they are vital components in responding to and mitigating cyber-attacks on essential healthcare providers. It follows a "Zero Trust" approach, which is being continuously implemented. This includes ongoing investments in the security of its IT systems and processes, as well as employee awareness to protect its infrastructure and data.

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

Your letter sets out detail regarding your understanding of the Joint Venture, the Trusts contractual arrangements with Synnovis and previous provider arrangements. As we have said in response to previous questions, confirmation of your understanding and any associated questions would need to be answered by the Trusts.

In terms of the contractual arrangements and relationship between the ICB, the Trusts and Synnovis I believe we have answered these questions previously. The SEL ICB holds the Trusts to account for the delivery of pathology services in line with the terms and conditions and requirements of the national standard contract, with a dedicated Contract Management Board

(CMB) that focusses on pathology as part of our overall contract monitoring and management arrangements. This meeting is attended by Trusts and ICB colleagues and is the forum where primary care/ GP direct access pathology is discussed in detail. As part of that meeting, we receive and review contract monitoring and performance reports. All agreed material performance issues reported are escalated to a monthly Pathology Management Group (PMG) where resolution plans are agreed and reported back to the CMB.

The ICB's wider governance also allows for the consideration and escalation of any performance or quality related issues and concerns through our ICB Executive and our Quality Committee.

In terms of conflicts of interest, we have a process of formally declaring and managing these within our ICB governance. In terms of the Trusts, our understanding is that there are separate structures (and people) in place which clearly differentiate between management of the contract with ownership interest of the joint venture. These structures ensure that conflicts of interest can be appropriately managed.

I hope this provides a helpful response to your letter.

Yours sincerely

Andrew Bland
Chief Executive Officer

cc.
Sarah Cottingham
Sam Hepplewhite