UHL ORAL AND MAXILLO-FACIAL SURGERY SERVICES – Update Report

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Executive Summary

Context

In July 2016, Health Education England - East Midlands (HEE-EM) undertook a Quality visit of the Oral & Maxillo-Facial Surgery (OFMS) service. This visit was triggered because HEE-EM had become aware of potential issues with the delivery of postgraduate education and training within the OMFS department at the Leicester Royal Infirmary (LRI) affecting both Dental Core Trainees (DCTs) and Higher Specialty Trainees (HSTs). The outcome of the Quality visit was that HEE-EM took the decision to withdraw the Dental Core Trainees. Their report also raised concerns that potentially affected clinical outcomes and so UHL took the decision to commission an external review of the OFMS service by the Royal College of Surgeons (RCS).

The RCS review team initially visited the Trust for two days in November 2016 and provided verbal feedback at the time on their preliminary findings which led to a decision to immediately suspend all resective cancer surgery of the oral cavity and oropharynx pending a further in-depth clinical records review by the RCS (as reported to the public Trust Board meeting of 1 December 2016 – Minute 292/16/3 refers). This review took place at the end of December 2016 and then further patient records were reviewed at our request in March 2017 – ultimately 73 sets of patient notes extending over a 3-year period were reviewed.

The RCS produced their report in April 2017 and concluded that ablative and reconstructive cancer surgery of the oral cavity and oropharynx should continue to be suspended until such point as it could be demonstrated that robust action has been taken to improve the standard of care the OMFS service was able to provide. In summary, the RCS report raised concerns as to whether patients had been appropriately consented, whether they were offered the best procedure to give them the best possible outcome and that Free Flap and Pedicle Flap failure rates were higher than should be expected.

The findings of RCS report were shared with the Trust Board and our external regulators and commissioners at the time. A multi-agency OMFS Oversight Group was established chaired by the Chief Executive, with representatives from NHS Improvement, NHS England, Leicester City Clinical Commissioning Group, Healthwatch and a UHL Non-Executive Director.

Interim updates on the work of the Oversight Group have been reported to the Quality and Outcomes Committee.

Progress to Date

Patient Contact Exercise

All patients (and their GPs) whose medical records were reviewed by the RCS team were contacted to explain what had occurred and offered an opportunity to meet with an OMFS surgeon to discuss any questions/issues they had. This review was initially undertaken by an UHL OMFS consultant with considerable experience in Head and Neck Cancer, who joined the department at the beginning of 2017. 17 patients were initially reviewed by this surgeon and on the basis of the findings, it was agreed that a further look back exercise to include all living patients over a 7 year period prior to suspension of the service was needed (circa 101 patients). In order to do this, UHL contacted the British Association of Oral & Maxillofacial Surgery (BOAMS) and subsequently commissioned two experienced independent OMFS surgeons through BOAMS to undertake this review.

The reviewers met with 38 patients and UHL received their report in August 2018. The findings concurred with those of the RCS in that the reviewers found significant failings in relation to patient consent processes; surgical decision making; type of reconstruction technique offered; and flap failure rates.

As part of the review, the reviewers were asked to identify patients where the reviewers had concerns and where they felt there was substandard care. The reviewers identified 5 cases where they felt care was *'very substandard'* leading to harm as a direct result of treatment and 4 cases of *'significant concern'* (treatment assessed to be substandard but due to multiple other factors not possible to attribute whether harm was caused to the patient directly as a result of substandard treatment).

However, an appendix to the report providing patient-level details of the reviewers' findings led the OMFS Oversight Group to conclude that notifiable harm as defined under Regulation 20: Duty of Candour (Health and Social Care Act 2008 (regulated Activities) Regulations 2014) may have been caused to other patients seen as part of this review; and so the Oversight Group has since attempted to identify those patients where 'harm' may have occurred based on the appendix and a further review of the patient medical records.

Of the 38 patient medical records that have been re-reviewed – 13 patients are felt to have definitely suffered physical harm, 2 patients possibly suffered physical harm and 1 patient has indicators to suggest psychological harm. The patients identified include the 9 cases identified by the external reviewers.

