Our Vision:
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Office of the Chief Executive
Norfolk & Norwich University Hospitals
NHS Foundation Trust
Norwich Research Park
Colney Lane
Norwich NR4 7UY

Private & Confidential
Ms Yvonne Blake
Area Coroner
Norfolk Coroner's Service
Carrow House
301 King Street
Norwich
NR1 2TN

By email and by post:

[redacted] [redacted]

23 July 2021

Dear Ms Blake

Re: John Slope (deceased) – Regulation 28 response
I am writing in response to the above Regulation 28 report (Report) that I received on 10 May 2021. I hope that this letter and the accompanying documents will satisfy you and Mr Slope's family that the matters of concern raised in the Report have been carefully considered by the Trust and appropriate action has been or is being taken.
In reviewing the Regulation 28 report, the following members of staff have been involved.

- [redacted] (Consultant Otolaryngologist, Head & Neck/Thyroid Surgeon)
- [redacted] (Consultant ENT Surgeon and Clinical Governance Lead)
- Dr [redacted] (Consultant Obstetrician and Gynaecologist, Associate Medical Director and Chief Clinical Information Officer).
- [redacted] (Governance Manager – Acute Service Integration)
- [redacted] (Divisional Nurse Director, Surgical)
- [redacted] (Associate Director Quality and Safety – Patient Safety Specialist)
- [redacted] (Matron for Theatres Governance, Risk and Education)
- [redacted] (Divisional Governance Manager – Surgical Division)

<u>SI reports and action plan</u>
At the outset, I acknowledge that the Actions in the original Serious Incident (SI) Action Plan annexed to the SI report were insufficiently robust. This has been revisited and revised and is attached to this letter. I will address the key changes made in light of your Regulation 28 Report further in this letter. You also highlighted

your concern that several months after Mr Slope's death, measures had not been put in place to prevent a similar occurrence.

[redacted] has circulated further advice and supporting information to the Corporate Governance teams to ensure that when they are reviewing draft SI reports, the recommendations made should address the care and service delivery problems identified through the analysis of the information gathered; and, the actions should address the recommendations. She has referred to the Action Hierarchy toolkit published by the Institute of Healthcare Improvement which gives some clear examples of what strong, medium and weaker actions look like. There is a hierarchy of actions in relation to their ability to bring about change. This is now covered in the RCA training that we deliver. With this is mind, the Action Plan in Mr Slope's case has been updated.

In terms of ensuring that Action Plans are completed, the Division adds new SI Action Plans to Datix within 10 working days of the SI being signed off by the Executive. With regards to robust follow up of SI action plans, within the last two months, the Surgical Division has implemented a process to enter individual actions into the 'actions module' within the Datix System (the Trust's Incident Reporting System). This allows for automated emails to be sent out to the individual action owners for update and advising the action owner if an action becomes overdue. This also allows for an audit trail of any updates made to the action. When SI actions are marked by the action owner as completed on Datix, a notification is sent to the person who has entered the action (the divisional governance team) to review the action update prior to its final closure, thus ensuring that it meets the necessary standard. The Corporate Risk & Patient Safety Team is also able to monitor this on the SI dashboard on Datix.

Monthly Datix generated reports of all overdue actions from all serious incidents which now being reviewed quarterly by Safety and Clinical Effectiveness Sub Board and monthly at the Divisional and Directorate boards.

Documentation of salivary tubes

Your Regulation 28 report highlights that there is no method of noting in the medical records that a salivary bypass tube is in place. Further, that specific mention of it was not on the consent form or anaesthetic checklist.

Your suggestion of a rubber stamp on the printed operation note has been given careful consideration. However, on a practical level, it is felt that this may not entirely address this issue given the practices and procedures in place within the hospital. It is common for more than one operation note to be printed for the notes. Also, if a surgeon, anaesthetist or member of theatre staff, is viewing the electronic copy of the note as part of the pre-operative planning or in a MDT, the rubber stamp would not be visible. Therefore, to address this, [redacted] has adapted ORSOS (Theatres documentation system) to include in the 'surgeon's notes' area of the template a section for documenting retained/implanted items and another for their planned management. This in effect creates a 'digital rubber stamp' and means that the information is visible on every printed copy of the operation note and also on the IT systems. This is also in keeping with the Trust's move towards electronic patient records. It will also be used for all surgical specialities, not just ENT. A copy of the revised template is attached.