We are now in the process of contacting the 38 patients to inform them of and discuss the review findings. For those patients where we feel that harm has occurred, they will be contacted by telephone to explain the findings and offer a further face-to-face meeting and this will be followed up with a letter to both them and their GP.

There were also an additional 63 living patients who either indicated they did not wish to attend for a review with the external reviewers (7 patients) or simply did not respond (56 patients). We are also writing again to these patients and their GPs again to advise them of our findings in relation to the external reviewers' findings and to offer them a further opportunity to be seen and assessed by the same external reviewers for any evidence of potential harm.

RCS Recommendations

The RCS report made 23 recommendations which were accepted in full by the Trust. These recommendations have all been implemented (implementation overseen by the OMFS Oversight Group) with the exception of those relating to training and the re-introduction of trainees into the department. This is because the department does not have any trainees and HEE - EM has indicated that they currently do not have any plans to reintroduce them into UHL. However, the department is continuing to work with HEE-EM on this matter.

Maintaining High Professional Standards in the Modern NHS

[redacted]

Restoration of UHL OMFS Services

Since the appointment of a new OMFS consultant with considerable experience in Head and Neck Cancer at the beginning of 2017, and with the agreement and oversight of NHS England Specialised Commissioning, the department has been piloting a gradual restoration of ablative and reconstructive cancer surgery to the oral cavity and oropharynx with external surgeon support. A second fellowship trained OMFS surgeon has been appointed and commenced work at UHL in September 2018.

Standard Operating Procedure documents and patient information leaflets have been developed and a database and scorecard of patient outcomes are now in use. These documents have been reviewed at the OMFS Oversight Group and NHS England has agreed to run these past the National Clinical Reference Group for further comment.

In order to restore a robust full capacity OMFS cancer service, UHL will need to appoint a third OMFS surgeon but, subject to further comments from the National CRG and any remedial changes

needed, it has been agreed that UHL will write to NHS England Specialised Commissioning for sign-off to restore a service [redacted] providing ablative and reconstructive cancer surgery to the oral cavity and oropharynx up to their capacity, with additional cases beyond this sent to surrounding units when UHL capacity is reached or an OMFS surgeon is on leave.

Governance

The OMFS Oversight Group has undertaken a timeline review dating back to 2006 and further work is planned to establish whether an 'Assured Service Checklist' can be developed.

The concept here is that the Trust will develop a checklist, to be applied to each clinical service, in order to provide assurance that (at least) minimum standards are in place and that appropriate arrangements are in place for their maintenance and oversight.

It is planned that this work will be taken forward via the UHL Quality Commitment; initially rolling out a validated Assessment & Accreditation process to ward and clinic areas and then extending this to service lines linking in with other triangulation work being undertaken by the Strategy & Operations teams to ensure that lessons are learned and applied in practice.

Input Sought

Trust Board is asked to note the current position in relation to UHL OMFS services, work undertaken by the OMFS Oversight Group to date and the current emerging position in relation to patient harm and the actions being taken – further updates will be provided to the Quality and Outcomes Committee and Trust Board in relation to this matter.

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For Reference

1. The following **objectives** were considered when preparing this report:

Safe, high quality, patient centred healthcare	[Yes]
Effective, integrated emergency care	[Not applicable]
Consistently meeting national access standards	[Yes]
Integrated care in partnership with others	[Not applicable]
Enhanced delivery in research, innovation &ed'	[Not applicable]
A caring, professional, engaged workforce	[Yes]
Clinically sustainable services with excellent facilities	[Not applicable]
Financially sustainable NHS organisation	[Not applicable]
Enabled by excellent IM&T	[Not applicable]

2. This matter relates to the following **governance** initiatives:

Organisational Risk Register	[No]
Board Assurance Framework	[No]

3. Related **Patient and Public Involvement** actions taken, or to be taken: [Affected patients have been informed]

4. Results of any **Equality Impact Assessment**, relating to this matter: [N/A]

5. Scheduled date for the **next paper** on this topic: [TBC]

6. Executive Summaries should not exceed **1page**. [My paper does not comply]

7. Papers should not exceed **7 pages.** [N/A]