Further work to highlight that a patient has a surgical device/implant is also ongoing. In terms of the salivary bypass tube, [redacted] has been in touch with the manufacturers to see if they have a card or leaflet that can be provided to a patient. They do not currently have one but this will be a legislative requirement for manufacturers from May 2024 when the transition period from the Medical Device Directive to the Medical Device Regulation is complete.
We have adopted an interim measure with the view to refining this once further information is available from the manufacturers of surgical implants and also advice sought from other NHS Trusts. To better inform our plan for the future, we are also auditing the revised documentation of patients with salivary bypass tubes to include the date of insertion; the point of discussion with the patient regarding the tube being inserted; at follow up whether there is clear evidence of it being in situ; and, a procedural note of it being inserted.

In addition to documenting tubes (and other surgical implants) in the operation records in a more robust fashion, we are also ensuring that patients are given more information about the tube and what to do if they have any symptoms which could give cause for concern. They will also have a visible reminder on a wristband that they have a tube in situ, which will alert other care providers, who do not have access to the patient's medical records at this Trust.

As an interim measure, handwritten information will be provided to patients regarding salivary bypass tubes and this is going to be documented as part of the discharge checklist for this group of patients. Longer term, a leaflet is being drafted by the ENT team. This will be reviewed by the Neck Breathers Association (a patient support group) for comment, prior to finalising it. This 'foreign body leaflet' will identify potential symptoms and when to seek medical review.

This will also be supported with a patient 'card' for temporary surgical devices in situ. It will include contact numbers for the Head and Neck Department, size of salivary tube, date inserted and names of key contacts.

A medical alert bracelet is also being devised. This will state that a device it is situ and will not be removed until the device is. Again, this is intended to be a visible alert to other caregivers.

Communication between clinical teams

Mr Slope's surgical care was under the Norfolk and Waveney ENT Service, which comprises the ENT services of the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) but treats patients throughout the region. Therefore, although his local hospital was the Queen Elizabeth Hospital, King's Lynn, Mr Slope's specialist head and neck cancer care was the responsibility of NNUH.

Concerns about the lack of inter-connectivity of IT systems between the Trusts has been discussed at the ENT governance meetings; a risk assessment was completed, added to the NNUH (lead provider) risk register and approved in December 2020. At present, the clinicians do not have access to the relevant IT systems across the region to obtain full information for all patients for which they have clinical responsibilities, whether working from any site or remotely. A system wide approach is required to align the different IT systems, for example e-mail accounts, risk and incident management systems, dictation programmes,

ICE/SystmOne access and versions, imaging packages and Electronic Prescribing and Medicines Administration (EPMA). Currently workarounds are being devised at an operational level allowing information sharing and transfer where appropriate of governance responsibilities.

Longer term, our three hospital (JPUH, QEH, NNUH) electronic records system is now at the strategic outline case stage, which has been approved by all three hospital Trusts and is now with the national regulatory team to approve. This will see, upon implementation, a single patient record known as Electronic Patient Record (EPR), accessible electronically at all sites. The timeline for implementation depends on the pace of regulatory approvals and the governance cycle. The earliest implementation is likely to begin is 2022.

In the meantime, a shared care record programme across the region will provide patient data to each Trust. In essence, active patient records are being scanned onto Electronic Document Management System (EDMS) each time a patient is admitted to hospital or attends a clinic. This will improve the visibility of patient records to all providers in a read-only format and will improve communication about patients such as Mr Slope as it will amalgamate records which previously may have been held in paper format by different teams and avoid messages such as those made by the nurse specialists not being within the records viewed by the Consultant. The target for full implementation is September 2021.

I hope that this information provides you with the assurances you require that the Trust has implemented changes in practice to ensure that the risk of future deaths from similar circumstances will not occur again. Learning does not end at this point but will also continue following audit of the use of salivary bypass tubes and the effectiveness of the measures now put in place.

Yours sincerely

[redacted]
Chief Executive

Enc: Updated Action Plan, ORSOS template